Is Group Physical Therapy Superior to Individualized Therapy in Ankylosing Spondylitis?

A Randomized Controlled Trial

Alita Hidding, Sjef van der Linden, Maarten Boers, Xandra Gielen, Luc de Witte, Arnold Kester, Ben Dijkmans, and Daniël Moolenburgh

Purpose. *To study the effects of adding supervised group physical therapy to unsupervised individualized therapy in ankylosing spondylitis.*

Methods. One hundred forty-four patients were randomized to exercises at home, or the same plus weekly group physical therapy for 9 months. Endpoints were spinal mobility, fitness (maximum work capacity by ergometry), functioning (Sickness Impact Profile, Health Assessment Questionnaire for the Spondylarthropathies, and Functional Index), and patient's global assessment of change on a 10-cm visual analogue scale.

Results. *Thoracolumbar flexion and extension increased by an average of 0.5 cm (9%) after home exercises, and by 0.9 cm (16%) after group therapy. Maximum load in ergometry decreased by 2 W (1%) after home exercises, but increased by 7 W (4%) after group therapy. Global assessment improved by 0.3 (6%) after home exercises, and by 1.7 (34%) after group therapy. These three differences were statistically significant. There were no significant differences in chest expansion, cervical rotation, or the self-assessments of functioning.*

Conclusions. *Group physical therapy proved superior to individualized therapy in improving thoracolumbar mobility and fitness, and had an important effect on global health reported by the patients.*

Key Words: *Ankylosing spondylitis; Randomized controlled trial; Physical therapy.*

Ankylosing spondylitis (AS) is a chronic systemic inflammatory disorder of unknown etiology, affecting mainly the axial skeleton. Sacroiliac joint involvement (sacroiliitis) is its hallmark.

Currently, there is no cure for AS, but most patients can be adequately managed [1]. The aim of treatment of AS is to maintain or improve general functioning and quality of life. Nonsteroidal anti-inflammatory drugs (NSAIDs) can reduce pain and inflammation, and regular exercises and physical therapy are thought to improve mobility, strength, and fitness [2].

Three kinds of physical therapy for AS can be distinguished: supervised individualized therapy, unsupervised self-administered individualized therapy, and supervised group therapy.

In The Netherlands, patients diagnosed as having AS usually first receive a 6-week course of individualized supervised physical therapy treatment. Afterwards, the patients are expected to exercise daily. Some patients then start supervised group physical therapy (supervised gym classes and pool sessions) to enhance the effects of the individual exercises. Frequently, the patients themselves initiate group physical therapy.

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However, the therapeutic effects of group physical therapy on mobility, fitness, and function are as yet unknown. Therefore, we studied the additional beneficial effects, if any, of group physical therapy compared to those of the self-administered individualized therapy in a randomized controlled trial.

METHODS

Selection of Patients

Patients with AS were recruited from two outpatient rheumatology clinics in Leiden and Alkmaar. These two cities were chosen because group physical therapy did not yet exist in these cities. In Leiden, 259 AS patients were located through the diagnostic register of the hospital. In Alkmaar, the patient records of the outpatient rheumatology clinic were checked for a diagnosis of AS, yielding 98 patients. Eligible patients had to be younger than 70 years, had to live within 25 km of a location of group physical therapy, and should not have had prior exposure to group physical therapy within the last year. Patients fulfilling these criteria (n = 333) were asked to participate in the study. A total of 163 (49%) subjects agreed to participate in the study and gave written informed consent. Questionnaires were sent to all 170 non-participants in order to detect differences between participants and non-participants and to explore reasons for non-participation. To compare health-related orientation between participants and non-participants, we used an adapted Dutch version of the Multi-Dimensional Health Locus of Control Scale [3,4]. This scale distinguishes three different controlling agencies: the person himself, doctors, and chance; doctor orientation and chance orientation can be seen as two specifications of external orientation.

All participants were examined by one rheumatologist to check for inclusion criteria. Patients were included if they fulfilled the modified New York criteria [1] and had one or more of the following features: symptoms of pain, stiffness, or functional limitations within the last 3 months. Patients unable to engage in physical therapy, those with total hip replacement, pregnant patients, those with severe hypertension (diastolic blood pressure >100 mm Hg at rest), 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. This resulted in 10 patients being excluded from the study (two patients did not satisfy the modified New York criteria, one had had a total hip replacement, four had cardiac problems, and three had emotional disorders). An additional nine patients stated that they were unable to exercise daily and were therefore excluded from the study. Thus, 144 patients were available for the study. They were randomized into two groups.

Study Design

Before randomization, all patients received supervised individual therapy for 6 weeks to standardize their pretreatment condition and to better reflect clinical practice. Afterwards, patients were randomized into two groups: self-administered, unsupervised daily individual therapy or the same plus weekly group physical therapy. Randomization was stratified by center (Alkmaar and Leiden). All patients were assessed by one "blinded" observer at baseline and subsequently every 3 months, up to 9 months.

Any additional therapeutic intervention, such as massage, sauna, or the use of NSAIDs, was recorded. There was no change in the patients' rheumatologic treatment.

Study Treatments

Before the trial, all patients received a series of 12 supervised individualized physical therapy treatment sessions from a physiotherapist who had been selected by the patient. This treatment was given two times a week for 30 min over a period of 6 weeks. All physiotherapists had received detailed oral and written instructions about the aims, goals, and methods of the physical therapy from the investigator [5]. The patients received an individual exercise program that was directed at the hip joints, peripheral joints, and the entire spine. 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 of whether they had indeed performed unsupervised individual therapy during the study.

After individual therapy and randomization, 50% of the patients received additional group physical therapy once a week over a period of 9 months. To improve compliance, the other 50% were promised group therapy after the trial period of 9 months.

Altogether, seven therapists trained seven groups with an average size of 10 patients (range 9–13). Before the study, these seven therapists had received instruction and training in group therapy from an expert who provided supervision during the study [2,6,7]. This expert had been trained in group physical therapy in the Rheuma and Rehabilitations Clinic at Leukerbad (Switzerland). Group therapy sessions consisted of 1 hr of physical training, followed by 1 hr of sporting activities and 1 hr of hydrotherapy. The physical training included exercises to improve the mobility of the spine and peripheral joints and to strengthen the mus-

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Impact of Group Physical Therapy

This trial showed a mean improvement of 0.5 cm (9%) on thoracolumbar flexion and extension and a mean additional improvement of 0.4 cm (7%) after group therapy. The notion of responsiveness to change expresses the idea that any measure used in a trial should be sensitive to clinically important changes in response to therapy [26]. A conceptual difficulty arises in specifying what is a clinically important change: an improvement of 16% in flexion/extension index, or an improvement of 34% in overall health? And after how much time: 9 months, 9 years, or a lifetime? Clearly, the ideal study on the effect of group therapy should have many years of follow-up. In that case, other significant outcomes could have emerged. This study focused on the impact of group therapy on physical factors. The contribution of nonphysical factors to overall well-being and perceived effect of treatment has not been studied in any detail. We feel that the difference observed in global health is important, because it reflects patients' values and priorities. It is worth noting that, in spite of the relatively small effects measured on physical parameters, our patients were very enthusiastic about the group physical therapy; 75% of them wanted to continue group physical therapy. Baumberger [7] mentions the following advantages of group physical therapy: opportunity to draw comparisons with other patients, mutual encouragement, reciprocal motivation, shared pleasures in gymnastics, exchange of experience, companionable contact with peers in similar circumstances, and saving of expenses. Further studies should address these added advantages of group physical therapy.

In summary, after 9 months, supervised group physical therapy was found to be superior to individualized therapy in improving thoracolumbar mobility and fitness, and had an important effect on overall health from the point of view of the AS patients.

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Some points about our study will now be discussed in more detail: assessments in AS, study design, and impact of group physical therapy.

Assessments in AS

Spinal Mobility. The thoracolumbar junction is a potential early site of decreased mobility [8]. The usefulness of the 10-cm segment method, a measure of thoracolumbar mobility, therefore, lies in the increased sensitivity conferred by the inclusion of the upper segment as opposed to both the classic and modified Schöber methods [23,24]. The present trial showed the greatest improvement after therapy in the middle segment (data not shown).

Physical Fitness. Fisher et al. [25] suggest that during physical therapy, efforts should be directed not only towards improving spinal mobility, but also towards increasing cardiorespiratory fitness in patients with AS. Our study shows that it is possible to improve fitness by group therapy, in spite of an already high level of fitness at baseline. Apparently, group therapy as described allows further, however moderate, improvement in physical fitness.

Functioning. Responsiveness to change is of paramount importance because the principal goal of the evaluation process is to detect clinically important changes in health status [26]. Some questionnaires may be relatively insensitive, others sufficiently responsive. Our study shows baseline scores on SIP and HAQ-S of zero in one-fourth of our patient population; any further improvement of function is impossible in such patients. Therefore, SIP and HAQ-S were also analysed excluding patients with scores of zero at baseline. Still no significant additional effect of group therapy relative to individualized therapy was found (t-test of change scores, $P > 0.05$). Sickness Impact Profile and HAQ-S may not be sensitive enough to detect change in patients with AS. These results, therefore, raise questions about the utility of SIP and HAQ-S for clinically relevant improvement. Sample size may also be a problem in detecting clinically important changes in health status. The present trial shows a heterogeneous population with respect to duration of disease and physical disability. Therefore, it would be wise to increase (if possible) the sample size in order to detect more precisely any differences in functioning after individualized and group therapy. With our sample size of 68 (n/group) it is possible to detect a true difference of 1.6 in the SIP and 0.1 points in the HAQ-S, with a power of 90% ($\alpha = 0.05$, $\beta = 0.1$, $SD_{SIP\ change} = 2.8$, $SD_{HAQ\text{-}S\ change} = 0.18$).

TABLE 3

Comparison of Participants and Eligible Non-Participants at Baseline

Variable	Participants (n = 144)	Non-participants (n = 88)	P
Age (years)			
Mean (SD)	42.6 (10.4)	44.4 (11.8)	NS[c]
Median (range)	44 (17–64)	43 (22–69)	
Duration of disease (years)			
Mean (SD)	8.8 (8.3)	12.1 (9.5)	<.01[d]
Median (range)	5 (0–33)	10 (1–38)	
Socio-demographic characteristics (%)			
Male	78	80	NS[e]
Married	67	79	NS[e]
Employed	72	61	NS[e]
Income[a]			
High	21	34	NS[d]
Middle	54	45	
Low	26	21	
Education level[b]			
High	21	24	NS[d]
Middle	44	33	
Low	35	43	
Medications (% taking)	76	76	NS[e]
NSAIDs	71	72	NS[e]
Analgesics	4	5	NS[e]
DMARDs	4	5	NS[e]

NSAIDs, nonsteroidal anti-inflammatory drugs; DMARDs, disease modifying antirheumatic drugs; NS, not significant ($P > 0.05$).
[a] U.S. dollars net per month: high, >2,000; middle, 1,000–2,000; low, <1,000.
[b] Years of education (including primary school): high, >15; middle, 10–15; low, <10.
[c] Two-sample t-test.
[d] Mann-Whitney test.
[e] χ^2 test.

Study Design

Prior to the study, the patients received supervised individualized therapy in order to standardize their pretreatment condition and to better reflect clinical practice. The disadvantage is that the supervised individualized therapy may already have taken away some room for improvement. Another solution for dealing with heterogeneity is to stratify individuals with major differences in disease duration and activity and to identify particular subgroups in order to answer specific questions. Using small subgroups, however, would decrease the generalizability of the results and reduce statistical power. In this trial, we deliberately chose to include patients who had a variable duration of disease, making them representative of the target population, and who had received supervised individualized treatment to better reflect clinical practice.

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TABLE 2

Baseline Scores and Change After 9 Months Therapy

	Individualized physical therapy (n = 68)		Individualized plus group physical therapy (n = 67)		Differences[a]	
	Baseline	**Change**	**Baseline**	**Change**		
Primary Outcomes						
Spinal mobility						
flex/ext (cm)	5.3	0.5	5.3	0.9	0.41	0.10, 0.72
expansion (cm)	4.0	0.4	3.7	0.6	0.20	−0.19, 0.59
rotation (deg)	96	12	95	16	4.6	−2.0, 11.3
Physical fitness max load (W)	174	−2	170	7	8.9	0.0, 17.6
Functioning						
SIP	2.8	0.3	3.7	0.7	0.47	−0.49, 1.42
HAQ-S	0.37	−0.02	0.33	0.03	0.05	0.0, 0.11
Functional Index	8.4	1.1	7.4	1.6	0.55	−0.76, 1.86
Global assessment of change (cm)	—	0.3	—	1.7	1.46	1.05, 1.87
Secondary Outcomes						
Pain (cm)	4.0	0.7	3.4	0.2	−0.43	−1.24, 0.38
Stiffness (cm)	3.7	0.2	3.2	−0.1	−0.31	−0.92, 0.29
Articular index	3.6	−0.3	3.3	0.3	0.60	−0.52, 1.72
Enthesopathy index	1.9	0.7	1.8	0.8	0.13	−0.73, 1.00

Values are means. Positive change implies improvement.
Flex/ext, flexion/extension; deg, degrees; SIP, Sickness Impact Profile; HAQ-S, Health Assessment Questionnaire for the Spondylarthropathies.
[a] Group differences with 95% confidence interval. Two-sample *t*-test.

(1), pregnant (1), spinal surgery (1), cardiac or lung disease (2), and inability to exercise individually (4). Therefore, the intention-to-treat analysis was made on 135 subjects.

Comparison of Participants and Non-Participants

A total of 114 (67.1%) of the 170 questionnaires sent out to the non-participants were returned. The inclusion and exclusion criteria of the non-participants were checked by questionnaire in order to get comparable groups. A total of 26 non-participants were excluded from the analysis for several reasons. Therefore, a comparison was made between a population of 144 participants and 88 non-participants (Table 3). The participants and the non-participants showed statistically significant differences in disease duration.

The reasons given for not participating in the group physical therapy included: personal circumstances (47%), opposed to therapy in groups (21%), therapy too demanding (21%), and not enough (16%) or too many (10%) complaints of AS. Analysis of the locus of control data showed a lower internal and doctor orientation, and a significantly higher chance orientation in non-participants than in participants ($P < 0.05$). Non-participants, who had longer average disease durations (13 years, compared to 7 years), might consider their disease to be less controllable by their own behavior and by doctors and, therefore, may be less willing to participate in group physical therapy.

DISCUSSION

This randomized controlled trial found statistically significant positive effects of group physical therapy on thoracolumbar mobility, fitness, and global effect on the health of AS patients. How do our findings compare with other studies? We found no randomized controlled trials of group physical therapy in AS in a MEDLINE literature search covering the period 1983–1991. Only one recent study of weekly outpatient group physical therapy over a 5-year period could be retrieved by MEDLINE search [22]. In this trial, mobility was maintained at a stable level. However, this study was not a randomized controlled trial.

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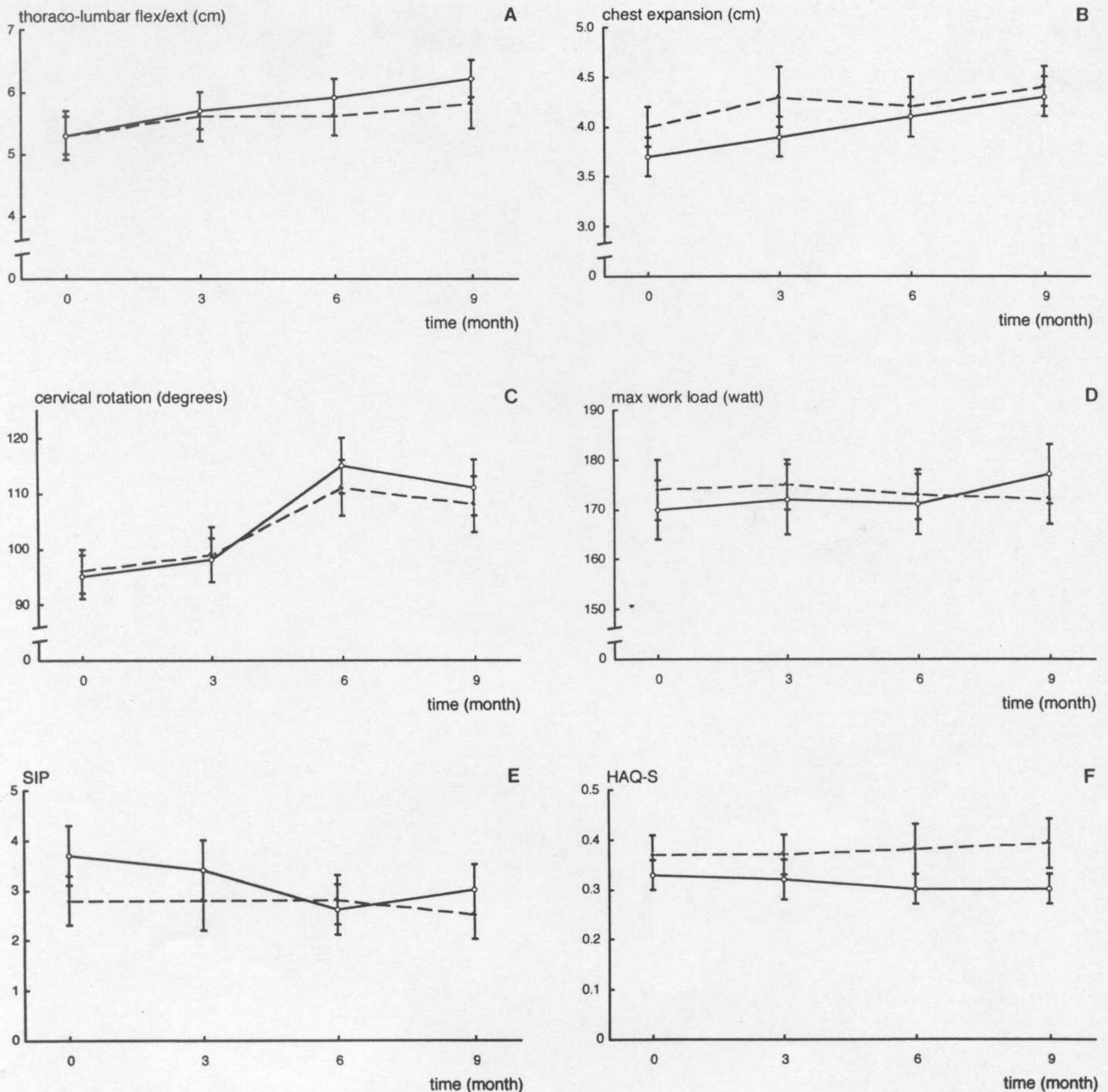

Figure 1. Scores on primary outcomes after self-administered individualized physical therapy (- - -●- - -) and after self-administered individualized plus supervised group physical therapy (——o——) at baseline, and after 3, 6, and 9 months of follow-up. Values are mean and standard error of the mean.

24.3; range 3–100). Eight patients (12%) had an attendance of <50% in group therapy.

Co-intervention with additional treatment and use of medication were checked in experimental and control patients. There were no significant differences in this type of treatment between experimental and control patients. In addition, no relevant changes in use of medication were found during the 9-month period (data not shown).

Drop-Outs

During the 9-month experimental period nine patients (eight in the individual and one in the group therapy) dropped out for the following reasons: moved

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TABLE 1

Scores on Descriptive Variables of Study Groups at Baseline

Variable	Individualized physical therapy (n = 76)	Individualized plus group physical therapy (n = 68)
Age (years)		
Mean (SD)	41.5 (10.3)	43.7 (10.4)
Duration of disease (years)		
Median (range)	4 (0–32)	5 (0–25)
Socio-demographic characteristics (%)		
Male	83	72
Married	67	68
Employed	76	66
Income[a]		
High	19	23
Middle	59	48
Low	22	29
Education level[b]		
High	21	22
Middle	41	46
Low	38	32
Physical therapy (% taking) supervised individual	85	81
Medication (% taking)	74	78
NSAIDs	70	72
Analgesics	4	3
DMARDs	3	6
Sporting activities (hr/week)		
Median (range)	1.4 (0–16.4)	1 (0–16.9)
Erythrocyte Sedimentation Rate (mm/hr)		
Median (range)	15 (2–78)	14 (4–48)

NSAIDs, nonsteroidal anti-inflammatory drugs; DMARDs, disease modifying antirheumatic drugs.

[a] U.S. dollars net per month: high, >2,000; middle, 1,000–2,000; low, <1,000.

[b] Years of education (including primary school): high, >15; middle, 10–15; low, <10.

domly chosen patients by the intraclass correlation coefficient of the following variables: mobility, fitness, pain, stiffness, articular index, and enthesopathy index. These measures were applied by the same "blinded" observer after 48 hr. The intraclass correlation scores for test–retest reliability were extremely high for mobility and pain (0.91–0.96), reasonably high for physical fitness, stiffness, and articular index (0.43–0.72), and moderately high for enthesopathy index (0.31).

Data Management and Statistical Analysis

An intention-to-treat analysis was done [21]. That means, all patients were analysed in the group to which they were originally assigned by randomization. Data were summarized by mean, standard deviation (SD), and, if appropriate, by median and range. Differences between treatment groups at baseline were calculated to check for imbalance after randomization. At 9 months, the treatment groups were compared for their mean improvement by the *t*-tests of change scores. Differences between participants and non-participants were checked by the χ^2 test for dichotomic variables, by the Mann-Whitney test for ordered categorical data, and by the *t*-test for continuous variables.

RESULTS

Effects of Intervention in Experimental and Control Groups

There were no relevant differences between the study groups at baseline (Table 1). Both groups improved on almost all primary outcomes (Table 2, Figure 1). On all primary outcomes, improvement after group therapy was greater than after individual therapy; this difference was statistically significant for thoracolumbar mobility, fitness, and overall (global) effect on health as assessed by the patients ($P < 0.05$). For functioning, and for all secondary outcomes, improvement was similar in the two groups (Table 2). In addition, we analysed SIP and HAQ-S, excluding patients with scores of zero at baseline. This still did not yield any significant additional effect of group therapy for functioning (data not shown).

Physical Fitness

The exercise test was adequately performed: mean peak heart rate was 153 beats per minute, and the mean perceived exertion (Borg score) was 15.2 at baseline (range 9–18). After individualized therapy, scores were 154 beats per minute (range 106–198) and 15.4 (range 12–19), and after group therapy 155 beats per minute (range 95–186) and 15.7 (range 13–19).

Compliance and Co-Intervention

During the 6-week period of supervised individual therapy before randomization, patients reported in their diaries that they had spent a median time of 2.6 hr per week on their exercises at home (range 0–10.2) and 1.0 hr per week on sports (range 0–17.5). During the subsequent 9-month period these medians were 1.9 (range 0–8.9) and 1.4 (range 0–12.0), respectively, excluding time for group physical therapy. No significant differences between the experimental and control groups were found in exercise behavior or time for sporting activities. The average attendance in group therapy as checked by the therapists was 73.5% (SD,

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cles 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, 31° C; range, 29°–32° C) to reduce pain and improve mobility of the spine and peripheral joints. Compliance with group physical therapy was checked by the therapists who monitored the attendance in the group sessions.

Assessments

Spinal mobility, physical fitness, functioning, and global assessment 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 using three methods. Thoracolumbar flexion and extension was assessed using the 10 cm segment method described by Miller [8]. Chest expansion was assessed by measuring the difference in circumference between maximum inspiration and expiration by means of a tape measure placed around the chest wall at the level of the xiphoid process. This was done while the patient was standing with hands on head [9,10]. Two readings were made, the second of which was recorded. To assess cervical rotation, a goniometer was placed horizontally on the crown of the head. Rotation was measured with the subject sitting in neutral position. The pivot of the goniometer was centered on the occiput, with a line through the nose. 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 the day for each patient.

Physical fitness or aerobic power was measured using an electronically braked bicycle ergometer (Jaeger ER 800, Breda, The Netherlands). The saddle height was adjusted to the patient's height. The internal power delivered by this bicycle remains constant over a pedalling range of 45 to 75 rpm. 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 W for 5 min and then increased by 10 W every minute. All subjects performed up to their subjective maximum workload. The exercise was interrupted if the patient developed chest pain or the heart rate exceeded 200 beats/min. At the end of the exercise, patients scored on the Borg Scale indicating the degree of perceived fatigue (range 6–20; 6 = extremely easy; 20 = extremely heavy; Borg score should be equal to heart rate divided by 10). To analyze exercise, maximum work load (W), heart rate at maximum load (hrmax), and perceived exertion at maximum load (Borg) [11–13] were used.

Functioning or health status was assessed by Sickness Impact Profile (SIP) [14–16], Health Assessment Questionnaire for the Spondylarthropathies (HAQ-S) [17], and the Functional Index for AS [18,19].

The SIP is a generic measure of health status. Answers to the 136-item questionnaire, divided into 12 categories, are computed using a weighted score and give a total score of dysfunction. We applied a simplified version, which avoids the weighting procedure and uses only 52 selected items, without losing much information. This shortened version has been validated, but not yet published (personal communication, A.F. de Bruin). The following factors are included in the 52-item SIP: mobility range, social participation, mobility control, psychic autonomy, somatic autonomy, and affective stability. Answers to the 52-item questionnaire are added, giving a total score of dysfunction (range 0–52). Higher scores indicate more dysfunction.

The HAQ-S, a valid measure, consists of three subscales: the original HAQ scale includes dressing, rising, eating, walking, hygiene, reach, grip, and activities; and two spondylitis subscales include carrying, sitting, working at a desk, and looking in the rearview mirror of a car and driving in reverse [17]. A score of 0 is given if the patient is able to perform the activity without any difficulty, 1 if with some difficulty, 2 if with much difficulty, and 3 if the patient is unable to perform the activity. Answers are added and divided by the number of items, yielding a mean HAQ-S score ranging from 0 (no difficulties whatsoever) to 3 (unable to do any of the activities).

The Functional Index is a valid measure and consists of 20 questions corresponding to activities of daily living [18,19]. These activities may be limited by AS. A score of 0 is given if the task can be accomplished without difficulty, 1 if it is possible but difficult, and 2 if it is impossible to do. The answers are added, giving a total score of dysfunction.

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

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

The joints and entheses were assessed by the "blinded" observer, who applied articular and enthesopathy indices [20].

The test–retest reliability was assessed in 19 ran-

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