

Physical activity to persons with fibromyalgia and osteoporosis

Submission date 04/03/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/04/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 05/11/2009	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
05/02

Study information

Scientific Title

Acronym

AFPFO/05/02

Study objectives

1. Physical activity enhances the health related to quality of life and physical fitness
2. Aquatic training is a cost-effective strategy in persons with fibromyalgia

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Bioethical Committee of University of Extremadura on 10/02/2002 (ref: 05/02)

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Fibromyalgia

Interventions

Patients are randomised to three groups:

Group 1: Aquatic training, 3 sessions per week for 3 months - 18 patients

Group 2: Usual care - 17 patients

Group 3: Land-based training, 3 sessions per week for 3 months - 30 patients

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Group 1 versus Group 2 = Isokinetic strength and electromyographic parameters, health related quality of life -Fibromyalgia Impact Questionnaire, EQ5D and SF-36 and its utilities to study cost-effectiveness, fitness, costs

Group 1 versus Group 3 = Health related quality of life -Fibromyalgia Impact Questionnaire, EQ5D and SF-36 and its utilities to study cost-effectiveness, fitness, costs

Group 2 versus Group 3 = Health related quality of life -Fibromyalgia Impact Questionnaire, EQ5D and SF-36 and its utilities to study cost-effectiveness, fitness, costs

Secondary outcome measures

Group 1 versus Group 2 = Psychological aspects - State Trait Anxiety Inventory

Group 1 versus Group 3 = Psychological aspects - State Trait Anxiety Inventory

Group 2 versus Group 3 = Psychological aspects - State Trait Anxiety Inventory

Overall study start date

01/04/2004

Completion date

01/10/2004

Eligibility

Key inclusion criteria

Women who suffer fibromyalgia according to American College of Rheumatism diagnosis

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

65 distributed in three groups

Key exclusion criteria

1. Contraindications to physical exercise
2. Other physical or psychological therapies
3. Cognitive disease
4. Drugs affecting the measures

Date of first enrolment

01/04/2004

Date of final enrolment

01/10/2004

Locations

Countries of recruitment

Spain

Study participating centre

Faculty of Sports Sciences

Caceres

Spain

10071

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 Department of Junta de 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