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

Submission date 28/06/2010	Recruitment status No longer recruiting	Prospectively registered
		☐ Protocol
Registration date	Overall study status	Statistical analysis plan
06/07/2010	Completed	[X] Results
Last Edited 23/10/2020	Condition category Injury, Occupational Diseases, Poisoning	[] Individual participant data
Z3/ TU/ZUZU	iniui v. Occupacional Diseases. Poisoning	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Narcis Gusi

Contact details

Av de la Universidad, s/n Cáceres Spain 10003

Additional identifiers

Protocol serial number N/A

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)

Study design

Randomised controlled trial

Primary study design

Interventional

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?
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Results article results 01/07/2012 23/10/2020 Yes No

Participant information sheet Participant information sheet 11/11/2025 No Yes