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Motor control Home ergonomics Elderlies' Prevention of falls (McHeELP)

Submission date
13/08/2020

Recruitment status
No longer recruiting

Registration date
17/08/2020

Overall study status
Completed

Last Edited
06/09/2023

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Early recognition of elderly people at risk of falling, their needs for appropriate personal-aids, and the provision of ergonomic solutions for arranging their home-environment, are part of the ongoing effort of clinicians to contribute in preventing falls. At the same time, in order to enhance their physical activity, elderly people are recommended exercise programs that usually require an initial relatively-good activity level, or the transfer of the elderly to specialized centers or facilities. These circumstances may pose certain difficulties since they require the individual's safety and compliance.

Updated data on the control of movement and the brain's ability to change and respond suggest that in certain areas of the brain changes in connections occur in relation to specialized practice: the repeated practice of an activity that is part of a functional task. The adult brain still has the ability to react to functional challenges, whilst inactivity leads to impaired cognitive function and increased reaction time.

This study involves the creation and evaluation of how applicable and effective a home-based program of motor control exercises of the lower extremities would be. The program is designed for a specific desired functional result, combined with individualized preventive ergonomic safety interventions, in frail ambulatory elderly (FAE) people. Additionally, the overall participants' compliance, the correlation of the extracted results with factors relating to clinical characteristics, functional capacity and health-status, the recording of new falls, and the fear of falling, will also be measured.

Given the above, the aim of this research is to develop and evaluate a combined intervention of motor control exercises and ergonomic arrangement of the home environment in order to reduce falls in FAE.

Who can participate?
Adults aged 65 and above

What does the study involve?
This study involves:

1. The creation of an evidence-based intervention program of movement control exercises of the lower extremities, appropriately designed for FAE
2. Personalized evaluation and changes in matters of safe behavior, clothing and footwear risk
3. The ergonomic evaluation of the residence of the elderly and ergonomic changes where needed
4. Checking the effectiveness of this combined program through this study
5. The comparison of outcomes of the program between the populations of Attica and Achaia

Participants will be randomly allocated to one of two groups, either receiving the individual home-based exercise program for movement control of the legs and home modification, or usual care only. Participants will be complete assessments at the start of the 12-week exercise program, immediately after and at 12 weeks after the exercise program has finished.

What are the possible benefits and risks of participating?
A key expected benefit is a reduction of the fall incidences and/or their severity, as well as an improvement in the functionality and quality-of-life of the FAE within their home environment. It is also expected that there will be a decrease in fear of falling and improved motor control, the reduction of reaction time by practicing specific functional activities, and transfer of this effect to daily-life activities. Also, adjustable lifestyle and environmental factors are expected to be easily identified, increasing the benefits for primary and secondary health care systems.

There are no notable risks of participating. Participation in the study is voluntary. Participants can refuse to participate or stop participating at any time. All information obtained for this study will be used for research purposes only and will be kept strictly confidential.

Where is the study run from?
1. Physiotherapy Department of the University of West Attica (Greece)
2. Physiotherapy Department of the University of Patras (Greece)

When is the study starting and how long is it expected to run for?
From February 2020 to July 2021

Who is funding the study?
European Social Fund, Programme Support of researchers with emphasis on young researchers – 2nd Phase (Grants 2019) of the program ESPA 2014-2020, E.P. Developing Human Resources, Education and Lifelong Learning 2014-2020 (Greece)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
80790

Study information

Scientific Title
The effect of the implementation of a combined motor control and ergonomic safety-improvement home-based program in the reduction of falls in ambulatory frail elderly

Acronym
McHeELP

Study objectives
To investigate if a motor control exercise programme could increase functionality and reduce falls

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/02/2020, the University of Patras (University Campus, 26504 Rio Achaia, Greece; +30 2610 997841; rescom@upatras.gr), ref: 9807/05/02/2020

Study design
Multicenter randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of falls in community-dwelling older adults

Interventions
After the baseline assessment, participants will be randomly assigned to one of two groups, group A or B. A quasi-random method, with a 1:1 allocation ratio, will be used for randomization, namely the first selected patient will be assigned to the intervention group, the second to the control group, and so forth. The randomization procedure will be performed by an independent clinician and the participants will be blinded to group allocation. Group A will receive the 12-week individual home-based exercise program for motor control of the lower extremities and individually assessed ergonomic home modification. Group B will receive usual care only.

Participants will be assessed before the 12-week exercise program, immediately after and at 12 weeks after the exercise program has finished.

Intervention Type
Behavioural

Primary outcome(s)
1. Function will be assessed using the Timed Up and Go Test at baseline, 12, and 24 weeks
2. Gait speed will be assessed using the 4-m test at baseline, 12, and 24 weeks
3. Fear of falling will be assessed using the Falls Efficacy Scale International (FES-I) questionnaire at baseline, 12, and 24 weeks

Key secondary outcome(s))
1. Quality of life will be evaluated using the Greek version of the EQ-5D questionnaire at baseline, 12, and 24 weeks
2. Depression and anxiety will be assessed using the Hospital Anxiety and Depression Scale (HADS) at baseline, 12, and 24 weeks
3. Balance will be assessed with the Tandem test and Functional Reach test at baseline, 12, and 24 weeks
4. Physical activity will be assessed with the international physical activity questionnaire (IPAQ) questionnaire at baseline
5. Ability to perform everyday tasks will be assessed using the Lower Extremity Functional Scale (LEFS) questionnaire at baseline, 12, and 24 weeks
6. Proprioception will be assessed using the Lord test and Foot taping test at baseline, 12, and 24 weeks
7. Muscle strength for lower limbs will be assessed using the sit to stand test (30seconds) at baseline, 12, and 24 weeks
8. The active range of the knee and ankle flexion motion and the extension motion will be measured at baseline
9. Coordination will be assessed using the heel-to-shin test at baseline, 12, and 24 weeks
10. Mental state is assessed with the Clock Drawing Task, CDT (Mini – Coq) at baseline
11. Home environment will be assessed using the home falls and accidents screening tool (HOMEFAST) questionnaire at baseline, 12, and 24 weeks
12. Adherence to prescribed home exercise will be assessed via Exercise Adherence Rating Scale (EARS) at 12 weeks
13. Shoe type will be assessed using the Footwear Assessment Tool at baseline, 12, and 24 weeks
14. Baseline data and demographic characteristics will be measured prior to study recruitment

Completion date

01/07/2021

Eligibility

Key inclusion criteria
1. Aged >65 years
2. Willing to be assigned to any of the two study intervention groups

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 years

Sex
All

Total final enrolment
20

Key exclusion criteria
1. Cognitive impairments
2. Neurological disorders
3. Cardiovascular diseases or high blood pressure not controlled with medication
5. Surgery on lower limbs affecting gait within the previous 6 months
6. Medical or other musculoskeletal problems that could affect the ability to complete objective assessments, or exercise with safety
7. Engaged in exercise training currently or within the previous 3 months

Date of first enrolment
01/09/2020

Date of final enrolment
01/04/2021

Locations

Countries of recruitment
Greece

Study participating centre

University of Western Attica
Egaleo
Athens
Greece
12243

Study participating centre
University of Patras
Rio campus, Achaia
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Greece
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Sponsor information

Organisation
University of West Attica

ROR
https://ror.org/00r2r5k05

Funder(s)

Funder type
Government

Funder Name
European Social Fund

Alternative Name(s)
European Social Fund, Европейският социален фонд, Европейският социален фонд плюс, Fondo Social Europeo, Fondo Social Europeo Plus, Ευρωπαϊκό Κοινωνικό Ταμείο, Ευρωπαϊκό Κοινωνικό Ταμείο+, Ciste Sóisialta na hEorpa Plus, Ciste Sóisialta na hEorpa, ESF, ESF+, ЕСФ, ЕСФ+, FSE, FSE+, EKT, EKT+, CSE, CSE+

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study will be stored in a non publically available repository. Access is only available to the corresponding author (Dr. Maria Tsekoura) and the 3 additional researchers (Dr. Stasi S., Prof. Sakellari V., Prof. Gliatis J.). During recruitment, participants will be informed of the purposes of the study. Participants will agree to participate and will sign an informed consent form. Names of participants on the datasets will be replaced with codes, ensuring anonymisation (not applicable via weblink). Individual participant data collected during the trial will be available after de-identification (text, tables, figures, and appendices), beginning 9 months and ending 36 months following article publication. Access will be granted to researchers who provide a methodologically sound proposal, in order for them to achieve the aims in the approved proposal. Proposals should be directed to mariatsekour@upatras.gr. To gain access, data requestors will need to sign a data access agreement. After 36 months the data will not be applicable.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/04/2021	11/05/2021	Yes	No
Results article		27/09/2021	06/09/2023	Yes	No
Protocol article		01/09/2021	06/09/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes