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

Submission date
09/12/2009

Registration date
21/12/2009

Last Edited
21/12/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Borja Sañudo

Contact details
Facultad de Ciencias de la Educación.
Avda. Ciudad Jardín nº 20-22
Seville
Spain
41005
bsancor@us.es

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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 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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/09/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Sample size calculations indicated that a total of 54 participants (18 per group) were needed

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)

Sponsor details
Dpto. Educación Física y Deporte
Facultad de Ciencias de la Educación
Avenida Ciudad Jardin, 20-22
Sevilla
Spain

E - 41005
+ 34 95 45 56 209
bsancor@us.es

Sponsor type
University/education

Website
http://www.us.es/

ROR
https://ror.org/03yxnpp24

Funder(s)

Funder type
University/education

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

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