Continuation of Group Physical Therapy is Necessary in Ankylosing Spondylitis

Results of a Randomized Controlled Trial

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Purpose. *Group physical therapy in patients with ankylosing spondylitis was studied to determine whether beneficial effects persisted after cessation of the intervention.*

Methods. *After a 9-month period of supervised group physical therapy, 68 patients were randomized for another 9 months to unsupervised daily exercises at home (discontinuation group) or continuation of weekly sessions of supervised group physical therapy (continuation group). Endpoints were spinal mobility (thoraco-lumbar flexion and extension, chest expansion, cervical rotation), fitness (maximum work capacity), functioning (Sickness Impact Profile (SIP), Health Assessment Questionnaire for the Spondylarthropathies [HAQ-S], Functional Index [FI]), and patient's global health assessment on a visual analogue scale.*

Results. *Time for exercises at home was significantly higher in the continuation than in the discontinuation group (mean duration 1.9 versus 1.2 hr per week, $P < 0.05$). The continuation group improved in global health (mean improvement 1.6; 32%) and in SIP score. Scores for thoraco-lumbar mobility and HAQ-S did not change very much, whereas chest expansion, cervical rotation, fitness, and FI deteriorated. The average attendance for group therapy sessions was 62%. The discontinuation group improved only marginally (0.2; 4%) in global health, whereas all other endpoints decreased. Only for global health and HAQ-S were the differences statistically significant in favor of the continuation group.*

Conclusions. *Global health and functioning are sustained or even improved further if group physical therapy is continued. Spinal mobility decreased slightly in both groups.*

Key Words: *Ankylosing spondylitis; Randomized control trial; Physical therapy; Spinal mobility; Fitness; Functional assessment; Health assessment; Disability.*

The treatment of patients with ankylosing spondylitis (AS) comprises medication to reduce pain and inflammation, as well as regular exercises and physical therapy in order to improve or maintain mobility, fitness, functioning, and overall health. Recently, we have reported a randomized controlled trial on the effects of supervised group physical therapy added to unsupervised, individualized, self-administered physical therapy, i.e., exercises at home [1]. At 9 months, group physical therapy significantly improved lumbar mobility, fitness, and overall health compared to unsupervised therapy at home. On average, thoraco-lumbar flexion and extension improved 0.4 cm more in patients who received weekly group therapy than in patients who did exercises at home. For fitness, the mean difference between both groups was 9 watts and for global health 28%, both in favor of group therapy.

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To investigate whether these beneficial effects persisted after cessation of group therapy, we designed the present study.

METHODS

Selection of Patients and Study Design

Altogether, 333 patients with AS from 2 out-patient rheumatology clinics were asked to participate in the study. A total of 163 gave written informed consent. All participants were examined by one rheumatologist to check for the inclusion and exclusion criteria. Only patients fulfilling the modified New York criteria were included [2]. Patients unable to engage in physical therapy, those with total hip replacement, pregnant patients, those with severe hypertension (diastolic blood pressure > 100 mm Hg), cardiovascular disease (history of ischemic event, angina pectoris, heart failure), severe lung disease, diabetes mellitus, renal failure, chronic liver disease, malignancy, recent major surgery, mental retardation, or serious emotional disorders were excluded. A total of 10 patients were excluded: 2 patients did not satisfy the modified New York criteria, 1 had a total hip replacement, 4 had cardiac problems, and 3 had emotional disorders, while an additional 9 patients stated they were unable to exercise daily. Thus, 144 patients were available and were randomized into two groups: 1) unsupervised daily individualized exercises at home during 9 months; and 2) the same plus weekly group physical therapy, also during 9 months. A total of 9 patients dropped out (8 in individualized and 1 in group therapy) for the following reasons: moved (n = 1), pregnant (n = 1), spinal surgery (n = 1), cardiac or lung disease (n = 2), inability to exercise individually (n = 4). Thus, 135 patients completed the first 9-month experimental period, of whom 68 had only exercised at home and 67 had also had group therapy. This last group of 67 patients plus the 1 patient who was pregnant in this period, were available for the present study and they were randomized again into two new groups: a discontinuation group, who now had to do daily exercises at home (n = 34) and a continuation group, who again received weekly supervised group physical therapy during 9 months (n = 34). All patients had to continue their daily exercises at home.

All patients were assessed by the same blinded observer at baseline and subsequently every 3 months, up to 9 months. Prescriptions of medication, such as NSAIDs, were recorded [3]. The decision to prescribe or to adjust such medication was not influenced by the research team.

Interventions

Before the trial all patients received a series of 12 supervised individualized physical therapy treatment sessions from a physiotherapist [4]. This comprised an individualized exercise program directed at the entire spine, hips, shoulders, and peripheral joints. The therapists encouraged the patients to continue the exercises at home for 30 min daily over the entire study period. The patients were asked to keep a diary and to note during the entire study whether they had indeed performed their daily exercises.

Group therapy consisted of sessions of 3 hr per week: 1 hr of physical training, 1 hr of sporting activities, and 1 hr of hydrotherapy. All sessions were supervised by a physical therapist [1]. The physical training included exercises to improve the mobility of the spine and the peripheral joints and to strengthen the muscles of the trunk and legs. During the sporting activities the therapists emphasized stretching of the back, for instance, through volleyball or badminton. Hydrotherapy was given in heated water (mean temperature 31° C; range 29–32° C) to reduce pain and improve mobility of the spine and peripheral joints. For standardization purposes the therapists received instructions and training in group therapy from an expert before the study. This expert also provided supervision during the study as described elsewhere [1,5–8]. Compliance with group therapy was checked by the therapists who registered the attendance to the group sessions.

Assessments

Spinal mobility, physical fitness, functioning, and global health were defined as primary endpoints before the start of the study. In addition, general pain and stiffness were assessed, as well as the number of painful joints and entheses. These measures were taken as secondary endpoints. Spinal mobility was assessed as follows:

- Thoracolumbar flexion and extension, using the 10-cm segment method (flex/ext) [9].
- Chest expansion, measured at the level of the xiphoid processus [10,11]. Two readings were made, the second of which was recorded.
- Cervical rotation, measured with a goniometer placed horizontally on the crown of the head [1]. Scores on cervical rotation were the sum of left and right rotation.

All spinal mobility assessments were standardized and executed by one trained observer at the same time of day for each patient.

Physical fitness or aerobic power was measured using an electronically braked bicycle ergometer (Jaeger ER 800, Breda, The Netherlands). During the test, heart

rate was measured continuously using a sports tester (Support PE3000, Almere, The Netherlands). An incremental exercise test was used. The protocol started at 50 watts for 5 min and then increased by 10 watts every minute. All subjects performed up to their subjective maximum workload. At the end of the exercise patients scored on the Borg Scale, indicating the degree of perceived exertion (range 6–20; 6 = extremely easy; 20 = extremely heavy; Borg score should be equal to heart rate/10). The analysis of ergometry used maximum work load (watt), heart rate at maximum load, and perceived exertion at maximum load [12–14].

Functioning or health status was assessed by the Sickness Impact Profile (SIP) [15–17], Health Assessment Questionnaire for the Spondylarthropathies (HAQ-S) [18], and a Functional Index for AS [19,20]. A shortened 52-item SIP, a general measure of health status, was used [15–17, and AF de Bruin, personal communication]. Answers to the questionnaire were added, giving a total score of dysfunction (range 0–52). Higher scores indicate more dysfunction. The HAQ-S is a disease-specific 13-item measure for AS [18]. Answers were added and divided by the number of items giving a mean HAQ-S score ranging from 0 (no difficulties whatsoever) to 3 (unable to do anything). The Functional Index is a 20-item questionnaire specifically designed for AS [19,20]. The answers were added, yielding a total score of dysfunction (range 0–40). Higher scores indicate more dysfunction.

Patient's global assessment was measured by asking the patient to describe his or her perceived change in general functioning after the 9-month treatment period on a 10-cm horizontal visual analogue scale (−5 = maximum worsening, 0 = no change, +5 = maximum improvement).

Pain and stiffness were each indicated by the patient on a 10-cm horizontal visual analogue scale (0 = no pain or stiffness, 10 = worst pain or stiffness I can imagine).

The joints and entheses examinations were assessed by the blinded observer, who applied articular and enthesopathy indices [19,21].

The 48-hr test–retest reliability was assessed beforehand in 19 randomly chosen patients. This has been described recently in this journal [1]. The intraclass correlation coefficients were high for mobility and pain (0.91–0.96), reasonable for fitness, stiffness, and articular index (0.43–0.72), and moderate for the enthesopathy index (0.31) [1].

Data Management and Statistical Analysis

Data were summarized by mean, standard deviation (SD), or standard error of the mean (SEM), or, where appropriate, as median and range. Baseline differences between the continuation and discontinuation groups were assessed by the chi-square test for dichotomic variables, by the Mann–Whitney test for ordered categorical data, and by the Student's *t*-test for continuous variables. At the end of the study the continuation and the discontinuation group were compared for mean improvement by means of the *t*-test of change scores. This analysis was made according to the intention-to-treat principle [3]. Thus, all patients remained in the group to which they were assigned by randomization. This included dropouts, insofar as they participated in the effect measurements, and patients with low compliance (attendance) in group therapy. To study the influence of compliance, an efficacy analysis was also applied. Patients with low compliance (attendance in group therapy below 50%) were excluded from the efficacy analysis. In order to study the relation between change scores on primary outcomes and attendance in group therapy, plots were made and correlations were calculated.

RESULTS

Drop-outs

No patient in the discontinuation group and 4 patients in the continuation group dropped out, for the following reasons: knee surgery (n = 1) and inability to continue exercises in group therapy (n = 3). Effect measurements were not available for these 4 patients. Therefore, the intention-to-treat analysis was done for 64 subjects. Because 8 patients had an attendance in group therapy below 50%, the efficacy analysis was done for 56 subjects.

Effects of Intervention in Experimental and Control Groups

At baseline, there were no relevant differences between the continuation and the discontinuation groups (Table 1). Scores on primary and secondary outcomes after 9 months of follow-up are given in Table 2. Global health assessment had improved in both groups, whereas SIP scores had improved in the continuation group only. For other primary endpoints, deterioration in the discontinuation group was more pronounced than in the continuation group. In this intention-to-treat analysis the differences were only statistically significant for the primary outcomes of patient's global health assessment and HAQ-S, and for the secondary outcome of articular index (*t*-test of change scores, $P < 0.05$). No striking differences were found between the

intention-to-treat and the efficacy analysis (results not shown).

Pearson correlation coefficients between change scores on primary outcomes and attendance in group therapy were not significant ($P > 0.10$): plots of the change scores and the attendance in group therapy showed no evident relations (results not shown).

Physical Fitness

The exercise test was adequately performed: mean peak heart rate and mean Borg score at 9 months were, respectively, 151 (range 96–178) and 16.1 (range 13–19) for those who exercised at home, and 156 (range 115–186) and 15.8 (range 13–19) for those who participated in group therapy.

Compliance and Co-intervention

Patients reported by diary that they had spent an average of 1.8 hr per week doing exercises at home (SD, 1.7; range 0–9.3). Time for exercises at home was significantly longer in the continuation group than in the discontinuation group (mean duration 1.9 versus 1.2 hr per week, $P < 0.05$). The mean attendance for group therapy was 62% (SD 35%, range 0–100%), whereas 8 patients (27%) had an attendance below 50%.

No relevant changes in reported use of medication were found between both groups, as reported elsewhere [22].

TABLE 1

Characteristics of Study Groups at Baseline

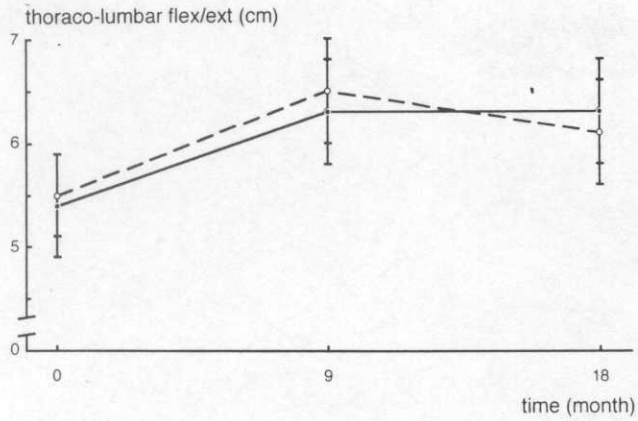
	Discontinuation group (n = 34)	Continuation group (n = 30)
Age (years), mean (SD)	44.3 (11.1)	42.3 (9.5)
Duration of disease (years), mean (SD)	6.8 (5.8)	7.9 (7.9)
Sociodemographic characteristics (%)		
Male	71	77
Married	71	63
Employed	74	63
Income[a]		
High	22	26
Middle	48	44
Low	30	30
Education level[b]		
High	24	23
Middle	46	50
Low	30	27
Medications (% taking)	74	80
NSAIDs	77	70
Analgesics	3	3
DMARDs	3	7
Sporting activities (hr/week), median (range)	1.1 (0–4.7)	1.2 (0–9.8)
Erythrocyte sedimentation rate (mm/hr), median (range)	12 (4–99)	18 (3–68)

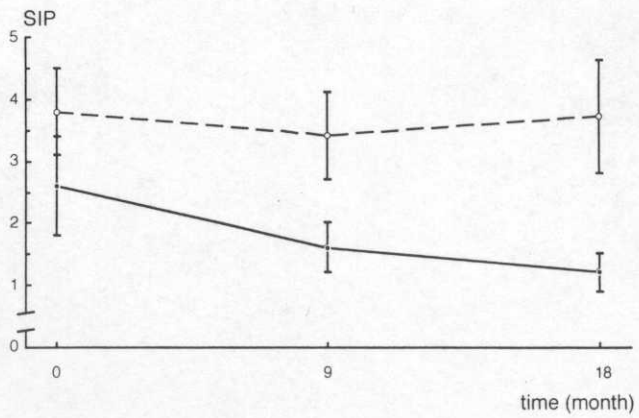
NSAIDs = nonsteroidal antiinflammatory drugs; DMARDs = disease-modifying antirheumatic drugs.
[a] US dollars net per month; high: > $2,000; middle: $1,000–2,000; low: < $1,000.
[b] Years of education (including primary school); high: > 15 years; middle: 10–15 years; low: < 10 years.

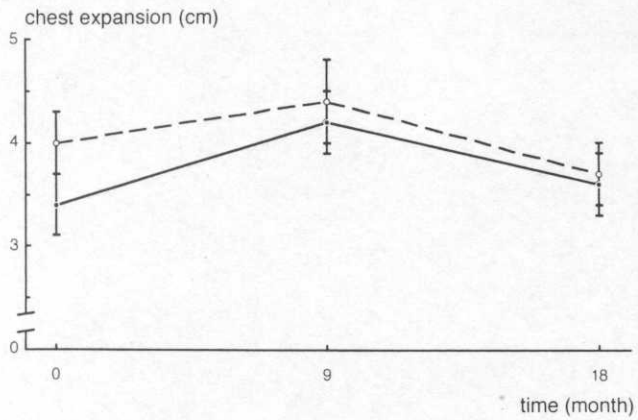
DISCUSSION

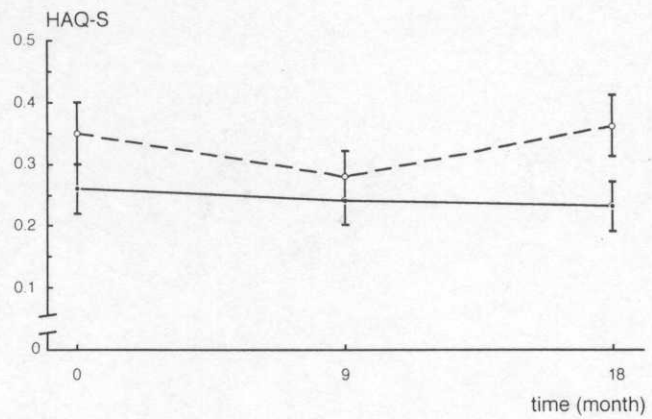
Continuation of group physical therapy proved to be necessary to sustain global health and functioning. It should be noted that the trial presented here is in fact a 9-month extension of a study recently published in this journal [1]. As many patients had already improved considerably before this extension period, room for further improvement during the second 9-month study period was limited [1]. Indeed, for both studies combined, the total mean improvement in functioning was rather impressive, e.g., a decrease in dysfunctioning from 2.6 to 1.2 in SIP score (Figure 1). Also, the total mean improvement in global health was striking: 70% on a visual analogue scale. These improvements in functioning and global health after the entire study are irrefutable clinically important changes. However, the measurements of spinal mobility only improved in the first 9-month period and decreased in the 9-month extension period. Therefore, much of the benefits of group therapy could have resulted from the conditioning effects of sustained exercise.

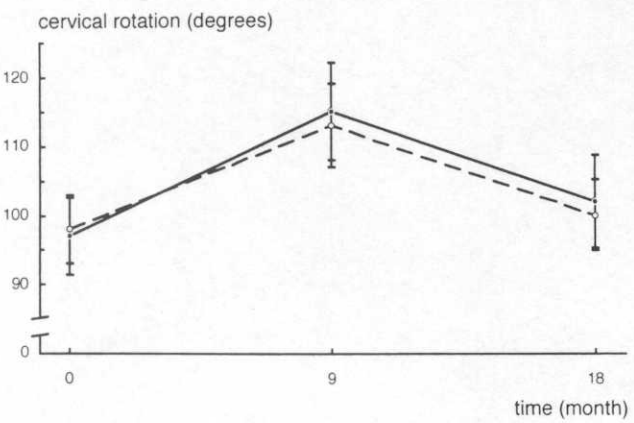
Compliance with group therapy in this study declined with time. The average attendance in group therapy decreased from 74% in the first 9-month period to 62% in the second 9-month period. Attendance was below 50% in 12% of the patients in the first study [1], increasing to 27% in this study. Surprisingly, we found no relation between the effects of group therapy and attendance. This suggests that the effectiveness of group therapy is relatively independent of the degree of attendance. This raises the question of which factors might be responsible for the beneficial effects of group therapy. During the entire study, compliance with unsupervised exercises at home decreased as well, from an average of 2.2 hr per week during the first study to 1.8 hr per week in this study [1]. However, the amount of time spent exercising at home was significantly higher in the continuation group (1.9, mean value) than in the discontinuation group (1.2, $P < 0.05$). Peer pressure, as would be applied by the group, as well as the added stimulus of the supervisor, could encourage compliance and, by inference, benefits. However, the

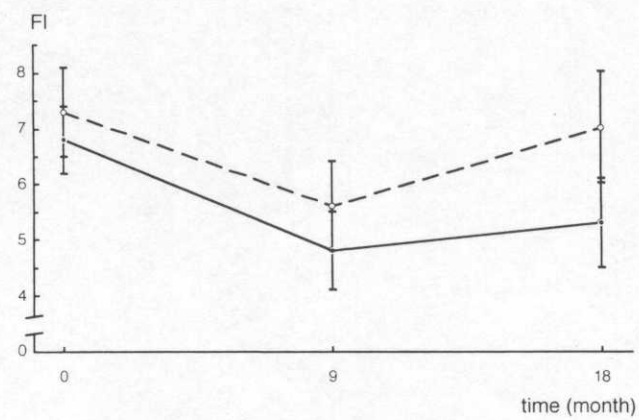












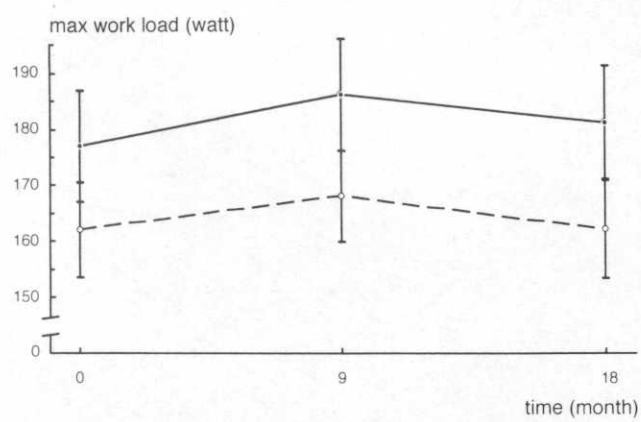


Figure 1. Scores of the continuation group (—•—) and discontinuation group (- - -○- - -) on primary outcomes at baseline after 9 months and after 18 months of group therapy. Values are mean and SEM. Both groups had group physical therapy during the first 9 months.

TABLE 2

Mean Scores at Baseline and Mean Change in Scores after 9 Months (Intention-to-Treat Analysis)

	Discontinuation group (n = 34)		Continuation group (n = 30)		
	0 months mean	9 months change[a]	0 months mean	9 months change[a]	Difference[b]
Primary outcomes					
Spinal mobility					
Flex/ext (cm)	6.5	−0.4	6.3	0	0.4
Expansion (cm)	4.4	−0.7	4.2	−0.6	0.1
Rotation (deg)	113	−13	115	−13	0
Physical fitness					
Max load (watt)	168	−6	186	−5	1
Functioning					
SIP	3.4	−0.3	1.6	0.4	0.7
HAQ-S	0.28	−0.08	0.24	0.01	0.09[c]
Functional index	5.6	−1.4	4.8	−0.5	0.9
Patient's global assessment of change on VAS (cm)	—	0.2	—	1.6	1.4[c]
Secondary outcomes					
Pain (cm)	2.7	−0.4	3.2	−0.1	0.3
Stiffness (cm)	3.3	−0.2	3.1	−0.6	−0.4
Articular index	2.2	−1.6	2.8	0.1	1.7[c]
Enthesopathy index	1.1	−0.9	0.7	0.3	1.2

[a] Positive change implies improvement.
[b] Indicates difference in favor of continuation group.
[c] Statistically significant difference. Two-sample *t*-test.

results do not suggest that the extent of compliance correlates with the outcome, so the reasons are open to speculation. The benefits seem not directly related to compliance with weekly group therapy sessions but are possibly related to the amount of time spent doing exercises at home. Indeed the relatively higher compliance to exercises at home for patients who had group therapy could have reinforced the beneficial effects of group therapy.

In summary, continuation of group physical therapy in AS seems to be important. It may have a positive influence on exercises performed at home. Continuation of group therapy can sustain positive effects on global health and functioning.

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