Scand J Rheumatol 1996; 25: 77–86

Effects of Aerobic Exercise Versus Stress Management Treatment in Fibromyalgia

A 4.5 year prospective study

S. Hørven Wigers[1,2,3], T. C. Stiles[2], and P. A. Vogel[2]

[1]Department of Physical Medicine and Rehabilitation, University Hospital of Trondheim, [2]Department of Psychiatry and Behavioral Medicine, University of Trondheim, [3]Department of Behavioral Sciences in Medicine, University of Oslo, Norway

To determine and compare short- and long-term effects of aerobic exercise (AE), stress management treatment (SMT), and treatment-as-usual (TAU) in fibromyalgia, 60 patients were randomized to 14 weeks of treatment by either AE, SMT or TAU. Outcome measures at baseline, midway through treatment, at treatment completion, and at 4 year follow up included a patient made drawing of pain distribution, dolorimetry of tender points, ergometer cycle test, global subjective improvement, and VAS registrations of: pain, disturbed sleep, lack of energy, and depression. Both AE and SMT showed positive short-term effects. AE was the overall most effective treatment, despite being subject to the most sceptical patient attitude prior to the study. At follow up, there were no obvious group differences in symptom severity, which for AE seemed to be due to a considerable compliance problem.

Key words: fibromyalgia/therapy, treatment outcome, aerobic exercise, relaxation techniques, cognitive therapy, follow-up studies, patient compliance

To find an effective way of handling fibromyalgia is a great challenge in modern medicine. The prevalence of this chronic condition, which mainly affects women, is about 2% (1). The patients suffer from widespread musculoskeletal pain and stiffness, disturbed sleep, and fatigue (2) and experience a significantly reduced quality of life (3). No changes pathognomonical for fibromyalgia have been found, and the etiology remains disputed. Treatment has proved to be difficult, with discouraging results (4). In fibromyalgia, as for other chronic pain syndromes, a multidisciplinary program has been recommended as the treatment of choice (4–6). In order to design an optimal multidimensional treatment program, it is essential to know the unique effects of each component to be included, as well as the overall effect of their combination. However, no controlled multidisciplinary treatment study has been published, and studies on single component treatments, other than medications, are relatively few (7–13). Moreover, they only describe short-term outcome.

The fibromyalgia syndrome implies both physical and psychological impairment (14), and treatment has been directed to both aspects. Most patients are physically unfit (15), and a number of the fibromyalgic symptoms and research findings may be explained as detraining effects (7, 15–17). It is therefore not surprising that cardiovascular fitness training has shown positive effects in fibromyalgia (7). EMG-biofeedback relaxation training, known as an effective treatment for psychosomatic syndromes, has also proved beneficial (11). With regard to the patients' chronic pain and abnormal scores on various psychological tests, cognitive behavioral therapy has been applied in fibromyalgia with promising results (9, 10).

The lack of objective, standardized outcome variables and measures (4, 18) represents a major problem in fibromyalgia treatment research, and complicates comparisons of outcome from different treatment programs. The present 4.5 year prospective study therefore aims at comparing short- and long-term outcome from three different treatment modalities in fibromyalgia: (I) aerobic exercise (AE), (II) stress management treatment (SMT) through a cognitive approach (19) and including applied relaxation (20), and (III) treatment-as-usual (TAU) controls.

Materials and methods

Patients

Sixty-five fibromyalgia patients were recruited from the local patient association and 12 from the Physical Medicine Outpatient Clinic of the University Hospital in Trondheim. The 77 patients underwent a detailed medical history and a thorough clinical examination (by SHW). To ensure comparability with other studies, each patient had to fulfil the diagnostic criteria of both Smythe (21) and Yunus et al. (22) to be included. Twelve patients did not meet the inclusion criteria, and 5 refused to take part in the treatment

Sigrid Hørven Wigers, Department of Behavioral Sciences in Medicine, University of Oslo, P.O. Box 1111 Blindern, N-0317 Oslo, Norway.

Received 26 June 1995
Accepted 11 December 1995

Table I. Demographic data in the total patient sample (n=60) and in each treatment group (n=20)

Variable	Total	AE Group	SMT Group	TAU Group
Sex (female/male)	55/5	18/2	18/2	19/1
Age (years)#	44 (10,23–73)	43 (9,23–62)	44 (12,28–69)	46 (9,29–73)
Symptom duration (years)#	10 (8, 1–42)	9 (5, 2–20)	11 (10, 1–40)	11 (9, 1–42)
Occupational work load n (%):				
Full time	13 (22%)	4 (20%)	5 (25%)	4 (20%)
Part time	14 (23%)	7 (35%)	5 (25%)	2 (10%)
Out of work:	33 (55%)	9 (45%)	10 (50%)	14 (70%)
Sick leave	17 (28%)	5 (25%)	6 (30%)	6 (30%)
Disability pension	13 (22%)	4 (20%)	3 (15%)	6 (30%)
Housewife or age retired	3 (5%)	0	1 (5%)	2 (10%)

Values are mean (SD, range). AE: Aerobic exercise, SMT: Stress management treatment, TAU: Treatment-as-usual.

study. Thus, 60 patients were finally admitted to the trial. Demographic data are given in Table I. Retrospective investigation of the patient data revealed that 58 of the 60 patients also fulfilled the American College of Rheumatology 1990 (ACR-90) criteria (23). The last two had widespread pain, but only 10 of the 16 ACR-90 tender points that had been examined. Most likely these two patients had at least one of the low cervical points (which had not been examined), and thus fulfilled the ACR-90 criteria, since both had marked their neck and throat as painful areas.

Study design

In the present prospective study, outcome assessments were made before=*baseline*, midway through=*midway* and after=*completion* the treatment period, and 4 years after completion=*follow up*. Apart from the midway investigation, which consisted of a mailed questionnaire containing a self-administered pain drawing and a visual analogue scale (VAS) scheme, all assessments were made at the Physical Medicine Outpatient Clinic. Patients were instructed not to reveal their group membership before treatment specific questions were asked at the very end of the completion test. Neither patients nor investigators had access to previous recordings on any test occasion.

At baseline, the patients were asked how effective they expected each intervention treatment to be, and how they would feel if they were allocated among the TAU controls. Eighty-two percent expected SMT to improve their condition, while only 50% thought they would improve from AE, 30% being convinced that AE would make them worse. The great majority (70%) were positively inclined towards the TAU Group where they would get thorough examinations and aid research, without having to invest or risk anything themselves. After baseline registration, the patients were randomized (by drawing lots) into an AE Group, a SMT Group or a TAU Group. They were all instructed to continue their baseline treatment unchanged throughout the intervention period. According to the protocol, patients that initiated new treatment regimens or acquired new diseases in the intervention period were considered as dropouts. Treatment started in November and ended in February, including 14 weeks of active treatment and a 2 week Christmas break. Only patients completing the treatment according to the protocol (=completers) were invited to the follow up investigation in March, 4 years after completion. Despite being designed as an on-treatment study, an attempt will also be made to present data according to the principle of intention to treat (24).

Outcome measures

Pain distribution was assessed on all test occasions by a patient made drawing. Patients were instructed to shade all areas which had been painful the last three days on two small figures representing the ventral and dorsal sides of the body respectively. No shading meant no pain. From these drawings the percentage of total body area affected by pain was later estimated using Wallace's "rule of nine" for assessing burns (25).

On all test occasions, the last three days' average intensity of the four most central fibromyalgia symptoms: *pain, disturbed sleep, lack of energy* (for fatigue), and *depression* were rated on a patient administered VAS-scheme. The scheme consisted of 100 mm horizontal lines placed one under another, each representing a symptom of its own. End descriptors were 0=nothing and 100=the worst you have ever experienced. On the top of the page, between the end descriptors of the uppermost VAS, the additional descriptors "some", "medium" and "severe" were added along the line to make it easier to understand and promote a more homogenous interpretation (26–28). To avoid clustering underneath these addi-

tional descriptors, the patients were informed about the continuity of the line. For validation of the VAS scheme, an open-ended question on physical and psychological changes was asked at treatment completion.

Pressure tenderness in all ACR-90 tender points, except the low cervical, was measured using a spring-loaded pressure dolorimeter (Pain Diagnostics and Thermography, Italy). It had a rubber head diameter of 1.15 cm and a capacity of 11 kg. SHW made all measurements.

Work capacity was measured directly by an ergometer cycle exercise test specially designed to fit the fibromyalgia condition. The patients started cycling at 50 W, and workload was increased with 25 W every third minute. Patients were instructed to cycle as long as they managed. ECG recordings of heart rate were made before start, at the end of every 3 minute period, and at test completion. This test was administered by blinded employees trained to do exercise ECGs. In the statistical analyses, work capacity is expressed as the ratio of maximum voluntary work in W per 3 minutes, and the corresponding maximum heart rate.

Global subjective improvement, from baseline to completion, was rated on a 4-step verbal rating scale (VRS, 0=worse, 3=much better), and from completion to follow up on a 5-step VRS (0=much worse, 4=much better).

Supplementary registrations.

Treatment quality was rated by the AE and SMT patients at completion, using a 5-step VRS (0=very poor, 4=very good). Patients were also asked whether or not they planned to continue with similar treatment. *Additional treatments/medications, acquirement of other diseases* and *occupational status/disability pension* were recorded on all test occasions, and the occurrence of *critical life events* and *physical activity level* were included at follow up.

Treatment

Aerobic Exercise. The AE Group contained 20 patients in two treatment groups of ten. They were given aerobic exercises for 45 minutes 3 times a week for 14 weeks, altogether 40 sessions (30 hours of active treatment). A physiotherapist experienced with rehabilitation of cardiac patients conducted both treatment groups. The exercise program involved the whole body and aimed at minimizing eccentric muscle strain. Tempo was gradually increased up to, and decreased down from, four periods of high intensity training at 60–70% of maximum heart rate (altogether 18–20 minutes). According to their age, the patients were told the pulse frequency level to reach in these periods, and learned how to check it themselves. The patients moved freely about and exercised in their own individual tempo. They wore appropriate shock absorbing shoes, and were allowed to take breaks at any time. The program started with a 23 minute music session, comprising warming up and two peaks of high intensity training, each of 3–4 minutes duration. This was followed by 15 minutes of aerobic "games" (different types of tag, ball games etc.), representing two high intensity periods of 5–6 minutes each, with 4 minutes calming down in between. The program ended with warming down and thoroughly stretching out.

Stress Management Treatment. The SMT Group contained 20 patients in two treatment groups of ten. Two clinical psychologists experienced in stress management treatment led one group each and collaborated closely to provide similar therapy. Patients met 90 minutes twice a week the first six weeks, and once a week the remaining eight, altogether 20 sessions (30 hours of active treatment). They were given a cognitive-behavioral stress management package including applied relaxation (20) and an introduction to cognitive therapy in coping with psychological problems (19). Each session consisted of equal portions of didactic presentations, group discussions and relaxation training. The didactic presentations concerned stress mechanisms and strategies for improving quality of life despite chronic pain. The group discussions concerned the participants' own experiences of stress and coping with pain and were kept positive in tone. The applied relaxation training followed the manual described by Öst (20). The aim of this technique is to learn a relaxation skill which may be applied very rapidly in practically any situation to help patients cope with stress and pain instead of being overwhelmed by it. Patients were given an audio-cassette containing the "progressive" and "release-only" relaxation procedures and practised relaxation techniques regularly at home. Compliance was recorded on registration sheets which were checked at each session. As an aid in monitoring their arousal, patients were also given a thermal biofeedback measure (Stress Test Card, Excelsior & Co., P.O. Box 5028, Westlake Village, CA 91362).

Treatment-as-usual. The 20 patients in the control group simply continued the treatments they had been using at baseline. These were: Aquatic therapy (n=3), psychomotor treatment (n=1), tricyclic antidepressants (low evening doses, n=8), and, mostly when needed, low doses of: analgesics (n=6), muscle relaxants (n=3), hypnotics (n=3), and tranquilizers (n=2).

Statistical analyses

One-way analyses of variance were performed on continuous baseline variables. Temporal effects within

each group were determined by paired t-tests. Group differences at completion and follow up were determined by regression analyses using completion and follow up scores as dependent variables and treatment group (in terms of two dummies, using TAU as reference) as explanatory, together with age and baseline scores which were controlled for. The significance of the difference between the AE and SMT Group regression coefficients was determined by comparing with a t-distribution (29). Results from ordinal data were assessed by Kruskal-Wallis tests, followed by Mann-Whitney tests. Nominal data were analyzed by chi-square tests for cross-tabulations.

Results

Forty-eight patients (AE:16, SMT:15, TAU:17) completed the treatment part of the study according to the protocol, and 44 of these (AE:15, SMT:13, TAU:16) were assessed at follow up. Dropout reason and time for the latest data recording are given in Table II.

Preliminary analyses

There were no significant group differences at baseline, neither in the total patient sample (N=60) nor among the completers (N=48), with respect to demographic data, outcome measures, or prior expectations to treatment. Moreover, prior expectations towards the group they were randomized into did not significantly influence global subjective improvement at treatment completion in any of the groups. Quality ratings of received treatment by the AE and SMT patients gave similar results for the two treatments (N=60): AE Group (1 missing): Very poor/Poor=0, Medium=5, Good=9, Very good=5. SMT Group (2 missing): Very poor/Poor=0, Medium=2, Good=10, Very good=6. Treatment attendance rate was also nearly identical, being 70% in the AE Group (completers: 80%), and 68% in the SMT Group (completers: 75%). No significant group differences with respect to additional treatments/medications or acquirement of other diseases were seen throughout the 4.5 year trial. Occupational work load remained mainly unchanged, but ten patients were granted a full, lifelong disability pension (AE:1, SMT:3, TAU:6), and five a half disability pension (AE:3, SMT:1, TAU:1), during the follow up period. At follow up, there were no group differences in terms of critical life events or physical activity level. The open-ended question on physical and psychological changes gave a satisfactory validation of the VAS scheme.

Temporal changes

Temporal changes within each group are shown in Figure 1 for the total patient sample. The latest data recordings available are used for the dropouts. TAU controls remained unchanged throughout the entire trial, apart from a significant reduction in pain distribution at midway and follow up.

Group differences

Data are presented according to the principle of intention to treat as well as for completers only (24). Outcome in each group at baseline, treatment

Table II. Dropout reasons for the 16 patients that either withdrew or failed to complete the trial according to the protocol. Only completers were invited to follow up

Time for dropout	Group	n	Reason for dropout	Attendance rate	Time for the latest data recording
During treatment:	AE	4	Acquired gastritis	15/40	Completion
			Acquired ischialgia	16/40	Completion
			Transport problems	13/40	Completion
	SMT	5	Transport problems	2/40	Midway
			Moved to an other town	4/20	Midway
			Acquired cancer	10/20	Completion
			Transport problems	5/20	Baseline
			Initiated additional treatments	4/20	Completion
	TAU	3	Initiated additional treatments	15/20	Completion
			Initiated additional treatments	–	Completion
			Initiated additional treatments	–	Completion
At follow up:	AE	1	Had died	–	Completion
	SMT	2	Moved to another town	31/40	Completion
			Did not wish to participate	18/20	Completion
	TAU	1	Moved to another town	15/20	Completion
				–	Completion

AE: Aerobic exercise (40 sessions totally), SMT: Stress management treatment (20 sessions totally), TAU: Treatment-as-usual controls. Midway = midway through the treatment period, Completion = at treatment completion, Follow up = at 4 year follow up.

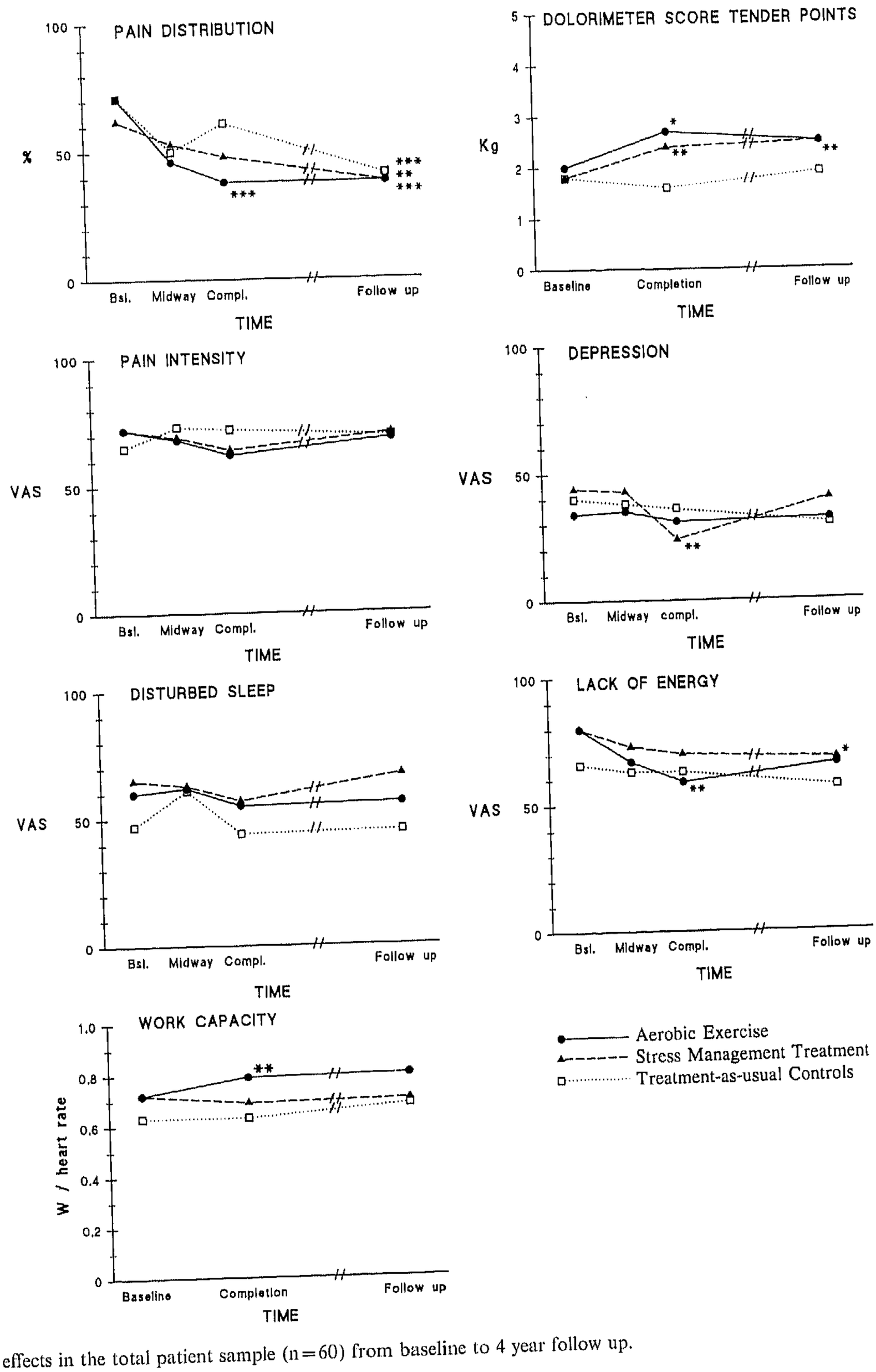

Fig. 1. Time effects in the total patient sample (n=60) from baseline to 4 year follow up.

Means (SD) are given in Table IIIa. Paired t-tests within each group on baseline (Bsl.) to completion (Compl.) scores and baseline to follow up scores. *p<.05, **p<.01, ***p<.001.

completion and follow up are presented in Table IIIa for the total patient sample, and in Table IIIb for completers only. As small changes in VAS scores may occur by chance, the number of completers noting from 11–20%, 21–30%, and more than 30% reduction in their VAS scores at treatment completion, are given in Table IV. These data (Table IV) clearly correspond with the results in Table IIIb, indicating that the significant VAS improvements truly represent therapeutic effects.

Table III. (a) Presentation of group effects according to the principle of intention to treat. Each group contains 20 patients

Variable	Baseline (n=60)			Treatment completion (n=60, 3●)			4-year follow up (n=60, 16●)		
	AE	SMT	TAU	AE	SMT	TAU	AE	SMT	TAU
Pain distribution (%)	71 (24)	62 (27)	71 (23)	38 (27)**	48 (29)	61 (27)	38 (26)	38 (19)	40 (29)
VAS Pain	72 (19)	72 (18)	65 (17)	62 (21)	64 (19)	72 (24)	68 (24)	70 (18)	69 (24)
VAS Disturbed sleep	60 (33)	65 (27)	47 (37)	55 (34)	57 (30)	44 (33)	56 (34)	67 (25)	47 (32)
VAS Lack of energy	80 (20)	80 (22)	66 (27)	59 (26)	70 (21)	63 (33)	66 (27)	68 (20)	61 (30)
VAS Depression	34 (29)	44 (32)	40 (37)	31 (32)	24 (22)	36 (35)	32 (34)	40 (28)	30 (31)
Dolorimeter score (kg)	2.0 (1.6)	1.8 (0.7)	1.8 (0.9)	2.7 (1.6)***	2.4 (0.9)**	1.6 (0.7)	2.4 (1.0)	2.5 (1.1)*	1.9 (1.1)
Work capacity¤	0.7 (0.2)	0.7 (0.2)	0.6 (0.2)	0.8 (0.1)*	0.7 (0.2)	0.6 (0.2)	0.8 (0.3)	0.7 (0.2)	0.7 (0.2)

Data from the latest available recording are used when patients are missing ● (see Table II).

Table III. (b) Presentation of group effects among patients that completed the trial according to the protocol

Variable	Baseline (n=48)			Treatment completion (n=48)			4-year follow up (n=44)		
	AE	SMT	TAU	AE	SMT	TAU	AE	SMT	TAU
Number of patients	16	15	17	16	15	17	15	13	16
Pain distribution (%)	69 (25)	76 (23)	68 (22)	30 (18)***##	51 (23)	66 (25)	30 (18)	38 (22)	39 (27)
VAS Pain	70 (20)	75 (18)	67 (14)	59 (20)*	57 (18) **	75 (22)	64 (25)	67 (20)	69 (23)
VAS Disturbed sleep	65 (31)	60 (30)	45 (36)	55 (33)	49 (31)	43 (35)	53 (32)	64 (30)	46 (32)
VAS Lack of energy	81 (20)	82 (25)	68 (27)	54 (27)*	68 (23)	71 (29)	63 (30)	67 (23)	63 (30)
VAS Depression	30 (28)	45 (31)	37 (37)	26 (32)	20 (18)*	37 (37)	25 (35)	43 (28)	27 (30)
Dolorimeter score (kg)	2.2 (1.7)	2.0 (1.2)	1.8 (0.8)	2.9 (1.8)**	2.5 (1.5)**	1.6 (0.7)	2.4 (1.1)	2.4 (1.2)	1.8 (1.1)
Work capacity¤	0.7 (0.1)	0.7 (0.2)	0.6 (0.2)	0.8 (0.2)**##	0.7 (0.2)	0.6 (0.2)	0.8 (0.3)	0.6 (0.2)	0.7 (0.2)

Values are mean(SD). AE:Aerobic exercise, SMT:Stress management treatment, TAU:Treatment-as-usual controls. Group effects were assessed by one-way ANOVAs on baseline scores and by separate multiple regression analyses on completion and follow up values, adjusting for age and baseline scores: *p<.05, **p<.01, ***p<.001 compared to TAU controls. #p<.05, ##p<.01 compared to the SMT Group.
¤Maximum work (W)/maximum heart rate.

Table IV. Number of patients reporting less than 11%, from 11–20%, 21–30%, and more than 30% reduction in VAS scores at treatment completion. (n = 48, see Table 3b)

Percent reduction in VAS score	Pain			Lack of energy			Depression			Disturbed sleep		
	AE	SMT	TAU	AE	SMT	TAU	AE	SMT	TAU	AE	SMT	TAU
Worse or unchanged	9	5	14	4	5	5	7	3	12	9	8	9
11–20% reduction	1	2	0	1	3	1	0	0	1	1	1	1
21–30% reduction	1	4	2	3	2	0	0	2	0	0	2	1
> 30% reduction	5	4	1	8	5	1	9	10	4	6	4	6

AE: Aerobic exercise (n = 16), SMT: Stress management treatment (n = 15), TAU: Treatment-as-usual controls (n = 17).

At treatment completion. When including the total patient sample, AE Group members showed significantly reduced pain distribution and tender point tenderness and a greater work capacity compared to TAU controls. The SMT Group showed reduced tenderness only (Table IIIa). When analyzing completers, AE Group members showed, in addition to less pain distribution and tenderness and improved work capacity, also reduced VAS pain and VAS lack of energy (Table IIIb) and increased global subjective improvement ($p < 0.001$) compared to TAU controls. (Global subjective improvement: AE:75%, SMT:47%, TAU:12% feeling better or much better.) Their pain distribution was also significantly reduced and work capacity increased, compared to the SMT Group. SMT completers showed, in addition to reduced tenderness, also reduced VAS pain and VAS depression compared to TAU controls.

Nine AE Group and three SMT Group members had experienced the treatment mainly as an additional daily life stressor, but interestingly, this experience did not influence the global subjective improvement significantly. AE Group members rated improved physical fitness and the social dimension as the most positive aspects of the treatment, while SMT Group members rated the learning of relaxation skills as the greatest benefit. At treatment completion, all AE and SMT Group members intended to continue with similar treatment, but 15 from the AE Group emphasized they would exercise only twice a week.

At follow up. In the total patient sample, the only group difference at follow up was reduced tenderness in the SMT Group compared to TAU controls. It should be noted that using the latest data recordings available for three SMT patients that had completed the SMT treatment but not the follow up investigation, may have biased the results. If baseline scores from these three patients had been used instead, no group differences would have been found at follow up. No group differences were seen among the completers. Six patients (AE:3, SMT:1, TAU:2) no longer fulfilled the ACR-90 criteria (23).

Compliance and effect of continued activity in the follow up period

Despite optimistic intentions to continue training, only four AE Group members reported they were doing AE at follow up, while nine SMT members were still practising relaxation regularly (from twice a week to daily). Outcome differences within each treatment group at follow up between patients that did or did not continue are shown in Table V. At baseline and treatment completion there were no significant differences between compliers and non-compliers, apart from age. AE continuers were younger, and SMT continuers older, than the rest in their groups. Controlling for the effect of age, AE continuers showed at follow up significantly less: pain, lack of energy, depression, and tenderness and increased work capacity and global subjective improvement ($p < 0.01$) compared to AE discontinuers. Moreover, three of the four continuers no longer fulfilled the ACR-90 criteria. In the SMT Group, however, no outcome differences between continuers and discontinuers were found.

Discussion

The present study demonstrates that both AE and SMT may induce positive short-term effects in fibromyalgia. However, when viewing each group as a whole, effects on symptom severity are few, if any, in the longer term.

Effects of AE. AE appears to be an effective treatment in fibromyalgia when patients adhere to it, as demonstrated by positive short-term outcome and the fact that three of four patients, having continued with AE, no longer fulfilled the diagnostic criteria at follow up. A considerable compliance problem may explain the lack of long-term effects on symptom severity in the AE Group as a whole.

The present findings confirm earlier studies that have shown aerobic exercise to reduce tender point tenderness (7), increase work capacity without

Table V. Differences at follow up between patients that had discontinued (=Discont.) or continued (=Cont.) training in each intervention treatment group

Variables	AE Group (n=15)		SMT Group (n=13)	
	Discont.	Cont.	Discont.	Cont.
Number of patients	11	4	4	9
Age (years)	51 (6)	39 (9)*	40 (9)	54 (11)*
Symptom duration (years)	16 (5)	10 (6)	10 (5)	18 (13)
Pain distribution (%)	35 (18)	16 (4)	29 (16)	42 (23)
VAS Pain	75 (19)	36 (13)**	67 (17)	67 (22)
VAS Disturbed sleep	59 (34)	38 (22)	65 (23)	64 (34)
VAS Lack of energy	77 (21)	24 (4)**	65 (20)	68 (26)
VAS Depression	33 (39)	4 (4)*	57 (29)	37 (28)
Dolorimeter score (kg)	2.0 (0.6)	3.4 (1.7)**	2.1 (1.2)	2.5 (1.2)
Work capacity	0.7 (0.1)	1.2 (0.3)*	0.7 (0.1)	0.6 (0.2)

AE: Aerobic exercise, SMT: Stress management treatment. Values are mean (SD). Outcome differences between discontinuers and continuers in each treatment group were assessed by separate multiple regression analyses adjusting for age and completion scores. Differences in age and symptom duration were assessed by two-sample t-tests. *$p<0.05$, **$p<0.01$.

adverse side effects (7, 8, 16), and increase global subjective improvement (7, 8, 16) in fibromyalgia. However, that AE may reduce pain distribution, VAS pain, and VAS lack of energy, have not been shown earlier.

One explanation to this variability in outcome may be differences in the exercise programs given. In previous studies (7, 8, 16), work was performed more or less continuously and mainly by the legs. In the present study the whole body was involved at varying intensities, with only 18–20 minutes of high intensity training per 45 minute session. Patients stretched out thoroughly, "listened to their bodies" and rested when they felt like it. Mengshoel et al. (8) found improved dynamic endurance and reduced exercise induced pain in patients' arms only. The arms had been exercised with intervals of rest, while the legs had been in continuous activity for 60 minutes. The exercise frequency may be another reason for the observed outcome differences. Most patients find three times a week – which is preferable in terms of increasing physical fitness (30), and which also has proved beneficial in fibromyalgia (7) – to be too frequent. In the AE Group 45% experienced the treatment mainly as an additional stressor, and 75% emphasized they would continue with AE only twice a week. Moreover, Mengshoel et al. (8) had to reduce the exercise frequency from thrice to twice a week because of compliance problems in the pilot study. Their patients did, however, not achieve increased physical fitness compared to controls.

As positive effects from AE generally are reversible (30), it is natural that they do not persist in fibromyalgia when training is terminated. At follow up, non-compliers had returned to baseline levels, while the four continuers, who were exercising 30 minutes or more at least 4 times a week and at a relatively high intensity (always/most often sweating and losing their breath), had improved further on all outcome measures. Due to the limited patient number, only reduction in VAS pain reached significance ($p<0.05$). However, compared to AE non-compliers, the compliers had improved significantly in six out of eight outcome measures. No firm conclusion may be drawn from such a limited patient number, but the findings indicate that positive effects from muscular and cardiovascular conditioning in fibromyalgia persist, and may develop further, provided a sufficient exercise level is maintained.

The considerable compliance problem is demonstrated by the fact that despite a positive intention to continue, 73% had discontinued training at follow up. Of these, 82% thought they would have felt better if they had continued. The lack of a suitable treatment group near home was given as the most common reason for discontinuation. However, at treatment completion they had all been offered a place in an AE program at the same institute, with the same physiotherapist, as in the treatment study. This program was terminated after half a year due to lack of participants. Thus, it appears that the patients' belief in AE, combined with the existence of a suitable program in their own town, is not enough to eliminate the compliance problem.

Effects of SMT. Outcome in the SMT Group suggests that a psychological intervention using relaxation and cognitive techniques to teach patients to cope with stress and discomfort, has beneficial short-term effects in fibromyalgia by reducing pain, tenderness, and depression. Moreover, it was successful with respect to long-term compliance. During treatment, patients' adherence to relaxation training at home had been continuously monitored, and their compliance problems discussed in the group. It is noteworthy that

69% of the patients were still performing relaxation exercises 4 years later, even though no obvious effects from this training could be demonstrated.

The improvement in pain and depression is in accordance with a study by Goldenberg et al. (10), reporting a highly significant reduction in the SCL-90-R global index of distress, after a 10 week meditation based stress-reduction, cognitive-behavioral treatment program in fibromyalgia. Their patients also showed significant reduction in VAS fatigue, tiredness, and pain. Nielson et al. (9) admitted fibromyalgia patients to a 3 week inpatient cognitive behavioral program, and achieved pain reduction (using various pain recording scales) as well as reduced depression and anxiety. In addition, EMG-biofeedback relaxation training has been shown to reduce VAS pain and tender point count in fibromyalgia (11). Fibromyalgia patients seem to respond to cognitive behavioral therapy and applied relaxation in the same way as other chronic pain patients do, i.e. with pain and mood improvement (31–34). However, with the possible exception of tenderness, positive effects of SMT on symptom reduction were not maintained over time, not even in the continuers.

By choosing TAU controls, the intervention treatments were compared to commonly given fibromyalgia treatments, and possible climatic influences (35) were controlled for.

Using one investigator only to perform the dolorimeter tests may be disadvantageous, as the exactness of the recordings was not verified against the results from another investigator. On the other hand, using one person to make all measurements has the benefit of eliminating the inter-rater variability problem.

Conclusion

Compared to TAU, both AE and SMT induced short-term fibromyalgia improvement, but no obvious group differences in symptom severity were seen in the longer term. The treatments are simple and cost-effective and well tolerated by the patients. Further studies are needed to investigate whether synergistic effects and perhaps improved AE long-term compliance could be obtained by combining the two treatment regimens. If so, this would represent a valuable supplement to the individual approach, which is fundamental in all fibromyalgia treatment.

Acknowledgements

We are indebted to Lena Brustad for conducting the AE groups, Kjell Røsdal for conducting one of the SMT groups, and Mary Dahl for her never failing patience in handling the patients at the test occasions. The support and advice from Prof. K. Gunnar Götestam are also appreciated. The present study was supported by The Research Council of Norway (project number: 101417/320) and The Norwegian Fibromyalgia Association.

References

1. Wolfe F, Ross K, Anderson J, Russell IJ, Hebert L. The prevalence and characteristics of fibromyalgia in the general population. Arthritis Rheum 1995; 38: 19–28.
2. Smythe HA, Moldofsky H. Two contributions to understanding of the "fibrositis" syndrome. Bull Rheum Dis 1977; 28: 928–31.
3. Burckhardt CS, Clark SR, Bennet RM. Fibromyalgia and quality of life: A comparative analysis. J Rheumatol 1993; 20: 475–9.
4. Goldenberg DL. Fibromyalgia: Treatment programs. J Musculoskel Pain 1993; 1(3/4): 71–81.
5. Masi AT, Yunus MB. Fibromyalgia – which is the best treatment? A personalized, comprehensive, ambulatory, patient-involved management programme. Baillieres Clin Rheumatol 1990; 4: 333–70.
6. Bennet RM. A multidisciplinary approach to treating fibromyalgia. In: Værøy H, Merskey H, eds. Pain Research and Clinical Management, Volume 6. Progress in fibromyalgia and myofascial pain. Amsterdam; Elsevier, 1993: 393–410.
7. McCain GA, Bell DA, Mai FM, Halliday PD. A controlled study of the effects of a supervised cardiovascular fitness training program on the manifestations of primary fibromyalgia. Arthritis Rheum 1988; 31: 1135–41.
8. Mengshoel AM, Komnœs HB, Førre Ø. The effects of physical fitness training in female patients with fibromyalgia. Clin Exp Rheumatol 1992; 10: 345–9.
9. Nielson WR, Walker C, McCain GA. Cognitive behavioural treatment of fibromyalgia syndrome: Preliminary findings. J Rheumatol 1992; 19: 98–103.
10. Goldenberg DL, Kaplan KH, Nadeau MG, Brodeur C, Smith S, Schmid CH. A controlled study of a stress-reduction, cognitive behavioral treatment program in fibromyalgia. J Musculoskel Pain 1994; 2(2): 53–66.
11. Ferraccioli G, Ghirelli L, Scita F, Nolli M, Mozzani M, Fontana S, et al. EMG-biofeedback training in fibromyalgia syndrome. J Rheumatol 1987; 14: 820–5.
12. Haanen HCM, Hoenderdos HTW, Van Romunde LKJ, Hop WCJ, Mallee C, Terwiel JP, et al. Controlled trial of hypnotherapy in the treatment of refractory fibromyalgia. J Rheumatol 1991; 18: 72–5.
13. Deluze C, Bosia L, Zirbs A, Chantraine A, Vischer TL. Electroacupuncture in fibromyalgia: results of a controlled trial. BMJ 1992; 305: 1249–52.
14. Yunus MB, Ahles TA, Aldag JC, Masi AT. Relationship of clinical features with psychological status in primary fibromyalgia. Arthritis Rheum 1991; 34: 15–21.
15. Bennet RM, Clark SR, Goldberg L, Nelson D, Bonafede RP, Porter J, et al. Aerobic fitness in patients with fibrositis. A controlled study of respiratory gas exchange and ^{133}Xenon clearance from exercising muscle. Athritis Rheum 1989; 32: 454–60.
16. Klug GA, McAuley E, Clark S. Factors influencing the development and maintenance of aerobic fitness: Lessons applicable to the fibrositis syndrome. J Rheumatol 1989; 16(Suppl 19): 30–9.
17. Bennet RM, Clark SR, Campbell SM, Burckhardt CS. Low levels of Somatomedin-C in patients with the fibromyalgia syndrome: a possible link between sleep and muscle pain. Arthritis Rheum 1992; 35: 1113–6.
Comments: Bennet RM: J Musculoskel Pain 1993; 1(2): 119.

18. Gabriel SE, Bombardier C. Clinical trials in fibrositis: A critical review and future directions. J Rheumatol 1989; 16(Suppl 19): 177–9.
19. Beck AT, Greenberg RL. Coping with depression (a booklet). New York; Institute for rational living. 1974.
20. Öst LG. Applied relaxation: Description of a coping technique and review of controlled studies. Behav Res Ther 1987; 25: 397–409.
21. Smythe HA. Non-articular rheumatism and psychogenic musculoskeletal syndromes. In: McCarty DJ, ed. Arthritis and allied conditions. Philadelphia; Lea and Febiger, 1979: 881–91.
22. Yunus MB, Masi AT, Calabro JJ, Miller KA, Feigenbaum SL. Primary fibromyalgia (fibrositis): clinical study of 50 patients with matched normal controls. Semin Arthritis Rheum 1981; 11: 151–71.
23. Wolfe F, Smythe HA, Yunus MB, Bennet RM, Bombardier C, Goldenberg DL, et al. The american college of rheumatology 1990 criteria for the classification of fibromyalgia. Report of the multicenter criteria committee. Arthritis Rheum 1990; 33: 160–72.
24. Bombardier C, Tugwell P. Controversies in the analysis of longterm clinical trials of slow acting drugs (Editorial). J Rheumatol 1985; 12: 403–5.
25. Masterton JP. Burns. In: Dudley HAF, ed. Hamilton Bailey's Emergency Surgery, 11th ed. Bristol; John Wright & Sons Ltd. 1986: 68–76.
26. Huskisson EC. Measurement of pain. Lancet 1974; 2: 1127–31.
27. Scott J, Huskisson EC. Graphic representation of pain, Pain 1976; 2: 175–84.
28. Tesler MD, Savedra MC, Holzemer WL, Wilkie DJ, Ward JA, Paul SM. The word-graphic scale as a measure of children's and adolescent's pain intensity. Res Nurs Health 1991; 14: 361–71.
29. Hanushek EA, Jackson JE. Statistical inference. In: Hanushek EA, Jackson JE, eds. Statistical Methods for Social Scientists. Orlando; Academic Press Inc. 1977: 120–2.
30. Åstrand PO, Rodahl K. Physical training. In: Åstrand PO, Rodahl K, eds. Textbook of work physiology. Physiological bases of exercise. Singapore; McGraw Hill Series in Health Education, Physical Education and Recreation, 1986: 412–85.
31. O'Leary A, Shoor S, Lorig K, Holman HR. A cognitive-behavioral treatment for rheumatoid arthritis. Health Psychol 1988; 76: 527–44.
32. Linton SJ, Götestam KG. A controlled study of the effects of applied relaxation and applied relaxation plus operant procedures in the regulation of chronic pain. Br J Clin Psychol 1984; 23: 291–9.
33. Turner JA, Jensen MP. Efficacy of cognitive therapy for chronic low back pain. Pain 1993; 52: 169–77.
34. Spence SH. Cognitive-behaviour therapy in the treatment of chronic, occupational pain of the upper limbs: a 2 year follow-up. Behav Res Ther 1991; 29: 503–9.
35. Moldofsky H. A chronobiologic theory of fibromyalgia. J Musculoskel Pain 1993; 1(3/4): 49–59.