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

Submission date
16/09/2020

Recruitment status
Stopped

Registration date
23/09/2020

Overall study status
Stopped

Last Edited
20/01/2022

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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 Nº. 6/2020

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

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

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 measure
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

Secondary outcome measures
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

Overall study start date
04/05/2020

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

Age group
Senior

Sex

Both

Target number of participants
Sample with a minimum of 30 participants

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
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Sponsor information

Organisation
Escola Superior de Enfermagem do Porto

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Sponsor type
University/education

Website
https://www.esenf.pt/pt/

ROR
https://ror.org/03562fh87

Organisation
Fraunhofer Portugal Research Center for Assistive Information and Communication Solutions

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Sponsor type
Research organisation

Website
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Funder(s)

Funder type
Research organisation

Funder Name
EIT Health InnoStars

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
26/02/2021

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?
Protocol file			08/10/2020	No	No
Protocol article	protocol	12/08/2021	16/08/2021	Yes	No