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Prevention of muscular strength and balance loss and osteoporosis using whole-body vibration in women with fibromyalgia

Submission date 28/11/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/02/2008	**Overall study status** Completed	
Last Edited 20/06/2012	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
11/05

Study information

Scientific Title

Acronym
EVFEO/11/05

Study objectives
1. Whole-body vibration exercise is effective in improving muscular strength in lower limbs and balance in women with fibromyalgia
2. Whole-body vibration exercise is effective in improving health related quality of life in women with fibromyalgia
3. Whole-body vibration is a cost-effective alternative compared to usual health care

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Biomedic Ethical Committee of the University of Extremadura on 12/06/2005; reference number 11/05 (academic research funded in 2007).

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Fibromyalgia

Interventions
Intervention group: Three sessions of whole-body vibration per week. Each session consisted of 6 repetitions at 12.6 HZ of whole-body vibration on reciprocal vibrating platform (Galileo 2000, Novotec. Germany). The feet of subject will be aligned perpendicular to usual use (this is a new technique). The time spent in each repetition will be increased 15 seconds every month from 30 second to 1 minute.

Control group: Usual care

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The following will be assessed at baseline and 3 months:
1. Balance (Fall risk and postural stability) measured by Biodex Balance
2. Neuromuscular function (isokinetic measurements with surface electromyography measurements) measured by System-3 Biodex Dynamometer and MP100 Biopac
3. Fear to Fall Questionnaire (FES-I)

4. Health related Quality of life:
4.1. EuroQol EQ-5D Instrument (utility index)
4.2. Fibromyalgia Impact Questionnaire
4.3. 15-D instrument (utility index)
4.4. 36-item Short Form health survey (SF-36) (utility index)
5. Health system and societal costs
6. Pain threshold measured by algometer

Key secondary outcome(s)
The following will be assessed at baseline and 3 months:
1. Hand-grip
2. Percentage of fat
3. Visual Analogue Scale for pain (0-10)
4. Visual Analogue Scale for general health (attached to EuroQOL 5D [EQ-5D])

Completion date
30/05/2008

Eligibility

Key inclusion criteria
1. Women who suffer fibromyalgia according to diagnosis by the American College of Rheumatology criteria
2. Older than 35 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Female

Key exclusion criteria
1. Contraindications to physical exercise
2. Other physical or psychological therapies different from usual care in the National Health Service (outpatient clinic)
3. Cognitive disease

Date of first enrolment
30/11/2007

Date of final enrolment
30/05/2008

Locations

Countries of recruitment
Spain

Study participating centre
Faculty of Sports Sciences
Caceres
Spain
10071

Sponsor information

Organisation
University of Extremadura (Spain)

ROR
https://ror.org/0174shg90

Funder(s)

Funder type
Government

Funder Name
Health & Dependence Department and Young & Sports Department of Junta de Extremadura (ref: 118/06) (Spain)

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	01/08/2011		Yes	No
Results article	results	01/02/2012		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes