

# 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**

06/07/2010

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

23/10/2020

**Condition category**

Injury, Occupational Diseases, Poisoning

☐ Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Narcis Gusi

**Contact details**

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Cáceres

Spain

10003

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

**Scientific Title**

Cost-effectiveness of a proprioceptive exercise program in institutionalised 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 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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Prevention

**Participant information sheet**

Not available in web format, please use contact details below to request a patient information sheet

**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 measure**

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

## **Secondary outcome measures**

Measured at baseline and three months:

1. Grade of satisfaction with programme
2. Weight, % fat

## **Overall study start date**

01/07/2010

## **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

## **Age group**

Senior

## **Sex**

Both

## **Target number of participants**

50

## **Total final enrolment**

**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)

**Sponsor details**

Av de Elvas s/n

Badajoz

Spain

06071

**Sponsor type**

University/education

**Website**

<http://www.unex.es/>

ROR

## Funder(s)

### Funder type

University/education

### Funder Name

University of Extremadura (Spain)

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### 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?
<a href="#">Results article</a>	results	01/07/2012	23/10/2020	Yes	No