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Enhancing falls rehabilitation through dynamic visualization of movement

Submission date
30/01/2012

Recruitment status
No longer recruiting

Registration date
13/03/2012

Overall study status
Completed

Last Edited
02/10/2018

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Strength and balance exercises have been shown in several studies to reduce the risk of falling in the elderly. However, older adults may not receive the full advantage offered by home rehabilitation either due to the lack of feedback on performance or due to reduced motivation to perform boring rehabilitation exercises. This study proposes:
1. The use of visual feedback of movement (visualisations) to provide advice on the recommended quality of movement to achieve the best recovery results; and advice on the main compensatory strategies, employed by the user, that may negatively affect the effectiveness of the exercises in the recovery of strength and balance.
2. The use of multimodal games to make rehabilitation more enjoyable for older adults.
We think that the use of visualizations and games for rehabilitation will be more effective than standard care, thereby improving adherence to home exercise, promoting independence, and improving the quality of life of older adults at risk of falling.

Who can participate?
Adults over the age of 65 who have been identified by the Glasgow Falls Service as being at risk of falling.

What does the study involve?
Participants will be randomly allocated to one of three groups. The control group will be given standard home rehabilitation care for falls (the Age UK instructional booklet). In the visualizations group, in addition to the standard rehabilitation care, participants will receive visual feedback during home exercise. These visualizations present the rehabilitation exercises to the participants using an animated mannequin that will demonstrate the correct range and speed of motion required for each exercise. They also show the users real-time feedback of their movements as they perform their exercises, provide a summary of their performance during the process, and provide information on the principles behind strength and balance exercises, and the role of these exercises in the prevention of falls. In the multimodal games group, in addition to standard care, the participants will be given multimodal games based on falls exercises to make rehabilitation more enjoyable. The games provide the users with a more interactive and

enjoyable way to perform home exercise, and inform them on their performance and progress during rehabilitation by tracking game scores, achievements and user repetitions of movements during exercise.

What are the possible benefits and risks of participating?
Participants will be provided with tools that could potentially increase their motivation to perform home exercise, which in turn could help improve their gait, balance and mobility. In addition, the use of these tools could reduce their fear of falling (if present) and increase their quality of life. The multimodal activities and visualizations also have the potential to help the participants understand why each of the exercises is important to their recovery and assure them of the progress they are making during their rehabilitation.
Prior to the start of the trial the tools will also be evaluated with fallers in pilot studies. Furthermore, there will be a visit by the chief investigator and a research nurse (both trained on environmental risk assessment) to give training on the equipment and to assess the participants' homes on the suitability of the environment for home exercise. The advice on the environment and safety during exercise, as well as the advantages offered through the use of visual feedback and multimodal games for home rehabilitation, may be very beneficial to the participants, who otherwise may not receive these benefits.

Where is the study run from?
The study will take place in the users homes, while outcome assessments will be performed in a laboratory at the start and at the end of the trial.

When is the study starting and how long is it expected to run for?
The study is expected to run from March 2012 to July 2013. Participants will take part for only 12 weeks during this period, with an extra week for data collection.

Who is funding the study?
Medical Research Council (MRC) (UK) - Lifelong Health and Wellbeing initiative.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Falls prevention advice and visual feedback to those at risk of falling: a randomized controlled trial

Study objectives
1. The home based use of visual feedback of movement during exercise will be more effective than standard care in engaging older adults at risk of falling in home based rehabilitation; thereby improving adherence to exercise, and hence the quality of life of the user
2. The use of multimodal games will encourage greater participation and adherence to community-based falls rehabilitation programmes, thereby improving the users confidence, independence and quality of life

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Greater Glasgow and Clyde Research Ethics Committee, 03 August 2011

Study design
Single-blind three arm parallel group randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Falls

Interventions
Participants who meet the inclusion criteria will be allocated to one of three groups:

1. Intervention A (Control): Participants in this group will be given that standard home rehabilitation care (Age UK instructional booklet).
2. Intervention B (Visualizations): In addition to the standard rehabilitation care, the participants in this group will receive visual feedback during home exercise. The main functions of these visualizations are:
2.1. To present the rehabilitation exercises to the participants using an animated mannequin that will demonstrate the correct range and speed of motion required for each exercise.
2.2. To show the users real time feedback of their movements as they perform their exercises and provide

a summary of their performance during the process.
2.3. To provide information on the principles behind strength and balance exercises, and the role of these
exercises in the prevention of falls.
3. Intervention C (Multimodal Games): In addition to standard care, the participants in this group will be given multimodal games based on falls exercises to make rehabilitation more enjoyable process for them. The games will serve two main functions during the trial:
3.1. To provide the users with a more interactive and enjoyable way to perform home exercise.
3.2. To inform the users on their performance and progress during rehabilitation by tracking game scores, achievements and user repetitions of movements during exercise.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Adherence to exercise will be recorded once at the end of the 12 week trial

Key secondary outcome(s))
1. Variability in stride length, stride time and double support time
2. Gait speed
3. Timed up and go (TUG) test
4. Falls efficacy scale international (FES-I)
5. Balance confidence (CONFbal scale)
6. Intrinsic motivation inventory scale
7. Romberg Test
8. SF-12
9. EuroQOL EQ-5D
Measured the start and at the end of the 12 week trial

Completion date
01/06/2013

Eligibility

Key inclusion criteria
1. Over the age of 65
2. Identified as at risk of falling by the Glasgow Falls Service
3. Living in the community
4. Able to perform home exercise
5. Able to give informed consent
6. Able to understand simple instructions using the English language (to understand instructions from visualizations/ games)

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Senior

Sex
All

Key exclusion criteria
1. Are unable to give informed consent
2. Have major cognitive impairments
3. Have major visual impairments
4. Have major aural impairments
5. Are unable to understand instructions in English (necessary to understand the instructions from the visualizations/ multimodal games)

Date of first enrolment
01/03/2012

Date of final enrolment
01/06/2013

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Bioengineering Unit
Glasgow
United Kingdom
G4 0NW

Sponsor information

Organisation
Glasgow Caledonian University (UK)

ROR
https://ror.org/03dvm1235

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK) - Lifelong Health and Wellbeing (Phase 2), ref: G0900583, Grant ID: 91021

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2014		Yes	No
Protocol article	protocol	19/03/2013		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes