

Comparative effect of two supervised exercise programs on key health outcomes in women with fibromyalgia syndrome

Submission date 09/12/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 21/12/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/12/2009	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

Protocol serial number

N/A

Study information

Scientific Title

Comparative effect of two supervised exercise programs on key health outcomes in women with fibromyalgia syndrome: a randomised controlled trial

Study objectives

1. A 24-week exercise programme based on a combination of aerobic exercise, muscle strengthening and flexibility, has a more positive impact on fibromyalgia syndrome (FS) specific symptomatology than one based exclusively on aerobic exercise, regardless of their initial level of impairment
2. A 24-week exercise programme based on a combination of aerobic exercise, muscle strengthening and flexibility has a more positive impact on physical fitness in women with FS than one based exclusively on aerobic exercise

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Seville Ethics Board approved on the 22nd January 2007

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Fibromyalgia syndrome

Interventions

Group A:

Patients performed two aerobic exercise sessions per week, which included a 10 minute warm up, 25 - 30 minutes at 60 - 65% HRmax and interval training at 75 - 80% HRmax and finally 5 - 10 minutes cool-down.

Group B:

Patients performed twice-weekly sessions of combined aerobic and muscle strength training exercises, including 10 minutes warm up, 10 - 15 minutes of aerobic exercise at 65 - 70% HRmax, 15 - 20 minutes of muscle training on 8 exercises (1 set of 8 - 10 reps with 1 - 3 kg) and finally 10 minutes of flexibility training on 8 - 9 exercises (1 set of 3 reps keeping the stretched position for 30 seconds).

Group C:

Patients continued their normal daily activities during the period of the intervention.

Patients were assessed at 24 weeks (end of intervention period).

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Health status: the Fibromyalgia Impact Questionnaire (FIQ) and The Medical Outcomes Study Short Form (SF-36) health survey
2. Physical fitness: the six-minute walk test was used to estimate aerobic capacity, hand-grip strength and range of motion (flexion/extension) in the shoulders and hips

Assessment of all outcomes was undertaken at baseline and immediately after the 24-week intervention and at the same time points in the usual care control group.

Key secondary outcome(s)

Depression was assessed using the Beck Depression Inventory (BDI). Assessment of all outcomes was undertaken at baseline and immediately after the 24-week intervention and at the same time points in the usual care control group.

Completion date

10/12/2009

Eligibility**Key inclusion criteria**

1. Women aged above 18 years
2. Met the American College of Rheumatology (ACR) criteria for classification of fibromyalgia

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

1. Presence of inflammatory rheumatic diseases
2. Severe psychiatric illness
3. Respiratory or cardiovascular diseases that prevent physical loading
4. Women with FM who attended another psychological or physical therapy

Date of first enrolment

01/09/2007

Date of final enrolment

10/12/2009

Locations

Countries of recruitment

Spain

Study participating centre

Facultad de Ciencias de la Educación.

Seville

Spain

41005

Sponsor information

Organisation

University of Seville (Spain)

ROR

<https://ror.org/03yxnp24>

Funder(s)

Funder type

University/education

Funder Name

University of Seville (Spain) - Research grant from Facultad de Ciencias de la Educación

Results and Publications

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes