Effects of an eight-month aquatic exercise programme in women with fibromyalgia

Submission date [] Prospectively registered Recruitment status 18/06/2006 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 14/07/2006 Completed [X] Results [] Individual participant data **Last Edited** Condition category 20/07/2009 Musculoskeletal Diseases

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

18/02

Study information

Scientific Title

Acronym

AF8PF/18/02

Study objectives

- 1. Aquatic exercise improves the health-related 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)

Bioethical Committee of the University of Extremadura on 11/07/2002, reference number 18/02

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Fibromyalgia

Interventions

Aquatic training, three sessions per week for eight months

In the eight-month fibromyalgia trial, there were two groups:

- 1. Control group: usual care (primary care based on antidepressants) without adding any physical or psychological therapy
- 2. Intervention group: we added three one-hour aquatic training sessions including:
- a. 4x12 knee flexo extension using body weight as charge
- b. 4x12 upper limb movements against the water drag using a pull-boy

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. Pain as measured by the visual analogue scale (VAS)
- 2. EuroQol 5-D
- 3. Short-form-36 questionnaire (SF-36) scores
- 4. Utility and costs

Isokinetic strength and electromyographic parameters

Fibromyalgia Impact Questionnaire

Fitness

Secondary outcome measures

Phychological aspects: state trait anxiety inventory

Overall study start date

01/10/2004

Completion date

01/06/2005

Eligibility

Key inclusion criteria

Women who suffer fibromyalgia according to diagnosis by the American College of Rheumatism

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

33 distributed in two 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

01/10/2004

Date of final enrolment

01/06/2005

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2008		Yes	No
Results article	results	01/09/2009		Yes	No