Effects of pool-based exercise in fibromyalgia symptomatology and sleep quality: a prospective randomized comparison between stretching and Tai Chi

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ABSTRACT

Objective. *To evaluate the effectiveness and tolerability of two pool-based physical therapies, stretching and Tai Chi, in fibromyalgia symptomatology and sleep quality.*

Methods. *Eighty-one patients, randomly assigned to stretching (n=39) or Tai Chi (n=42), received 18 physiotherapy sessions and were evaluated at baseline, at treatment termination, and after 4 and 12 weeks of follow-up. Main outcome measures were the Fibromyalgia Impact Questionnaire (FIQ) and the Pittsburgh Sleep Quality Index (PSQI). Secondary outcome measures included the Beck Depression Inventory (BDI), the State and Trait Anxiety Inventory (STAI), and the SF-12 Health Survey (SF-12). Data analysis was done with repeated measures ANOVA and effect sizes' estimation.*

Results. *No differences were found between groups but significant reduction in the FIQ and the PSQI scores were observed in Tai Chi but not in stretching group, with larger effect sizes and longer effect duration on sleep measures. BDI scores decreased in stretching but not in Tai Chi group with small effects sizes. Trait-anxiety scores decreased in both groups also with small effect sizes. The mental component summary of the SF-12 increased only in stretching group with effects sizes moderate to large.*

Conclusions. *Although no global differences were found between groups, Tai Chi significantly improved fibromyalgia symptomatology and sleep quality, whereas stretching only improved subjects' psychological well-being.*

Introduction

Fibromyalgia is a chronic disorder with a complex symptomatology. Although generalized pain is the cardinal symptom of the disease, other associated symptoms, such as nonrestorative sleep, chronic fatigue, anxiety and depressive symptoms play also a relevant role in the disability of the disease (1).

Nonrestorative sleep is one of the factors which worsen fibromyalgia symptomatology (2, 3). Intrusion of alpha sleep waves during sleep stages 3 and 4 (4), and decreased sleep spindles and lower mean spindle time during sleep stage 2 (5) have been described in fibromyalgia. Sleep disturbance exerts a noticeable impact on fibromyalgia symptomatology: one study found a negative correlation between pain threshold and sleep quality (6), and another one showed that poor sleep quality was associated with greater pain and fatigue the following day (7).

Pharmacologic treatment remains the primary therapeutic approach in fibromyalgia management, but different non-pharmacologic measures, especially physical therapies and psychologically-based interventions, have also shown to be effective in the treatment of this disease (8). It is generally assumed that a multidisciplinary approach, combining both pharmacologic and non-pharmacologic measures, is probably the optimal treatment approach for most fibromyalgia patients (9-12).

In relation to physical therapies, exercise in warm water is considered a good option, as both temperature and water buoyancy minimize body weight's stress and help patients to minimize pain (8). Concerning the effects of warm water on sleep, an afternoon warm bath has shown to increase slow wave sleep on the following night (14), and water exercise in older people increased total sleep time in contrast with subjects performing aerobic exercise or doing strength training (15). In addition, a recent study found that exercise

in warm water increased the cognitive performance in women with fibromyalgia (16), and another study found that physical activity lessened the severity of fibromyalgia in male patients experiencing post-traumatic stress disorder and fibromyalgia (17).

Several controlled studies have been published comparing pool-based exercise either with a control group or with land-based exercise which have been the subject of a recent review article (18). Of these, only two evaluated the effects of warm water exercise on sleep, both of them showing a positive effect of water exercise on sleep parameters (19, 20).

Tai Chi, a technique which combines mind-body therapy with exercise, has shown to exert beneficial effects on fibromyalgia symptomatology in an uncontrolled study (21). Tai Chi is an adaptation of land Tai Chi movements to water and has been suggested to be suitable for fibromyalgia patients (22); however, evidence of its clinical efficacy is currently lacking.

The objective of this pilot randomized controlled study was to compare the efficacy and tolerability of two different modalities of active low-impact exercise in warm water, stretching and Tai Chi, on fibromyalgia symptomatology and sleep quality.

Methods

Patients

Patients were recruited among those attending the Pain Unit of the Institute of Neurosciences as well as among those treated in the Rehabilitation Department of the University Hospital "Virgen de las Nieves" of Granada (Spain) where the study was carried out. Patients were included if they were aged 18 years or older, had a diagnosis of fibromyalgia according to the current American College of Rheumatology criteria (13), and provided written informed consent to participate. Patients who had never attended a swimming pool as well as those suffering any concomitant disease susceptible to worsen with warm water exercise, such as coronary disease, severe chronic respiratory disease, known allergy to chlorine, etc. were excluded. Patients were instructed to follow their previously prescribed pharmacological treatment without any change during all study duration, including both treatment and follow-up periods.

Study protocol

The study protocol had a randomized, parallel groups and open-label design. According to the Spanish regulations, it was submitted and approved by the Ethics Committee of the Hospital Universitario "Virgen de las Nieves" of Granada (Spain).

Participants were randomly assigned to stretching (S) or to Tai Chi (AC) groups by means of a computer-generated table of random numbers. As the study was not blinded, patients knew that they have been assigned to a specific kind of exercise, and either stretching and Tai Chi characteristics were detailed in the patient's information form.

Each group was given a total of 18 physiotherapy sessions of 60 minutes of duration performed 3 times a week during 6 weeks. Both stretching and Tai Chi sessions were performed in the same days of the week but at a different time of the afternoon, so that patients appertaining to different groups did not meet. Patients were evaluated just before entering in the study (baseline), at treatment termination (end) and 4 and 12 weeks after termination (1- and 3-month follow-up). Patients needed to attend a minimum of 14 sessions to be considered completers of the study. No exercise was performed during the follow-up period.

Exercise programme

Training was done in a pool with water heated at 36ºC of temperature and was preceded by a shower with warm water (34.5ºC to 35.5ºC) to condition patients' body. Room temperature was maintained between 20ºC to 25ºC. A trained physiotherapist, always the same for all of the exercise groups, supervised the exercises, marking up the rhythm of the exercises, and adjusting the exercise intensity to the individual needs, depending on the degree of pain severity and fatigue experienced in each session. When a patient realized that he/she was experiencing too much pain or felt excessive tiredness, was instructed to stop exercises for a while until recovered. Exercise sessions were carried out in groups of 13 to 15 subjects.

In the stretching groups, in order to facilitate the stretchings, subjects were given 1 metre long wooden sticks, 1.5 metres long flexible strings and flexible tubes of 8 cm of diameter and 1.5 metres long. The stretchings were performed over muscles of the main body areas: cervical area, upper and lower extremities, and trunk. In the Tai Chi groups patients were taught the 16 movements which constitute the Tai Chi therapy without the help of any additional material. Tai Chi is performed standing in shoulder-depth water using a combination of deep breathing and slow, broad movements of the arms, legs, and torso. In both groups, during the first and last 10 minutes of each session, patients relaxed in warm water; the central 40 minutes were dedicated to exercises. Patients could freely talk in the stretching but not in the Tai Chi groups, in which they needed to concentrate on breathing and movements.

Outcomes

The two primary outcome measures were the Fibromyalgia Impact Questionnaire (FIQ) and the Pittsburgh' Sleep Quality Index (PSQI). The FIQ is a self-administered scale developed to assess specifically health status in fibromyalgia patients (23). We applied a Spanish validated version (24). We evaluated the total scores as well as the seven VAS subscales scoring from one to ten measuring difficulty at work, pain, fatigue, morning tiredness, stiffness, anxiety and depression. For obtaining the total score, all subscores of the FIQ with the exception of the two work-related subscores were summed yielding a range from 0 to 80. The PSQI is also a self-administered questionnaire intended to assess sleep quality during the four preceding weeks and contains 19 questions yielding seven components: subjective sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbances, use of sleep medications, and daytime dysfunction (25). We administered the Spanish validated version (26).

Secondary outcomes measures included the Beck Depression Inventory (BDI), the State and Trait Anxiety Inventory (STAI), and the Short-Form-12 Health Survey (SF-12). The BDI is a well known 21-item self-administered scale to measure depression severity (27); it can be subdivided in two components: cognitive/affective and physiological (28). The STAI is a 40-item self-reported scale differentiating between state-anxiety (temporary/situational) and trait-anxiety (long-term/chronic) (29). The SF-12, an abbreviated version of the Medical Outcomes Study SF-36, is a general indicator of health status in adults, and produces a mental component summary (MCS) and a physical component summary (PCS) (30). We applied the Spanish validated versions of BDI (31), STAI (32), and SF-12 (33).

Data analysis

The population for the analysis of efficacy included all patients who were randomized to treatment and for whom at least one efficacy assessment was available at baseline. This was the intent to treat (ITT) population. If efficacy data were not available at one time point after baseline, they were imputed using the last observation carried forward approach (LOCF), either at exercise end as at the follow-up visits.

Effect sizes were calculated according to Cohen's formula (34), and considered small when ranging from 0.20 to 0.49, moderate when ranging from 0.50 to 0.79 and large when equal or higher than 0.80.

Comparison of demographic and clinical patients' data in both treatment groups was done by means of a χ^2 test. Global comparison of primary and secondary outcome measures, excepting improvement PGI, was carried out by applying a two-way repeated measures analysis of variance (ANOVA). Differences within groups over time were analysed with a one-way repeated measures ANOVA with the Dunnett's post-test (end of treatment and follow-up values versus baseline values). Differences between groups at each time point were assessed with the Student's *t*-test for unpaired data. Statistical analyses were performed using GraphPad Prism version 5.00 for Windows (GraphPad Software, San Diego, CA; www.graphpad.com).

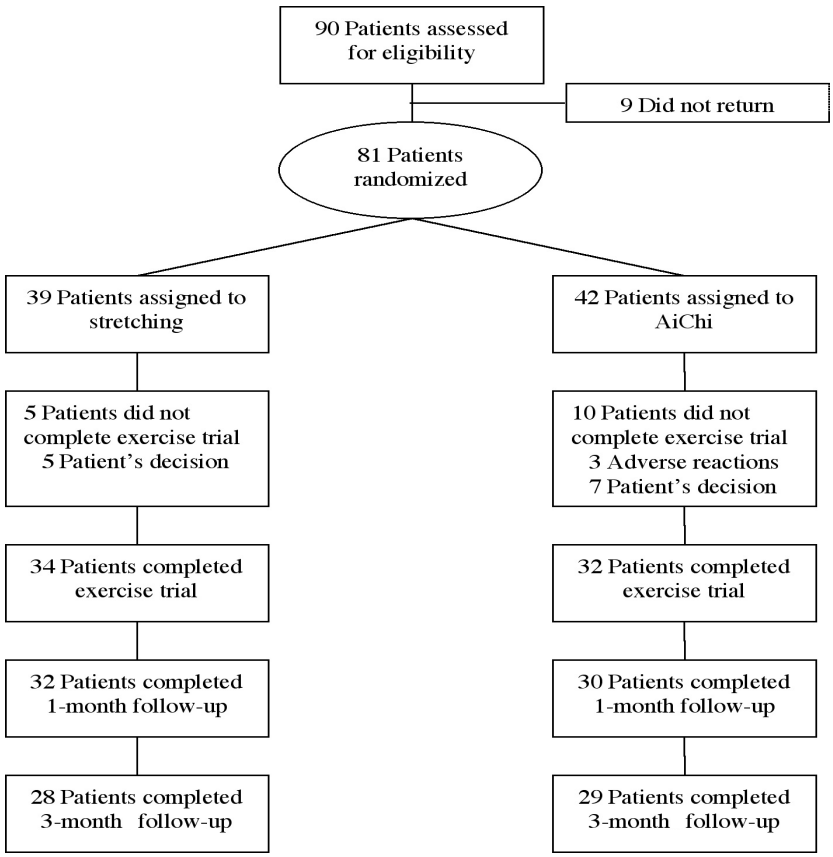

Fig. 1. Patients' flow diagram.

Table I. Demographic and clinical data of patients at baseline.

	Stretching (n=39)	Ai Chi (n=42)	*p*-value
Sex (female/male)	34/5	39/3	n.s.
Age (years, mean ± s.d.)	51 ± 8.0	49 ± 8.4	n.s.
Illness duration (years, mean ± s.d.)	14.1 ± 8.4	15.6 ± 8.7	n.s.
FIQ total score at baseline	59.0 ± 9.9	58.5 ± 12.7	n.s.
Comorbid conditions [n. (%)]			
Temporomandibular dysfunction	35 (89.7)	37 (88.1)	n.s.
Tension-type headache	32 (82.0)	30 (71.4)	
Migraine	21 (53.8)	31 (73.8)	
Irritable bowel syndrome	24 (61.5)	35 (83.3)	
Chronic fatigue syndrome	7 (17.9)	14 (33.3)	
Thyroid disease	7 (17.9)	8 (19.0)	
Rheumatoid athritis	9 (23.1)	8 (19.0)	
Drug treatment			
NSAIDs/paracetamol	27 (69.2)	24 (57.1)	n.s.
Opioids	12 (30.8)	14 (33.3)	
Antidepressants	16 (41.0)	23 (54.8)	
Anxiolytics/hypnotics	23 (58.9)	26 (61.9)	
Other drugs*	37 (94.9)	37 (88.1)	

*muscle relaxants, antiepileptic drugs, atypical antipsychotics.

Patients' sample

As it is shown in Figure 1, a total of 90 patients willing to participate were screened; however, 9 of them did not

return when appointed to fill the baseline evaluation scales. Therefore, 81 patients were randomized: 39 to the stretching group and 42 to the Tai Chi group, and constituted the ITT efficacy sample.

Results

Main demographic and clinical data of patients are shown in Table I. Age range varied from 32 to 69 years in group S, and from 28 to 69 years in group AC. The duration of fibromyalgia symptomatology ranged from 1 to 40 years in group S, and from 4 to 34 years in group AC. Fifteen patients withdrew the trial without completing the required minumum of 14 sessions: five (12.8%) from the stretching group and ten (23,8%) from the Tai Chi group (Fisher's exact test, p=0.145). Three of them, all belonging to the AC group, were due to adverse reactions: one case of chlorine hypersensitivity and two cases of pain exacerbation. The remaining twelve patients alleged lack of time to attend sessions three times per week. Four patients missed the 1-month follow-up, and nine patients missed the 3-month follow-up.

There was not any significant time-treatment interaction for the main outcome variables nor fot the secondary outcome variables but, as it is shown in Figures 2 to 4, a significant time effect was found in most of the cases. Mean values and effect sizes of the different outcome variables, as well as statistical significance within and between groups are shown in Figures 2 to 4. As it can be seen, statistically significant differences and moderate ES were seen in the Tai Chi group for FIQ total scores and several FIQ subscales scores (Fig. 2), and for the PSQI total scores and several PSQI components, whereas in the stretching group no statistically significant differences were found for these variables, excepting daytime dysfunction, and all of the ES were small (Fig. 3). As for the secondary outcome variables, BDI scores decreased significantly in the stretching group, and trait-anxiety scores decreased significantly in both groups but the ES were small. The most relevant changes were observed in the scores of the SF-12 mental component

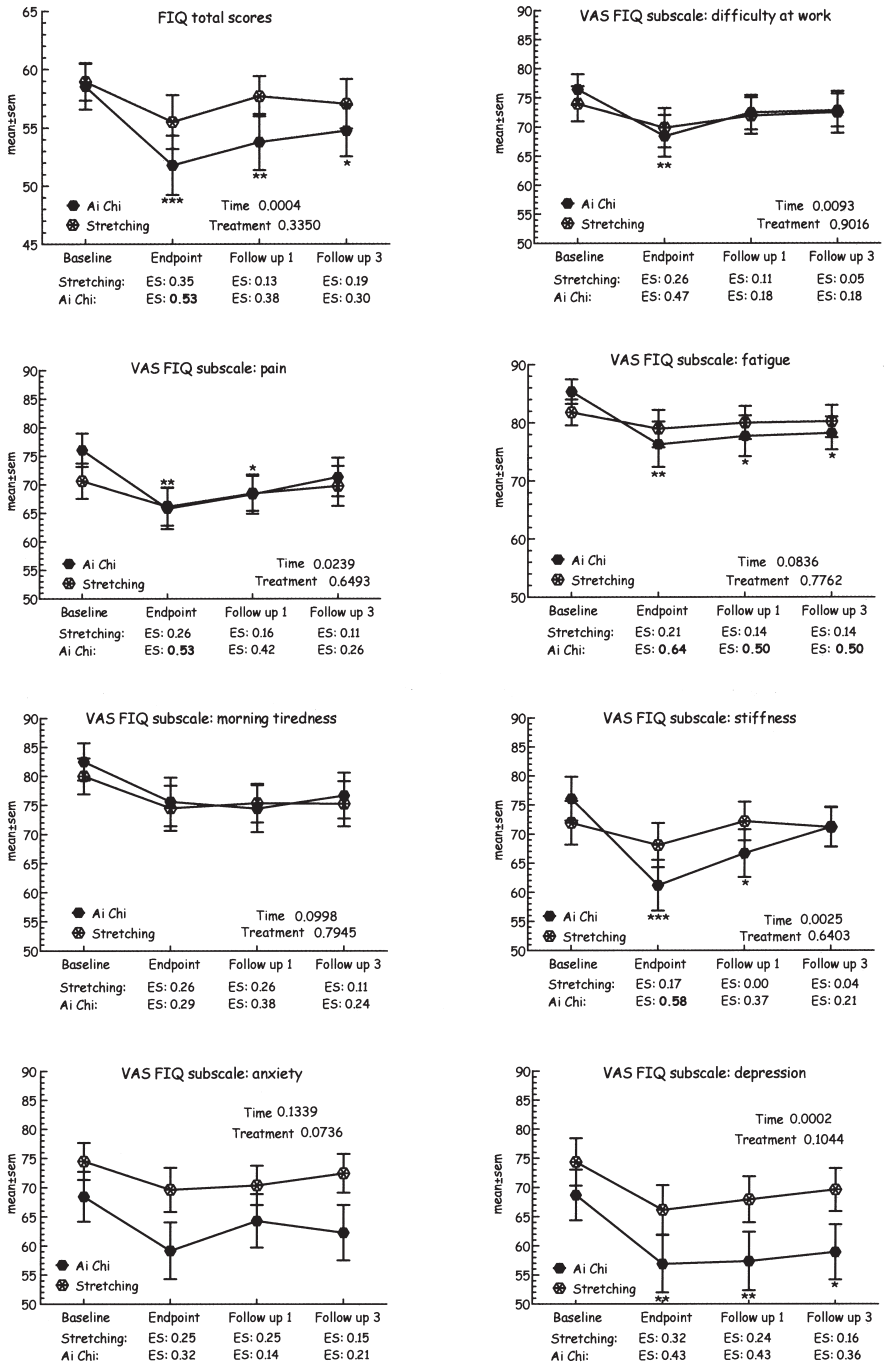

Fig. 2. Comparison of baseline, treatment termination (end) and follow-up (FU 1 and 3) of the VAS' FIQ subscales in both treatment groups. ES: effects size. $^{*}p<0.05$, $^{**}p<0.01$, and $^{***}p<0.001$ in relation to the baseline values.

which showed a progressive and statistically significant improvement in both groups, although moderate to large ES were seen only in the stretching group (Fig. 4).

Discussion

Our total sample was mainly composed of severely impaired patients, with a long duration of the disease and a high frequency of comorbid conditions (Table I), mostly with diseases in which pain is also a cardinal symptom such as temporomandibular disorder, tension-type headache, migraine, irritable bowel syndrome, and rheumatoid arthritis. These data could explain the low scores found in baseline SF-12 scores. In another study, which also measured FIQ scores and quality of life by means of

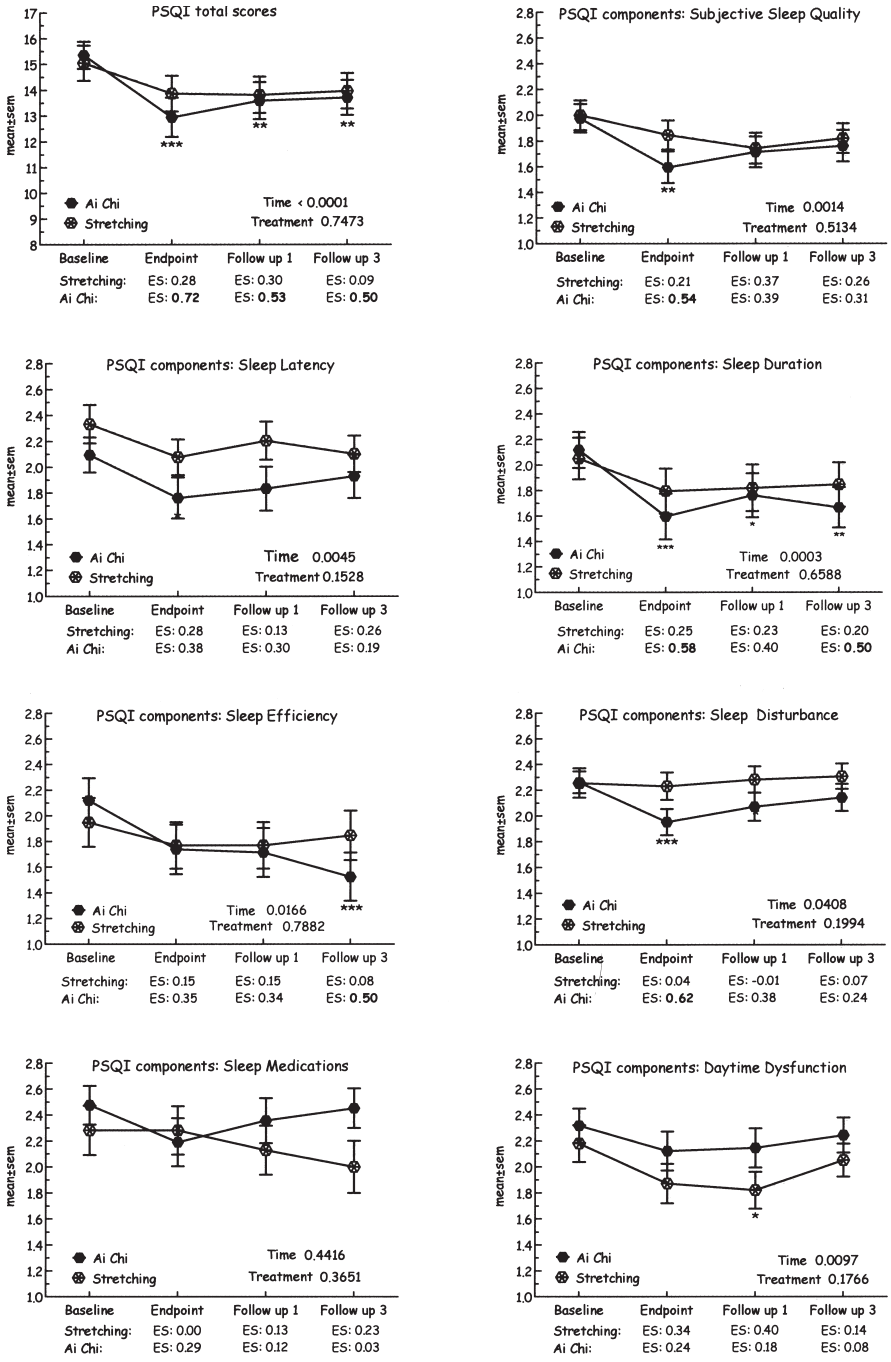

Fig. 3. Comparison of baseline, treatment termination (end) and follow-up (FU 1 and 3) values of PSQI and its seven components in both treatment groups. ES: effects size. **p*<0.05, ***p*<0.01, and ****p*<0.001 in relation to the baseline values.

SF-36, patients at study entry had similar levels of fibromyalgia-related health status but reported substantially higher scores both in the physical and in the mental component of the SF-36 (35). Similarly, the sample in the study of Valim *et al*. (36), which also included FIQ total and SF-36 scores as outcome variables, had lower total FIQ scores at baseline and higher scores in the physical and mental summary components of the SF-36.

Although differences in the proportion of withdrawals between the two study groups were not statistically significant, it seems clinically suggestive that only 12.8% of the patients withdrew in the stretching group as compared with the 23.8% in the Tai Chi group. Tai Chi requires a higher level of concentration and involves more physical strain than stretching. Both the pain increase reported by two patients as well as the higher proportion of patients not attending a minimum of 14 sessions could have been a consequence of these factors. On the other hand, the difficulty to attend the sessions three times a week during six weeks was a problem stated by many patients, especially those who lived far from downtown. Perhaps an exercise programme based in one weekly session during a longer period of time would have been a more practical approach.

Despite the lack of a significant time-treatment interaction between groups, which was probably due to the dispersion in the individual data within each group, Tai Chi patients showed a significant and clinically meaningful improvement both in FIQ and in the PSQI scores which was not seen in stretching patients. Particularly striking and long-lasting were the scores observed in the PSQI total scores and in the fatigue subscale of the FIQ; these data seem to agree with the findings of Nicassio *et al*. (7) who found that sleep quality was strongly related with daily fatigue and that a poor sleep predicted fatigue before and after taking in account the effect of pain.

Among the seven sleep components of the PSQI, statistically significant improvement and moderate effect sizes at treatment's end were found for subjective sleep quality, sleep disturbances, and sleep duration in the Tai Chi group. The scores of this last component maintained a moderate effect size and statistical significancy at the last follow-up visit. In agreement with our results, in a recent publication, Vitorino *et al*. (20) found that both conventional physiotherapy and pool hydrotherapy improved total sleep time and reduced total nap time, being both effects more pronounced in the hydrotherapy group. A data worthy of mention is the fact that, always in the AC group, sleep efficiency showed a progressive tendency to improve along the time, reaching statistical significance and a moderate effect size in the 3-month follow-up visit. A positive effect on sleep which persisted 3 months after the end of treatment

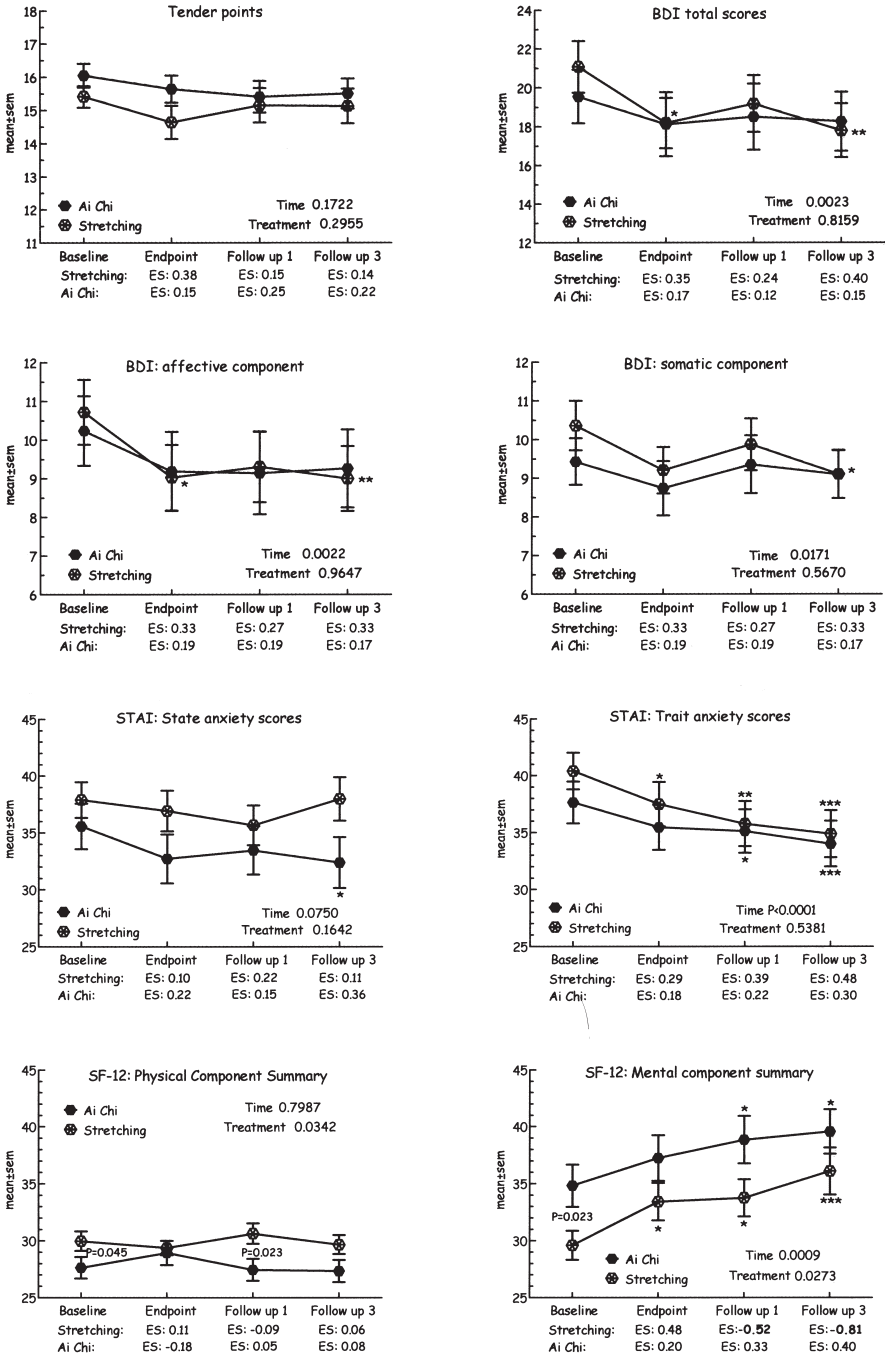

Fig. 4. Comparison of baseline, treatment termination (end) and follow-up (FU 1 and 3) values of number of tender point, BDI, STAI, and SF-12. ES: effects size. *p<0.05, **p<0.01, and ***p<0.001 in relation to the baseline values.

has been also described by Altan *et al.* in their two study groups (19); as these authors compared physiotherapy in a mineralized warm pool with immersion in the same pool without exercise, their data seem to support the potential benefits of warm water on sleep described by other authors (14, 15).

The more pronounced beneficial effects in the stretching group were seen in the secondary variables which were related with mood and general health. Particularly noticeable effects sizes were observed in the mental health summary of the SF-12, whose scores increased progressively at all time points across the study until reaching its maximum at 3-month follow-up. A similar trend, but reaching statistical significance only at 3-month follow-up, was seen in the Tai Chi group. Two factors can be responsible of the differences between both groups. On the one hand, despite randomization, the Tai Chi group showed significantly better scores of mental health at baseline, a point which could have obscured the benefits provided by physiotherapy. On the other hand, a very important point is the beneficial effect of performing exercise in groups, since subjects can exchange feelings regarding their illness and share impressions related to the physiotherapy programme. In our study, the capacity to interchange these experiences was fully operative in the stretching but not in the Tai Chi group due to the necessity to be quiet and concentrate on breathing and movement during most of the session duration. This nonspecific benefit derived from belonging to a therapeutic group has been highlighted by several authors (37-39).

The beneficial effects of both stretching and Tai Chi on anxiety symptoms were seen in trait anxiety scores. This fact suggests that exercise improved chronic anxiety, which is measured by trait anxiety scores and is a prominent feature in most of fibromyalgia patients, without affecting significantly to situational anxiety, reflected in state anxiety scores and in the anxiety subscales of the FIQ.

The minimal improvement observed in the stretching group excepting for mood and quality of life variables agrees with the data of authors who compared stretching with other physiotherapy procedures. Either McCain *et al.* (40), who compared a cardiovascular fitness programme with flexibility training, Jones *et al.* (41), who compared muscle stretching versus muscle strenghthening, and Valim *et al.* (36), who compared stretching with aerobic fitness training, found that their results were inferior in the stretching groups. Perhaps, as stated by Jones *et al.* (41), stretching can be considered as a light exercise intervention and, thus, not providing substantial benefits on fibromyalgia symptomatology. However, as stated by Valim *et al.* (36), it should be neither considered as a placebo intervention, since some gains were observed.

A strength of our study was the follow-

up period without active exercise. This allowed us to observe that the physical gains induced by exercise showed a trend to lessen over time but were still apparent at 3 months follow-up for the main outcome variables (*i.e.* FIQ and PSQI total scores) whereas the gains found in mood and mental health tended to become stabilized, and even to increase, during the follow-up period. The only other study which specifically forbade physical exercise during a 3-month follow-up period, found also that several outcome variables, namely self care, anxiety/depression and isokinetic strength in several knee muscles, were still significantly ameliorated after 12 weeks of sedentary follow-up (42). It can be concluded that improvement produced by warm water physiotherapy last at least several weeks even in the absence of active exercise. As warm pools are not easily available in communities, intermittent periods of exercise in warm water alternating with resting periods could be a practical option for deconditioned fibromyalgia patients unable to tolerate aerobic land exercise.

A limitation of our study was the lack of a control group receiving no therapy. Studies which compared physiotherapy against a control group, commonly patients in waiting list, found significant differences between exercise versus no therapy (37-39, 42, 43), whereas those studies who compared two active treatment modalities usually did not find significant differences between them (19, 20, 41, 44), the exceptions being the studies of Valim *et al*. (36) and Assis *et al*. (35) which found that both exercise groups improved similarly in several outcome variables but one of the groups achieved significantly better results for some of them. The inclusion of a control group together with both exercise groups would have allowed a higher degree of certainty regarding the clinical benefits provided by each active treatment. Other important limitation of our study is the lack of blinding but the use of self-administered and otherwise well accepted and validated, outcome measures together with the nature of the interventions under study precluded the masking. Finally, another previously mentioned shortcoming of our study is the fact that, despite randomization, baseline SF-12 values were significantly different in both groups, with higher scores in the Tai Chi than in the stretching group.

In summary, our study did not find significant differences between stretching and Tai Chi. However, the pronounced and long-lasting beneficial effects observed in the main outcome variables suggest that Tai Chi could be a valuable physiotherapy method in fibromyalgia management. Further randomized controlled trials aimed to evaluate the efficacy of this modality of pool-based exercise seem warranted.

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