**Research Protocol**

# Methodology of a home-based motor control exercise and ergonomic intervention programme for community-dwelling older people: The McHeELP study

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**Abstract**

The aim of this research (Motor control Home ergonomics Elderlies' Prevention of falls; McHeELP study) was to develop a novel intervention combining motor control home-based exercises and a home ergonomic safety-improvement strategy in order to reduce falls in frail ambulatory older adults. A randomized controlled trial of a novel intervention is proposed including motor control exercises and home ergonomic assessment and modification in older adults who have at least one fall experience. Participants are randomized to control or intervention group in a 1:1 ratio. Participants will be assessed three times: at baseline, at 3rd month (end of intervention period) and again at 6th month (follow-up measurement). The primary outcome is of the effect on functional mobility using the Timed Up and Go test. Secondary outcomes include assessments of functionality, fear of falling and quality of life. This will be the first study to develop an exercise intervention approach that combines home-based motor control exercise intervention with home assessment and modification. This study is expected to explore a low-cost, easy-to-popularize, and effective exercise intervention approach for improving functional mobility and prevent falls among older adults.

**Keywords:** Exercise, Falls, Home modification, Lower extremities, Motor control

## Introduction

Falls are a common and serious health problem with serious consequences such as disability and morbidity[1]. Approximately 30 per cent of people over 65 years, living in the community fall each year; the number is higher in institutions. Various multidisciplinary interventions targeting multiple risk factors have been proved to be effective ways for fall prevention[2].

Exercise has been described as the most cost-effective strategy for preventing falls and fractures in community dwelling older adults[3,4]. Most exercise interventions include strength, gait retraining, balance exercises or other group training, i.e. Tai Chi. Research findings regarding motor control exercises and falls are limited Home safety interventions also have a role in prevention especially in those patients with a history of falling[2,5]. These interventions include adaptations necessary for older adults in order to make the living environment safe and accessible[6]. Home

hazard assessment with modification of risk factors has been proven efficient for older adults with most obvious beneficial effect in high-risk groups. The methods for home hazards assessment and the methods recording falls and injuries varied among the studies. The appropriate selection of existing interventions is critical to minimize the incidence of falls and their consequences in older adults[7]. Research findings regarding motor control exercises and falls are
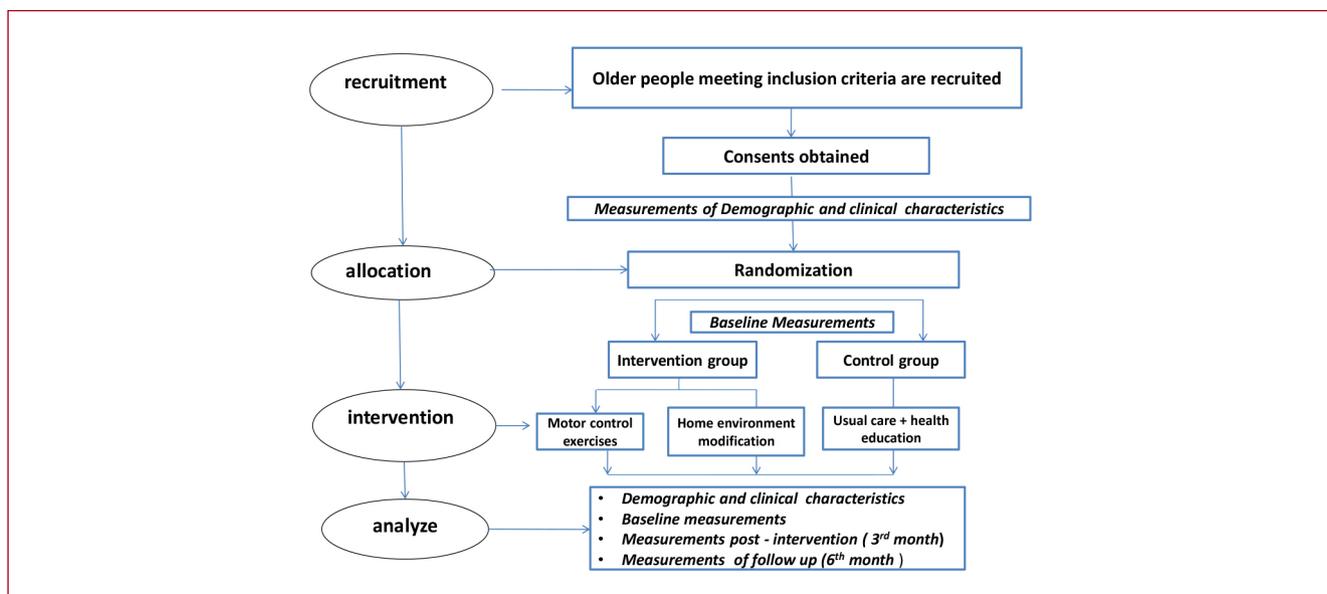
**Figure 1.** Study design-Flow chart

limited and information regarding home interventions are inconsistent and more research is needed that explores the impact of home modifications on fall prevention[8]. Thus, the aim of this research is to develop and evaluate a combined intervention of home-based motor control exercises and ergonomic arrangement of the home environment in order to reduce falls in older adults. We hypothesize that this intervention will improve functionality and reduce potential possible fall-risk factors in home's environment, and the fear of falling in older adults. In addition, it will make a significant contribution to physiotherapists and health practitioners, by developing a novel evidence-based approach to fall prevention in older adults.

## Materials and Methods

### Study design

This protocol describes the setting of a 3-months intervention period and 6-months follow-up period assessing the impact of a "motor control exercise intervention and home assessment and intervention program", on preventing falls and health in older people. Participants will be randomly assigned to different groups; either an intervention or a control group. Figure 1 presents the complete process for this study.

### Ethics approval

The study protocol was approved by the Ethics Committee of University of Patras (9807/05/02/2020). Additionally, the study has been registered at www.isrctn.com following identification number: ISRCTN15936467.

### Recruitment and consent

Participants are recruited from the regions of Attica and Achaia, using flyers, posters, and advertisements in newsletters. Eligible individuals will be provided with consent forms before participating in the study.

### Inclusion criteria

Before recruitment, each participant is screened for eligibility whether he/she meet the following inclusion criteria: (i) aged ≥65 years old and (ii) have at least 1 fall in the past year.

### Exclusion criteria

Participants will be excluded if they are already participating in an exercise programme, have been told not to exercise by a physician, have a cognitive impairment (according to medical diagnosis), or if there is medical problem that could affect ability to complete objective assessments and/or exercise intervention.

### Randomization

After participant written informed consent have been obtained, he/she is will be allocated into either an intervention (Group A) or control group (Group B). The 1:1 allocation ratio, will be used for randomization, as it has been reported that this allocation ratio provides the greatest power for testing effectiveness for the future randomized controlled trial (RCT)[9]. 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 the group allocation.

| Exercise domains | Stage 1 (weeks 1-4) | Stage 2 (weeks 5-9) | Stage 3 (weeks 10-12) |
|---|---|---|---|
| **Warm up exercises** | Activity: Ankle heel toe, figure of eight shoulder exercises, free knee extension-flexion, knee raises | Activity: As in phase 1 | Activity: As in phase 2 |
| **Serial skills exercises-alternating and/or successive movements** | Activity: Heel shin sliding, sit to stand, leg to target, scroll ball, toe towel, rhythmic feet tapping 1 to 1, Knee raises to target (stick), obstacle cross on the side | Activity: As in phase 1 Added leg to 2 targets, feet tapping 2 to 1, torso stretch without support | Activity: As in phase Added leg to 5 targets, foot tapping 3 to 1, sit to stand without support |
| **Cognitive skills** | Activity: Rhythmic feet movements while singing, knee extension with fruits spelling or counting or Reciting categories of flowers, animals etc, side lunch holding a glass | Activity: As in phase 1 Added , side lunch holding and fixating a glass | Activity: As in phase 2 side lunch holding and fixating a glass and counting |
| **Balance** | Activity: Functional reach (sitting position), tandem balance, (sitting position), lean forward & sideling with stick support, Lean and rotate trunk Holding and fixating a raised ball with width feet base, trunk forwards the wall. | Activity: As in phase 1 Added Lean and rotate trunk holding and fixating a raised ball narrow feet base, trunk sideward the wall | Activity: As in phase 2 Added Lean and rotate trunk Holding and fixating a raised ball narrow feet base in tandem feet base, trunk backwards the wall. |
| **Sensory strategy** | Activity: Raised arms holding and fixating a ball towards and away from the eyes (sitting position). Facing the wall corner-alternative turning to color targets placed sideways (standing position). Facing a wall corner, palm placing on the wall alternative placing Imans on the target (sitting). Knee raises with closed eyes. closed eyes and leg to 1 target | Activity: As in phase 1 Added Raised arms holding and fixating a ball towards and away from the eyes (standing with width feet base). Facing the wall corner-alternative turning to color targets with closed eyes. Facing a wall corner, palm placing on the wall alternative placing Imans on the target (standing wide). Knee to target (stick) with closed eyes | Activity: As in phase 2 Added Raised arms holding and fixating a ball towards and away from the eyes (standing with narrow base). Facing the wall corner-alternative placing raised palms (standing position) with open eyes or closed eyes. Facing a wall corner, palm placing on the wall alternative placing Imans on the target (standing narrow). Heel- shin sliding with closed eyes. Knee to target (stick) with closed eyes and counting |
| **Dynamic control** | Activity: Sit to stand armrest support, Foot placement on a stair with support, Ankle raises (standing position) with 2 hands support, Reaching the sealing, seated, Imaginary obstacle sideways crossing (shin support) | Activity: As in phase 1 sit to stand pushing thighs, Foot placement on a stair with support , Ankle raises (standing position) with 1 hand support, Reaching the sealing and holding the cupboards, obstacle crossing forward (shin support) | Activity: As in phase 2 sit to stand without support, Ankle raises (standing position) without support, reaching the sealing and holding the cupboards on toes |

**Table 1.** The McHeELP Exercise Programme.

### Control group

The older adults allocated in the control group do not receive exercise during the time of the study. This group will receive a health and wellness education session. This session is designed to last 30-45 minutes. Instructional topics will include areas such as healthy eating habits, and preventive health care (e.g. health screenings for various systems)[10].

### The concept of McHeELP exercise programme

Motor control is the "ability to regulate or direct the mechanisms essential for movement". The exercise movements are patterns interacting with different body systems (e.g. sensory/perceptual, cognitive, and motor/action)[11].

The design of McHeELP exercise programme was based on the more prevalent approaches used in motor learning research. Firstly we adapt the Schmidt's classification, in which the skills differentiated as discrete skills (having a clear and defined beginning and end), continuous skills (having no recognizable beginning and end; they require repetition of movement patterns), and serial skills (involving various steps or a series of movements to complete the task)[12]. Moreover, the Cratty's classification of gross motor skills, in which a great deal of muscular involvement - total body and/or multi limb movements were required, is taking into account[13]. The intention was to design a motor control exercise programme that could be customized to individual skills, and could be performed efficiently and safely at

| Demographic, behavior performance, and history of physical illness: | Face-to-face interview, assessment of cognitive function (baseline) |
|---|---|
| Physical Performance Measures: | Timed up and go test (TUG), 4 meters walking test, sit to stand test (baseline, 12, and 24 weeks) |
| Balance assessment: | Tandem stance test, functional reach test at baseline, 12, and 24 weeks |
| Proprioception assessment: | Lord, and foot taping test at baseline, 12, and 24 weeks |
| Coordination assessment: | Heel-to-shin test at baseline, 12, and 24 weeks |
| Mental state assessment: | Clock drawing task, cdt (mini - Cog) at baseline |
| Self-reported Fear of falling assessment: | Falls efficacy scale international (FES-I) questionnaire at baseline, 12, and 24 weeks |
| Self-reported Quality of Life assessment: | The Euro Qol 5d questionnaire at baseline, 12, and 24 weeks |
| Self-reported functional assessment: | Lower extremity functional scale (LEFS) questionnaire at baseline, 12, and 24 weeks |
| Home environment assessment: | Home falls and accidents screening tool (HOMEFAST) questionnaire at baseline, 12, and 24 weeks |

**Table 2.** Outcome measures.

home without supervision. The role of physiotherapists will be to evaluate the functional level of the individual, so to tailor the best possible exercises for the individual from the McHeELP package. The McHeELP programme includes a package of motor control exercises, which are divided into 6 domains, namely: "Warm up", "Serial skills", "Cognitive skills", "Balance", "Sensory strategy", and "Dynamic control" (Table 1). Each domain was named in respect to the body system, in which the exercises are mainly/ principally targeted. This separation will also be helping the physiotherapists and the easier implementation of the programme. The underlying philosophy of the McHeELP's domains is briefly descripted below.

### Warm up domain

An appropriate warm up period including simple preparatory exercises from seated position is recommended in order to get older adults into the mood of practicing and maximising performance[14].

### Serial skills domain

This domain includes repeated exercises with oriented motor skill movements. The concept is that movement variability refers to an individual's overall consistency of an executed task across trials. Increased variability may reflect decrements in the motor system in its ability to produce the same movement output repeatedly. This domain's exercises included -as suggested- two types of movement variability: variability of the end point and variability of the components of the movement trajectory[15].

### Cognitive skills domain

It is well known that benefits of training may become particularly apparent in situations where participants must perform motor and cognitive tasks concurrently[16].

### Balance domain

Balance training may improve stability, posture and balance control. Multifactor balance training requires several modalities of sensory information to be processed and integrated simultaneously[15].

Based on the facts that older adults rely more on visual control when acquiring and performing a precision locomotor task[17], and that individual differences in motor plasticity of the elderly might be strongly associated with sensory (hearing and vision) and cognitive functioning (i.e. memory)[13], we designed the exercises of this domain.

### Dynamic control domain

This domain includes both stepping and walking patterns, with continued implementation. These specific exercises by regular activation of the local stability muscles, enhanced balance skills which is required for the performance of daily-life activities[18].

### Intervention

A 12-week individual home-based exercise programme for motor control of the lower extremities and individually assessed ergonomic home modification will be implemented to the research group. Participants of research group will be receiving a personalized home therapeutic motor control and learning exercise programme, which will be performed 3 times per week for 12 weeks. We estimated that the programme will be lasts for 20-30 minutes per session in addition to the warm-up exercises (2 exercises of each domain, a total of 12 exercises in each session). Participants will be instructed by the physiotherapist to perform the exercises, within their individual range of motion. The strategy is to start low load motor control exercises from a basic level and continue to a gradually increased level of

difficulty. Progression of the exercises will be determined by the researcher based on the number of repetitions, the patient's fatigue, abilities and/or observed movement control and the functional level of participants[18-20]. For the sets of repetitions taking into account in accordance with the American College of Sports Medicine Position Stand for exercise and activity in older adults (first stage: 1set x10 repetitions; second stage: 2 sets x10 repetitions; third stage:3 sets x10 repetitions)[21]. Details of the stages of the exercises are presented in Table 1. The first stage consists of exercises that are more stable and the main focus is learning a pattern of movement at a low intensity and without fatigue. The exercises become increasingly difficult requiring more stability, balance and concentration. The McHeELP exercise programme will be delivered by two well-trained and highly-experienced geriatric physiotherapists.

Each participant will be received a detailed booklet outlining the exercises of the programme. For each participant, the physiotherapist supervising the home programme by visiting each participant's at home to instruct him/her on how to perform exercise safely and properly and revisited his/her individual programme, three more times, to make progressive adjustments to the exercise protocol. During each visit the recruitment of the trunk muscles, posture, movement pattern, and breathing are assessed and corrected by the physiotherapists. In addition, older adults will be asked to keep an exercise diary and record the days they completed the exercises. All participants will receive a health and wellness education session (same as the control group) and will be instructed not to perform any additional individual and/or group exercise during the programme.

### Ergonomic home assessment and modification programme

In terms of home modification programme a booklet is given to each participant with basic advices and modifications for kitchen, bedroom, living room, bathroom and stairs of the home environment.

Participants of research group will be receiving general instructions regarding home assessment and modification intervention. During our three intermediate sessions-appointments the participants of the intervention group will be reminded to make these modifications. All participants will perform exercises in the same room during the intervention. In addition all material will be the same (chair etc). The adaptations are of low cost such as removing hazards (e.g., throw rugs); moving furnishings to create clear pathways; replace lamps with insufficient lighting; changing places where activities occur (i.e., sleeping on the first instead of the second floor)[8].

### Outcome measures and measurement procedures

A full list of measurable outcomes is presented in Table 2. Participants will be assessed at baseline, immediately post-intervention (3rd month), and at 6th month (follow up measure). Measures included an interview survey, and objective physical performance tests and self-reported questionnaires, regarding functionality, balance, fear of falling and quality of life. Assessment will be undertaken by two licensed physiotherapists and experienced in the management of geriatric patients. Both researchers involved in data collection were trained in study procedures before the study.

### Interview Survey

Each participant is interviewed face-to-face to assess his/her history of falls (from last 12 months), falls characteristics (indoor/outdoor; consequences and injuries) lifestyle habits, exercise habits. Medication (both number and type of drugs) will also be collected (with the approval of the participants) by medical records through the national electronic system and digital social service. Demographic variables, including age, gender, living status (alone or with another person), and educational level are also assessed. Information on smoking ("not currently smoking" and "currently smoking") and drinking ("not currently drinking" and "currently drinking"; amount of alcohol) statuses are also obtained from the questionnaire[22]. The Mini-Cog test (v.01.19.16) will also be administered to the participants. Cognitive impairment will be established according to the medical diagnosis. Additionally, and in order to verify cognition state changes at admission, cognition will be assessed by the Mini-Cog test. The Mini-Cog is a simple screening tool that is well accepted, takes up to only 3 minutes to administer and shows signs of cognitive function[23].

### Description of Outcome measures

1. Timed Up and Go test. The Timed Up and Go (TUG) Test has been recommended to assess gait and balance and it has been validated as an appropriate method for evaluating elderly individuals' risk of falling[21,24,25]. Participants were seated in a standard 45 cm height chair, with the back against the chair, both arms resting along their body and both feet completely resting on the floor. The TUG assesses the number of seconds needed for an individual to stand up from a chair, walk 3 meter at their usual pace past a line on the floor, turn around, walk back to the chair, and sit down again with the back against the chair[26].

2. The 4 meters walking test. Walking speed was assessed via the four meter (4 m) walking test. Participants are informed to walk 4 m with their usual speed. Walking speed is assessed in seconds by a manual chronometer. Timing started at the first foot movement and ended when a foot completely crossed the finish line[27].

3. Sit to stand test. The sit-to-stand test (STST) investigates the ability to stand up from a sitting position; investigating functionality and lower limb strength. The test is administered using a chair without arms, with seat height of 17 inches. The 30-second

STST records the number of stands a person can complete in 30-seconds[28,29].

4. Tandem stance test (heel-toe). The participant places the foot immediately in front of the other (heel to toe), arms down by their side. The test requires the participant to maintain balance while standing in a tandem heel-to-toe position[30].

5. Functional Reach Test (FRT). The participant barefoot and standing upright, is positioned with one side (e.g. right) of the body close to the wall. A yard stick is attached to a wall at about shoulder height. The instruction is to "reach forward along the yardstick as far as you can without taking as step" along the yardstick. The location of the 3rd metacarpal is recorded. The researchers measures the distance the person can reach forward beyond's arm length while standing in a fixed position[31,32].

6. Lord test. Lower limb proprioception is assessed using a lower limb-matching task, using a protractor inscribed on a vertical clear acrylic sheet placed between the legs[33]. In this test, older participants are seated with their eyes closed and are asked to align their lower limbs simultaneously on either side of a vertical clear acrylic sheet (60×60×1 cm) inscribed with a protractor and placed between their legs. Each trial is undertaken relatively quickly, with rests between trials, to avoid weakness unduly influencing the results. Any difference in aligning the lower limbs (indicated by disparities in matching the great toes on either side of the acrylic sheet) is measured in degrees. After 2 practice trials, an average of 5 experimental trials is recorded[34].

7. Foot tapping test. The participant sits on a chair with its height adjustable, so that the bilateral soles made contact with the floor, with the hip and knee joints flexed at approximately 90°. He/she moves their toes up and down repeatedly, tapping the floor as quickly and vigorously as possible with their heels firmly planted on the floor for 10 sec. The researcher counts the number of taps[35].

8. The heel to shin test. The older participant is in sitting position and places his/her heel on the opposite knee and then slide it down their shin to the top of their foot, repeating as quickly and as accurately as possible. The researcher tests both legs[36,37].

9. Falls self-efficacy international scale (FES-I). This tool was developed by members of the Prevention of Falls Network Europe (ProFaNE) consensus group and has excellent psychometric properties. FES-I, a 16 item questionnaire has been widely used assessing fear of falling[38,39].

10. Lower Extremity Functional Scale (LEFS). The LEFS, is a functional status questionnaire. The aim is to assess functional status and investigates the degree of difficulty a patient experiences in performing everyday activities, in patients with disability of the lower extremity[40,41].

11. Euro QoL questionnaire. The EQ-5D-5L is a well-known and widely used health status instrument; measuring health related quality of life. The EQ-5D-5L assesses five dimensions of health (mobility, self-care, usual activity, pain/discomfort, and anxiety/depression). The second part of the questionnaire used the VAS Scale and ask responders to self-rate themselves on a "thermometer" scale[42,43].

12. Home falls and accidents screening tool questionnaire (HOMEFAST). The HOMEFAST questionnaire is used to identify hazards in older adults' homes. It consists of 25 items focusing on seven main areas of potential hazards: floors, furniture, lighting, bathroom, storage, stairways/steps and mobility[44].

## Statistical analyses

An independent senior biostatistician will be support the analysis and interpretation of data gathered during the completion of this clinical trial. Prior to the main study, a pilot study will be performed in order to examine the feasibility of the study protocol, the acceptability of intervention, the selection of the most appropriate primary outcome measure, and the exact sample size calculation. Sample size estimation will be performed using G*Power vr 3.1.9.2[45]. Additional subjects may be added to the programme (10-20%) to compensate for data loses and/or withdrawals. For both the pilot and the main study, data will be expressed as mean $\pm$ SD for quantitative variables and as percentages for qualitative variables. The Kolmogorov-Smirnov test will be utilized for normality analysis of the quantitative variables. The homogeneity between compared groups will be examined using Student's t-test, the chi-squared test and Fisher's exact test for the quantitative and qualitative demographic and clinical variables, respectively. The efficacy of the intervention during the observation period will be evaluated by calculating the mean percentage changes from baseline to post-intervention (3rd month) and at 6th month (follow up). Comparison of percentage change from baseline of clinical variables during the observation period between the 2 groups will be analyzed using the Independent samples t-test or Mann-Whitney tests in case of violation of normality. The comparison of change of categorical variables from baseline to 3rd and 6th month, between groups will be examined using the Chi-square test. All tests will be two-sided and a p-value of <0.05 will be used to denote statistical significance. All analyses will be carried out using the statistical package SPSS vr 21.00 (IBM Corporation, Somers, NY, USA).

## Discussion

The main McHeELP study will be a randomized controlled trial examining the efficacy of a motor control exercise intervention plus a home modification programme giving a novel look at healthy aging and prevention of falls. Motor performance deficits in older adults include difficulty in

coordination[46,47], increased variability of movement[48,49], slowing of movement[50], and balance and gait difficulties[46,51]. Literature data shows the impact of peripheral changes in the neuromuscular and sensory systems on motor control in older adults and it is clear that central brain changes play a role as well[46,52]. Since a decline in the quality of motor representations, or an impoverished motor control might enhance the risk of traumatic injuries in older adults[53], this study aims to develop a motor control exercise training programme for the lower limps, including both motor and cognitive tasks. Researchers suggest that reduced automaticity of lower limb motor control in healthy older subjects leads to the recruitment of additional premotor resources even in the absence of basic gait functional disabilities[54].

We created a new home-based exercise programme - the McHeELP - including motor control exercises of the lower limp. This exercise programme is based on research and literature review of various published data[46,55-60]. Motor skill is designed as the selection of the minimum capacities to meet task demands, or the most appropriate motor plan for the task[54]. Furthermore in older adults with walking difficulty (slow gait speed and variable gait patterns), the task-oriented motor learning intervention may promote greater gains in clinical measures of gait (gait efficiency, gait speed and self-perceived walking ability) compared to a standard exercise program[56,61]. Exercise focus in adjustments are made for changes in the limbs, muscles and posture, which enables the skilled mover to focus on the movement goal, while spinal and supraspinal motor centers organize and implement successful movement strategies[59,62]. In addition, this programme follows the principle of specificity in that it is based on exercises targeting various systems for balance control. Training specificity is a key element of motor learning[58,60].

The McHeELP programme is a personalized home-based exercise training program. It includes a package of exercises divided into 6 domains [1 (warm up) and 5 motor control domains]. Each session includes 12 exercises chosen from all domains. However the exercise programme and the specific exercises are chosen according to an individual's physical function, health status, exercise responses, and stated goals[63]. The exercise selection must consider the level of training of the practitioner. In the prescription of exercise at home, an initial challenge is to adapt the level of difficulty of the proposed exercises to people's capacity. Personalized home-based exercise programmes may optimize the training's effectiveness, help lower the risk of falls and improve physical performance for older adults. It will also may increase the pleasure of exercising[19,20].

In terms of location, a home based exercise programme has been chosen. Various researchers suggest that interventions with home-based exercise programmes are effective for older adults[19,64,65]. Additionally, home based exercise programmes are cost effective and many older adults can benefits due to various limitations accessing an on-site program. In exceptional times, like a pandemic (e.g. COVID-19 pandemic), home-based programmes can expand to accommodate patients who are suddenly displaced from on-site care, enabling uninterrupted care while both patients and health professionals can remain safely at home[66]. Home based exercises following physical activity guidelines (e.g. for older adults[7] are proposed as an essential part of the self-isolation/ protection guidelines[68]).

The dose of exercise is described by the duration, frequency and intensity[69,70]. The intensity guidance on the intensity of stimuli is necessary, since the general recommendation that the intensity be moderate. Most motor control exercises, whether focused on muscle recruitment pattern or retraining of optimal movement pattern, are usually performed with lower loads[71]. The intensity of physical exercise is indirectly regulated at levels where the impact on positive feelings and emotions would be minimal[68].

Making older adults exercise and keeping them in exercise programmes is a major challenge[72]. Important factors for engagement in exercise are frequency, intensity, type, location and social setting. In order to maintain adherence the 2 physiotherapists/instructors visits regularly the participants in order provide: i) ongoing support and motivation and ii) proper progression of exercises. Furthermore, all components of the program are 'easy to perform'[64,65]. One more possible advantage of the McHeELP program is the ability to provide a well-structured comprehensive programme without added special and expensive equipment and/or technology expenditures[65].

Finally the intervention includes home assessment and modification programme. Home environment assessments and interventions for people with known fall risk factors or a history of falling is an important strategy to reduce the likelihood of falls[8,73]. The methods for home hazards assessment and the methods recording falls and injuries varied among the studies[74]. The assessment is performed according guidelines and the HOMEFAST is a reliable and valid instrument[44]. The researchers give to all patients a booklet with advices and suggestions for modifications of the home environment. The proposed modifications are low cost adaptation in order all participants to be able to manage.

Exercise programmes easy-to-administer need to be developed and implemented, in order to reduce the burden of falls in elderly people. The McHeELP study will investigate the effectiveness of a novel home-based and cost effectiveness intervention programme for improving health and prevent falls among older adults. Results of this study may provide important evidence for guidelines to prevent falls and improve health in older people.

## Limitations

The present study has some limitations. The final number of participants required for each group in this study is not possible to be estimated in the methodology section.

Therefore a pilot study of the McHeELP programme will be performed in order to address this issue.

The exercises involved in this protocol are not very demanding physically. However, joint pain and/or muscle weakness may preclude an older adult from being able to perform them on a 'difficult' day. Also, a percentage of participants may not attend for a variety of reasons. The COVID pandemic is a potential threat to our study. In addition, it is not possible to record compliance with the listed medication. The use of inappropriate dosage, such as the elderly failing to use a low dose of benzodiazepines or irrational use of drugs with side effects may affect the balance, especially those that cause orthostatic hypotension or confusion. Finally, the protocol will be performed by very experienced clinicians, so the results cannot be generalized at least not without previews training of the trainers.

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