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Use of virtual reality based therapy in the elderly

Submission date
11/11/2019

Recruitment status
No longer recruiting

Registration date
18/12/2019

Overall study status
Completed

Last Edited
23/06/2022

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Impaired functional mobility of elders is frequently associated with loss of independence. Maintaining functional independence must be a priority in elderly care plans. Achieving autonomous participation in their own real everyday environment would contribute to improving their community involvement and also their overall health. The rehabilitation programs that include the practice of real activities are more effective. The use of virtual reality game technology (VRGT) has the potential to offer treatment settings very similar to actual environments and tasks. Interactive simulations allow elders to practice repetitive motor exercises directly connected with the movements needed in activities of daily living. The aim of this study is to evaluate the effectiveness of virtual reality systems for rehabilitation and improvement of quality of life of the elderly.

Who can participate?
Frail and pre-frail adults aged 60 or over

What does the study involve?
Participants are randomly allocated to one of two groups. The experimental group receives 24 individual training sessions with Virtual Reality systems (45 minutes, twice a week), provided by an occupational therapist. Twelve exergames (Nintendo and Xbox) were selected according to their cognitive and motor demands. The sequence of the games was pre-determined at the start of the study. Each game is repeated twice in each session and scores are recorded for each attempt. The first attempt is with the assistance of an occupational therapist to correct the movements and posture of participants using manual guidance and verbal feedback, while the subsequent attempt is performed independently but under the supervision of the occupational therapist. The duration of each game is about 4-5 minutes. The time required to change one game to another is about three minutes, during which time participants sit on a chair to rest. The control group is not treated with virtual reality systems. They only perform their daily activities.

What are the possible benefits and risks of participating?
The possible benefits of using virtual reality technology in rehabilitation processes with elderly

people include improvement of balance and walking ability, improvement of cognitive status and improvement in the performance of daily life activities.
The possible adverse effects include fatigue, muscle pain and headaches.

Where is the study run from?
The study has been designed from the University of Castilla La Mancha (Spain) and rehabilitation sessions with technology based on virtual reality are being developed in two nursing homes: Nursing Home “El Lucero” (Talavera de la Reina, Spain) and Nursing Home “Benquerencia” (Toledo, Spain).

When is the study starting and how long is it expected to run for?
January 2019to January 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
1. Ana Isabel Corregidor Sánchez
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Scientific

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Additional identifiers

EudraCT/CTIS number
2019-004392-40

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effectiveness of virtual reality based therapy in the rehabilitation of the elderly

Acronym
VR Elderly

Study objectives
1. The use of virtual reality devices improves the balance and wandering of older people.
2. The use of virtual reality games improves the cognitive situation of older people
3. Participation in a virtual reality exercise program produces changes sensation of well-being and quality of life

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/09/2014, Clinical Research Ethical Committee of the Talavera de la Reina Integrated Management Area (CEIC del AGI de Talavera de la Reina, Hospital Nuestra Señora del Prado. Ctra. Nacional V, km. 114 . 45600, Talavera de la Reina (Toledo); Tel: +34 (0)925 80 36 OO Ext. 86.316; Email: varroyo@sescam.org), ref: 5/2018

Study design
Longitudinal multicenter prospective and analytical study of random assignment with experimental group and control group

Primary study design

Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use conact details to request a participant information sheet

Health condition(s) or problem(s) studied
Functional impairment and frailty in the elderly

Interventions
Rehabilitation programs using Virtual Reality. The use of commercial game consoles and exergames, as well as games specifically designed for the rehabilitation process were both admitted.

The assignment to each of the groups was parallel. Participants were randomly assigned to the experimental group (EG) or control group (CG), with an allocation ratio of 1:1. Blinding of trial participants and the intervention facilitator was not possible.

Experimental group:
Participants received 24 individual training sessions with Virtual Reality systems (45 min, twice a week), provided by an occupational therapist. Twelve exergames (Nintendo and Xbox) were selected according to their cognitive and motor demands. The sequence of the games was pre-determined at baseline of the study. Each game was repeated twice in each session and scores were recorded for each attempt. The first attempt was with the assistance of an occupational therapist to correct the movements and posture of participants using manual guidance and verbal feedback, while the subsequent attempt was performed independently but under supervision of the occupational therapist. The duration of each game was approximately 4-5 min. The time required to change one game to another was approximately three minutes, during which time participants sat on a chair to rest.

Control group:
The control group was not treated with virtual reality systems. They only performed their daily activities.

Intervention Type
Behavioural

Primary outcome measure
1. Functional performance (capacity to perform the activities of daily living) is measured using AMPS scale (Assessment Motor and Process Skill) and Barthel Index at baseline and the end of study (3 months)
2. Walking capacity and balance is measured using Tinetti Test and Test Up and Go (TUG) at baseline and the end of study (3 months)

3. Physical capacity is measured using the Senior Fitness Test (SFT) at baseline and the end of study (3 months)
4. Perceived quality of life is measured using the Filadelfia Test (SFT) at baseline and the end of study (3 months)
5. Cognition capacity is measured using Mini Mental State Examination (MMSE) at baseline and the end of study (3 months)

Secondary outcome measures
Opinion on the use of technology is measured using Subjective Scale Use of Virtual Reality, a questionnaire developed for this study, at 3 months after the participants have completed 24 treatments

Overall study start date
02/01/2019

Completion date
02/01/2020

Eligibility

Key inclusion criteria
Persons over age 60 without neurological, osteoarticular, or other type of disease that severely affects functional independence

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
20 participants in each group

Total final enrolment
40

Key exclusion criteria
Neurological and osteoarticular conditions that severely affect functional independence

Date of first enrolment
02/05/2019

Date of final enrolment
02/09/2019

Locations

Countries of recruitment
Spain

Study participating centre
Ana Isabel Corregidor Sánchez. Universidad de Castilla la Mancha: Facultad Ciencias de la Salud
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Sponsor information

Organisation
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Sponsor type
University/education

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ROR
https://ror.org/05r78ng12

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date
01/03/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Ana Isabel Corregidor Sánchez (Anaisabel.corregidor@uclm.es) .

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		18/02/2021	18/02/2021	No	No