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

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.afycav.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

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

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 measure
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

Secondary outcome measures
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])

Overall study start date
30/11/2007

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

Age group
Not Specified

Sex
Female

Target number of participants
50

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
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Sponsor information

Organisation
University of Extremadura (Spain)

Sponsor details
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Sponsor type
University/education

Website
http://www.unex.es

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

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	01/08/2011		Yes	No
Results article	results	01/02/2012		Yes	No