

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

Registration date
12/02/2008

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
20/06/2012

Condition category
Musculoskeletal Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.afycav.com>

Contact information

Type(s)

Scientific

Contact name

Prof Narcis Gusi

Contact details

Faculty of Sports Sciences
University of Extremadura
Caceres
Spain
10071
+34 927 257460
ngusi@unex.es

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

10071

Sponsor information**Organisation**

University of Extremadura (Spain)

Sponsor details

Avda Elvas s/n

Badajoz

Spain

06071

+34 92 428 93 05

vicein@unex.es

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