Outcome of an education and home-based exercise programme for patients with ankylosing spondylitis: a nationwide randomised study

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Abstract

Objectives

This study aims to assess the impact of a structured education and home exercise programme in daily practice patients with ankylosing spondylitis.

Methods

A total of 756 patients with ankylosing spondylitis (72% males, mean age 45 years) participated in a 6-month prospective multicentre controlled study, 381 of whom were randomised to an education intervention (a 2-hour informative session about the disease and the implementation of a non-supervised physical activity programme at home) and 375 to standard care (controls). Main outcome measures included Bath Ankylosing Spondylitis Disease Activity and Functional Index (BASDAI, BASFI). Secondary outcome measures were 0–10 cm visual analog scale (VAS) for total pain, nocturnal pain and global disease activity and quality of life (ASQoL), knowledge of disease (self-evaluation ordinal scale) and daily exercise (diary card).

Results

At 6 months, the adjusted mean difference between control and educational groups for BASDAI was 0.32, 95% confidence interval (CI) 0.10–0.54, p=0.005, and for BASFI 0.31, 95%CI 0.12–0.51, p=0.002. Significant differences were found also in VAS for total pain, patient´s global assessment and in ASQoL. Patients in the education group increased their knowledge about the disease and its treatments significantly (p<0.001) and practised more regular exercise than controls (p<0.001).

Conclusion

A structured education and home exercise programme for patients with ankylosing spondylitis in daily practice was feasible and helped to increase knowledge and exercise. Although statistically significant, the magnitudes of the clinical benefits in terms of disease activity and physical function were poor.

Key words

ankylosing spondylitis, education, exercise, outcome

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Introduction

Ankylosing spondylitis (AS) is a chronic inflammatory rheumatic disease which may progress to limitation of spine mobility and patient disability. The disease may have an important economic impact for the patient and for the society (1, 2). Pharmacological treatment is aimed to reduce the inflammatory process that takes place along the sacroiliac joints, spine, peripheral joints and enthesis with the intention of preventing new bone formation and ankylosis. The 2006 'Assessment of SpondylArthritis International Society' and the European League Against Rheumatism (ASAS/EULAR) recommendations for the management of AS patients (3) and the 2011 update (4) include education and exercise as part of the global management plan of AS patients. Nonpharmacological treatments may be a complement to drug treatment in order to improve symptoms and function and to prevent deformities. However, it is usually difficult to implement these types of interventions in routine clinical practice. Even, it is more difficult to measure its beneficial effects in these patients, usually with low to moderate disease activity. The evidence of the benefits of education and regular exercise is sparse, mainly derived from studies with small sample populations (5). Therefore, long-term adequately powered, prospective and randomised studies on the benefits of education and specific physical therapy programmes are lacking (6).

In 2007, the Spondyloarthritis Study Group of the Spanish Society of Rheumatology (GRESSER) developed an educational programme for AS patients to provide rheumatologists and health professionals with a comprehensive guide to facilitate education of their AS patients about the disease and its treatments, and to provide AS patients with an homogeneous and extensive programme of home-exercises. The programme included a 2-hour group session in which professionals provided information about the disease and its management, together with the implementation of a physical activity programme at home, with the help of an educational kit. The present prospective nationwide randomised study was conducted to assess feasibility and efficacy of this structured educational programme in daily practice patients with AS. After 6 months of implementation of the programme, data of these patients were compared with a control non-intervention group.

Patients and methods

Study design

A 24-week prospective randomised study was conducted in patients with AS visited in the outpatient clinics of the Services of Rheumatology of 24 hospitals throughout Spain, as part of the routine follow-up rheumatologic practice. The objective of the study was to assess the effect of a structured educational and exercise programme on different outcome measures in patients with AS attended in daily practice conditions as compared with AS patients who did not have this educational programme. The study protocol was reviewed by the Ethics Committee of Hospital Universitario de Gran Canaria Dr Negrín, Las Palmas de Gran Canaria, and the institutional review boards of all participating hospitals approved the study. Written informed consent was obtained from all patients.

Patients

Patients of both sexes, aged 18 to 70 years, with a diagnosis of AS based on the modified New York criteria (7) were included in the study. Patients were excluded if they suffered from a very severe form of AS with a significant loss of motion and ankylosis precluding physical exercise. Patients with a diagnosis of other spondyloarthritis or concomitant diseases in which exercise could be contraindicated were also excluded.

Randomisation

Eligible patients were fully informed and received written information about the characteristics of the study. Once the informed consent was signed, patients were assigned at random to the intervention group (education programme) or the non-intervention group (standard care). Concealment of allocation was assured by opening an opaque envelope

which contained the assignation number. These envelops were previously sent from a central agency to every participating hospital and contained a consecutive numeration and an assignation code, unknown to the investigators, with the intention of avoiding a randomisation process bias.

Education programme

Patients randomised to the intervention group were divided into groups of ten patients, each to attend the educational sessions. One family member for each patient could also attend these sessions. The intervention included a 30-min session in which a rheumatologist provided information about the normal musculoskeletal system, including general aspects of anatomy, functioning and normal spine movements, and about the disease, including general ideas of physiopathology and disease process, genetics, symptoms, prognosis, and pharmacologic management. This was followed by a 30-min session in which a rheumatology nurse provided information about the general management of the disease, including rest, aids to reduce pain, ergonomics (at home, driving, and at work), proper diet, importance of alcohol and tobacco avoiding, and aspects related with sexuality and pregnancy. Psychological support was also given by using a previous filmed interview driven by a psychologist, which included psychological counselling and relaxation exercises. In the same way, a previous filmed intervention of AS patient's association representatives explained the importance of joining to one of these AS associations and self-help support group. Finally, the programme included a 60-min session in which a physiotherapist firstly reviewed the theoretical purposes of exercises and, finally, patients had an 'on site' practice session to carry out the most difficult exercises with the help of the physiotherapist. Patients were invited to implement the physical activity programme at home, which involved stretching, deep breathing, spinal extension, and range of motion exercises for the three spine segments, shoulders and hips (written version available on line at http://www.gresser.es).

Patients received the whole education programme in a printed and audiovisual DVD format to take home. The kit included 30 home exercises and 10 water exercises for the swimming pool, which were developed by a rehabilitation specialist (APA) and were previously recorded by two professional sport monitors. The DVD included an 'off voice' explaining each exercise and the number of repetitions recommended. Patients were invited to practise at least half of the programme one day and the other half the next day.

A leaflet with the 2007 recommendations about physical activity and public health for adults between 18 and 65 years old from the American College of Sports Medicine and the American Heart Association was also provided (8). No other special considerations were made about sports, recreational or aerobic activities that patients used to practice as they liked. The education intervention was developed in the same way in each of the participating hospitals.

Patients assigned to the non-intervention group followed the usual pharmacological and non-pharmacological treatments recommended by the rheumatologist in charge. No further educational programme was implemented apart from clinical practice general recommendations. The magnitude and characteristics of the non-pharmacological recommendations in each hospital were not collected, but a self-evaluation ordinal scale questionnaire about knowledge on various aspects of the disease was completed at baseline and at final visit by both groups. The pharmacological treatment was offered to interventional and control group patients as it was needed because of their disease, independently of their participation in the study.

Study procedures

All patients from both groups completed a weekly diary card in which they pointed out the numbers of days taking non-steroidal anti-inflammatory drugs (NSAIDs) and the number of exercises performed, including aerobics and sports. Patients from the education group also rated the percentage of the recommended exercise programme that they actually carried out each week. At the end of each month, they completed a pain and global assessment of disease activity using a 0–10 cm visual analogue scale (VAS) and the Bath AS Disease Activity Index (BASDAI) (9) questionnaire. Patients from both groups also received a monthly telephone call, carried out by a central phone agency operator, to remind them to fill out the patient diary card, and for patients from the education group to remind them to carry out the recommended exercises of the DVD.

Data collection

Study assessments were performed at baseline and at the final visit after 24 weeks. For each patient, demographics, education level (no studies or primary education, secondary education or higher), work activity (no activity, sedentary/minor effort, moderate/high effort), employment status (unemployed/transient work incapacity/employed, permanent work incapacity/retired), clinical findings, and treatment-related data were recorded.

Pharmacologic treatment included use of analgesics ("yes" or "no"), use of NSAIDs ("yes" or "no"), frequency of NSAID intake ("none", "occasionally", "one or two days a week", "three or four days a week", "five or six days a week", "seven days a week"), use of disease-modifying anti-rheumatic drugs (DMARDs) ("yes" or "no"), type of DMARDs (sulfasalazine, methotrexate or others), anti-TNFα agents ("yes" or "no") and type of anti-TNF-α agent (infliximab, etanercept, adalimumab). Nonpharmacological treatment included type and frequency of physical therapy ("none", "occasionally", "one or two days a week", "three or four days a week", "five or six days a week", "seven days a week"), number of exercise per week, and attendance to a rehabilitation service in the last year. The patient's level of knowledge about the disease, knowledge about proper life style aspects and ergonomics, and knowledge about exercise was assessed using a self-evaluation ordinal scale, rated as 0 = "very poor", 1 = "poor", 2 =f air, 3 ="good", and 4 = "very good". Primary outcome measures included the BASDAI questionnaire (0–10 scale)

(9) and the Bath AS Functional Index (BASFI) (0–10 scale) (10). Secondary efficacy endpoints were VAS scores for total pain, nocturnal pain, and global disease activity, the AS Quality of Life questionnaire (ASQoL) (0–18 scale, higher values indicate worst) (11), and the Patient Acceptable Symptom State (PASS) according to the following question: "*Is it your current condition satisfactory, when you take your general functioning and your current pain into consideration?*" (12, 13).

At the 24-week final visit, all patients completed the same questionnaires as at the initial visit, but patients in the education group also evaluated different aspects related to the exercise programme and the education intervention with the VAS, including comprehension of the programme (from 0 ="very incomplete" to 10 ="very complete"), feasibility (from 0 ="very difficult to carry out" to 10 ="very easy to carry out"), degree of perceived benefit (from 0="none" to 10 ="high"), compliance (from 0 ="no practice of any exercise of the programme" to 10 ="practice of the whole programme every day"), overall assessment (from 0 ="no interesting at all" to 10 ="very interesting"), and degree of satisfaction (from 0 ="very dissatisfied" to 10 ="very satisfied").

Statistical analysis

The sample size was calculated to detect differences in two independent samples using a two-sided Student's *t*-test with a level of significance of 5% and statistical power of 80%, assuming a mean BASDAI score of 4.5 in the control group and 3.5 in the intervention group, with a standard deviation of 1 in both groups. A total of 782 patients, 391 in each group were recruited. Patients with data at the initial and the final visit were included in the analysis. The chi-square (χ^2) test was used for the comparison of categorical variables and the Student's *t*-test or the Mann-Whitney U-test for the comparison of continuous variables. Within group differences between the initial and the final visit were compared with the Student's *t*-test or the Wilcoxon signed-rank test for continuous data and the McNemar's test or the Stuart-Maxwell test for categorical variables. Between group differences were assessed with the Mann-Whitney U-test. ANCOVA analysis with adjustments for baseline BASDAI value, sex, age and educational level were also performed. All analyses were done with the STATA release 10.1 (State Corp., College Station, TX, USA). Statistical significance was set at $p<0.05$.

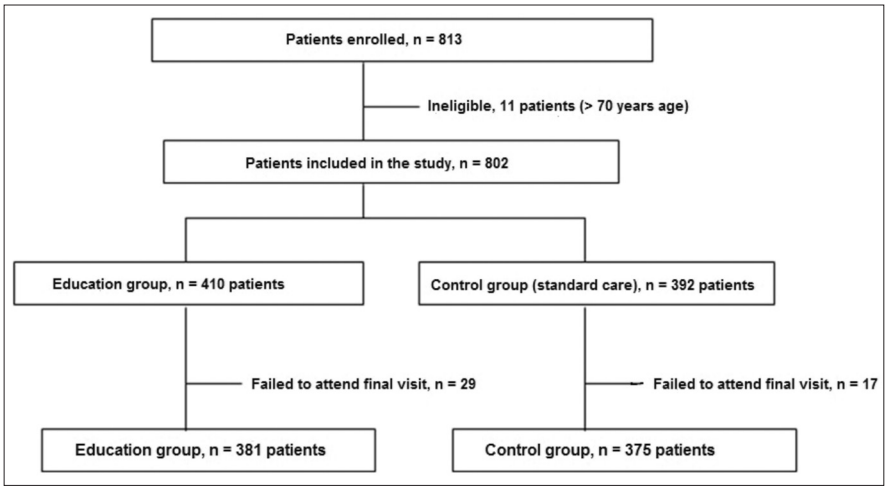

Fig. 1. Flow diagram of the study population.

Table I. Demographic, clinical data, and outcome measures of AS patients according to study groups.

Parameter	Education group (n=381)	Control group (n=375)	*p*-value
Male sex, n (%)	71	73	0.585
Age, mean±SD years	45 ± 12	46 ± 11	0.300
Disease duration, mean±SD years	17 ± 10	18 ± 11	0.597
Educational level, n (%)			0.118
No studies/primary education	163 (42.8)	179 (47.7)	
Secondary education or higher	210 (55.1)	184 (49.1)	
Work activity, n (%)			0.286
No activity	48 (12.6)	61 (16.3)	
Sedentary/minor effort	143 (37.5)	148 (39.5)	
Moderate/high effort	134 (35.2)	129 (34.4)	
Employment status, n (%)			0.713
Unemployed/transient work incapacity/employed	260 (68.2)	255 (68.0)	
Permanent work incapacity/retired	74 (19.4)	74 (19.7)	
Current pharmacologic treatment, n (%)			
Analgesics	49 (12.9)	38 (10.1)	0.289
NSAIDs regularly	284 (74.5)	286 (76.3)	0.641
Corticosteroids	13 (3.4)	17 (4.5)	0.546
Disease-modifying anti-rheumatic drugs	59 (15.5)	86 (22.6)	0.012
Sulfasalazine	30 (7.9)	41 (10.9)	0.188
Methotrexate	24 (6.3)	41 (10.9)	0.032
Biologic agents	146 (38.3)	149 (39.7)	0.746
Regular physical exercise (≥1 day/week), n (%)	182 (47.8)	190 (50.7)	0.423
Attendance of rehabilitation service last year, n (%)	71 (18.6)	63 (16.8)	0.596
BASDAI (0–10 scale), mean (SD)	3.5 (2.3)	3.7 (2.3)	0.142
BASFI (0–10 scale), mean (SD)	3.6 (2.5)	3.7 (2.6)	0.946
Patients' global assessment (0–10 cm VAS)	3.9 (2.6)	4.1 (2.7)	0.351
Total pain (0–10 cm VAS), mean (SD)	3.5 (2.8)	3.7 (3.0)	0.433
Nocturnal pain (0–10 cm VAS), mean (SD)	4.2 (2.6)	4.3 (2.6)	0.572
ASQoL (0–18 scale), mean (SD)	6.9 (5.0)	6.6 (4.9)	0.423
PASS affirmative response, n (%)	209 (54.8)	222 (59.2)	0.348

NSAIDS: non-steroidal anti-inflammatory drugs; VAS: visual analogue scale; BASDAI: Bath Ankylosing Spondylitis Disease Activity; BASFI: Bath Ankylosing Functional Index; ASQol: Ankylosing Spondylitis Quality of Life questionnaire; PASS: Patient Acceptable Symptom State.

Table II. Changes of outcome measures at week 24 as compared with baseline and differences of mean values at final visit between control and educational groups.

	Education group (n=381)	Control group (n=375)	Difference of values between control and educational groups at final visit			
Outcome measure	Compared with baseline		Non adjusted values		Adjusted values*	
	Mean (95%CI)	Mean (95%CI)	Mean (95%CI)	*p*-value	Mean (95%CI)	*p*-value
BASDAI (0–10 scale)	-0.65† (-0.82 to -0.47)	-0.37† (-0.55 to -0.19)	0.52 (0.21 to 0.82)	0.001	0.32 (0.10 to 0.54)	0.005
BASFI (0–10 scale)	-0.54† (-0.68 to -0.40)	-0.21‡ (-0.36 to -0.007)	0.37 (0.01 to 0.72)	0.043	0.31 (0.12 to 0.51)	0.002
Patient's global assessment (0–10 cm VAS)	-0.75† (-0.98 to -0.53)	-0.36‡ (-0.58 to -0.13)	0.48 (0.13 to 0.82)	0.006	0.33 (0.06 to 0.61)	0.019
Total pain (0–10 cm VAS)	-0.76† (-0.99 to -053)	-0.44† (-0.68 to -0.20)	0.49 (0.14 to 0.84)	0.006	0.33 (0.05 to 0.62)	0.020
Nocturnal pain (0–10 cm VAS)	-0.70† (-0.94 to -0.47)	-0.46† (-0.71 to -0.21)	0.44 (0.06 to 0.82)	0.022	0.27 (-0.03 to 0.56)	0.075
ASQoL (0–18 scale)	-0.98† (-1.29 to -0.68)	-0.23 (-0.54 to 0.07)	0.49 (-0.19 to 1.18)	0.157	0.55 (0.13 to 0.96)	0.009

CI: confidence interval; VAS: visual analogue scale; BASDAI: Bath Ankylosing Spondylitis Disease Activity; BASFI: Bath Ankylosing Functional Index; ASQol: Ankylosing Spondylitis Quality of Life questionnaire; PASS: Patient Acceptable Symptom State.
*Values were adjusted for baseline visit BASDAI value, sex, age and educational level; †$p<0.001$; ‡$p<0.05$.

Results

A total of 813 patients with AS were enrolled in the study, but 11 (1.3%) were deemed ineligible because they were older than 70 years. Of the remaining 802 patients, 410 were assigned to the education group and 392 to the control group. However, 29 and 17 patients in each group failed to attend the final visit and were excluded from the analysis. Therefore, the final per protocol study population included 381 patients in the education group and 375 in the control group (Fig. 1).

Baseline characteristics are shown in Table I. Seventy-two percent of the patients were men, with a mean (standard deviation, SD) age of 45 (n=12) years, and a mean duration of disease of 17 (n=10) years. There were no statistically significant differences between the study groups in relation to clinical data and outcome variables at the initial visit, except for a higher percentage of patients treated with DMARDs (22.9% *vs*. 15.5%, $p=0.012$) in the control group due to a higher use of methotrexate (10.9% *vs*. 6.3%, $p=0.032$). Baseline outcome measures (Table I) were indicative of a population of AS patients with low to moderate disease activity. Clinical characteristics of patients who failed the 6-month visit were similar to those of the study population. Changes of primary and secondary outcome variables within the two study groups at week 24 are shown in Table II. There were statistically significant decreases in BASDAI, BASFI values as well as VAS scores for patient's global assessment, total pain, and nocturnal pain. Only patients in the education group showed significant differences in ASQoL between baseline and the final visit. In the education group 18% of patients changed to an affirmative PASS answer and 6% to a negative one, whereas in the control group 12% and 8% of patients changed to an affirmative and negative response, respectively.

Between group differences at week 24 in primary and secondary outcome measures

At week 24, there were statistically significant differences between control and educational groups for the mean scores of the two main outcomes. The mean difference for BASDAI, adjusted for the baseline BASDAI value, age, sex and the educational level, was 0.32, 95% confidence interval (CI) 0.10–0.54, $p=0.005$, and for BASFI 0.31, 95%CI 0.12–0.51, $p=0.002$ (Table II). Moreover, significant differences in VAS scores for patient's global assessment and total pain and for ASQoL in favour of the education group were also observed (Table II). There were not significant between-group differences in VAS for nocturnal pain and in the probability of an affirmative response to the PASS question.

Pharmacologic and non-pharmacologic treatment

As shown in Table III, the percentage of patients treated with NSAIDs decreased significantly in the education group, whereas the use of anti-TNF-α agents increased significantly in controls, mainly due to the increase in patients treated with adalimumab. Nonetheless, there were not significant between-group differences for any pharmacological treatment at week 24. Data from the patients diaries showed a greater decrease in the number of days per week, in which NSAIDs were taken among patients in the education group (median [interquartile range, 25th–75th percentile] 2.2 [0.48–6.18] *vs*. 3.2 [0.72–6.84], $p<0.05$).

Regular exercise increased significantly in both groups, although there were between group differences in favour of the education group (increase of 32.1% *vs*. 13.4%, $p=0.001$), with most increases noted in the percent-

Table III. Changes of pharmacologic and non-pharmacologic treatment at week 24 as compared with baseline and between group differences.

Variables	Education group (n=381)			Control group (n=375)			Between group differences, *p*-value
	Baseline	24 weeks	*p*-value	Baseline	24 weeks	*p*-value	
Pharmacologic treatment, % of patients							
Analgesics	12.9	7.6	0.005	10.1	5.1	0.002	0.316
NSAIDs	74.5	69.0	0.017	76.3	72.5	0.075	0.089
None	26.5	32.2		24.6	28.2		
Occasionally	23.0	20.2		19.1	17.5		
1 or 2 days/week	4.9	7.4		5.5	7.1		
3 or 4 days/week	6.3	7.4		6.1	8.5		
5 or 6 days/week	4.1	5.2		4.4	4.9		
Daily	35.2	27.8		40.3	33.7		
Corticosteroids	3.4	4.5	0.248	4.5	4.0	0.564	0.469
DMARDSs	15.5	16.0	0.683	22.9	22.1	0.631	0.104
Sulfasalazine	7.9	7.6	0.763	10.9	9.9	0.371	
Methotrexate	6.3	7.1	0.257	10.9	10.7	0.796	
Anti-TNFα agents	38.3	40.2	0.209	39.7	43.7	0.022	0.264
Infliximab	16.8	17.3	0.655	18.4	18.4	1.00	
Etanercept	12.3	12.3	1.00	10.7	11.2	0.527	
Adalimumab	10.0	10.8	0.439	11.2	14.7	0.005	
Nonpharmacologic treatment, % of patients							
Physical exercise, % of patients	50.7	82.8	< 0.001	54.0	67.4	< 0.001	< 0.001
None	25.1	5.6		21.6	17.8		
Occasionally	24.2	11.5		24.4	14.8		
1 or 2 days/week	14.2	15.0		16.8	19.5		
3 or 4 days/week	20.6	35.9		17.3	21.9		
5 or 6 days/week	7.8	24.9		9.4	11.8		
Daily	8.1	7.0		10.5	14.2		
Duration of weekly physical exercise in hours, mean (SD)	3.2 (3.4)	3.8 (3.1)	< 0.001	3.2 (3.0)	3.8 (3.7)	< 0.001	0.274

NSAIDS: non-steroidal anti-inflammatory drugs; DMARDs: disease-modifying anti-rheumatic drugs.

age of patients in the education group exercising 3–4 days/week or 5–6 days/week. The duration of weekly physical exercise also increased significantly in the two groups. In the education group, the mean (SD) hours per week that patients spent practising the recommended exercises was 3.6 (1.8) and mean (SD) percentage of adherence to the number and repetition of the exercise programme 54.6 (26.2). There were no differences between both groups in the time spent in other types of aerobic exercises such as swimming, gymnastics, running or walking.

Knowledge about the disease and assessment of the education programme

The acquisition of knowledge was greater among patients in the education group than in controls (Fig. 2), with significant differences in the percentage of patients who rated good or very good their knowledge about the disease (75% *vs*. 66%, p=0.0041), knowledge about proper lifestyle and ergonomics (77% *vs*. 64%, p=0.003), and knowledge about exercise (85% *vs*. 53%, p=0.001). In the education group, median (IQR) values were 9 (7–9) for comprehension of the programme, 9 (7–10) for feasibility, 8 (7–9) for degree of perceived benefit, 6 (5–8) for compliance, 9 (8–10) for overall assessment of the programme, and 9 (8–10) for the degree of satisfaction with the programme.

Discussion

In this study, an intervention based on a programme of group education and non-supervised home exercises, supported by written and audiovisual material, was associated with significant improvements in disease activity, physical function, and quality of life of AS patients with a relatively good control of the disease at baseline. As compared with controls, patients in the education group had significantly higher decreases in BASDAI, BASFI, VAS for patient's global assessment, and ASQoL scores. Although statistically significant, the differences between groups on the primary and secondary outcome measures were small, below the minimum clinical significance (1-point or 10 mm on the Bath AS scales), so the clinical relevance of these results may be poor. There are some possible explanations. Patients were collected from clinical practice and the primary and secondary outcome measures were usually low at baseline visit, so the potential of improvement was moderate. Moreover, most of outcome values improved at 6-month visit of control group patients, reflecting the efficacy of the standard care offered by rheumatologists. The individual strategies offered to the patients of the control group were not known. Probably, the difference between the intervention offered to the experimental group and the standard care given to the control group was not large enough to sort out the effects of the intervention.

Since significant changes in the pharmacologic treatment between groups were not observed, the extra benefit could be assigned to the increment in

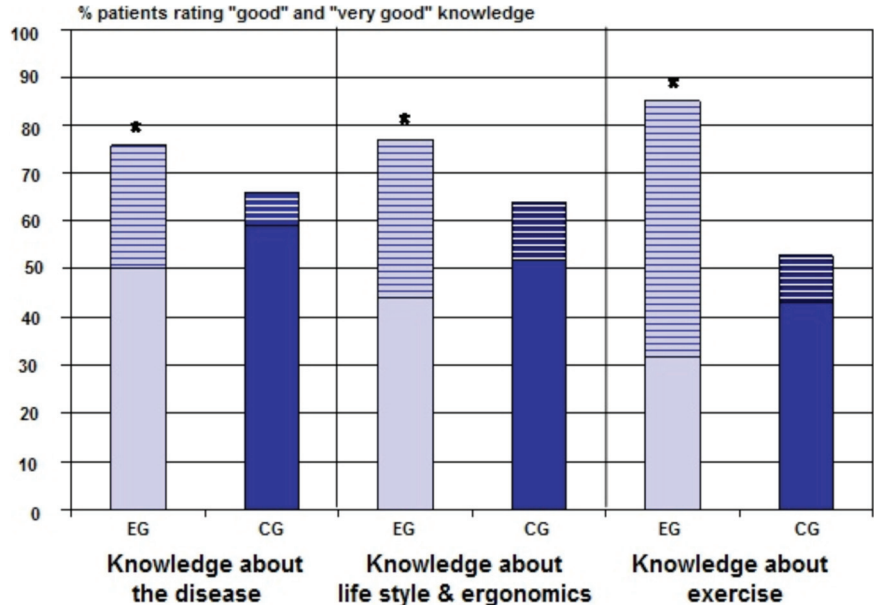

Fig. 2. Changes of patient self-assessment of knowledge from baseline to the final visit. Plain plots represent values at baseline; linear plots represent the observed changes of knowledge at week 24 (EC: education group; CG: control group).

knowledge about the disease and its management and to the increase in regular exercise observed in the intervention group. The education programme was feasible to implement in routine clinical practice and, although the actual rate of compliance with exercises was moderate (60%), the degree of perceived benefit and satisfaction of the patients was high.

Interventions directed to improve education have been shown to promote self-efficacy, to improve patient's abilities for the management of pain and disability, and to facilitate the adoption of healthy life style behaviours and coping with exercise (14, 15). Although these beneficial effects have been reported in many rheumatic diseases, there are few reports of the benefits of education interventions in AS patients. A Self-Management Course-Ankylosing Spondylitis (SMC-AS) demonstrated positive effects on arthritis self-efficacy and psychological well-being at 6-month follow-up (16). In a study of patients with rheumatoid arthritis and AS, a high level of received information was a significant predictor to current involvement in medical decisions (17). Two similar studies using a self-administered questionnaire showed that AS English patients had a high level of knowledge (18), whereas knowledge by French patients was lower (19). In our study, patients completed a self-evaluation ordinal scale to assess the level of knowledge, which was rated from "very poor" to "very good". At the initial visit, knowledge about the disease and knowledge about exercise was rated as good or very good by only 50% and 33% of patients in the education group. These percentages increased to 76% and 85%, respectively, at the final visit, which indicates a good grade of accomplishment of one of the initial objectives of the programme. The high rates of satisfaction with the educational programme found in our study are in line with this positive feeling. Moreover, there was probably an additional psychological benefit obtained with the contact with other patients in the same situation at the group sessions.

Exercise in AS patients is recommended to reduce pain, to maintain and improve spinal mobility, to avoid spinal deformity, and to improve overall function and quality of life. However, there are relatively few high-quality studies supporting this recommendation in AS patients. A recent Cochrane review (5) summarised the available scientific evidence up to 2007 on the effectiveness of physiotherapy in the management of AS patients. Only 11 randomised or quasi-randomised controlled studies carried out in 763 patients were included. Globally these trials provide some evidence showing small benefits of physiotherapy, especially for the improvement in physical function, mobility, and overall well-being. Individual home-based or supervised exercises are better than no exercise, supervision of exercises is better than non-supervision, specific programmes of exercises are better than conventional programmes, and spa-exercise therapy may have a little additive beneficial effect. A review of physiotherapy for AS patients concluded that exercise was an effective intervention, although the overall effect is difficult to determine given the large variety of exercise protocols and study outcomes (20). In a recent review of 12 randomised trials, the studies included cardiorespiratory exercise, muscular strength training, flexibility training, but the programmes were poorly described overall, and only one provided sufficient information to evaluate the possible influence of the adherence (21).

In our study, the exercise programme consisted of an initial supervised session imparted by a physiotherapist to a small group of patients, and a set of recommended exercises to be done individually at home and in water. Patients had the assistance of an educational kit, with written and DVD support. We aimed for the most feasible and simple way to induce AS patients to practise physical therapy. Our proposal was to provide the rheumatologists a tool to improve education of their patients, and to provide patients a tool to improve the self-management of their diseases and facilitate the practice of exercise. The exercise programme was designed with the intention to be valid for almost every patient with AS. The recommendations about physical activity from the American College of Sports Medicine and the American Heart Association were also provided. Other useful types of exercise, such as cardiovascular or muscle strengthening, were not included as they should be individualised to every patient. On the other hand, this programme of group education and home-exercise

should be considered as a complementary tool to the specialised in-patient rehabilitation, needed by most disabled patients. Only 18% of our patients had attended a rehabilitation service during the past year, a low proportion considering that Spanish patients have a free and easy referral to these services.

We compared an education and home exercise programme with no intervention and our results are in line with those observed in the literature. A 4-month study in 53 patients found improvement in the experimental group in some measurements of spinal mobility and in a physical function score (22). In a study of 155 patients with AS, the intervention was an education programme delivered by mail, which consisted of a video and an educational booklet with a home-based exercise programme. At 6 months, only a small difference in pain was seen in the intervention group (23). In another study with 50 AS patients, the intervention was a home-based exercise programme of 30-min duration during 8 weeks (24). Patients in the exercise group had small benefits in pain, spine mobility and physical function (BASFI). A study that investigated the effects of a 12-week multimodal exercise programme including aerobics, stretching, and pulmonary exercises in a sample of 30 patients, showed improvements in spinal mobility, work capacity, and chest expansion (25). Another study in a group of 43 patients with AS showed that a 12-week home-based exercise programme reduced the fatigue and improved the quality of life measured with the Short Form 36 questionnaire (26). Compared with these previous studies, the strength of our work is the large number of participants, as it was a large-scale multicentre randomised controlled trial. In line with these studies, we found only a little additive beneficial effect to pharmacological treatment in BASDAI, BASFI, ASQoL and VAS scales. Non-intervention patients followed the usual recommendations of rheumatologists or nurses in routine clinical practice and, in fact, most of the outcome measures also improved in this group. This may be one explanation for the small differences in final results between educational and control groups. In a recent study of Masiero *et al*. (27), 62 AS patients stabilised with TNF inhibitor therapy were randomised to rehabilitation plus an educational-behavioural programme, to an educational-behavioural programme only or to a control group. The educational-behavioural programme included 2 educational meetings and 12 rehabilitation exercise sessions which patients then performed at home. Only the intensive rehabilitation group showed significant improvement in BASDAI, as well as in some motion measurements and in the Bath Ankylosing Spondylitis Metrology Index (BASMI). BASFI and cervical and lumbar VAS scores improved in both the rehabilitation and educational-behavioural groups. In our study, patients had similar baseline disease activity, but only 40% of patients were treated with anti-TNF-α agents, so they seem more representative of the general population of AS patients visited at outpatient rheumatology services. Our patients did not attend an intensive exercise programme of rehabilitation. However, the improvements in activity, function, and VAS scores seen in both studies reinforce the concept that education and physical therapy have additional benefits even in patients with low disease activity. These findings are consistent with a preliminary clinical prediction rule described by Alonso-Blanco *et al*. (28), in which AS patients with less severe disease are likely to experience short-term follow-up success with a specific exercise programme.

Our study has some limitations. Spine mobility was not measured, as it was considered unaffordable to carry out the required measurements to each patient in the setting of an educational group session. Laboratory data were not included as study variables. They might have been interesting in order to calculate the ASDAS composite index (29), but at the time of the study design, the indices were in development and the cut-off values for disease activity states and improvement were not yet established (30). We used changes in most common patient-centred outcomes to assess the impact of the intervention. We did not include measures of self-efficacy, reasons behind the low adherence to the exercise programme and changes in attitude towards exercise. Probably, these outcomes would have been more relevant to capture the effects of the type of intervention in this study. Nonetheless, at the end of the study, comprehension, feasibility, perceived benefits, and satisfaction with the programme were rated very high by participants. The impact of the results should be viewed in the light of the conditions for this study, with patients blindly collected from daily clinical practice with low to moderate values for BASDAI and BASFI scores. So, we cannot generalise the results to other more active patient populations who may have different responses. Despite these limitations, our findings are strengthened by the large number of patients included in the study.

Data on compliance with the recommended programme and number of repetitions of the exercises were recorded by patients in their diaries, each week for the 24-week period. We found a 54.6% of adherence to the whole programme, with 3.7 hours per week of exercise in the intervention group. In another study about the effects of adding supervised group physical therapy to unsupervised individualised therapy in AS, patient diaries were also used to assess adherence, which was 62% and 1.8 hours per week of exercises at home (31). In our study, compliance with the exercise programme was rather low, considering that patients had a monthly remind telephone call. It is possible that a further group session at 3 months could have been helpful to enhance adherence. Passalent *et al*. (32) have also shown that, despite positive perceptions, the majority of patients with AS did not report participating in exercise on a frequent basis. As the recommendations for the management of patients with AS include regular lifelong exercise as the mainstay of rehabilitation (33), every effort should be made to facilitate the adherence to exercise.

Conclusion

In conclusion, in patients with AS attended in daily practice, an education intervention in small groups of patients

followed by a home-based programme of exercises was feasible. It improved the knowledge about the disease and increased the practice of exercise, but added only marginal benefits to pharmacologic treatment in terms of activity, function, and quality of life. New strategies are needed to evaluate and find the best way to educate and recommend physical therapy to patients with ankylosing spondylitis in clinical practice as well as to overcome barriers for the practice of exercise.

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