



# Effectiveness of a multifactorial program versus a multicomponent program on falls prevention in older adults: randomized clinical trial protocol

Efectividad de un programa multifactorial frente a un programa multicomponente para la prevención de caídas en personas mayores: protocolo de ensayo clínico aleatorizado

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## ABSTRACT

**BACKGROUND //** Falls in older adults represent a major public health problem due to their high prevalence, associated morbidity and mortality, and healthcare costs. More than 400 risk factors have been identified, many of them modifiable. Previous studies show heterogeneous results regarding the effectiveness of multifactorial and multicomponent interventions, especially in community-dwelling populations. In this context, a clinical trial is proposed to assess the comparative efficacy of both approaches in preventing falls among people aged 65 years and older.

**METHODS //** A two-arm randomized clinical trial will be conducted with 264 participants recruited from urban primary care centers in the Talavera de la Reina Healthcare Area. The inclusion criteria consider functional independence, the ability to ambulate, and a high risk of falling. After baseline assessment, participants will be assigned either to a multifactorial intervention including supervised *Vivifrail*<sup>®</sup> exercise, home assessment, medication review, and multidisciplinary educational session or to a multicomponent intervention consisting of unsupervised exercise and a single educational session. Follow-up will last twenty-four months. The primary outcome will be the number of recorded falls. Negative binomial and logistic regression models will be used for the analysis.

**ETHICAL CONSIDERATIONS //** Protocol Version 1 was approved by the Research Ethics Committee of Talavera de la Reina Healthcare Area (Ref. 57/2020).

**DISCUSSION //** The multifactorial intervention is expected to reduce falls by 15% and improve functional capacity and quality of life. The findings may support the development of a standardized fall-prevention protocol applicable in primary care.

**KEYWORDS //** Risk of falls; Elderly; Prevention; Clinical trial.

**REGISTER //** *ClinicalTrials.gov* Identifier: NCT05682872.

## RESUMEN

**FUNDAMENTOS //** Las caídas en personas mayores representan un importante problema de Salud Pública por su elevada prevalencia, morbilidad y costes sanitarios. Se han identificado más de 400 factores de riesgo, muchos de ellos modificables. Estudios previos muestran resultados heterogéneos sobre la efectividad de intervenciones multifactoriales y multicomponentes, especialmente en población comunitaria. En este contexto, se propone un ensayo clínico para evaluar la eficacia comparada de ambos enfoques en la prevención de caídas en personas mayores de sesenta y cinco años.

**MÉTODOS //** Se realizará un ensayo clínico aleatorizado de dos brazos con 264 participantes reclutados en centros de salud urbanos del Área Sanitaria de Talavera de la Reina. Los criterios de inclusión contemplan independencia funcional, capacidad de deambulación y riesgo elevado de caída. Tras la valoración basal, los participantes serán asignados a una intervención multifactorial que incluirá ejercicio supervisado *Vivifrail*<sup>®</sup>, valoración domiciliaria, revisión farmacológica y sesiones educativas multidisciplinares o a una intervención multicomponente con ejercicio no supervisado y una sesión formativa única. El seguimiento será de veinticuatro meses. El resultado primario será el número de caídas registradas. Se emplearán modelos de regresión binomial negativa y logística para el análisis.

**CONSIDERACIONES ÉTICAS //** La Versión 1 del Protocolo fue aprobada por el Comité de Ética en Investigación del Área Sanitaria de Talavera de la Reina (Ref. 57/2020).

**CONCLUSIONES //** Se espera que la intervención multifactorial reduzca las caídas en un 15% y mejore la capacidad funcional y la calidad de vida. Los resultados podrían permitir estandarizar un protocolo de prevención aplicable en Atención Primaria.

**PALABRAS CLAVE //** Riesgo de caídas; Adulto mayor; Prevención; Ensayo clínico.

**REGISTRO //** Identificador de *ClinicalTrials.gov*: NCT05682872.

## AUTHOR CONTRIBUTIONS

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## INTRODUCTION

The probability of falling increases with age and frailty level. A fall is defined by WHO as *inadvertently coming to rest on the ground, floor or other lower level, excluding intentional change in position to rest in furniture, wall or other objects*. Falls are a major public health global issue. It is estimated that 684,000 fatal falls. It makes them the second death cause in the world by non-intentional injuries. Greater mortality rates by this cause correspond to adults over the age of sixty years (1).

The Joint Commission on Accreditation of Healthcare Organization (JCAHO) classifies falls as a sentinel event, defined as an unforeseen event that causes death, permanent damage or temporary damage derived from healthcare and is directly related to the quality of a service. Falls occupy the sixth position on the list of international participant safety objectives both in hospital and community environment since 2019 (2).

Falls involve an economic repercussion for the health system. For Canadian Healthcare System preventable injuries supposes 29,400 million dollars per year (3) and 34,000 million dollars per year for USA Healthcare System (4). The economic costs produced by falls

are not quantified in Spain, although it is well known that 400 million euros as direct costs are expended yearly (5).

3,095 deaths caused by falls have been produced in Spain in people over sixty-five in 2022 (6). Falls incidence for community people stands between 13,9 to 16,2% (7).

Falls aetiology has been the subject of epidemiological studies in the last decades. More than 400 risk factors have been identified (8). The classification of fall risk factors varies according to the literature (9-11). The Professional Association of Ontario Nurses (RNAO), author of the Clinical Best Practice Guideline (BPG) *Preventing Falls and Reducing Injuries from Falls*, classify this risk factors as environmental (or extrinsic), biological (or intrinsic), behavioural, social and economic. These risk factors include: balance disorders, gait, polypharmacy, previous falls, elderly, female sex, visual impairment, cognitive deterioration and environmental factors (12).

Most of the risk factors can be eliminated or modified to reduce or remove the number and the risk of falls. There are many interventions carried out to prevent the falls among older people living in the community. These interventions are described in the Cochrane systematic reviews in 2021 (13), 2018 (14),

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2019 (15) y 2024 (16,17). Interventions are classified as multifactorial or multicomponent interventions in these reviews. These studies showed several interventions over the modifiable risk factors associated with falls. Multifactorial interventions are designed according to the risks to be minimize for each individual, while multi-component interventions are applied equally for every participant of the intervention. In both strategies, physical exercise constitutes an essential component and has been shown to be the intervention with the strongest evidence for reducing both the rate and the risk of falls (13,15).

Different physical exercise programmes have been designed to improve the strength, the balance or flexibility in older people. Among the best-known exercise programs are the *Otago Exercise Programme*, which promotes individualized strength and balance routines at home supervised by professionals (18), and the *Vivifrail*® Project, promoted by the Ministry of Health and various regional entities within the European Union's *Strategy for the Promotion of Health and Quality of Life* (19). *Vivifrail*® classifies older adults according to their functional capacity and proposes adapted exercises, monitored every three months by healthcare professionals.

However, the evidence on the effectiveness of these interventions is inconclusive.

It has been described that physical exercise programs focused on actions to improve home safety reduce the rate of falls and the risk of falls (20-22), while multifactorial programs reduce the rate of falls but not the risk of falls (13). The most recent reviews indicate heterogeneous results: some suggest that mul-

ticomponent interventions can reduce falls and injuries (14), while others do not confirm their effectiveness (16). However, Colón-Emeric et al. (2024) indicate that multifactorial interventions based on a systematic clinical assessment of modifiable risk factors can reduce the fall rate in high-risk individuals (17).

In this context, the objective of this project is to evaluate the effectiveness of a multifactorial intervention versus a multicomponent intervention for fall prevention in community-dwelling individuals over sixty-five years of age, with the number of falls at twenty-four months being the primary outcome measure.

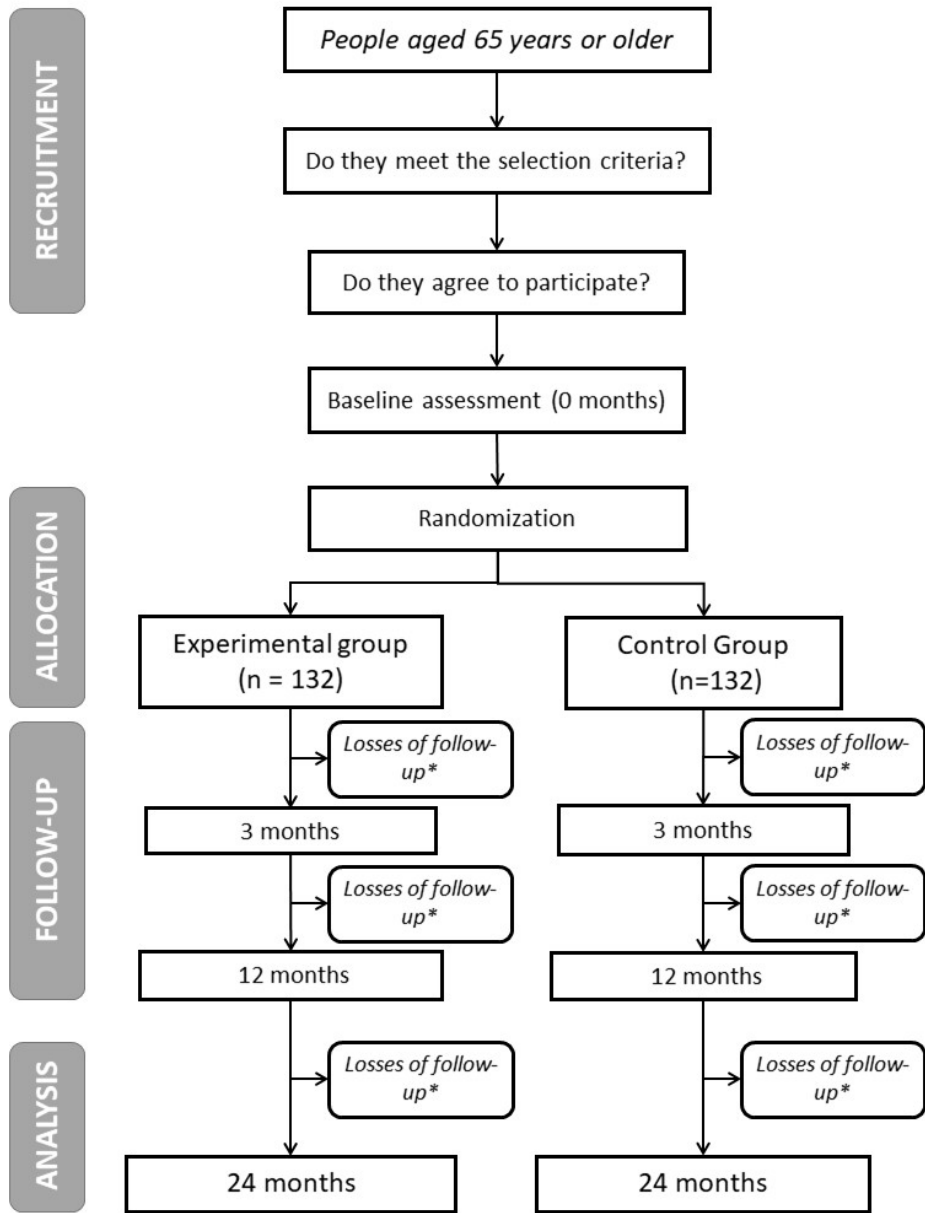
## MATERIAL & METHODS

**Study Design.** Two-arm parallel-group randomised controlled clinical trial and third-party blind assessment [FIGURE 1]. The study will be carried out according to the *CONSORT Statement*. *ClinicalTrials.gov* Identifier: NCT05682872.

**Study Setting and Participants.** Participants will be recruited from the four urban primary healthcare centres in the Talavera de la Reina Healthcare Area (Toledo, Spain). Each participant will be followed for two years from baseline evaluation.

**Selection Criteria.** People aged sixty-five and over will be invited to participate. They must be able to walk to the healthcare centre, must be independent in daily living activities (Barthel Index >90) and must have a risk of falling equal or greater than 3 on Downton scale. It will assess whether the participant has any impediment to participate in the study. The reasons for the exclusion will be to practice an intense physical activity on a regular basis,

Figure 1  
Study design and development.



(\*) Loss to follow-up: Difficulty in continuing with the intervention, change of address, death, side effects, failure to attend scheduled appointments and others.

such as playing paddle tennis, swimming, running or similar for at least one hour a day. Also some exclusion criteria will be using a wheelchair on daily live to move around, be a person with total deafness, blindness or have mild or moderate cognitive impairments that do not allow communication or perform the activities scheduled in the interventions. Finally, people who have suffered a vertebral, pelvic or lower limb fracture in the last twelve months or who have a medically contraindicated for physical exercise will not allowed to participate.

**Recruitment.** Participant's recruitment will be performing at healthcare centres by the doctor or nurse who usually provides their healthcare. These professionals will ensure that participants meet the inclusion criteria and inform them about the participation in the study. Participants interested will send to a specially trained nurse for this study who will continue with the selection process. The nurse will evaluate selection criteria and participants will be explained in depth what their participation would consist of. The objective, activities and follow-up to be carried out, risks and benefits of participation in the study will be explained. Participants will have a reasonable time to make a decision and will be able to ask questions they consider. Finally, they will must provide their signed consent to continue. Then, participants will be scheduled for the first evaluation or baseline assessment and will provided with the opportune contacts.

**Sample Size Calculation.** Sample size calculation to demonstrate the effect on multifactorial interventions for fall prevention will be based on similar studies(23) Using an exact test with an

alpha level of 0,05 and a power of 0,80, a sample size of 264 participants will be considered to detect a 15% reduction of falls during the twenty-four months' follow-up. Sample size will be calculated with *Epidat* 4.2 (24).

**Randomization.** 264 participants will be randomly and distributed in the two arms of the study. Random distribution of participants will be carried out by blocks. The randomization sequence will be carried out by the Research Support Unit team of the Talavera de la Reina Healthcare Area using the statistical program *Epidat* 4.2 (24). Block randomization will allow for a balanced distribution among groups and will facilitate the intervention planning. Blocks of four participants will be generated. And within each block, 50% of the participants will go to the experimental group and the other 50% to the control group. For example, in a block of four participants, if A is the control group and B is the experimental group, there will be six possible randomization sequences AABB, BBAA, ABAB, BABA, ABBA, BAAB. As many blocks of this type as possible will be made until the sample will be complete. Participants' randomization will be performed after baseline assessment completion to avoid risk of selection bias.

**Blinding.** Due to the characteristics of the study healthcare area and the features of the interventions it is not possible to ensure the blindness of the participants. Specifics interventions of the groups will make impossible to ensure the blinding of professionals applying these interventions. The trained professionals who evaluate the results of the interventions and the professionals who perform the statistical analy-

sis, will be the only ones whose blinding can be assured.

## **Procedure. [TABLE 1]**

**1. Initial Phase:** The initial phase includes recruitment and initial assessment of all participants:

- Recruitment has already been explained in the participant's *recruitment* section.
- Baseline evaluation will be carried out by a specially trained nurse who also participates in the recruitment phase. In this phase, after the patient has signed the informed consent, nurse will collect data based on validated questionnaires or scales. Information collected will be: Lawton-Brody Instrumental Activities of Daily Living Scale (25), Folstein's Mini Mental State Examination, Mini-exam cognitive of Lobo (26), Yesavage Geriatric Depression Scale (short form) (27), health related quality of life Euroqol-5D-5L (28) Mini Nutritional Assessment (29), Gijón social-family scale (30), International Physical Activity Questionnaire (IPAQ) (31), Downton Fall Risk Index (32), Barthel Index (33), Fall Efficacy Scale (FES I) (34) and Behavioral Regulation in Exercise Questionnaire (35). *Vivifrail*® passport method will be used as the most appropriate physical activity for the participants. For this purpose, the nurse will collect data based on: Tinetti Scale (36) and Short Physical Performance Battery (SPPB) (37).
- In order to track and record participants' physical activity, they will

be provided with a physical activity wristband.

## **2. Allocation and Intervention Phase:**

Randomization sequence will keep hidden from the people who actually determine the treatment procedure. After the participant provided informed consent, the nurse will open a sequentially numbered, sealed, opaque envelope containing the participant's group assignment and participants were randomly allocated, in a 1:1 ratio, to receive either multifactorial intervention (experimental group) or multicomponent intervention (control group). Both groups have the *Vivifrail*® program as a common basis, used as a standard component of physical exercise.

A multifactorial intervention based on the RNAO best practice guidelines *Preventing Falls and Reducing Injury from Falls* (12) will be performed for experimental group. The following interventions will be carried out during the first three months from the inclusion in the study:

- Initially, and after randomization, a leaflet will be provided to sensitize participants about the importance of physical exercise.
- Physical exercise program *Vivifrail*®, will be guided and supervised by a primary care physiotherapist on alternate days during the first three months. Based on the level of functionality and risk indicated by the passport, participants will be distributed into groups eight people to perform the proposed exercises. On days when supervised exercise is not

Table 1  
Follow-up of interventions and outcome measurements during the two-year study.

**FOLLOW-UP (interventions to be carried out)**

| INITIAL PHASE 0-3 months                          |  |  |  |  |  |  |  |  |  |  |  |  |  | 4-6 months                                                                                                                  |  |                   |  | 7-12 months |  |    |  | 24 months |  |    |  |  |  |
|---------------------------------------------------|--|--|--|--|--|--|--|--|--|--|--|--|--|-----------------------------------------------------------------------------------------------------------------------------|--|-------------------|--|-------------|--|----|--|-----------|--|----|--|--|--|
| ALL                                               |  |  |  |  |  |  |  |  |  |  |  |  |  | MF <sup>(1)</sup>                                                                                                           |  | MC <sup>(2)</sup> |  | MF          |  | MC |  | MF        |  | MC |  |  |  |
| Activity bracelet delivery                        |  |  |  |  |  |  |  |  |  |  |  |  |  | X                                                                                                                           |  |                   |  |             |  |    |  |           |  |    |  |  |  |
| Physical exercise program (VIVIFRAIL)             |  |  |  |  |  |  |  |  |  |  |  |  |  | Passport stamping every 3 months <sup>(3)</sup>                                                                             |  |                   |  |             |  |    |  |           |  |    |  |  |  |
|                                                   |  |  |  |  |  |  |  |  |  |  |  |  |  | First 3 months (1 day/week)                                                                                                 |  |                   |  |             |  |    |  |           |  |    |  |  |  |
| Support and supervision-provided by physiotherapy |  |  |  |  |  |  |  |  |  |  |  |  |  | 4-6 months (1 day/2 weeks+1 follow-up call)                                                                                 |  |                   |  |             |  |    |  |           |  |    |  |  |  |
|                                                   |  |  |  |  |  |  |  |  |  |  |  |  |  |                                                                                                                             |  |                   |  |             |  |    |  |           |  |    |  |  |  |
|                                                   |  |  |  |  |  |  |  |  |  |  |  |  |  | 7-12 months (1 day/month+1 follow-up call)                                                                                  |  |                   |  |             |  |    |  |           |  |    |  |  |  |
|                                                   |  |  |  |  |  |  |  |  |  |  |  |  |  | Medication review-START/STOP criteria (MED <sup>(4)</sup> )                                                                 |  |                   |  |             |  |    |  |           |  |    |  |  |  |
|                                                   |  |  |  |  |  |  |  |  |  |  |  |  |  | Assessment of feet, footwear, nutritional status, cognitive function and psychological well-being (MED-NUR <sup>(5)</sup> ) |  |                   |  |             |  |    |  |           |  |    |  |  |  |
|                                                   |  |  |  |  |  |  |  |  |  |  |  |  |  | Case review and establishment of a specific care plan                                                                       |  |                   |  |             |  |    |  |           |  |    |  |  |  |
| Other activities                                  |  |  |  |  |  |  |  |  |  |  |  |  |  | Health education-Fall prevention. Single session (NUR)                                                                      |  |                   |  |             |  |    |  |           |  |    |  |  |  |
|                                                   |  |  |  |  |  |  |  |  |  |  |  |  |  |                                                                                                                             |  |                   |  |             |  |    |  |           |  |    |  |  |  |
|                                                   |  |  |  |  |  |  |  |  |  |  |  |  |  | Health education-4 sessions (MED, NUR, PT <sup>(6)</sup> , OT <sup>(7)</sup> )                                              |  |                   |  |             |  |    |  |           |  |    |  |  |  |
|                                                   |  |  |  |  |  |  |  |  |  |  |  |  |  | Informational leaflets on the importance of physical exercise                                                               |  |                   |  |             |  |    |  |           |  |    |  |  |  |
|                                                   |  |  |  |  |  |  |  |  |  |  |  |  |  | Home assessment-environmental adaptation recommendations (OT)                                                               |  |                   |  |             |  |    |  |           |  |    |  |  |  |

(1) Multifactorial Intervention (MF). (2) Multicomponent intervention (MC). (3) In MF intervention: stamped by physiotherapy; in MC intervention: stamped by nursing. (4) Medicine. (5) Nursing. (6) Physiotherapy. (7) Occupational Therapy.

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Table 1 (continuation)  
Follow-up of interventions and outcome measurements during the two-year study.

|                                                            | ASSESSMENTS (measurements to be carried out)                              |          |           |           |   |
|------------------------------------------------------------|---------------------------------------------------------------------------|----------|-----------|-----------|---|
|                                                            | 0 months                                                                  | 3 months | 12 months | 24 months |   |
| Sociodemographic, anthropometric, social and psychological | Sociodemographic: sex, age, marital status, education level, cohabitation | X        |           |           |   |
|                                                            | Anthropometry: height and weight                                          | X        | X         | X         | X |
|                                                            | Lawton and Brody index for instrumental activities of daily living        | X        |           |           |   |
|                                                            | Cognitive assessment: Mini-Mental State Examination (Folstein)            | X        |           |           |   |
|                                                            | Geriatric Depression Scale (Yesavage, short version)                      | X        |           |           |   |
|                                                            | Nutritional status: Mini Nutritional Assessment                           | X        |           |           |   |
|                                                            | Socio-family assessment: Gijón Scale                                      | X        |           |           |   |
|                                                            | Behavioral Regulation in Exercise Questionnaire (BREQ-3)                  | X        |           |           |   |
|                                                            | Fall risk screening test in people over 65 years                          | X        |           |           |   |
|                                                            | Average number of steps                                                   |          | X         | X         | X |
| Related to physical activity                               | Physical activity (IPAQ short version)                                    | X        | X         | X         | X |
|                                                            | Vivifrail passport classification                                         | X        | X         | X         | X |
|                                                            | Balance and gait: Tinetti Test                                            | X        | X         | X         | X |
|                                                            | Short Physical Performance Battery (SPPB)                                 | X        | X         | X         | X |
|                                                            | Falls efficacy scale (FES-I)                                              | X        | X         | X         | X |
| Related to falls                                           | Post-fall syndrome                                                        | X        |           |           |   |
|                                                            | Self-reported falls record                                                |          | X         | X         | X |
|                                                            | Falls recorded in medical history                                         |          |           |           | X |
| Related to quality of life                                 | Quality of life: <i>Euroqol-5D-5L</i>                                     | X        | X         | X         | X |

(1) Multifactorial Intervention (MF). (2) Multicomponent Intervention (MC). (3) In MF intervention: stamped by physiotherapy; in MC intervention: stamped by nursing. (4) Medicine. (5) Nursing. (6) Physiotherapy. (7) Occupational Therapy.

conducted, the participant should engage in independent walks of approximately thirty minutes in duration (or alternative activity).

From the fourth to the twelfth month of intervention, participants will independently perform the activities outlined in their passport. The physiotherapist will make follow-up calls to verify and encourage the completion of the agreed-upon exercises based on the results recorded in the *Vivifrail*® passport. One-two calls will be made monthly. In addition, participants will have their *Vivifrail*® passport stamped every three months, and their functionality and risk will be reassessed before a new passport is issued. From the thirteenth month until the end of the follow-up period (twenty-four months from enrollment), participants will be seen by the physiotherapist every three months for passport stamping.

- Occupational therapy staff will conduct a study of the home and its immediate surroundings to diagnose environmental risks associated with falls. To do this, they will visit the participant's home (with prior consent) and analyze various critical points such as: the immediate surroundings (sidewalks, curbs, stairs, access to the home/building entrance, etc.), the building entrance (presence of stairs and/or elevator, their regulatory dimensions, ramps, handrails, etc.), and the home itself (door width, rugs, cables, flooring, light fixtures, access to and height of the bed, furniture layout, bathroom fixture

layout, bathtub/shower, etc.). Finally, recommendations for improving safety and preventing falls will be provided in a detailed report [ANNEX 1].

- An independent doctor will review participant's medication and possible interactions related to falls. The *START-STOPP* criteria will be used for this purpose (38). This information will be communicated to routine doctor who will make the decision regarding any changes.
- Moreover, routine doctor will conduct a feet check, footwear check, nutritional status check, cognitive function check, and psychological well-being check.
- After the assessments, a group of professionals (participant's routine doctor and nurse, an occupational therapist and a geriatrician) will agree to establish a specific plan for correcting any predisposing modifiable factors for falls.
- Four specific and interactive sessions will be performing in small groups (eight to ten participants). Session 1 will cover fall risk factors, medication, vitamin D, nutrition and falls, delivered by a doctor or nurse. Session 2 will focus on accident prevention through environmental modifications, conducted by an occupational therapist. Session 3 will emphasize the importance of physical exercise in fall prevention, led by physiotherapy. Session 4 will address footwear, foot care and how to react to a fall, led by nursing.

From fourth until twelfth month of intervention, participants will carry out the proposed activities in the passport independently. The physiotherapist will make follow-up calls to verify and motivate the completion of the agreed exercises. One-two calls will be made monthly. Additionally, participants will have their *Vivifrail*® passport stamped every three months and their functionality and risk will be reassessed before provide a new passport. From thirteenth month until the of the follow-up (twenty-four months from inclusion), participants will be seen every three months by the physiotherapist in order to stamp the passport, conduct reassessment and deliver a new passport.

For control group, an intervention based on routine clinical practice is proposed. The intervention will be carried out by the primary healthcare doctor and nurse as a part of their routine work. The intervention consists of:

- As in experimental group, participants will receive a brochure with the intention of promoting physical exercise after randomization.
- Physical exercise program *Vivifrail*® will be supervised and the passport will be stamped every three months, following the protocol outlined by the program.
- A forty-five-sixty minutes' single session will be conducted. During this session, various topics will be addressed including fall risk factors, medication, vitamin D, and nutrition. Additionally, accident prevention through environmental modification, the importance of physical exercise for fall prevention, foot-

wear, foot care, and how to react to a fall will be exposed. Participants must attend this session during the first three months from their inclusion in the study.

- Routine doctor and/or nurse who attend to the participants will perform the usual assessment on risk factors related to falls (footwear, feet, nutrition, hearing, vision, psychological and social).

**3. Monitoring and analysis:** The monitoring and information gathering activities, for both groups, will be distributed over a period of two years (three months, twelve months and twenty-four months, from inclusion in the project).

- **The primary outcome** is the number of falls prospectively recorded in the electronic health record of each participant during the twenty-four-month follow-up period. A fall is defined as any involuntary event that results in a loss of balance and the body striking the ground or any other firm surface that stops it (39).
- **Secondary measures:** Data will be collected at twenty-four months on the number of falls recorded in the electronic medical record that required hospital care, resulting in fractures or trauma. In addition, the impact of the intervention on quality of life will be assessed using the *EuroQol 5D-5L*. This tool evaluates five dimensions: mobility, self-care, usual activity, pain/discomfort, and anxiety/depression. Each dimension will be assessed on five levels, ranging from no problems to extreme problems. Fur-

thermore, the EQ-5D-5L incorporates a visual analogue scale (VAS), which is a continuous response scale ranging from 0 (worst possible health status) to 100 (best possible health status), used to record each participant's self-reported perception of their health at the time of the assessment (40).

In addition to these measures, information will be collected at three, twelve and twenty-four months on self-reported falls by the participants, anthropometric variables (weight and height), Tinetti Scale, Short Physical Performance Battery (SPPB), International Physical Activity Questionnaire (IPAQ), number of steps and Falls-related Self-Efficacy Scale (FES I).

**Data Compilation.** Each participant will be identified with a code that contains a consecutive three-digit number (Example: 001 until 264). This code will be assigned once the participant will be randomised to any group. Study data will be collected and managed using the Research Electronic Data Capture (REDCap) tool (41).

**Statistical Analysis Plan.** Outcome analysis will be performed on an intention-to-treat basis. Once the database has been cleaned, baseline characteristics will be summarized by intervention group using frequency and percentage, the mean and standard deviation or by the median and interquartile range. To compare baseline characteristics groups, unpaired t-tests and chi-square tests were used for continuous and categorical variables, respectively.

- **Main outcome analysis:** Total number of falls, fall rate (number of falls per person/year) and the number of individuals who have fallen during the follow-up period will be calculated for both groups. To determine the difference between groups in the fall rate by calculating the incidence rate ratios a negative binomial regression will be used. Negative binomial regression is a generalization of the Poisson regression which attempts to take into account the dependence of events by the same individual and is recommended for use in the evaluation of fall prevention (42). Similarly, to determine differences between the proportion of subjects who have fallen at least once, odds ratios will be calculated through logistic regression analysis.

- **Secondary outcomes analysis:** The results will be compared between groups using multilevel regression analysis for continuous outcomes and multilevel logistic regression for binary outcomes. An exploratory subgroup analysis by sex will be conducted to assess whether there is a potential difference in the intervention's effect between women and men. Interaction terms will be included in the corresponding statistical models for this purpose. These analyses will be interpreted with caution and will not constitute the main analysis of the study.

The analysis will be made with the IBM Corp. Released 2022. IBM SPSS Statistics for Windows, Version 29.0.

Armonk, NY: IBM Corp. Software. And StataCorp. 2016. *Stata Statistical Software*: Publicación 13. College Station, TX: StataCorp LLC.

## ETHICAL CONSIDERATIONS

Version 1 of the Protocol, the Participant Information Sheet and the Informed Consent (Date: December 1, 2020) have been approved by the Ethics Committee for Research with Medicines of the Talavera de la Reina Health Area (Ref. 57/2020).

In accordance with current regulations, all study participants will receive the Participant Information Sheet and will be required to sign the informed consent form prior to inclusion in the study.

This study will be carried out in accordance with the WMA *Declaration of Helsinki*, the *Ley 14/2007 sobre Investigación Biomédica* and the *Ley Orgánica 3/2018, de Protección de Datos Personales y Garantía de los Derechos Digitales*. This protocol will be carried out in accordance with the Good Clinical Practices guide, the rights of the participants will be respected at all times and the validity of the data and results obtained will be guaranteed. Participants' data will not be disclosed to third parties, and will remain under the custody of the principal investigator.

## DISCUSSION

A randomized clinical trial with two arms with 264 participants will be performed. Sixty-five years' participants from primary healthcare centres will be recruited. The aim of this study will be to compare the effectiveness of a multifactorial interven-

tion for fall prevention in comparison with a multi-component intervention in people over sixty-five years old from community.

Previous systematic reviews have shown heterogeneous results regarding the effectiveness of fall prevention interventions in older adults. Some studies demonstrate that physical exercise programs and interventions aimed at improving home safety reduce both the fall rate and the risk of falls (20-22). Similarly, multifactorial programs have been observed to reduce fall rates, although not necessarily the risk of falls (13). Furthermore, multicomponent interventions, including exercise, have been shown to reduce both the fall rate and the risk of falls (14). However, other reviews indicate that multicomponent interventions are effective in reducing falls and fall-related injuries in older adults (16). Finally, multifactorial interventions may decrease the fall rate among high-risk individuals (17).

This protocol introduces several innovative elements that strengthen its contribution to the existing evidence. First, the use of activity trackers as an objective monitoring tool for physical activity levels stands out, a strategy whose usefulness has been demonstrated in the assessment and promotion of exercise in older adults (43,44). This continuous measurement will allow for a more precise exploration of the relationship between exercise adherence and the occurrence of falls. Furthermore, the inclusion of the variable *falls requiring hospital care* as a secondary outcome provides a particularly relevant health impact indicator, given that falls requiring hospitalization account for the greatest econo-

mic burden and associated morbidity and mortality (45,46).

From a methodological standpoint, the protocol presents several strengths. These include the randomized design with blinded assessment, the extended follow-up of twenty-four months, the multidisciplinary approach recommended by international guidelines such as the RNAO (12), and the standardization of exercise using the *Vivifrail*® program, whose effectiveness in improving function and reducing the risk of falls has been previously documented (19,47). Furthermore, the use of a multifactorial intervention based on clinical practice guidelines and the analysis using robust statistical models align this protocol with the recommendations of Cochrane systematic reviews, which highlight the need for well-designed studies to clarify the comparative effectiveness of existing interventions (13,48,49).

Taken together, these elements position this study to generate solid and applicable evidence in the primary care setting, contributing to the advancement toward a standardized fall prevention protocol for older adults.

Health professionals and primary care training specialists (doctors and nurses), physiotherapists and occupational therapists will participate in this clinical trial. In addition, physicians from the frailty unit (geriatrician), professionals from the research support unit and other specialized care professionals participate according to the needs of the participants themselves. An added value of this trial is the incorporation of the occupational therapist as a member of the multidisciplinary team. Analysis of daily living

activities and in the assessment and modification of the environment, will provide key interventions for the prevention of falls. Several studies have shown that occupational therapy interventions generate an additional economic saving by reducing the rate and fall risk (13) and reducing significantly mortality in older adults (50).

**Limitations.** Blinding procedure of interventions is one of the main problems of this clinical trial due to their characteristics. Participants and professionals could suspect in which group are they included. To minimize this problem:

1. Random assignment to interventions will be carried out after completing your baseline assessment. Educational interventions and individual interventions will be adjusted in schedule to avoid coincidences.
2. Evaluator who collects the resulting data at three, twelve and twenty-four months will not know at which group has been allocated to each participant, to avoid detection bias.
3. Professional who performs the statistical analysis will not know the assignment group.

Moreover, the use of an active control based on *Vivifrail*® may reduce the observable magnitude of the difference between groups, but it increases the clinical relevance and external validity of the results. The personalized nature of the multifactorial intervention limits the ability to isolate the effect of each component, but it reflects the approach recommended in real-world practice for fall prevention. Despite these limitations, the trial can provide evidence, based on a randomized clinical trial, of

an individualized multifactorial intervention versus a standard multicomponent exercise program in people over sixty-five years of age. Consequently, the results should be interpreted as the overall effectiveness of a complex fall prevention strategy, rather than the isolated efficacy of a specific component.

There will likely be dropouts or exclusions from the project, which will be recorded and considered in the final analysis. There will be significant recall bias when asking participants about previous falls, which will be addressed by reviewing electronic health records. We will obtain cases that result in clinical care, but we will also miss cases that may not require it, which can decrease the subject's confidence and increase their fear of falling.

Due to the nature of the interventions carried out with the participants in this study, individuals with cognitive impairment who are unable to communicate or perform the activities have been excluded. Results will not be applicable to this population group at high risk of falls. This will be taken into account in the presentation and discussion of the results.

In conclusion, through this multifactorial intervention it is expected to reduce falls in 15% of participants. This will mean an improvement in functional capacity and quality of life. As a consequence, healthy and free of disability years of life are expected to be increased. At the end of the project and according to its results, a standardized and adapted work procedure of Talavera de la Reina Health Area will be proposed. 

## REFERENCES

1. World Health Organization. *Falls* [Internet]. 2021 [cited 2023 oct 17]. Available from: <https://www.who.int/news-room/fact-sheets/detail/falls>
2. The Joint Commission. *Sentinel event policy and procedures* [Internet]. 2026 [cited mar 31]. Available from: <https://www.jointcommission.org/resources/sentinel-event/sentinel-event-policy-and-procedures>
3. Parachute Canada. *Cost of injury in Canada-Parachute* [Internet]. 2026 [cited 2026 mar 31]. Available from: <https://parachute.ca/en/professional-resource/cost-of-injury-in-canada>
4. Stevens JA, Burns E. *A CDC compendium of effective fall interventions: what works for community-dwelling older adults*. 3<sup>rd</sup> ed. Atlanta: CDC; 2015.
5. Ministerio de Sanidad, Servicios Sociales e Igualdad. *Documento de consenso sobre prevención de fragilidad y caídas en la persona mayor*. Madrid: MSSSI; 2014.
6. Instituto Nacional de Estadística. *Defunciones por causas (lista reducida) por sexo y grupos de edad (7947)* [Internet]. 2022 [Cited 2023 oct 17]. Available from: <https://www.ine.es/jaxiT3/Tabla.htm?t=7947&L=0>
7. Franse CB, Rietjens JAC, Burdorf A, Van Grieken A, Korfage IJ, Van der Heide A et al. *A prospective study on the variation in falling and fall risk among community-dwelling older citizens in 12 European countries*. *BMJ Open*. 2017;7(6):e015827. doi: <https://doi.org/10.1136/bmjopen-2017-015827>
8. Royal College of Occupational Therapists. *Occupational therapy in the prevention and management of falls in adults* [Internet]. England:RCOT; 2020 [Cited 2023 oct 17]. Available from: [www.rcot.co.uk/publications](http://www.rcot.co.uk/publications)
9. Ambrose AF, Cruz L, Paul G. *Falls and fractures: a systematic approach to screening and prevention*. *Maturitas*. 2015;82(1):85-93. doi: <https://doi.org/10.1016/j.maturitas.2015.06.035>
10. Callis N. *Falls prevention: identification of predictive fall risk factors*. *Appl Nurs Res*. 2016;29:53-58. doi: <https://doi.org/10.1016/j.apnr.2015.05.007>
11. Ambrose AF, Paul G, Hausdorff JM. *Risk factors for falls among older adults: a review of the literature*. *Maturitas*. 2013;75(1):51-61. doi: <https://doi.org/10.1016/j.maturitas.2013.02.009>
12. Grinspun D. Registered Nurses' Association of Ontario. *Prevención de caídas y disminución de lesiones derivadas de las caídas*. 4<sup>a</sup> ed. Ontario: RNAO; 2017.
13. Gillespie LD, Robertson MC, Gillespie WJ, Sherrington C, Gates S, Clemson L et al. *Interventions for preventing falls in older people living in the community*. *Cochrane Database Syst Rev*. 2012;9:CD007146. doi: <https://doi.org/10.1002/14651858.cd007146>
14. Hopewell S, Adedire O, Copsey BJ, Boniface GJ, Sherrington C, Clemson L et al. *Multifactorial and multiple component interventions for preventing falls in older people living in the community*. *Cochrane Database Syst Rev*. 2018;7:CD012221. doi: <https://doi.org/10.1002/14651858.cd012221.pub2>
15. Sherrington C, Fairhall NJ, Wallbank GK, Tiedemann A, Michaleff ZA, Howard K et al. *Exercise for preventing falls in older people living in the community*. *Cochrane Database Syst Rev*. 2019;1:CD012424. doi: <https://doi.org/10.1002/14651858.cd012424.pub2>
16. Lewis SR, McGarrigle L, Pritchard MW, Bosco A, Yang Y, Gluchowski A et al. *Population-based interventions for preventing falls and fall-related injuries in older people*. *Cochrane Database Syst Rev*. 2024;1:CD013789. doi: <https://doi.org/10.1002/14651858.CD013789.pub2>
17. Colón-Emeric CS, McDermott CL, Lee DS, Berry SD. *Risk assessment and prevention of falls in older community-dwelling adults: a review*. *JAMA*. 2024;331(16):1397-1406. doi: <https://doi.org/10.1001/jama.2024.1416>
18. Kyrðalen IL, Moen K, Røysland AS, Helbostad JL. *The Otago exercise program performed as group training versus home training in fall-prone older people: a randomized controlled trial*. *Physiother Res Int*. 2014;19(2):108-116. doi: <https://doi.org/10.1002/pri.1571>
19. Izquierdo M, Casas-Herrero A, Zambom-Ferraresi F, Martínez-Velilla N, Alonso-Bouzon C, Rodríguez-Mañas L. *A practical guide for prescribing a multi-component physical training program to prevent weakness and falls in people over 70*. Spain: VIVIFRIL; 2017.
20. Ladlow P, Western MJ, Greaves CJ, Thompson JL, Withall J, De Koning J et al. *The Retirement in ACTION exercise programme*

and its effects on elements of long term functionality in older adults. *Front Public Health*. 2023;11:1151035. doi: <https://doi.org/10.3389/fpubh.2023.1151035>

**21.** Cockayne S, Pighills A, Adamson J, Fairhurst C, Crossland S, Drummond A et al. Home environmental assessments and modification delivered by occupational therapists to reduce falls in people aged  $\geq 65$  years: the OTIS RCT. *Health Technol Assess*. 2021;25(46):1-118. doi: <https://doi.org/10.3310/hta25460>

**22.** Bruce J, Hossain A, Lall R, Withers EJ, Finnegan S, Underwood M et al. Fall prevention interventions in primary care to reduce fractures and falls in older adults: the PreFIT trial. *Health Technol Assess*. 2021;25(34):1-114. doi: <https://doi.org/10.3310/hta25340>

**23.** Clemson L, Stark S, Pighills AC, Fairhall NJ, Lamb SE, Ali J et al. Environmental interventions for preventing falls in older people living in the community. *Cochrane Database Syst Rev*. 2023;3:CD013258. doi: <https://doi.org/10.1002/14651858.CD013258.pub2>

**24.** EPIDAT [software]. Versión 4.2. Santiago de Compostela: Xunta de Galicia; 2017.

**25.** Lawton MP, Brody EM. Assessment of older people: self-maintaining and instrumental activities of daily living. *Gerontologist*. 1969;9(3):179-186. doi: [https://doi.org/10.1093/geront/9.3\\_Part\\_1.179](https://doi.org/10.1093/geront/9.3_Part_1.179)

**26.** Lobo A, Ezquerro J, Gómez-Burgada F, Sala JM, Seva Díaz A. El mini-examen cognoscitivo. *Actas Luso Esp Neurol Psiquiatr*. 1979;7:189-202.

**27.** Yesavage JA, Brink TL, Rose TL, Lum O, Huang V, Adey M et al. Development and validation of a geriatric depression screening scale. *J Psychiatr Res*. 1982;17(1):37-49.

**28.** Herdman M, Badia X, Berra S. El EuroQol-5D: una alternativa sencilla para medir la calidad de vida relacionada con la salud en atención primaria. *Aten Primaria*. 2001;28(6):425-429. doi: [https://doi.org/10.1016/S0212-6567\(01\)70406-4](https://doi.org/10.1016/S0212-6567(01)70406-4)

**29.** Guigoz Y, Vellas B, Garry PJ. Assessing the nutritional status of the elderly: the Mini Nutritional Assessment. *Nutr Rev*. 1996;54(1):S59-65. doi: <https://doi.org/10.1111/j.1753-4887.1996.tb03793.x>

**30.** Cabrera González D, Menéndez Caicoya A, Fernández Sánchez A, Acebal García V, García González JV, Díaz Palacios E et

al. Evaluación de la fiabilidad y validez de una escala de valoración social en el anciano. *Aten Primaria*. 1999;23(7):434-440.

**31.** Craig CL, Marshall AL, Sjöström M, Bauman AE, Booth ML, Ainsworth BE et al. International physical activity questionnaire: reliability and validity. *Med Sci Sports Exerc*. 2003;35(8):1381-1395. doi: <https://doi.org/10.1249/01.MSS.0000078924.61453.FB>

**32.** Aranda-Gallardo M, Morales-Asencio JM, Canca-Sánchez JC, Morales-Fernández Á, Enríquez de Luna-Rodríguez M, Moya-Suarez AB et al. Consequences of errors in the translation of questionnaires: Spanish version of the Downton index. *Rev Calid Asist*. 2015;30(4):195-202. doi: <https://doi.org/10.1016/j.calid.2015.04.003>

**33.** González N, Bilbao A, Forjaz MJ, Ayala A, Orive M, García-Gutiérrez S et al. Psychometric characteristics of the Spanish version of the Barthel Index. *Aging Clin Exp Res*. 2018;30(5):489-497. doi: <https://doi.org/10.1007/s40520-017-0809-5>

**34.** Alcalde Tirado P. Miedo a caerse. *Rev Esp Geriatr Gerontol*. 2010;45(1):38-44. doi: <https://doi.org/10.1016/j.regg.2009.10.006>

**35.** González-Cutre D, Sicilia Á, Fernández A. Medición de la regulación integrada en el ejercicio físico en España. *Psicothema*. 2010;22(4):841-847.

**36.** Guevara CR, Lugo LH. Validez y confiabilidad de la escala de Tinetti para población colombiana. *Rev Colomb Reumatol*. 2012;19(4):218-223. doi: [https://doi.org/10.1016/s0121-8123\(12\)70017-8](https://doi.org/10.1016/s0121-8123(12)70017-8)

**37.** Cabrero-García J, Muñoz-Mendoza CL, Cabañero-Martínez MJ, González-Llopis L, Ramos-Pichardo JD, Reig-Ferrer A. Valores de referencia de la Short Physical Performance Battery en pacientes  $\geq 70$  años en atención primaria. *Aten Primaria*. 2012;44(9):540-548. doi: <https://doi.org/10.1016/j.aprim.2012.02.007>

**38.** O'Mahony D. STOPP/START criteria for potentially inappropriate medications in older people. *Expert Rev Clin Pharmacol*. 2020;13(1):15-22. doi: <https://doi.org/10.1080/17512433.2020.1697676>

**39.** Lamb SE, Jørstad-Stein EC, Hauer K, Becker C. Development of a common outcome data set for fall injury prevention trials. *J Am Geriatr Soc*. 2005;53(9):1618-1622. doi: <https://doi.org/10.1111/j.1532-5415.2005.53455.x>

**40.** EuroQol Research Foundation. EQ-5D-5L User Guide. Version

- 3.0. 2019 [Internet; citado el 17 de octubre de 2023]. Available from: <https://euroqol.org/publications/user-guides>
- 41.** Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap). J Biomed Inform. 2009;42(2):377-381. doi: <https://doi.org/10.1016/j.jbi.2008.08.010>
- 42.** Robertson MC, Campbell AJ, Herbison P. Statistical analysis of efficacy in falls prevention trials. J Gerontol A Biol Sci Med Sci. 2005;60(4):530-534. doi: <https://doi.org/10.1093/gerona/60.4.530>
- 43.** Wu S, Li G, Du L, Chen S, Zhang X, He Q. Effectiveness of wearable activity trackers in older adults. Digit Health. 2023; 9:20552076231176705. doi: <https://doi.org/10.1177/20552076231176705>
- 44.** Zhang Z, Giordani B, Margulis A, Chen W. Efficacy and acceptability of wearable activity trackers in older adults in retirement communities. BMC Geriatr. 2022;22(1):231. doi: <https://doi.org/10.1186/s12877-022-02931-w>
- 45.** World Health Organization. WHO global report on falls: prevention in older age. Geneva: WHO; 2007.
- 46.** Florence CS, Bergen G, Atherly A, Burns E, Stevens J, Drake C. Medical costs of fatal and nonfatal falls in older adults. J Am Geriatr Soc. 2018;66(4):693-698. doi: <https://doi.org/10.1111/jgs.15304>
- 47.** Casas-Herrero Á, Sáez de Asteasu ML, Antón-Rodrigo I et al. Effects of Vivifrail multicomponent intervention on functional capacity. J Cachexia Sarcopenia Muscle. 2022;13(2):884-893. doi: <https://doi.org/10.1002/jcsm.12925>
- 48.** Tricco AC, Thomas SM, Veroniki AA et al. Comparisons of interventions for preventing falls in older adults. JAMA. 2017;318(17):1687-1696. doi: <https://doi.org/10.1001/jama.201715006>
- 49.** Sherrington C, Michaleff ZA, Fairhall N et al. Exercise to prevent falls in older adults: updated systematic review. Br J Sports Med. 2017;51(24):1750-1758. doi: <https://doi.org/10.1136/bjsports-2016-096547>
- 50.** Jutkowitz E, Gitlin LN, Pizzi LT, Lee E, Dennis MP. Cost-effectiveness of a home-based intervention for older adults. J Aging Res. 2012;2012:680265. doi: <https://doi.org/10.1155/2012/680265>

## Annex I

Environmental adaptation by occupational therapist. Home visit.

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### Environmental assessment

A study of the home and its immediate surroundings will be carried out to identify environmental fall risks. For this purpose, the occupational therapist will visit the patient's home (with prior consent) and will analyze critical points such as:

- Immediate surroundings (sidewalks, curbs, stairs, access to the building/entrance, etc.).
- Building entrance (presence of stairs and/or elevator, compliance with regulatory measures, ramps, handrails, etc.).
- Home interior (door widths, rugs, cables, flooring, lighting points, bed access and height, furniture layout, bathroom layout, bathtub/shower, etc.).

This information will be recorded using the following forms:

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Annex I (continuation)

Environmental adaptation by occupational therapist. Home visit.

NAME: \_\_\_\_\_ DATE: \_\_\_\_\_

HOUSING

**TYPE OF HOUSING**

- ☐ APARTMENT
- ☐ HOUSE
- ☐ SUBSTANDARD HOUSING
- ☐ SHARED HOUSING
- ☐ COMMUNITY / RESIDENTIAL FACILITY
- ☐ SCHOOL / CENTER
- ☐ NO HOUSING

HOUSING

**TENURE STATUS**

- ☐ OWNED
- ☐ RENTED
- ☐ LOANED FOR USE
- ☐ OCCUPIED
- ☐ COMMUNITY / RESIDENCE

**OVERCROWDING**

☐ YES ☐ NO

**EQUIPMENT / FACILITIES**

- ☐ ELECTRICITY
- ☐ ELEVATOR
- ☐ RUNNING WATER
- ☐ HOT WATER
- ☐ BATHROOM
- ☐ KITCHEN
- ☐ HEATING
- ☐ TELEPHONE

CONTINUED ON NEXT PAGE

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## Annex I (continuation)

Environmental adaptation by occupational therapist. Home visit.

|                                                           |                                                               |
|-----------------------------------------------------------|---------------------------------------------------------------|
| ENVIRONMENTAL CONDITIONS                                  | <input type="checkbox"/> OTHERS                               |
|                                                           | <b><u>CONDITION</u></b>                                       |
|                                                           | <input type="checkbox"/> GOOD (NO DAMAGE)                     |
|                                                           | <input type="checkbox"/> FAIR (SOME DAMAGE)                   |
|                                                           | <input type="checkbox"/> POOR (SEVERE DAMAGE)                 |
|                                                           | <b><u>HYGIENE</u></b>                                         |
|                                                           | <input type="checkbox"/> GOOD (ORDER AND CLEANLINESS)         |
|                                                           | <input type="checkbox"/> FAIR (CLEANLINESS DEFICIT)           |
|                                                           | <input type="checkbox"/> POOR (SERIOUS PROBLEMS)              |
|                                                           | <b><u>LIGHTING</u></b>                                        |
| <input type="checkbox"/> GOOD (MOSTLY NATURAL LIGHT)      |                                                               |
| <input type="checkbox"/> FAIR (ELECTRIC LIGHT)            |                                                               |
| <input type="checkbox"/> POOR (MOSTLY ELECTRIC LIGHT)     |                                                               |
| ENVIRONMENTAL CONDITIONS                                  | <b><u>VENTILATION</u></b>                                     |
|                                                           | <input type="checkbox"/> GOOD (MOSTLY WITH WINDOWS)           |
|                                                           | <input type="checkbox"/> FAIR (SOME WITH WINDOWS)             |
|                                                           | <input type="checkbox"/> POOR (SEVERAL AREAS WITHOUT WINDOWS) |
|                                                           | <b><u>HUMIDITY</u></b>                                        |
|                                                           | <input type="checkbox"/> YES                                  |
|                                                           | <input type="checkbox"/> NO                                   |
|                                                           | <b><u>WASTEWATER DISPOSAL</u></b>                             |
|                                                           | <input type="checkbox"/> SEWER SYSTEM                         |
|                                                           | <input type="checkbox"/> CESSPIT                              |
| <input type="checkbox"/> SEPTIC TANK                      |                                                               |
| <input type="checkbox"/> OTHERS                           |                                                               |
| <input type="checkbox"/> ANNOYING / UNSANITARY ACTIVITIES |                                                               |
| <input type="checkbox"/> TOXIC EXPOSURE                   |                                                               |
| <input type="checkbox"/> INSUFFICIENT CONDITIONS          |                                                               |
| <input type="checkbox"/> RADIATION                        |                                                               |

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## Annex I (continuation)

Environmental adaptation by occupational therapist. Home visit.

|                                       |                                                               |                                    |                                      |
|---------------------------------------|---------------------------------------------------------------|------------------------------------|--------------------------------------|
|                                       | <input type="checkbox"/> NOISE                                | <input type="checkbox"/> TOLERABLE | <input type="checkbox"/> INTOLERABLE |
|                                       | <input type="checkbox"/> POLLUTION                            |                                    |                                      |
|                                       | <input type="checkbox"/> OTHERS                               |                                    |                                      |
| RISKS                                 | <b><u>HEATING SYSTEMS</u></b>                                 |                                    |                                      |
|                                       | <input type="checkbox"/> BUTANE                               |                                    |                                      |
|                                       | <input type="checkbox"/> BRAZIER                              |                                    |                                      |
|                                       | <input type="checkbox"/> FIREWOOD                             |                                    |                                      |
|                                       | <b><u>INADEQUATE SPACES FOR HYGIENE AND PERSONAL CARE</u></b> |                                    |                                      |
|                                       | <input type="checkbox"/> YES                                  |                                    |                                      |
|                                       | <input type="checkbox"/> NO                                   |                                    |                                      |
|                                       | <b><u>INADEQUATE STAIRS</u></b>                               |                                    |                                      |
|                                       | <input type="checkbox"/> HOME                                 |                                    |                                      |
|                                       | <input type="checkbox"/> BUILDING                             |                                    |                                      |
| <input type="checkbox"/> SURROUNDINGS |                                                               |                                    |                                      |
| <input type="checkbox"/> NO           |                                                               |                                    |                                      |
| RISKS                                 | <b><u>SLIPPERY OR UNEVEN FLOORING</u></b>                     |                                    |                                      |
|                                       | <input type="checkbox"/> HOME                                 |                                    |                                      |
|                                       | <input type="checkbox"/> BUILDING                             |                                    |                                      |
|                                       | <input type="checkbox"/> SURROUNDINGS                         |                                    |                                      |
|                                       | <input type="checkbox"/> NO                                   |                                    |                                      |
|                                       | <b><u>PROBLEMATIC DOORS</u></b>                               |                                    |                                      |
|                                       | <input type="checkbox"/> HOME                                 |                                    |                                      |
|                                       | <input type="checkbox"/> BUILDING                             |                                    |                                      |
|                                       | <input type="checkbox"/> NOT RELEVANT                         |                                    |                                      |
|                                       | <b><u>PRESENCE OF SIGNIFICANT LEVEL DIFFERENCES</u></b>       |                                    |                                      |
| <input type="checkbox"/> HOME         |                                                               |                                    |                                      |
| <input type="checkbox"/> BUILDING     |                                                               |                                    |                                      |
| <input type="checkbox"/> SURROUNDINGS |                                                               |                                    |                                      |
| RISKS                                 | <b><u>INADEQUATE SIDEWALKS</u></b>                            |                                    |                                      |
|                                       | <input type="checkbox"/> YES                                  |                                    |                                      |

CONTINUED ON NEXT PAGE

## Annex I (continuation)

Environmental adaptation by occupational therapist. Home visit.

|                                                         |                                                    |
|---------------------------------------------------------|----------------------------------------------------|
| RISKS                                                   | <input type="checkbox"/> NO                        |
|                                                         | <b><u>ABSENCE OF ELEVATOR</u></b>                  |
|                                                         | <input type="checkbox"/> HOME                      |
|                                                         | <input type="checkbox"/> BUILDING                  |
|                                                         | <input type="checkbox"/> NOT RELEVANT              |
|                                                         | <b><u>DISPERSION BETWEEN ROOMS</u></b>             |
|                                                         | <input type="checkbox"/> YES                       |
|                                                         | <input type="checkbox"/> NO                        |
|                                                         | <b><u>ARCHITECTURAL BARRIERS</u></b>               |
|                                                         | <input type="checkbox"/> YES                       |
|                                                         | <input type="checkbox"/> NO                        |
|                                                         | <b><u>ANIMALS</u></b>                              |
|                                                         | <input type="checkbox"/> YES                       |
|                                                         | <input type="checkbox"/> NO                        |
|                                                         | <b><u>Domestic (poses risk)</u></b>                |
|                                                         | <input type="checkbox"/> YES                       |
|                                                         | <input type="checkbox"/> NO                        |
|                                                         | <b><u>Farm/production animals (poses risk)</u></b> |
|                                                         | <input type="checkbox"/> YES                       |
|                                                         | <input type="checkbox"/> NO                        |
| <b><u>OTHER ACCIDENT RISKS</u></b>                      |                                                    |
| <input type="checkbox"/> ELECTRICAL UNSAFETY            |                                                    |
| <input type="checkbox"/> GAS INSECURITY                 |                                                    |
| <input type="checkbox"/> TOXIC PRODUCTS                 |                                                    |
| <input type="checkbox"/> LIGHT SWITCHES ACCESSIBILITY   |                                                    |
| <input type="checkbox"/> UNPROTECTED ELECTRICAL OUTLETS |                                                    |
| <input type="checkbox"/> MEDICATION STORAGE LOCATION    |                                                    |
| <input type="checkbox"/> POOR LIGHTING – STAIRS         |                                                    |
| <input type="checkbox"/> OTHERS                         |                                                    |

## Annex I (continuation)

Environmental adaptation by occupational therapist. Home visit.

| <b><u>AROUND THE HOME</u></b>                                                   |                                                                    |
|---------------------------------------------------------------------------------|--------------------------------------------------------------------|
| <i>Mark with an X if it corresponds to the observation/assessment performed</i> |                                                                    |
| <input type="checkbox"/>                                                        | There are non-adapted curbs in the block where the home is located |
| <input type="checkbox"/>                                                        | Is there a curb at the entrance?                                   |
| <input type="checkbox"/>                                                        | Does it fail to comply with regulations?                           |
| <input type="checkbox"/>                                                        | Stairs at the entrance                                             |
| <input type="checkbox"/>                                                        | Do they fail to comply with regulations?                           |
| <input type="checkbox"/>                                                        | Elevator                                                           |
| <input type="checkbox"/>                                                        | Does it fail to comply with regulations?                           |
| <input type="checkbox"/>                                                        | Poor lighting at the entrance                                      |
| <input type="checkbox"/>                                                        | Level changes                                                      |
| <input type="checkbox"/>                                                        | Ramps                                                              |
| <input type="checkbox"/>                                                        | Handrail on the ramp                                               |
| <input type="checkbox"/>                                                        | Does it fail to comply with regulations?                           |
| <input type="checkbox"/>                                                        | Elevator                                                           |
| <input type="checkbox"/>                                                        | Does it fail to comply with regulations?                           |
| <b>OBSERVATIONS:</b>                                                            |                                                                    |
|                                                                                 |                                                                    |

CONTINUED ON NEXT PAGE

## Annex I (continuation)

Environmental adaptation by occupational therapist. Home visit.

### **INSIDE THE HOME**

**Mark with an X if it corresponds to the observation/assessment performed**

- ☐ Stairs/steps
- ☐ Rugs
- ☐ Loose cables
- ☐ Slippery floors
- ☐ Poor lighting, glare, or darkness
- ☐ Uneven flooring (rails, different floor heights, etc.)
- ☐ Irregular terrain
- ☐ Low furniture
- ☐ Bathtub
- ☐ Shower tray with raised edge
- ☐ Poorly positioned bathtub/shower grab bars
- ☐ Low toilet seat
- ☐ Poorly positioned grab bars on the toilet
- ☐ Limited bathroom space
- ☐ No telephone/alarm system available
- ☐ Pets
- ☐ Presence of young children

**OBSERVATIONS:**

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## Annex I (continuation)

Environmental adaptation by occupational therapist. Home visit.

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### Advice on environmental modification

A detailed report will be prepared with recommendations and possible adaptations to be carried out at the patient's home, based on:

- *Law 1/1994 of May 24 on accessibility and elimination of barriers in Castilla-La Mancha (36).*
- *Decree 158/1997 of December 2 on the Accessibility Code of Castilla-La Mancha (37).*

These recommendations will be directly related to the critical points identified during the environmental assessment that may represent fall risk factors.

If the patient agrees to implement adaptations requiring specific training, the occupational therapist will visit the home again to train the patient in performing activities of daily living safely, minimizing risks.

### Advice on assistive devices

A detailed report will be prepared with recommended assistive devices to reduce environmental fall risks.

If the patient decides to acquire these devices, the occupational therapist will revisit the home to train the patient/caregiver in their correct use, ensuring adherence and safe application.