

# Technology-based platform for risk assessment, detection and prevention of falls among home-dwelling elderly

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<b>Registration date</b> 23/09/2020	<b>Overall study status</b> Stopped	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 20/01/2022	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The worldwide population aged over 65 is rapidly growing and the consequences are simultaneously social, health-related and economic. The process of ageing impacts mobility, muscle strength and balance control which contributes to the increase occurrence of falls in this population. Currently, there are a variety of solutions to address only specific stages of the fall management lifecycle: assessing multiple fall risk factors, detecting falls automatically, and providing strategies for falls prevention that focus on attenuating specific fall risk factors. It was also been shown that some simple exercises, performed by the elderly in their home at least three times a week, help to decrease the probability of falling and injuries resulting from them. A first home visit, these exercises are taught and trained by a health professional who will monitor the process through regular telephone calls and occasional visits. More recently, new technologies have been integrated into this exercise program that have helped to improve the elderly's adherence to physical exercise, because the exercise is carried out in a "more playful" way. This technology also helps to monitor aspects related to the person's health/functionality (e.g. strength of the lower limbs, balance, range of motion of the joints) and to issue alerts to family caregivers if they suffer a fall. Recent investigations demonstrate that there has been a positive effect on adherence and overcoming barriers to physical exercise by the elderly through programs that simultaneously integrate physical exercise and technological solutions. The aim of this study is to evaluate the impact of Otago's physical exercise program with a common technological platform, on the functionality of the elderly in a home context.

### Who can participate?

People aged 65 years or over who are living at home

### What does the study involve?

The study will last for 8 weeks. Participants who start the intervention program will be accompanied by a rehabilitation nurse (face-to-face and/or by phone). Participants will have to answer a questionnaire and perform functional tests (assessment of muscle strength of the

lower limbs, assessment of balance) using a technological platform before the intervention and at the end of 8 weeks. Participants will have a tablet with interactive games to perform Otago exercises autonomously three times a week.

What are the possible benefits and risks of participating?

There are no immediate benefits but there are indirect benefits. The participants will have access to the results of the falls risk assessment and environmental risk factors assessment, which will allow the initiation of measures to prevent falls. Participants will have home visits by rehabilitation nurses to teach, instruct and train exercises aimed to fall prevention. No risks are foreseen for the participants.

Where is the study run from?

Living Lab COLABORAR Network (Portugal)

When is the study starting and how long is it expected to run for?

May 2020 to December 2020

Who is funding the study?

EIT, a body of the European Union

Who is the main contact?

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## Contact information

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Scientific

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## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **ClinicalTrials.gov (NCT)**

Nil known

### **Protocol serial number**

Nil known

## **Study information**

### **Scientific Title**

Physical exercise programme with a common technological platform for risk assessment, detection and prevention of falls among home-dwelling elderly: study protocol for a one group pre- and post-test design

### **Acronym**

FRADE

## **Study objectives**

After an exercise program at home, for 8 weeks, the elderly show improvements in terms of muscle strength, balance, mobility, risk of falling and perception of fear of falling, compared to the initial assessment.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 10/09/2020, Nursing College of Porto (ESEP) Ethics Committee (Rua Dr António Bernardino de Almeida, 4200-072 PORTO - Portugal; +351 (0)225073 500; secretariado@esenf.pt), ref: Annex 2 to Minutes N.º. 6/2020

## **Study design**

Quasi-experimental study (before and after a single group)

## **Primary study design**

Interventional

## **Study type(s)**

Prevention

## **Health condition(s) or problem(s) studied**

Elderly falls

## **Interventions**

The physical exercise program to be implemented is based on the Otago exercise program (PEO), including exercises aimed at balance, gait and muscular strength of the lower limbs. The program is carried out by the elderly independently in their homes, based on a paper-based manual, after face-to-face training with a health professional. In addition to the manual, there will be a common technological platform, consisting of an Android Tablet and a wearable sensor, which will enable the elderly to access the PEO through interfaces with interactive feedback during the execution of the exercises. This technological platform also allows the interactive monitoring of the five strength exercises and three balance exercises (Knee flexion, unipedal balance, and sit and stand).

In the first session, in a home context, the rehabilitation nurse will teach, instruct and train participants in performing the exercises. Participants will be motivated to carry out this program three times a week for 8 consecutive weeks. During these weeks, participants will be accompanied in person or by telephone by the rehabilitation nurse.

## **Intervention Type**

Mixed

## **Primary outcome(s)**

1. Muscle strength measured using 30 Seconds Chair Stand Test (30-CST) at the beginning and at the end of 8 weeks
2. Gait measured using the Timed-Up and Go Test (TUGT), at the beginning and at the end of 8 weeks
3. Risk of falling measured through 30 CST + TUGT and through the technological platform at the beginning and at the end of 8 weeks

**Key secondary outcome(s)**

1. The incidence of falls measured by the number of falls during the 8 weeks by the participants
2. Functional capacity measured through Lawton & Brody at the beginning and at the end of 8 weeks.
3. Fear of falling measured using the Falls Efficacy Scale - International (FES-I) at the beginning and at the end of 8 weeks
4. The usability of the technology measured through the System Usability Scale (SUS) at the end of 8 weeks
5. The environmental risk measured through the Home Fall Prevention Checklist for Older Adults (HFPC) at baseline

**Completion date**

31/12/2020

**Reason abandoned (if study stopped)**

The study was closed due to public health guidance causing restrictions to study activities

**Eligibility****Key inclusion criteria**

1. 65 years or older
2. Living at home
3. Able to walk independently
4. Do not present cognitive impairment according to the Portuguese version of the Mini Mental State Examination (MMSE)
5. Do not have severe visual or hearing impairment
6. Have the motivation to participate in a physical exercise program with technological support

**Participant type(s)**

Other

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**Total final enrolment**

9

**Key exclusion criteria**

1. Chronic or acute illness reported by the participant, for which exercise is contraindicated
2. History of hip or knee surgery or history of lower limb fractures in the last 12 months
3. Be participating or have participated in physical exercise programs in the last 6 months
4. To be participating in another research study involving fall prevention programs

**Date of first enrolment**

01/10/2020

**Date of final enrolment**

30/10/2020

## Locations

**Countries of recruitment**

Portugal

**Study participating centre**

Fraunhofer Portugal collaborating network - COLABORAR

Rua Alfredo Allen 455

Porto

Portugal

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## Sponsor information

**Organisation**

Escola Superior de Enfermagem do Porto

**ROR**

<https://ror.org/03562fh87>

**Organisation**

Fraunhofer Portugal Research Center for Assistive Information and Communication Solutions

## Funder(s)

**Funder type**

Research organisation

**Funder Name**

EIT Health InnoStars

## Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to the item data collection and information security, which is part of the informed consent (annex) for study participants, which specifies the following:

The information collected will be of exclusive use for the present study, which will be shared between the entities promoting the investigation, namely ESEP and Fraunhofer Portugal. Access to the database will only be granted to the entities promoting the investigation and the data will be stored and maintained in restricted access areas and subject to the security rules in force at ESEP and Fraunhofer Portugal facilities. Participants will have guaranteed the right to data portability if they express this desire and the right to erase personal data if they abandon the study. After writing the report and publishing the results, the database will be destroyed.

## IPD sharing plan summary

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	12/08/2021	16/08/2021	Yes	No
<a href="#">Protocol file</a>			08/10/2020	No	No