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

Submission date
18/06/2006

Recruitment status
No longer recruiting

Registration date
14/07/2006

Overall study status
Completed

Last Edited
20/07/2009

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

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
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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 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