

Treatment of patients with fibromyalgia syndrome using the Rességuier and Qi Gong methods

Submission date 21/12/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/02/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 14/08/2014	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Fibromyalgia syndrome (FMS) is a long-term condition that causes pain all over the body. Rehabilitation has an important role in the treatment of FMS. Mind body therapies (MBT) are treatments that facilitate the mind's capacity to affect bodily function and symptoms. Among the different MBT utilized in FMS, the Rességuier method (RM) and Qi Gong (QG) have been shown to relieve FMS symptoms when used alone. QG integrates body, energetic, respiratory, and mental training and improves posture, breathing and concentration by low impact movements. RM aims to obtain patient awareness and control of bodily perceptions, thus reaching a modulation of responses to pain. The aim of our study is to evaluate the effectiveness of two protocols sequentially integrating RM and QG: the first using RM first and then QG (RM to QG) and the second using QG and then RM (QG to RM).

Who can participate?

The study includes female patients aged over 18 with FMS.

What does the study involve?

Participants are randomly allocated to either group 1 or group 2. Group 1 patients are treated first with RM for 7 weeks and, after a break of 1 week, with QG. Group 2 patients are treated with QG for 7 weeks and, after a break of 1 week, with RM. All patients are assessed at the start of the study, at the end of the first and second treatments, and after 9 weeks of follow-up. At each study point, patients are evaluated for pain, disability, tender points, quality of life, anxiety, depression, and quality of sleep.

What are the possible benefits and risks of participating?

Patients treated with both protocols are expected to improve in FMS-related symptoms, such as disability, pain, local tenderness, disturbed sleep and mood alterations. QG and RM are rehabilitative techniques with a soft approach, thus they are generally safe and do not cause adverse effects.

Where is the study run from?

Division of Rheumatology of the Department of Biomedicine of Florence University (Italy).

When is the study starting and how long is it expected to run for?

The study started in April 2011 and ran for about 7 months. The trial recruited participants for 2 months.

Who is funding the study?

University of Florence (Italy).

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

Rességuier and Qi Gong methods applied sequentially in patients with fibromyalgia syndrome: a randomised controlled trial

Study objectives

Rehabilitation has an important role in the treatment of fibromyalgia syndrome (FMS). Despite numerous studies, an agreement on a specific rehabilitation line has not been found yet.

Mind body therapies (MBT), defined as 'interventions that use a variety of techniques designed to facilitate the minds capacity to affect bodily function and symptoms' may be useful in the rehabilitative therapy of FMS. Among the different MBT utilized in FMS, the Rességuier method (RM) and Qi Gong (QG) have shown efficacy on FMS symptoms when used alone. Hereby, we propose two rehabilitation protocols integrating sequentially RM and QG for the non-pharmacological treatment of FMS patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of Azienda University Hospital Careggi, Italy [Comitato Etico Azienda Ospedaliera Universitaria Careggi (AOUC)], ref: 673/11

Study design

Randomised controlled single centre 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

30 FMS patients are recruited and randomly assigned to the Group A and Group B.

Group A:

15 patients, treated firstly with RM for 7 weeks (two sessions per week in the first 3 weeks and once per week in weeks 4-7 = total of 10 sessions). After a 1-week break, patients are treated with QG for 7 weeks (two sessions per week in the first 3 weeks and once per week in weeks 4-7 = total of 10 sessions).

Group B:

15 patients, treated firstly with QG for 7 weeks (two sessions per week in the first 3 weeks and once per week in weeks 4-7 = total of 10 sessions). After a 1-week break, patients are treated with RM for further 7 weeks (two sessions per week in the first 3 weeks and once per week in weeks 4-7 = total of 10 sessions).

Total duration of the study: 27 weeks, divided into 15 weeks of intervention (7 weeks for each method, with an interval of 1 week between the two techniques) and 12 weeks of follow up. All patients are assessed at baseline (T0), at the end of treatment (week 15: T1) and after 12 weeks of follow-up (week 27: T2).

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

The following items are assessed at baseline (T0), at end of the first (week 7: T1) and the second treatment (week 15: T2) and after 9 weeks of follow-up (week 27: FU):

1. Pain assessed by regional pain scale (RPS)
2. Disability assessed by Fibromyalgia Impact Questionnaire (FIQ) and Health Assessment Questionnaire (HAQ)

Secondary outcome measures

The following items are assessed at baseline (T0), at end of the first (week 7: T1) and the second treatment (week 15: T2) and after 9 weeks of follow-up (week 27: FU):

1. Tenderness in specific FMS sites (by the tender points evaluation)
2. Quality of life by Medical Outcomes Survey Short Form 36 (SF-36)
3. Anxiety and Depression by Hospital Anxiety and Depression Scale (HADS), with subscales for anxiety (HADS-a) and depression (HADS-d)
4. Quality of sleep by a number rating scale 010 (NRS- 010)

Overall study start date

01/04/2011

Completion date

15/11/2011

Eligibility

Key inclusion criteria

Diagnosis of fibromyalgia syndrome according to the American College of Rheumatology (ACR) criteria

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

30 patients

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/04/2011

Date of final enrolment

15/11/2011

Locations**Countries of recruitment**

Italy

Study participating centre

Department of Biomedicine

Florence

Italy

50139

Sponsor information**Organisation**

University of Florence (Italy)

Sponsor details

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Sponsor type

University/education

Website

<http://www.unifi.it>

ROR

<https://ror.org/04jr1s763>

Funder(s)

Funder type

University/education

Funder Name

University of Florence (Italy)

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