

The efficacy of the Rességuier method in the treatment of fibromyalgia syndrome: a randomised controlled trial

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ABSTRACT

Objectives. In fibromyalgia syndrome (FMS) defined rehabilitation guidelines are yet to be validated. Our aim is to evaluate the efficacy of the Rességuier method (RM) in FMS.

Methods. Forty-one patients were randomly assigned to Interventional (22 pts) and Observational (19 pts) Group (IG and OG). The study lasted 8 months. Patients were assessed at baseline (T0) after a 2-month rehabilitation (T1) and at a 6-month follow-up (T2) (only IG) with SF-36 Physical (PSI) and Mental Synthetic Index (MSI), Regional Pain Scale (RPS), Fibromyalgia Impact Questionnaire (FIQ), Number Rating Scales 0-10 to measure pain, movement quality, sleep, relax ability, analgesics number/per week. OG patients maintained their lifestyle for the duration of the study. RM aims to obtain patient awareness and control of bodily perceptions, thus reaching a modulation of responses to pain. Therapist controls patient attention and perception by verbal and manual contacts and leads them to perform bodily and respiratory active and conscious movements.

Results. In IG, at T1 all items were improved: PSI and MSI ($p < 0.001$ and $= 0.001$), FIQ ($p < 0.0001$), RPS ($p < 0.001$), pain ($p < 0.0001$), movement quality ($p = 0.001$), relax ability ($p < 0.0001$), sleep ($p < 0.001$); analgesics number/per week was reduced ($p < 0.001$). All results obtained at T1, except FIQ, were maintained at T2. In OG at T1 versus T0, no difference in any of the assessed parameters was observed.

Conclusion. In FMS patients, the rehabilitation with RM improves HRQoL, FMS-related disability and perceived pain, thus reducing the assumption of analgesics.

Introduction

Fibromyalgia syndrome (FMS) is characterised by chronic widespread pain

for more than 3 months and bilateral sites of focal tenderness (tender points) (1) associated with fatigue, sleep dysfunction, stiffness, depression and cognitive disruption.

The causes and the pathogenic mechanisms of FMS are not completely known at present. Current hypotheses propose atypical sensory processing in the central nervous system, dysfunction of skeletal muscle nociception and hypothalamic-pituitary-adrenal axis (2).

Pain is a complex sensation-perception interaction, involving not only nociceptive input and somatic reflexes in the spinal cord, and activating a central network in multiple regions of the brain, to whose subjective intensity pathways and regions of brain concerned with emotional, motivational and cognitive aspect of pain may contribute (3). Emotions may represent the psychological correlates of biological systems attempting to restore homeostasis in response to the pain experience (3).

Like other conditions characterised by chronic pain and Chronic Fatigue Syndrome, FMS constitutes a huge societal burden that traditional western medicine is currently failing to approach efficaciously. Pharmacotherapy is often insufficient to control persistent symptoms, or to improve functional limitations and quality of life (HRQoL). On the other hand, non-pharmacological therapies play an important role, are increasingly recommended (4) and found to be efficacious (5) for the treatment of patients with FMS. Although numerous scientific studies concerning rehabilitation treatment in FMS, especially physical training, have been published, well-defined rehabilitation guidelines are not validated. However, within the various populations with FMS, treatment showed considerable individual variation in the outcomes. In particular, FMS patients, characterised by

Competing interests: none declared.

relatively high levels of psychological or emotional distress, seem to benefit most by non-pharmacological interventions (6).

Preliminary evidence of retrospective treatment analyses suggests that the efficacy may be enhanced by offering tailored treatment approaches at an early stage to patients who are at risk of developing chronic physical and psychological impairments (7). Previous studies suffered from low volunteer rates, (8) high number of dropouts (9) or poor compliance due to increased pain after exercise (10).

Some mind-body techniques, defined as “interventions that use a variety of techniques designed to facilitate the mind’s capacity to affect bodily function and symptoms” (11) showed some efficacy in FMS treatment. Concentration based mind-body techniques, such as Cognitive Behavioural Therapies are beneficial in FMS (12), while other techniques, both concentration based, such as Mindfulness Meditation (13) and movement based, such as body awareness techniques, Tai Chi and Qi Gong, have obtained encouraging, although non-unequivocal, results (14–20).

The rehabilitation with the Rességuier method (RM) (21, 22) proposed in this study, is close to mind-body method approaches (and RM itself could be regarded as a mind-body technique) (11) as it is tailored to patient’s necessities and accessible to everyone, also to patients suffering from severe forms of FMS with fatigue, asthenia and psychological distress.

The aim of this study was to evaluate the efficacy of the rehabilitation with RM in the treatment of FMS patients.

Materials and methods

Participation was proposed to 44 consecutive patients diagnosed with FMS and living in the metropolitan Florence area. Inclusion criterion was the diagnosis of FMS according to the American College of Rheumatology (1). Patients gave their written informed consent and the study was approved by the local ethical committee.

After baseline assessment, participants were randomly allocated to Interventional Group (IG: 22 patients) or Obser-

vational Group (OG: 22 patients). Randomisation was made by using a random number sequence prepared by an independent person not connected with the study, who also provided sequentially numbered and sealed envelopes. The results of the randomisation were unknown until the participant accepted or declined to participate in the project. The study had a total duration of 8 months. Patients of both groups were assessed at baseline (T0), at the end of the 2-month rehabilitation period (T1) and after 6 months of follow-up (only patients of IG).

Participants of both groups continued their pharmacological treatments (analgesics/NSAIDs – non-steroidal anti-inflammatory drugs, antidepressants, benzodiazepines), throughout the period of the study and were asked to refrain from starting any new pharmacological intervention for FMS. Patients of the IG were individually treated with the RM for a period of 8 weeks (2 months), 1 session a week (lasting 1 hour), and were taught to perform daily home exercises for the whole duration of the study and during follow-up. All RM treatments were performed by the same physiotherapist (CDF). OG patients, allocated in a “waiting list”, were asked to maintain their lifestyle for the whole duration of the study and to refrain from starting any new regular physical activity or exercise programs unrelated to the study or other non-pharmacological interventions for FMS.

Assessment

Physical Synthetic Index (PSI) and Mental Synthetic Index (MSI) of the Italian version of the Medical Outcomes Survey Short Form 36 (SF-36) (23) and the Italian version of the Fibromyalgia Impact Questionnaire (FIQ) (24) were used to measure HRQoL and disability related to FMS. Perceived pain, quality of movement, sleep and ability to relax body and mind were assessed by a number rating scale 0–10 (NRS-0–10). Regional pain scale (RPS), a self-administered count of the number of painful non-articular regions (with scores ranging from 0 to 19), was also used to assess pain (25).

Moreover, the number of NSAIDs or

analgesics assumed in the previous week at the different time points of the study were registered. At T1 and T2, the perception of the overall benefits due to the treatment, expressed in %, was also assessed. All the assessment examinations were performed by an operator blinded to group assignment.

The Rességuier method

The mainstay of the Rességuier method (RM) is the relationship between therapist and patient based on the continuous attention to the patient during all the session. This attitude of the therapist, called “accompanying posture”, is taught with a specific training session during the formation courses of the method (21, 22).

The therapist maintains and continuously monitors the state of attention and perception of the patient. Simultaneously, the patient participates in the session with active and conscious guided movements, respectful of the pain threshold, in different positions (supine, sitting and standing). The purpose of the session is to obtain patient awareness and control of perceptions, derived from individual parts of the body. This may allow the patient to modulate the response to pain perception.

The capacity to perceive the body and to regulate the sensations and the emotions is obtained by the instruments of RM as follows:

1. *Verbal contact of the therapist.* The therapist asks the patient about his 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.

2. *Manual contacts of the therapist on the patient,* essential to promote patient’s perception of specific areas.

3. *“Petite gymnastique”,* consisting of exercises performed during the sessions:

- i. Exercises of conscious respiration;
- ii. Active and conscious movements of head, trunk, upper and lower limbs, firstly in a supine position, then sitting and standing. The therapist chooses the appropriate movements and exercises, tailoring them to the patient;

4. *Home exercises*, consisting of the movements of “Petite gymnastique” chosen by the therapist and tailored on the patient, were performed daily (30 minutes/day) both during the treatment period, and during follow-up.

Statistical analysis

Data are presented as mean±standard deviation and as number and percentages. Student's *t*-test and χ^2 test were used to compare for groups characteristics at T0. For outcome measures, ANOVA for repeated measures, with Bonferroni Multiple Comparison Test for post-hoc analysis, and *t*-test for repeated measures were used to detect effects of the treatment. Data analysis was performed using the SPSS statistical package 12.0 for Windows.

Clinical trial registration

The study was registered with Current Controlled Trials (www.controlled-trials.com), nr. ISRCTN62054712.

Results

After baseline evaluation, the 44 patients enrolled in the study were randomly allocated to IG (n=22) or OG (n=22). Three patients assigned to OG withdrew because they did not accept their group allocation and to postpone their treatment.

Thus, a total of 41 FMS patients (3 males and 38 females; age and disease duration 45.5±11.79 and 51±4.7 years, respectively) participated in the study: 22 in the IG (2 males and 20 females; age and disease duration: 44.36±13.08; 5.3±4.8 years, respectively), and 19 in the OG (1 male and 18 females; age and disease duration: 46.64±10.50; 4.9±4.7 years, respectively).

Some patients (7 in IG and 8 in OG) had already performed kinesitherapy or other physical therapies as chiropractic, massotherapy, hydrotherapy, ultrasound therapy, laser therapy, Mézières method and acupuncture, with poor and short duration benefits.

Clinical and demographic characteristics of FMS patients, homogeneous in IG and OG, are presented in Table I.

The application of RM resulted in being safe to FMS patients, as no patient of IG dropped out of the study and no

Table I. Characteristics at the study entry (T0) of patients of Interventional and Observational Group.

| | Interventional group | Observational group | <i>p</i> -value |
|---------------------|----------------------|---------------------|-----------------|
| PSI (SF-36) | 37.24 ± 7.74 | 34.60 ± 7.35 | NS |
| MSI (SF-36) | 36.85 ± 10.87 | 33.85 ± 11.17 | NS |
| FIQ | 49.54 ± 17.05 | 50.09 ± 18.06 | NS |
| Pain | 6.31 ± 1.6 | 6.42 ± 1.89 | NS |
| Movement | 4.40 ± 1.65 | 4.50 ± 1.70 | NS |
| Relax | 3.32 ± 1.76 | 3.16 ± 2.33 | NS |
| Sleep | 4.27 ± 3.76 | 5.20 ± 1.89 | NS |
| Regional pain scale | 8.41 ± 2.48 | 8.0 ± 2.02 | NS |
| N analgesics/week | 4.72 ± 3.58 | 5.0 ± 3.23 | NS |

PSI: Physical Synthetic Index of SF-36; MSI: Mental Synthetic Index of SF-36; FIQ: Fibromyalgia Impact Questionnaire.

Table II. Items assessed at baseline (T0), at the end of treatment (T1) and after follow-up (T2) in Interventional group.

| | T0 | T1 | T2 | T0 -T1 <i>p</i> | T0 -T2 <i>p</i> | T1-T2 <i>p</i> |
|---------------------|---------------|---------------|---------------|--------------------|--------------------|-------------------|
| PSI (SF-36) | 37.24 ± 7.74 | 44.48 ± 8.01 | 42.67 ± 9.73 | <0.001 | <0.001 | NS |
| MSI (SF-36) | 36.85 ± 10.87 | 47.31 ± 9.74 | 42.27 ± 10.30 | 0.001 | NS | NS |
| FIQ | 49.54 ± 17.05 | 34.10 ± 17.03 | 46.66 ± 16.32 | <0.0001 | NS | <0.0001* |
| Pain | 6.31 ± 1.6 | 3.72 ± 1.78 | 4.0 ± 1.63 | <0.0001 | <0.0001 | NS |
| Movement | 4.40 ± 1.65 | 6.13 ± 1.7 | 5.86 ± 1.86 | 0.001 | <0.01 | NS |
| Relax | 3.32 ± 1.76 | 6.27 ± 1.66 | 5.18 ± 2.08 | <0.0001 | <0.001 | NS |
| Sleep | 4.27 ± 3.76 | 7.27 ± 3.41 | 6.68 ± 3.38 | p<0.001 | <0.01 | NS |
| Regional pain scale | 8.41 ± 2.48 | 7.73 ± 2.67 | 7.59 ± 2.32 | <0.001 | <0.001 | NS |
| N°analgesics/week | 4.72 ± 3.58 | 2.9 ± 2.42 | 3.14 ± 2.28 | <0.001 | <0.001 | NS |

PSI: Physical Synthetic Index of SF-36; MSI: Mental Synthetic Index of SF-36; FIQ: Fibromyalgia Impact Questionnaire; *T2>T1.

adverse event was registered. This was confirmed by the attendance rate to the sessions, which resulted 100% for all the patients. Accordingly, no patient was lost at the treatment follow-up (T2) evaluation.

In the IG, the application of RM for 2 months was useful in ameliorating perceived HRQoL and disability related to FMS, as well as pain, sleep, movement and ability to relax. In fact, at the end of the rehabilitation period (T1), IG patients were significantly improved in all of the following items: PSI and MSI of SF36 ($p<0.001$ and $p=0.001$, respectively), FIQ ($p<0.0001$), RPS ($p<0.001$), perceived pain ($p<0.0001$), quality of movement ($p=0.001$), sleep ($p<0.001$) and ability to relax mind and body ($p<0.0001$). In keeping with the reduction of perceived pain, the mean number of NSAIDs and analgesics assumed per week in IG patients was significantly reduced at T1 *versus* T0 ($p<0.001$).

The results obtained by RM in FMS

patients of IG were maintained also after 6 months of follow-up. In fact, all the results obtained at T1 (except the FIQ score) were maintained at T2 ($p=NS$ for all comparisons) (Table II). Accordingly to these results, in IG patients, the subjective perception of treatment benefits resulted 76.1±21.9 % at the end of the treatment and 46.3±29.5% at follow-up.

As shown in Table III, in FMS patients of OG, at T1 *versus* T0, no change was shown in the perceived HRQoL and disability related to the disease, as assessed by PSI and MSI of SF36 and FIQ ($p=NS$ for all the comparisons). Concordantly, the items evaluating self-perceived pain, movement, ability to relax and sleep, as well as the mean number of NSAIDs and analgesics assumed per week were unchanged at T1 *versus* T0 ($p=NS$ for all the comparisons).

Discussion

This is the first study assessing the

Table III. Items assessed at baseline (T0) and at the end of treatment (T1) in Observational group.

| | T0 | T1 | p-value |
|---------------------|---------------|---------------|---------|
| PSI (SF-36) | 34.60 ± 7.35 | 35.71 ± 9.37 | NS |
| MSI (SF-36) | 33.85 ± 11.17 | 35.45 ± 13.41 | NS |
| FIQ score | 50.09 ± 18.06 | 48.00 ± 18.82 | NS |
| Pain | 6.42 ± 1.89 | 6.55 ± 1.62 | NS |
| Movement | 4.50 ± 1.70 | 4.52 ± 1.86 | NS |
| Relax | 3.16 ± 2.33 | 3.36 ± 2.32 | NS |
| Sleep | 5.20 ± 1.89 | 5.14 ± 1.66 | NS |
| Regional pain scale | 8.0 ± 2.02 | 8.10 ± 2.42 | NS |
| N analgesics/week | 5.0 ± 3.23 | 4.89 ± 3.33 | NS |

PSI: Physical Synthetic Index of SF-36; MSI: Mental Synthetic Index of SF-36; FIQ: Fibromyalgia Impact Questionnaire.

effect of RM application in a cohort of FMS patients. Our data show that a 2-month long rehabilitation program with RM is effective in improving FMS-related symptoms, namely HRQoL and FMS-related disability, perceived pain, sleep, movement, and relaxation. RM was also effective in reducing the number of analgesics assumed per week. All the results achieved with RM application (except the improvement in FIQ scores) were maintained after a 6-month follow-up.

The management of FMS, often impairing function and HRQoL (26) is difficult and based on a wide array of pharmacological and non-pharmacological interventions including hydrotherapy, aerobic exercises, muscular strengthening or stretching, and mind-body therapies (6, 27). Aerobic exercise and strength training are beneficial mostly in conditioning patients and in interrupting a pain/reduced movement vicious circle (6). However, these interventions suffer from high dropout percentages, because of the difficulty of FMS patients to introduce activities potentially exacerbating pain into their daily life habits (8-10, 28). This may be reduced by individualising and tailoring the exercises according to patients personal limits (28, 29) and by using different approaches such as hydrotherapy (30-33), able in improving, although for a short period, pain, health status and tender point counts (6, 33). Cognitive Behavioural Therapy (CBT), a concentration based mind-body technique is beneficial to FMS, with highly distressed patients showed as being the

most susceptible to intervention (5, 7, 12). Differently from CBT, which should be administered by a psychologist, RM is executed by a physiotherapist. This could render the patient better compliant to the therapy, in that FMS patients generally do not accept the psychological determinants of the disease (4). In FMS, encouraging results were obtained by other mind-body methods, such as Mindfulness Meditation (13), body awareness techniques, Tai Chi and Qi Gong (14-20).

The feasibility of a rehabilitation treatment should guarantee a high adherence to the program and reduces the probability of dropouts (34, 35). In our study, differently from other mind-body techniques applied in FMS (13, 20, 36), the adherence to RM program was complete. Concordantly, RM resulted to be feasible and safe as no dropouts nor adverse events were registered and no patient was lost at follow-up.

RM, based on an individualised approach, comprising only few and moderate body and respiratory exercises ("petite gymnastique"), is accessible to everyone, as it is respectful of pain threshold, is feasible also for asthenic patients and does not include any manipulative therapy, not tolerated by the majority of patients, due to the changes in nociception typical of FMS (37).

The inclusion of a "soft" home self management in the program (30 daily minutes of "petite gymnastique"), both in the treatment period and in the follow-up, could be important for maintaining the results obtained by RM sessions performed under the guide of the

therapist. This result is in keeping with the well-known concept that self-management is fundamental in non-pharmacological management of chronic diseases (38).

As well as Qi Gong, in our study, RM was able to improve pain (39, 40) and FMS-related disability (40) and as well as Tai Chi, RM improved FMS-related disability and HRQoL (20). Moreover, RM improved movement, sleep, and relaxation.

In contrast with techniques directly inducing relaxation, and somewhat similarly to Mindfulness Meditation (13), RM promotes a nonjudgmental awareness to sensations and emotions as they arise that, in turn, induces self-observation and thoughtful responses to pain.

Acting on these mechanisms, RM in FMS may potentially disconnect the affective response to pain from focusing on pain, thus breaking the vicious circle of chronic pain-stress typical of the disease, and may lead to a more attentive vision on the immediate experience and, ultimately, to an improved perception of HRQoL and FMS-related disability, as we observed in our patients.

This is also supported by the reduction of the assumption of analgesics during the application of RM, that was maintained, as well as the reduction of pain, also at follow-up.

It is important to note that the benefits achieved during the treatment are maintained at follow-up. It is therefore conceivable that RM not only helps the patients to reduce the affective component of pain, but also to cope with it, by regulating the pain perception and the emotional response to pain, thereby leading to a balance between somatic pain and stressful habits.

Although our study underlines the benefits of RM in FMS patients, the feasibility of this intervention may have some limits. Potential obstacles to its wide use are represented by a commitment of time for physiotherapists and patients as well as a specific training of the physiotherapist (21, 22).

Because of its rapidly effectiveness and its safety, RM can be regarded as a "first step" non-pharmacological intervention in FMS patients, particularly in

those unable to deal with usual training programs.

Our study, although showing promising results, has some limitations such as the small sample size of our casuistry. Thus, studies on larger groups of patients and with a longer intervention period, conducted with specific clinimetric instruments, are advocated to confirm the effectiveness of RM on the wide spectrum of FMS symptoms.

In conclusion, in FMS patients a 2-month-long rehabilitation with RM improved HRQoL and FMS-related disability as well as perceived pain, movement, sleep and relaxation, assumption of analgesics, with the achieved results maintained after a 6-month follow-up. Given our results, RM could be a useful non-pharmacological tool to side drug therapy in managing FMS and in helping many patients to cope more effectively with the disability and the pain related to their condition.

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