

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

<b>Submission date</b> 28/11/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/02/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 20/06/2012	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**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).

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**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

<b>Output type</b>	<b>Details</b>	<b>Date created</b>	<b>Date added</b>	<b>Peer reviewed?</b>	<b>Patient-facing?</b>
<a href="#">Results article</a>	results	01/08/2011		Yes	No
<a href="#">Results article</a>	results	01/02/2012		Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes