ISRCTN99342127 https://doi.org/10.1186/ISRCTN99342127

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

**Submission date**
21/12/2011

**Recruitment status**
No longer recruiting

**Registration date**
17/02/2012

**Overall study status**
Completed

**Last Edited**
14/08/2014

**Condition category**
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 minds 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?
Dr Susanna Maddali Bongi
susanna.maddalibongi@unifi.it

# Contact information

### Type(s)
Scientific

### Contact name
Dr Susanna Maddali Bongi

### Contact details
Department of Biomedicine
University of Florence
viale G. Pieraccini 18
Florence
Italy
50139

# Additional identifiers

### Protocol serial number
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

## Study type(s)
Treatment

## 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(s)

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 Questionnarie (FIQ) and Health Assessment Questionnaire (HAQ)

### Key secondary outcome(s))
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)

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### 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)

**ROR**
https://ror.org/04jr1s763

# Funder(s)

**Funder type**
University/education

**Funder Name**
University of Florence (Italy)

# 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 |