

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

Av de la Universidad, s/n

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