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Effects of breathing training on respiratory muscle efficiency, pain, health-related quality of life and intake of drugs in sedentary women with fibromyalgia

Submission date
11/09/2012

Recruitment status
No longer recruiting

Registration date
27/10/2014

Overall study status
Completed

Last Edited
16/04/2018

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 condition of unknown cause in which patients suffer from a variety of symptoms, such as pain, muscle weakness, or tiredness. Muscle weakness can also affect the heart and lung muscles and thus can lead to poor quality of life. We want to see how well the breathing training works in increasing the strength of the lung muscles and also in alleviating symptoms such as pain and tiredness.

Who can participate?
Adult women who have been diagnosed with fibromyalgia

What does the study involve?
Women were randomly allocated to one of two groups: experimental or control group. Women in the experimental group received 12 weeks of breathing training, while the control group did not receive the training. We checked the effectiveness of the breathing technique at the start of the study, after 12 weeks and immediately after the end of the training.

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

Where is the study run from?
Not provided at time of registration

When is study starting and how long is it expected to run for?
January 2012 to April 2012

Who is funding the study?
University of Évora (Portugal)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled trial investigating the effects of 12 weeks of breathing training techniques on respiratory muscle efficiency, pain, health-related quality of life and intake of drugs in sedentary women with fibromyalgia

Study objectives
1. 12 weeks of breathing training may lead to changes in respiratory muscle efficiency, pain and health-related quality of life, and intake of drugs of sedentary women with fibromyalgia
2. Gains in respiratory muscle efficiency are related to improvements in pain intensity of tender points and self-reported pain of sedentary women with fibromyalgia
3. Gains in respiratory muscle efficiency are related to improvements in health-related quality of life and reduced intake of specific drugs of sedentary women with fibromyalgia
4. Gains in respiratory muscle efficiency are related to reduction of intake of specific drugs of sedentary women with fibromyalgia

Ethics approval required

Old ethics approval format

Ethics approval(s)
University of Évora Ethics Committee, June 2012, ref: 1200

Study design
Single-centre interventional randomized 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 the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Syndrome of fibromyalgia

Interventions
The breathing therapy consisted of 30 minutes/session for 7-times/week (1-time supervised by an expert in breathing training techniques, and 6-times unsupervised at home with regard to audiovisual training) and for 12 weeks. Each session included five breathing exercises (3 minutes for each) were used in the form of circuit: an exercise on awareness of breathing, an exercise on costal expansion, and three exercises on diaphragmatic breathing. This circuit was performed twice, with a total time of 30 minutes per session

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The primary endpoint with respect to effects of breathing training techniques on respiratory muscle efficiency. Therefore, the functional respiratory examination was measured with global body plestimograph. The standard parameters of ventilatory pattern were recorded: minute ventilation (VE), respiratory frequency (f), tidal volume (VT) and the ratio of inspiratory and the total times (Ti/Ttot). In the study of muscle efficiency, two parameters were monitored: the maximal inspiratory pressure (MIP) and maximum occlusion pressure (P0.1). The maximal expiratory pressure (MEP) was measured as a component of the study of evaluation of respiratory muscles. Measurements were taken at baseline and post-intervention at 12 weeks.

Secondary outcome measures
1. Pain was evaluated by the rheumatologist as follows:
1.1. Pain in tender points with digital dolorimeter
1.2. Widespread pain index (WPI) and total symptom severity (SS) by applying the 2010 ACR preliminary classification criteria diagnoses of fibromyalgia
1.3. Overall pain by using a visual analog scale (VAS)
2. Health-related quality of life (HRQoL) was evaluated using the Portuguese language version of the Short Form 36 Health Survey (SF-36)
3. The Portuguese version of the Fibromyalgia Impact Questionnaire (FIQ) was used to evaluate the impact of FM on patients physical and mental health
4. Type and number of drugs taken in relation to fibromyalgia were recorded

Overall study start date
23/01/2012

Completion date
30/04/2012

Eligibility

Key inclusion criteria
1. Diagnosis of fibromyalgia by a rheumatologist
2. Non-smokers and not consumers of alcohol
3. Age between 25 and 70 years

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
48 potentially eligible, 35 gave consent (exercise group: 18; control group: 17)

Key exclusion criteria
1. History of severe trauma
2. Peripheral nerve entrapment
3. Inflammatory rheumatic diseases
4. Severe psychiatric illness
5. Respiratory diseases
6. Other diseases that prevent breathing training
7. Pregnancy
8. Attend to another psychological or physical therapy

Date of first enrolment
23/01/2012

Date of final enrolment
30/04/2012

Locations

Countries of recruitment
Portugal

Study participating centre
University of Évora
Évora
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7000-671

Sponsor information

Organisation
University of Évora (Portugal)

Sponsor details
Department of Sports and Health
Research Centre in Sports Sciences
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Sponsor type
University/education

Website
http://www.uevora.pt/

ROR
https://ror.org/02gyps716

Funder(s)

Funder type
University/education

Funder Name
University of Évora (Portugal)

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	01/08/2018		Yes	No