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Effect of a standard physical rehabilitation intervention program in persons with fibromyalgia

Submission date
10/03/2016

Recruitment status
No longer recruiting

Registration date
16/03/2016

Overall study status
Completed

Last Edited
26/04/2023

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Fibromyalgia is a long term (chronic) condition that causes pain all over the body. Other symptoms include an increased sensitivity to pain, feeling extremely tired, stiff muscles, difficulty sleeping, problems with memory and concentration, headaches and irritable bowel syndrome. There isn't a cure for the condition, but the symptoms can be alleviated though, for example, medication, counselling and exercise. The aim of this study is investigate the effect of a 20 week exercise programme, called a Standard Physical Rehabilitation Intervention (SPRI) program, taking place in in a pool or in the gym for women with light or moderate symptoms of fibromyalgia.

Who can participate?
Women aged between 30-59 and diagnosed with fibromyalgia.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 do an exercise programme in the gym for 20 weeks, involving two 50 minute sessions every week. Those in group 2 do an exercise programme in the pool for 20 weeks, involving two 50 minute sessions every week. All participants are assessed every two weeks where they have their heart rate and weight measured, are asked about their level of pain, and mood, undergo respiratory and aerobic function tests and are asked about how their fibromyalgia is affecting them at that time.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
International University of Catalunya (Spain)

When is the study starting and how long is it expected to run for?
September 2011 to January 2013

Who is funding the study?
International University of Catalunya (Spain)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Multidisciplinary study in chronic muscle pain

Study objectives
To assess the effect of a Standard Physical Rehabilitation Intervention (SPRI) program, in pool-based (SPRI-P) and land-based (SPRI-L) environments, applied to women patients with light to moderate symptoms (FIQ<70) during a period of 20 weeks.

Ethics approval required
Old ethics approval format

Ethics approval(s)
International University of Catalunya, 12/09/2011

Study design
Interventional open controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Fibromyalgia

Interventions
The program duration was 20 weeks with two 50-minute sessions each week (with a 2 day interval between in order to avoid muscle fatigue). The patients were divided into four groups, two in a Standard Physical Rehabilitation Intervention program in pool-based environment and two in a Standard Physical Rehabilitation Intervention program in land-based environment, accommodating the personal schedule of each patient.

Warm-up:
Each session began with a 10-minute warm-up which consisted of activities based primarily on walking (slower or faster). Participants were asked to walk sideways or backwards, to change their pace, or to pass a ball between them while walking, etc.

Activity:
This was the most important part of the SPRI program, and consisted of a mix of activities based on aerobic exercise, strength, proprioception, balance, and breathing. The principal of progressive load increase was taken into consideration, and the patients never attained high intensity workloads. This period lasted approximately 25 minutes.

Stretching:
At the end of the activity period, stretching was performed for about 10 minutes, with a focus on the muscles most used.

Relaxation:
The session ended with approximately 10 minutes of relaxation with an emphasis on controlled breathing.

Intervention Type
Behavioural

Primary outcome measure
Muscle pain, measured using the Fibromyalgia Impact Questionnaire (FIQ)., assessed at baseline and after 4 weeks

Secondary outcome measures
1. Heart rate, measured by Heart Rate Monitor Polar RC3
2. Weight
3. Self-perceived pain, measured by the visual analog scale (VAS) used to measure the intensity of self-perceived pain by the patient. This instrument was also used to measure the intensity of perceived fatigue by the patient.
4. Respiratory and aerobic function, measured by the six minute walk test (6MW)
5. Depression, measured using the Hamilton depression scale (HAM-D)
6. Overall impact of fibromyalgia using the FIQ.

All measured every two weeks for 20 weeks

Overall study start date
13/09/2011

Completion date
18/01/2013

Eligibility

Key inclusion criteria
1. Female
2. Aged between 30 to 59 years
3. Have an accredited medical certificate with an established diagnosis of FM according to the American College of Rheumatology
4. Have a light to moderate degree of impairment due to FM (FIQ less than 70)
5. Capable of walking without aid

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
120

Total final enrolment
73

Key exclusion criteria
1. Suffering from an unstable cardiovascular pathology or any other medical condition that impedes physical exercise
2. History of fractures of the upper or lower members during the last three months
3. Suffering from neuromuscular disease or ingestion of drugs which affect neuromuscular function
4. Presence of any serious or terminal illness, history of myocardial infarction during the last three months
5. In litigation with management for recognition of occupational disability

Date of first enrolment
13/09/2011

Date of final enrolment
13/11/2011

Locations

Countries of recruitment
Spain

Study participating centre
International University of Catalunya
Spain
08017

Sponsor information

Organisation
International University of Catalunya

Sponsor details
Alfa & Beta buildings Immaculada, 22
Barcelona
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08017

Sponsor type
University/education

ROR
https://ror.org/00tse2b39

Funder(s)

Funder type
University/education

Funder Name
International University of Catalunya

Results and Publications

Publication and dissemination plan

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/11/2018	26/04/2023	Yes	No