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Cost-effectiveness of a proprioceptive exercise program in institutionalised elderly with fear of falling

Submission date
28/06/2010

Recruitment status
No longer recruiting

Registration date
06/07/2010

Overall study status
Completed

Last Edited
23/10/2020

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Cost-effectiveness of a proprioceptive exercise program in institulionalised elderly with fear of falling: randomised controlled trial

Study objectives
1. Proprioceptive exercise program will reduce fear of falling in institutionalised elderly with fear of falling
2. Proprioceptive exercise program will improve static and dynamic balance in institutionalised

elderly with fear of falling
3. Proprioceptive exercise program will reduce the risk of falling in institutionalised elderly with fear of falling
4. Proprioceptive exercise program is a cost-effective addition to usual care in in institutionalised elderly with fear of falling

Ethics approval required
Old ethics approval format

Ethics approval(s)
Biomedical Ethical Committee of the University of Extremadura approved on the 16th June 2010 (ref: 30/2010)

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Fear of falling

Interventions
The participants will be randomly assigned to intervention or control group by a random table built by computer:
1. Interventional group: three-month progressive proprioceptive exercise program, applied twice a week
2. Control group: care as usual

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Measured at baseline and three months:
1. Falls Efficacy Scale International (FES-I)
2. Balance (Fall risk and postural stability) measured by Biodex Balance
2. Muscular function (isokinetic measurements) measured by System-3 Biodex Dynamometer
3. Health related quality of life:
3.1. EuroQol EQ-5D Instrument (utility index)
3.2. 36-item Short Form Health Survey (SF-36) (utility index)
4. Fitness
5. Health system and societal costs

Key secondary outcome(s)

Measured at baseline and three months:
1. Grade of satisfaction with programme
2. Weight, % fat

Completion date
01/10/2010

Eligibility

Key inclusion criteria
1. Patients with fear of falling (Falls Efficacy Scale International [FES-I] Score, 16 item questionnaire, greater than 23)
2. Institutionalised people
3. Informed consent
4. Aged 65 years and older, male and female
5. Ability to understand instructions

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
40

Key exclusion criteria
1. To have an artificial prosthesis
2. Other physical or psychological therapies different from usual care in the National Health Service and the nursing home
3. Show symptoms during the medical examination to recommend their exclusion
4. Cognitive disease
5. Any drug intake that may affect balance significantly - to avoid external influences

Date of first enrolment
01/07/2010

Date of final enrolment
01/10/2010

Locations

Countries of recruitment

Spain

Study participating centre
Av de la Universidad, s/n
Cáceres
Spain
10003

Sponsor information

Organisation
University of Extremadura (Spain)

ROR
https://ror.org/0174shg90

Funder(s)

Funder type
University/education

Funder Name
University of Extremadura (Spain)

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	01/07/2012	23/10/2020	Yes	No