Rességuier method and Qi Gong sequentially integrated in patients with fibromyalgia syndrome

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ABSTRACT

Objectives. *In fibromyalgia syndrome (FMS), the Rességuier Method (RM) and Qi Gong (QG) can be efficacious. QG aims to improve posture, respiration, concentration, while RM aims to obtain patient awareness and control of pain perception. We evaluate 2 protocols integrating RM and QG in FMS.*

Methods. *Thirty FMS patients were assigned to Group 1, treated by RM and then by QG or Group 2, treated by QG and then by RM. In both protocols, patients are treated 7 weeks by each technique (with 1 week interval), and followed up for 12 weeks.*

Patients were assessed at T0, at end of 1st (T1) and 2nd intervention (T2), at follow-up (FU) by number rating scale (NRS) for sleep quality and pain, Regional Pain Scale (RPS),Tender Points (TPs), FIQ, HAQ, SF36, HADS for anxiety and depression (HADS-a/d).

Results. *In Group 1 at T1 (after RM), NRS for pain, RPS, FIQ, HAQ were reduced, HADS-a and SF36 ameliorated; at T2 (after QG) FIQ were further reduced and TPs and HADS-d improved; HADS-a and SF36 maintained.*

In Group 2 at T1 (after QG), NRS for pain, RPS, TPs, FIQ, HAQ, reduced with reduction maintained at T2 (after RM). HADS-a and -d and SF36 ameliorated at T1, with improvement confirmed at T2; sleep quality ameliorated only at T2. Effects of both protocols are similar at T2 and maintained at FU.

Conclusions. *In FMS, both protocols improve pain, disability, quality of life, tenderness, anxiety. RM also ameliorates sleep and QG improves depression. Sequential integration of RM and QG is efficacious in FMS.*

Introduction

Fibromyalgia syndrome (FMS) is characterised by widespread musculoskeletal pain for more than 3 months and tenderness at multiple tender points (1), associated with fatigue, sleep dysfunction, stiffness, depression and cognitive disruption, leading to disability and impairment in daily and work activities. The optimal management of FMS requires an individually tailored multidisciplinary approach combining pharmacological and non-pharmacological treatment (2, 3). The latter approaches aim to deal with the long-term consequences of FMS, such as disability, psychological distress, muscular deconditioning and fatigue and, overall, are more effective than pharmacological treatments (4).

Among non-pharmacological approaches, mind body therapies (MBT), defined as 'interventions that use a variety of techniques designed to facilitate the mind's capacity to affect bodily function and symptoms' (5), may be useful in FMS.

Despite their conceptual and technical differences, all MBT yield a global approach and involve both individual physical and mental dimensions by focusing on the relationships among brain, mind, body, and behaviour and their effect on health and disease. Both concentration-based and movement-based MBT have no or low physical impact and allow the patients to play a more active role in their treatment (6).

As a disordered central pain processing and an abnormality in pain perception are the pathogenic hallmarks of FMS (7), MBT, by different modalities, are potentially useful in treating chronic pain, the cardinal clinical feature of FMS, as well as its central derived symptoms such as fatigue, difficulty sleeping, depression, anxiety, and psychological distress, and, thereby, to improve activities of day living, disability and Health Related Quality of Life (HRQoL) (8), often severely affected.

Qi Gong (QG) is an ancient Chinese exercise method, integrating body, en-

ergetic, respiratory and mental training, aiming to increase and restore the flow of "qi" (vital energy). QG allows physical, psychic and emotional rebalancing, thus improving posture, respiration, and concentration by low impact movements. Although for its characteristics QG has potential therapeutic benefits in patients with FMS, its effects are discordant. QG significantly improved pain, psychological health and distress *versus* a control group in adult with FMS (9) but had minor effect than aerobic exercise in children with FMS (10).

The Rességuier method (RM) (11, 12) is close to MBT, and, for its characteristics, it could also be regarded as a MBT (5). RM aims to obtain patient nonjudgmental awareness and control of bodily perceptions and, in particular, nociception, potentially disconnecting the affective response to pain, and breaking the vicious circle of chronic pain-stress typical of the disease.

In FMS patients, we showed that RM improves HRQoL, disability, relaxation, sleep and pain, as also confirmed by the decrease of analgesics intake (13).

The aim of our study is to evaluate the efficacy on FMS patients of 2 protocols integrating sequentially QG an RM: the first using firstly RM and then QG and the second using QG and then RM.

Patients and methods

Thirty patients with FMS participated in the study. Inclusion criterion was the diagnosis of FMS according to the American College of Rheumatology (ACR) (1). Patients gave their written informed consent and the study was approved by the local ethics committee. After baseline assessment, participants were assigned randomly to Group 1, treated firstly with RM and then with QG or Group 2, treated firstly with QG, then with RM.

Randomisation was made by a random number sequence prepared by a person not connected with the study, who also gave sequentially numbered and sealed envelopes. The results of the randomisation were unknown until the participant accepted or declined to participate. FMS patients were assessed for the clinical symptoms and for the pharmacological and non-pharmacological treatments executed.

The sample size calculation performed for the present study was based on the changes on number rating scale (NRS) 0–10 assessing pain after a treatment with RM and QG and with QG and RM, obtained in preliminary experiences of our group, and on a desired power of 0.80 and an alpha of 0.05. The required sample size was of 30 patients, to be allocated, after a randomisation with an allocation ratio of 1:1, to treatment with RM and QG (Group 1) or QG and RM (Group 2), each composed by 15 patients. Given the probable attrition rate, 38 patients were enrolled and randomised.

Study design

Group 1 was treated firstly with RM for 7 weeks and, after 1 week break, with QG for 7 weeks.

Group 2 was treated for 7 weeks with QG, and, after a 1 week break, with RM for further 7 weeks.

Patients were treated with 2 sessions/week in the first 3 weeks and 1/week in weeks 4–7 for both interventions, with a total of 10 sessions both for RM and QG. RM and QG treatments lasted 60 and 45 minutes, respectively.

Patients were assessed at the beginning of the protocol (T0), and at the end of the first (T1) and second intervention (T2). The evaluation at follow-up (FU) was performed at 12 weeks from the end of the second intervention to assess the long term effects of the protocols. Thus, the total duration of the study was 27 weeks, with 15 weeks of intervention (7 weeks for each method, with an interval of 1 week between the 2 techniques) and 12 weeks of follow-up.

Assessment

Disability related to FMS was assessed by the Italian version of Fibromyalgia Impact Questionnaire (FIQ) (14).

The tender points evaluation was performed by assessing the tenderness at palpation on the 18 tender points recognised by the ACR as criterion for FMS classification (1).

Pain was assessed by a number rating scale 0–10 (0 = no pain and 10 = pain as bad as it could be) and by regional pain scale (RPS), a self-administered count of the number of painful non-articular regions (with scores ranging from 0 to 19) (15).

Disability was assessed also by the Italian version of Health Assessment Questionnaire (HAQ) (16) and HRQoL by the Italian version of Medical Outcomes Survey Short Form 36 (SF-36) (17), composed by 8 subscales (physical functioning, role limitations due to physical problem, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems, and mental health) from which 2 summary scores (physical and mental component summaries) are derived.

Hospital Anxiety and Depression Scale (HADS), with subscales for anxiety (HADS-a) and depression (HADS-d) (18) was used to evaluate psychological distress.

Quality of sleep was assessed by a number rating scale (NRS) 0–10 with 0 = the worst perceived sleep quality and 10 = the best perceived sleep quality.

The adverse effects leading or not to drop-out, the attrition rate, the percentage of attendance at the classes and the number of patients lost at FU were registered.

Table I. Evolution of QG procedure in FMS patients: intervention, sequence, skills that should be reached by the patients in order to pass to the subsequent intervention

Phase	Exercise	Outcome
1	Breathing and concentration	overcoming of the muscular tension - relaxation
2	Postural control	5 consecutive minutes for each variable of posture and upper limb positioning, maintained without fatigue or pain.
3	Postural control and movement	5 consecutive minutes for each variable. Upper limbs without fatigue or pain plus 8 repetitions for movement.
4	Self-massage	Fluidity movement and correct integration of respiration and concentration.

Interventions

– Qi Gong

For the aim of our study, among the wide range of QG Chinese Medical Exercises, the interventions regarded as more suitable to FMS characteristics were chosen and further adapted to the needs of the single patients and executed progressively in individual sessions. The progression of the interventions was also used to evaluate the patient capacity of motor, breathing, relaxing, postural and concentration controlling (Table I).

First intervention (respiration) includes 2 phases:

- natural breathing: used to allow relaxation and obtain a higher participation of the patient.
- concentration and breathing exercises: characterised by short and deep breaths, with exercises of "Dan Tien control" (concentration and visualisation of "*dan tien"*, a point localised 3-4 centimetres under the umbilicus and inside the abdomen), used to improve concentration capacity.

Second intervention (postural control exercises or "zhang zhuang")

This is characterised by a series of static postures, including 3 possibilities of upper limbs positioning (to be executed with a specific progression and to be maintained for at least 5 minutes), associated to natural breathing. Through the postural control, the patient is allowed to recover a direct contact with the body and the surrounding environment.

Third intervention (respiration, concentration, and postural exercises combined with movement)

The passage to dynamic exercises is possible when the patient is able to maintain, without fatigue and pain, the 3rd variation of upper limbs positioning of postural exercises. The intervention includes the repetition of at least 8 continuous QG movements without fatigue and pain.

Fourth intervention (all the previous methods combined with an image formation)

it is a self-massage (taken from the series of exercises known as "Flying Phoenix") to be executed following the direction of energetic flow in the Meridians (Meridian Massage), combined with a correct breathing. The exercise includes the repetition of at least 8 complete cycles, with the possibility to repeat other cycles for a number of multiples of 8.

All QG treatments were performed by the same physiotherapist (MC), certified teacher in QG.

– Résseguier method

RM aims to obtain patient control of bodily perceptions, mainly nociception, leading to thoughtful responses to pain. The mainstay of RM, to be executed in individual sessions, is the relationship between the therapist and the patient based on the continuous attention to the patient during the session, regarded as "accompanying posture" (18-20).

The therapist, aware and attentive, maintains and continuously monitors the state of attention and perception of the patient. The purpose is to obtain patient awareness and control of perceptions, derived from each parts of the body, potentially allowing to modulate the response to pain perception. This is obtained by the following instruments of RM:

- *Verbal contact of the therapist*.
  The therapist asks the patient about the perception of specific body segments, particularly of painful areas. Guided by the therapist, the patient describes the perceived characteristics of these areas in terms of dimensions, weight, consistency and symmetry and builds her/his "sensitive body", meant as her/his "bodily perception". The therapist maintains a constant attention, not inferring on the data emerging from the patient.
- *Manual contacts* of the therapist on the patient, essential to promote perception in all the body and specific areas. The therapist executes light and constant pressures with the hand and the wrists on specific bodily areas, mainly on abdomen.
- "*Petite gymnastique"*: exercises respectful of the pain threshold, chosen and guided by the therapist and tailored to the patient, consisting of:
  - Exercises of conscious respiration, combined with:
  - movements of head, trunk, upper and lower limbs, firstly in supine position, then sitting and standing.
  - *Home exercises*, consisting of the same movements of "petite gymnastique", to be performed daily (30 mins/day) during the treatment period (20).

All RM treatments were performed by the same physiotherapist, certified teacher in RM (CDF).

Statistical analysis

Data are presented as mean ± standard deviation and as number and percentages. Student's *t*-test for unpaired data and χ^2 test were used to compare for groups characteristics at T0. For outcome measures, ANOVA for repeated measures, with Bonferroni test for *post-hoc* analysis, was used to detect effects of treatment. The effects at the end of treatments (T2) between Group 1 and 2 were assayed with Student's *t*-test for unpaired data. Analysis was performed using the SPSS statistical package for Windows.

Trial registration

http://www.controlled-trials.com/ISRCTN99342127

Results

After baseline evaluation and randomisation, 8 of the 38 enrolled FMS patients withdrew for different reasons: 4 of them for problems in reaching the rehabilitation gymnasium, 2 for the onset of new health problems (1 patient had a wrist fracture and 1 was diagnosed with a breast cancer) and 2 for concerns in work and familiar organisation. Thus, a total of 30 FMS patients (15 in each group) participated in the study.

Patients of Group 1 and 2 were similar in their demographic and clinical characteristics, (apart for the years from FMS diagnosis, higher in Group 1), in the treatments executed (Table II) and in the results of the tests evaluated at T0 (Table III).

Group 1 (treated with RM and QG)

– Disability

FIQ and HAQ improved significantly at the end of the treatment with RM (T1). The results of FIQ were further improved by the treatment with QG (T2) and maintained at FU (12 weeks), while HAQ improvement shown at T1 was stable at T2 and FU.

Table II. Demographic data, symptoms and treatments in FMS patients.

		Total Group (30 patients)	Group 1 (15 patients)	Group 2 (15 patients)	*P* in Group 1 *vs*. Group 2
Demographic data	Age	57.30 ± 11.46	56.56 ± 9.1	57.91 ± 13.50	n.s.
	Years from FMS symptom onset	7.2 ± 6.80	11.22 ± 8.55	5.77 ± 3.83	n.s.
	Years from FMS diagnosis	2.42 ± 2.92	4.33 ± 3.50	0.86 ± 0.74	<0.05
Accompanyng symptoms	Irritable bowel syndrome	73.33% (22/30 pts)	86.66% (13/15 pts)	60 (9/15 pts)	n.s.
	Irritable bladder syndrome	20% (6/30 pts)	20% (3/15 pts)	20% (3/15 pts)	n.s.
	Cephalalgia	56.66% (17/30 pts)	53.33% (8/15 pts)	60% (9/15 pts)	n.s.
	Restless leg syndrome	56.66% (17/30 pts)	46.66% (7/15 pts)	66.66% (10/15 pts)	n.s.
	Orthostatic hypotension	30% (9/30 pts)	40% (6/15 pts)	20% (3/15 pts)	n.s.
Previous and present Treatments	Drugs	100% (30/30 pts)	100% (15/15 pts)	100% (15/15 pts)	n.s.
	Physical therapies	76.66% (23/30 pts)	80% (12/15 pts)	73.33% (11/15 pts)	n.s.
	Complementary alternative medicine	36.66% (11/30 pts)	33.33% (5/15 pts)	40% (6/15 pts)	n.s.
Drugs assumed	NSAIDs/analgesics	70% (21/30 pts)	66.66% (10/15 pts)	73.33% (11/15 pts)	n.s.
	Glucocorticoids	46.66% (14/30 pts)	33.33% (5/15 pts)	60% (9/15 pts)	n.s.
	Antidepressant drugs	70% (21/30 pts)	66.66% (10/15 pts)	73.33% (11/15 pts)	n.s.
	Anxiolityc drugs	46.66% (14/30 pts)	66.66% (10/15 pts)	26.66% (4/15 pts)	n.s.
	Sleep-inducing drugs	10% (3/30 pts)	13.33% (2/15 pts)	6.66% (1/15 pts)	n.s.
	Pregabalin - Gabapentin	16.6% (5/30 pts)	13.33% (2/15 pts)	20% (3/15 pts)	n.s.

FMS: fibromyalgia syndrome; QG: Qi Gong; RM: Resseguièr Method; NSAIDs: non-steroidal anti-inflammatory drugs. Data compared by Student's *t*-test for unpaired data and χ^2 test.

– Pain and tenderness

Pain, as assessed by NRS 0-10 and RPS, was ameliorated by RM (T1), with the results maintained, in both cases, by QG treatment (T2) till follow-up.

Tender points, evaluating tenderness, were improved only at T2, after QG, with the results maintained at FU.

– Sleep and psychological assessment

Sleep quality was not affected by RM neither by QG intervention.

Anxious symptoms (assessed by HADS-a) were improved after RM (T1), with the results maintained after QG intervention (T2) till FU.

Depressive symptoms (evaluated by HADS-d) improved after QG (T2), with the improvement remaining stable till FU (Table IV).

– Quality of life

The scores of SF36 scale evaluating bodily pain ameliorated after RM, concordantly with RPS, (T1) and were maintained after the treatment with QG, till FU.

Physical functioning scores improved after RM (T1), with the results remaining stable after QG intervention (T2), till FU.

General Health scale improved after QG treatment (T2), with the amelioration maintained till FU.

The Physical Component Summary improved after RM, with the results remaining stable after QG and at FU.

The other single scales of SF36 and Mental Component Summary were not affected by the intervention (Table IV).

Group 2 (treated with QG and RM)

– Disability

FIQ and HAQ improved significantly at the end of QG treatment (T1). For both items, the results were maintained at T2, after RM, and at FU.

– Pain and tenderness

Pain, as evaluated by RPS and NRS 0-10 and tenderness, concordantly with tests assessing disability, improved af-

Table III. Disability, pain, tenderness, sleep, mood, quality of life at the baseline (T0) in Group 1 and 2.

	Group 1 (15 patients)	Group 2 (15 patients)	*p*-value
FIQ	66.05 ± 13.50	64.58 ± 16.54	n.s.
HAQ	0.98 ± 0.52	0.89 ± 0.24	n.s.
Pain (NRS)	7.58 ± 0.89	7.82 ± 0.89	n.s
RPS	11.36 ± 5.33	12.67 ± 4.0	n.s.
TPE	12.91 ± 3.42	14.89 ± 3.14	n.s.
Sleep quality (NRS)	6.41 ± 1.93	5.33 ± 1.8	n.s.
HADS a	8.91 ± 2.51	9.56 ± 5.0	n.s.
HADS d	9.45 ± 2.88	7.89 ± 6.09	n.s.
SF-36 PF	54.55 ± 17.67	61.67 ± 20.92	n.s.
SF-36 PP	31.82 ± 46.22	19.44 ± 32.54	n.s.
SF-36 BP	30.91 ± 16.33	31.33 ± 12.38	n.s.
SF-36 GH	42.91 ± 20.59	29.89 ± 15.70	n.s.
SF-36 V	35.0 ± 22.02	31.11 ± 16.91	n.s.
SF-36 SF	48.45 ± 25.29	58.0 ± 24.21	n.s.
SF-36 EP	51.27 ± 43.02	25.78 ± 39.89	n.s.
SF-36 MH	42.91 ± 18.16	47.11 ± 21.80	n.s.
SF-36 PCS	34.0 ± 7.44	33.44 ± 6.46	n.s.
SF-36 MCS	36.55 ± 10.64	33.56 ± 9.9	n.s.

FIQ: fibromyalgia impact Questionnaire; HAQ: Health Assessment Questionnaire; NRS: number rating scale; RPS: Regional Pain Scale; TPE: tender point evaluation; SF-36: short form 36; PF: physical functioning; PP: role limitations due to physical problems, BP: bodily pain, GH: general health perceptions, V: vitality, SF: social functioning, EP: role-limitations due to emotional problems, MH: mental health,, PCS: physical component summary, MCS: mental component summary; HADS a: Hospital Anxiety and Depression Scale, anxiety subscale; HADS d: Hospital Anxiety and Depression Scale, depression subscale. Data compared by Student's *t*-test for unpaired data and χ^2 test.

Table IV. Disability, pain, tenderness, sleep, mood, quality of life at T0, T1, T2 and follow-up in Group 1.

	T0	T1 (after RM)	T2 (after QG)	FU	*p*-value (T1 *vs*. T0)	*p*-value (T2 *vs*. T0)	*p*-value (FU *vs*. T0)	*p*-value (T2 *vs*. T1)	*p*-value (FU *vs*. T1)	*p*-value (FU *vs*.T2)
FIQ	66.05 ± 13.50	53.25 ± 15.13	41.59 ± 15.35	44.72 ± 16.67	<0.001	<0.0001	<0.0001	<0.001	n.s.	n.s.
HAQ	0.98 ± 0.52	0.53± 0.30	0.40 ± 0.27	0.45 ± 0.27	<0.0001	<0.0001	<0.0001	n.s.	n.s.	n.s.
Pain (NRS)	7.58 ± 0.89	3.12 ± 0.71	3.44 ± 0.64	3.51 ± 0.65	<0.0001	<0.0001	<0.0001	n.s.	n.s.	n.s.
RPS	11.36 ± 5.33	6.64 ± 5.55	5.55 ± 4.48	6.18 ± 4.85	<0.0001	<0.0001	<0.0001	n.s.	n.s.	n.s.
TPE	12.91 ± 3.42	11.45 ± 4.08	10.64 ± 3.29	11.09 ± 4.01	n.s.	<0.05	n.s.	n.s.	n.s.	n.s.
NRS sleep quality	6.41 ± 1.93	7.14 ± 1.21	7.46 ± 1.13	6.64 ± 1.63	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
HADS a	8.91 ± 2.51	6.09 ± 4.25	5.09 ± 3.59	5.64 ± 3.32	<0.0001	<0.0001	<0.0001	n.s.	n.s.	n.s
HADS d	9.45 ± 2.88	7.54 ± 2.88	6.00 ± 2.97	6.64 ± 3.01	n.s.	<0.0001	<0.001	n.s.	n.s.	n.s.
SF-36 PF	54.55 ± 17.67	67.27 ± 10.81	69.09 ± 10.68	65.45 ± 11.72	<0.05	<0.001	n.s.	n.s.	n.s.	n.s.
SF-36 PP	31.82 ± 46.22	50.00 ± 38.73	56.82 ± 38.88	54.55 ± 41.56	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
SF-36 BP	30.91 ± 16.33	45.00 ± 18.81	45.4 ± 21.44	44.64 ± 21.28	<0.05	<0.001	<0.05	n.s.	n.s.	n.s.
SF-36 GH	42.91 ± 20.59	52.18 ± 16.49	57.73 ± 17.71	56.64 ± 18.40	n.s.	<0.05	n.s.	n.s.	n.s.	n.s.
SF-36 V	35.00 ± 22.02	43.18 ± 18.20	48.64 ± 18.04	44.73 ± 17.66	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
SF-36 SF	48.45 ± 25.29	53.27 ± 16.86	57.64 ± 15.06	55.82 ± 16.08	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
SF-36 EP	51.27 ± 43.02	45.18 ± 34.21	54.27 ± 34.29	49.45 ± 35.16	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
SF-36 MH	42.91 ± 18.16	47.27 ± 16.18	54.18 ± 15.73	51.09 ± 17.33	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
SF-36 PCS	34.0 ± 7.44	41.91 ± 7.445	41.55 ± 8.1	41.18 ± 8.36	<0.001	<0.001	<0.001	n.s.	n.s.	n.s.
SF-36 MCS	36.55 ± 10.64	35.27 ± 8.53	36.82 ± 7.0	36.0 ± 7.12	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.

FU: Follow-up; FIQ: fibromyalgia impact Questionnaire; HAQ: Health Assessment Questionnaire; NRS: number rating scale; RPS: Regional Pain Scale; TPE: tender point evaluation; HADS a: Hospital Anxiety and Depression Scale, anxiety subscale; HADS d: Hospital Anxiety and Depression Scale, depression subscale; SF -36: short form 36; PF: physical functioning; PP: role limitations due to physical problems; BP: bodily pain; GH: general health perceptions; V: vitality; SF: social functioning; EP: role-limitations due to emotional problems; MH: mental health; PCS: physical component summary.
Data compared by ANOVA for repeated measures, with Bonferroni test for *post-hoc* analysis.

ter QG intervention (T1), with the results remaining stable, in all the items, at T2 till FU.

– *Sleep and psychological assessment*

Sleep quality was ameliorated after RM (T2), with the results maintained at FU.

Anxious and depressive symptoms were improved after QG (T1), with the results unchanged after RM (T2) till FU (Table V).

– *Quality of life*

The scores of SF36 scale evaluating bodily pain, concordantly with the results on pain and ternderness, improved after QG (T1), with the results maintained at T2 till FU.

Role limitations due to physical problems improved only after RM treatment (T2), with the amelioration remaining stable at FU.

Vitality improved after RM, with the results maintained at FU.

Physical Component Summary improved after QG, with the results stable after RM and at FU.

The other single scales of SF36 and Mental Component Summary remained stable throughout the study (Table V).

Comparison of the effects of the two protocols

The comparison at the end of protocols (T2) of the effects of treatment in Group 1 in respect to Group 2 showed that the scores of all the items were not different between the 2 groups.

Safety

QG and RM were safe, did not cause adverse effects and were well accepted by FMS patients, as shown by the high compliance to both the protocols, witnessed by an attriction rate = 0, an attendance to the sessions = 100% and no patient lost at follow-up.

Discussion

This is the first study evaluating the effect of two 15-week protocols integrating consequentially QG and RM in FMS patients: Group 1 using firstly RM and then QG and Group 2 using QG and then RM in FMS patients. Our data show that RM and QG reduce pain, tenderness and disability and improve anxious symptoms and HRQoL. RM also ameliorates sleep quality and QG acts on depressive symptoms. Most of the results are confirmed at a long-term follow-up.

Interestingly, the effects of treatment in the two groups were no different in all the items as evaluated at the end of protocols, meaning that the 2 techniques are complementary and act synergically on FMS, independently from the protocol used.

However, it could be hypothesized that better results could come from a protocol using firstly RM as a "first step intervention", as this technique allows an adequate relaxation and processing of pain and a proper disposition to a conscious execution of QG exercises, useful in order to improve capability of motor and respiratory control and posture.

In FMS, often, drug therapy is not sufficient and has short duration effects on symptoms. Thus, multidisciplinar treatment, using rehabilitation, individually tailored exercises and/or cognitive behavioural therapies, together with appropriate pharmacological treatments, as suggested by the international guidelines and recommendations (3, 19) is advocated.

Apart from cognitive behavioural therapies (20), other MBT, such as Mindfulness Meditation (21), body awareness techniques (22), Yoga (23) and Tai Chi (24) have obtained encouraging, despite non-unequivocal, results in FMS.

Although our work is the first combining QG and RM, the efficacy on FMS of the 2 techniques used singularly was already demonstrated on pain, depression, and HRQoL (9, 12).

Table V. Disability, pain, tenderness, sleep, mood, quality of life at T0, T1, T2 and follow-up in Group 2.

	T0	T1 (after QG)	T2 (after RM)	FU	*p*-value (T1 *vs*.T0)	*p*-value (T2 *vs*.T0)	*p*-value (FU *vs*.T0)	*p*-value (T2 *vs*.T1)	*p*-value (FU *vs*.T1)	*p*-value (FU *vs*.T2)
FIQ	64.58 ± 16.54	43.16 ± 21.86	40.32 ± 23.11	44.40 ± 29.41	<0.05	<0.001	<0.05	n.s.	n.s.	n.s.
HAQ	0.89 ± 0.24	0.49 ± 0.33	0.51 ± 0.36	0.51 ± 0.38	<0.0001	<0.0001	<0.001	n.s.	n.s.	n.s.
Pain (NRS)	7.82 ± 0.89	2.47 ± 1.06	2.86 ± 0.85	3.20 ± 1.60	<0.0001	<0.0001	<0.0001	n.s.	n.s.	n.s.
RPS	12.67 ± 4.00	7.00 ± 3.54	7.00 ± 3.04	7.11 ± 3.69	<0.0001	<0.0001	<0.0001	n.s.	n.s.	n.s.
TPE	14.89 ± 3.14	11.11 ± 2.26	11.44 ± 3.21	11.44 ± 3.00	<0.05	<0.05	<0.05	n.s.	n.s.	n.s.
NRS Sleep quality	**5.33 ± 1.80**	**6.11 ± 1.54**	**6.44 ± 1.13**	**5.89 ± 1.27**	**n.s.**	**<0.05**	**n.s.**	**n.s.**	**n.s.**	**n.s.**
HADS A	9.56 ± 5.00	5.33 ± 2.60	5.33 ± 2.55	5.33 ± 2.29	<0.001	<0.001	<0.001	n.s.	n.s.	n.s.
HADS D	7.89 ± 6.09	3.56 ± 4.64	3.67 ± 4.36	3.78 ± 4.52	<0.001	<0.001	<0.001	n.s.	n.s.	n.s.
SF-36 PF	61.67 ± 20.92	68.33 ± 18.03	68.89 ± 18.67	66.67 ± 20.00	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
SF-36 PP	19.44 ± 32.54	44.67 ± 17.65	50.56 ± 25.30	52.58 ± 31.73	n.s.	<0.05	<0.001	n.s.	n.s.	n.s.
SF-36 BP	31.33 ± 12.38	43.78 ± 12.78	45.11 ± 12.89	45.89 ± 17.74	<0.05	<0.001	<0.001	n.s.	n.s.	n.s.
SF-36 GH	29.89 ± 15.70	52.78 ± 31.73	51.22 ± 12.54	43.11 ± 11.90	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
SF-36 V	31.11 ± 16.91	45.11 ± 15.41	47.22 ± 14.60	44.56 ± 14.68	n.s.	<0.05	n.s.	n.s.	n.s.	n.s.
SF-36 SF	58.00 ± 24.21	63.67 ± 25.30	63.67 ± 25.30	62.22 ± 23.25	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
SF-36 EP	25.78 ± 39.89	59.00 ± 40.04	59.00 ± 40.04	59.00 ± 40.04	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
SF-36 MH	47.11 ± 21.80	56.44 ± 14.48	54.67 ± 13.56	52.89 ± 13.68	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
SF-36 PCS	33.44 ± 6.46	38.00 ± 8.71	38.89 ± 9.06	38.67 ± 9.05	<0.05	<0.001	<0.001	n.s.	n.s.	n.s.
SF-36 MCS	33.56 ± 9.9	36.89 ± 7.85	37.11 ± 7.78	36.33 ± 6.98	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.

FU: Follow-up; FIQ: fibromyalgia impact Questionnaire; HAQ: Health Assessment Questionnaire; NRS: number rating scale; RPS: Regional Pain Scale; TPE: tender point evaluation; HADS a: Hospital Anxiety and Depression Scale, anxiety subscale; HADS d: Hospital Anxiety and Depression Scale, depression subscale; SF -36: short form 36; PF: physical functioning; PP: role limitations due to physical problems; BP: bodily pain; GH: general health perceptions; V: vitality; SF: social functioning; EP: role-limitations due to emotional problems; MH: mental health; PCS: physical component summary; MCS: mental component summary.
Data compared by ANOVA for repeated measures, with Bonferroni test for *post-hoc* analysis.

However, the combination of QG with other MBT gave discordant results in FMS patients (25, 26). A protocol combining QG with Mindfulness Meditation was able as well as an educational programme in improving pain, disability, depression and myalgic score (25). QG combined with Body Awareness Therapy did not yield significant improvement on FMS symptoms and physical function in respect to a control group (26). Moreover, in the Mannekorpi study, QG practice was perceived as demanding by the majority of participants, because exercises increased low back and hip pain while standing and due to the difficulty on concentrating on the movements (26).

These works using QG in combination with other MBT are not comparable with our protocols: both Astin (25) and Mannekorpi (26) combined QG with Mindfulness Meditation and Body Awareness Therapy, respectively, in the same session of the same duration; the patients were treated in groups, and, in both cases, the QG exercises were not detailed in depth.

Unlike these studies, our patients were treated singularly with complete cycles of QG and MR sessions, lasting 60 and 45 minutes, respectively. Moreover, probablybecause of the progression of the QG procedure, gradually introducing new interventions based on patient capacity of reaching motor, breathing, relaxing, postural and concentration control, no pain worsening or difficulty in concentration was registered.

It can be argued that the notable efficacy, with no side effect, of QG on FMS patients in our series could be due to the execution of a complete cycle of individual QG sessions, whose exercises were also adapted and fitted on complains and symptoms of FMS.

In FMS, a peripheral and central sensitisation causes an amplification of sensory impulses that may alter pain perception. An increased transmission of nociceptive information from the periphery leads to pain and to central neuroplastic changes (27) and allows normally non-noxious stimuli to be amplified and perceived as noxious. These changes result in a disordered central pain processing and in dysfunctional pain (7, 28).

In FMS patients, chronic pain is one of the most important determinant of disability. From our data, treatment with both protocols significantly improved pain, tenderness, disability, and HRQoL, with the results maintained also at a 12 week follow-up.

Similar results have been shown for other MBT, and are putatively also due to their capacity in disconnecting the affective response to pain (29), thus decreasing pain catastrophising, and the associated emotional distress and sympathetic activation (20, 24, 30, 31).

RM allows a non-judgmental awareness to sensations as they arise that, in turn, induces self-observation and thoughtful responses to pain. Thus, RM, in FMS, may potentially disconnect the affective response to pain, thus breaking the vicious circle chronic pain-stress typical of the disease, and may lead to a more attentive vision on the immediate experience and, ultimately, to ameliorate perception of noxious and painful stimuli, as we demonstrated (12).

It can be hypothesized that QG, similarly to RM, by improving awareness and perception, ameliorates FMS central symptoms and induces a relaxation response, thus reducing muscular tension, leading to pain and stress, and improves mood. These positive changes, on their part, may be responsible for the amelioration of psychosocial well-being, disability and HRQoL, especial-

ly on physical domains (12, 21, 31).

The good results on FIQ obtained by both protocols are of particular interest, because FIQ is a sensitive index of change in FMS related symptoms, which correlates with degree of disability, and is one of the most reliable outcome measures in trials evaluating pharmacological and non-pharmacological treatment in FMS patients (32).

Regarding the efficacy of RM and QG on anxious and depressive symptoms, improvements were shown in both groups, although QG had major effects on depression than RM. It may be hypothesized that QG could act on depressive symptoms in what it utilises, more than RM, tailored physical exercises (postural techniques and conscious movements).

It is known that, in FMS patients, depression and anxiety are related with disease severity (33) and that exercise improves global well-being (34), depressive and anxious symptoms (35) and helps both in reconditioning patients and in preventing the frequent deconditioning syndrome and the vicious cycle of pain, avoidance from movement and activities, potentially causing fatigue and pain and inactivity behaviours (36). Recently, in FMS, we showed the efficacy not only on pain and body posture, but also on general wellbeing of the association of RM with movement, by treating FMS patients with the "Body Movement and Perception" method, that integrates RM with low impact physical exercises (37).

For their characteristics, QG and RM are safe, do not cause adverse effects and are well accepted by FMS patients, as demonstrated by the high compliance to the protocols. This is an important result, as, often, FMS patients have a low adherence to programmes including aerobic exercises (38-40) or exercises of muscle strengthening (41).

The high compliance to our protocols may be due to the absence of any manipulative technique, potentially worsening pain, and by the presence of feasible exercises for FMS patient, including postures and low impact movements, always respectful of the pain threshold and of the exercise capability of the patient. Moreover, controlled breathing and movements, present in both techniques, lead to a restful state and mental tranquility, potentially raising pain thresholds and helping to break the vicious circle "pain-movement-pain (9, 12).

The relatively long follow-up of our study confirms the persistent efficacy of the protocols in a prolonged term, helping, ultimately, the FMS patients to turn their unfavorable behaviour into new more adapted attitudes necessary to the maintenance and the progression of the benefits. Thus, as FMS is a chronic affection needing a constant rehabilitation, cycles may potentially be repeated only twice a year (28).

Although our data show interesting and promising results, the small number of participants is a limitation of our work**.** Thus, in order to confirm the efficacy on FMS of a protocol composed by RM and QG, studies evaluating a major number of patients, assessing additional objective measures, such as putative fibromyalgia biomarkers (42), and with a longer follow-up are needed.

In conclusion, our data show the efficacy of protocols integrating QG and RM in FMS, that, independently from the technique that is used firstly, act synergically on FMS symptoms improving pain, disability, tenderness, HRQoL, sleep and mood.

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