The Effect of a Home Based Exercise Intervention Package on Outcome in Ankylosing Spondylitis: A Randomized Controlled Trial

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ABSTRACT. ***Objective.*** Home based self-care is essential for successful management of ankylosing spondylitis (AS). We designed an intervention package aimed at promoting self-care and regular longterm exercise and evaluated its effect on outcome.

Method. Members of our database (n = 4569) were randomly selected and randomized to an intervention group (IG) or a followup control group (CG). The intervention consisted of an exercise/information video, exercise progress chart, patient education booklet, and AS exercise reminder stickers. The outcome measures were function (BASFI), disease activity (BASDAI), global well being (BAS-G), exercise self-efficacy (ESE), arthritis self-efficacy (SES), and quantity of AS mobility/aerobic exercise assessed at baseline and 6 months.

Results. Of the 200 subjects, 155 completed the study (75 IG and 80 CG). Baseline analysis showed no differences between the CG and the IG. At 6 months, analysis revealed no statistically significant between-group differences for the BASFI, BASDAI, and BAS-G, although the p value of 0.08 for function approached significance. Self-efficacy for exercise showed a significant improvement in the IG ($p = 0.045$). There were no between-group differences for the SES pain and other symptoms subscales. Finally, there was a significant increase in self-reported AS mobility ($p < 0.001$) and aerobic exercise ($p < 0.05$) in the IG.

Conclusion. An exercise intervention package designed to promote self-management in AS (1) significantly improves self-efficacy for exercise; (2) significantly improves self-reported levels of exercise; (3) reveals a trend for improvement in function (BASFI). (J Rheumatol 2002;29:763–6)

Key Indexing Terms:
ANKYLOSING SPONDYLITIS EXERCISE OUTCOME

Ankylosing spondylitis (AS) is a chronic progressive inflammatory disorder of unknown etiology that primarily affects the axial skeleton and peripheral joints. The course of AS is unpredictable, with some patients experiencing minimal symptoms, while others have more severe disease resulting in poor function.

There is no cure or definitive treatment for AS. Drug therapy can aid symptom control, but at present it is recognised that the bedrock of AS management is physiotherapy and exercise with the ultimate objective of maintaining normal posture, flexibility, and function. Research has shown that various improvements can be achieved with both inpatient and outpatient physiotherapy and or educational regimes[1-11]. However, it remains unclear whether these improvements can be maintained over the long term.

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Patient education is an adjunct to physical therapy that has been advocated as a means to improve symptoms and/or slow disease progression in chronic arthritis through promoting self-care. Not only do experienced clinicians know that the knowledgeable and responsible patient generally does better, there is mounting descriptive and experimental evidence to support this view. For example, Mullen, *et al*[12] demonstrated that health education can benefit the patient in terms of symptoms, mood, and physical and social activities. More recently a study by Mazzuca, *et al*[13] used a modest educational intervention for patients with osteoarthritis of the knee and found that after a period of one year physical function and pain were reduced, whereas no such improvements were observed for the control group. Given the minimal nature of the education program and the modest but significant benefits, the authors speculate that more detailed or prolonged education would yield increases and more prolonged benefit particularly with usual medical care practices.

Using our validated outcome instruments the Bath AS Disease Activity Index[14] (BASDAI), the Bath AS Functional Index[15] (BASFI), and the Bath AS Global Index[16] (BAS-G), which assess disease activity, function, and well being, respectively, we have shown that over a 2 week intensive

inpatient treatment program we can improve outcome by a mean of 18–27%. Further, we have recently[17] demonstrated that, over a period of 2 years, we can stabilize disease progression from baseline in these patients, in contrast to subjects who have not had access to our inpatient program. However, given the lack of resources available to treat patients, either on an inpatient or outpatient basis, home based self-care is a treatment modality that merits investigation.

Thus, at the Royal National Hospital for Rheumatic Diseases (RNHRD) we developed an educational and exercise intervention package for use at home, and investigated whether this intervention can improve outcome of standard care patients over a period of 6 months.

MATERIALS AND METHODS

Subjects. Two hundred subjects above the age of 16 and below the age of 65 were randomly selected from our database of 4569 members who were outpatients of the RNHRD or members of the National Ankylosing Spondylitis Society (NASS). All database members have completed an initial questionnaire directed toward demographic data, personal and family history, date of onset of symptoms, date of diagnosis, major spinal, extraspinal, articular and extraarticular symptoms, functional outcome, and therapeutic modalities, including medication and surgery. The data were validated by (1) a random cohort of 50 patients (confirmed diagnosis in 98%); (2) an analysis of subjects who had seen a hospital specialist; and (3) where necessary by review of radiographs and source data from general practitioners and hospitals.

The selected patients were then randomly assigned to 2 groups, the intervention group (IG) and the control group (CG).

Design. Study design was a 6 month randomized controlled trial with analysis of intervention and control subjects completing 6 month questionnaires.

Measures. The outcome measures were the BASFI, BASDAI, BAS-G for well being, exercise self-efficacy (ESE)[18], the Stanford Self-Efficacy Scale (SES)[19], and quantity of AS mobility and aerobic exercise (minutes per week). Data were collected at baseline and at 6 months.

Intervention. The intervention, delivered by mail, consisted of: (1) an exercise/educational video that has an introduction led by a consultant rheumatologist, an easy to follow exercise regime suitable for all degrees of severity of AS, and a concluding discussion, led by a health psychologist, a physiotherapist, and a patient, that focuses on the benefits and barriers to exercise and methods of maintaining adherence to a regular exercise regime; (2) an educational booklet; and (3) an exercise progress wall chart and exercise reminder stickers.

Analysis. Independent t tests and Mann-Whitney U tests were conducted on the pre and post-test changes scores for each individual.

RESULTS

Table 1 presents values for the intervention and control groups at baseline. Randomization resulted in closely matched groups, and there were no statistically significant group differences between program participants and controls.

Demographics and baseline scores were compared to detect any differences between completers and dropouts. Table 2 presents these data, which reveal that there were no differences between dropouts and completers.

Table 1. Baseline demographics for treatment and control groups; mean values (SD).

	Treatment Group	Control Group
n	100	100
Age, yrs	47 (10.2)	47 (9.6)
Male	70	68
Female	30	32
Disease duration, yrs	22.3 (12.7)	21.1 (11.1)
BASFI, 0–10	3.5 (2.4)	3.6 (2.4)
BASDAI, 0–10	3.9 (2.4)	3.8 (2.3)
BAS-G, 1–10	4.0 (2.6)	3.7 (2.6)
ESE, 0–20	15.1 (6.2)	15.2 (4.2)
SES, pain, 1–10	6.49 (1.8)	6.06 (2.1)
SES, other symptoms, 1–10	6.58 (1.7)	6.95 (2.3)
Aerobic exercise	67	72
AS exercise	55	50

Table 2. Demographic details for completers in each group.

	Intervention Group	Control Group
N	75	80
Age, yrs	46.5	45.9
Male	51	53
Female	24	27
Disease duration, yrs	21.1	21.9

Table 3 presents data for the completers in each group at baseline and 6 months with change scores indicated. Between-group differences for the intervention group revealed positive changes for aerobic ($p \leq 0.001$) and AS mobility exercise ($p \leq 0.05$) as well as exercise self-efficacy ($p \leq 0.05$). The p value of 0.08 for the BASFI group difference approached significance. There were no group differences for BASDAI, BAS-G, and the SES.

DISCUSSION

This study examines the effect of a home based exercise and educational intervention on outcome in AS using a randomized controlled trial.

Various drawbacks of the study are apparent. First, this was a study of completers in each group, and it was not possible to perform an intent-to-treat analysis. Second, the study used self-report endpoints. However, the value of such self-report ratings by patients with AS has been described[20,21]. Further, patients' subjective perceptions have also been shown to be important for health outcomes[22]. Additionally, all but one of the measures have been validated and provide reliable and valid data. The exercise measure was the only measure that was not a standardized questionnaire. Nevertheless, the 2 questions pertaining to exercise were very simple and are often used in intervention studies.

Table 3. Mean values at 6 months and mean change over 6 months (SD) for IG and CG.

	Intervention Group		Control Group		Between Groups	
	Mean	Mean Change	Mean	Mean Change	t	p
BASFI	3.06 (2.35)	–0.43 (1.78)	3.43 (2.61)	–0.23 (1.89)	–1.75	0.08
BASDAI	3.65 (2.00)	–0.33 (1.87)	3.49 (2.16)	–0.58 (0.58)	–0.33	0.8
BAS-G	3.60 (2.61)	–0.21 (2.86)	3.61 (2.81)	–0.35 (2.56)	–0.72	0.47
ESE	17.8 (4.62)	3.56 (5.12)	15.10 (3.56)	1.6 (3.5)	2.4	0.045*
SES, pain	6.80 (1.21)	0.31 (1.49)	6.24 (1.1)	0.21 (1.54)	0.431	0.67
SES, other symptoms	6.92 (0.98)	0.37 (1.65)	6.40 (1.25)	0.10 (1.46)	1.14	0.26
Aerobic exercise	85.0	18.9	55.0	21.4	2.56	0.001*
AS exercise	99.0	45.8	55.0	2.7	5.05	0.05*

* $p < 0.05$.

This intervention is ultimately aimed at improving outcome through increased and maintained levels of exercise. Our results indicate that for both AS mobility exercise and aerobic exercise, the intervention group in contrast to the control group showed a significant increase in physical activity. Although exercise is a behavior that is difficult to promote in a normal or clinical population, the majority of our subjects belong to the NASS and thus were already a motivated group of people. The observed increase in exercise levels in a group of people who had previous experience of exercise and are aware of the effect exercise has on their disease was therefore unsurprising. It also seems likely that the control group exercise more than random patients with AS who have not been self-motivated to join a self-help group. Thus, it is unclear whether the package would be successful in a cohort not associated with NASS. Future studies that target subjects not in NASS could utilize other techniques for enhancing compliance, e.g., a "buddy" system, where a member of NASS would followup the mailout.

The importance of considering patients' self-efficacy has been increasingly recognized in recent years, particularly in relation to patients' self-management of their condition. According to the social learning theory[23] the self-efficacy regarding a certain behavior is important for the actual execution of that behavior. In the context of this study exercise self-efficacy refers to the patients' perceived ability to exercise. Further, empirical evidence[24] suggests that 4 main sources of information are used as a basis for determining self-efficacy beliefs (i.e., mastery experience, role modeling, verbal persuasion, and physiological state). These concepts of this behavioral change framework are utilized in the exercise intervention, thus we expected significant increases in exercise self-efficacy, with corresponding increase in exercise levels. This indeed occurred and further supports the hypothesis that self-efficacy bears an important relationship to certain health behaviors, including exercise.

Arthritis self-efficacy refers to the patient's perceived ability to control or manage various aspects of arthritis (e.g., pain, fatigue). As an intervention that included patient education, some of which was verbalized by health professionals in the video, it was hypothesized that the Stanford Self-Efficacy Scale for Pain and Other symptoms would reveal improvements in the intervention group. Analysis revealed no between-group differences for either scale of the SES. However, the educational component of the intervention was specifically targeted at exercise, suggesting that more specific education may be required to affect self-efficacy for the particular behaviors represented in the Pain and Other symptoms scale of the SES.

The outcome measure we would expect to be affected by increased exercise levels is function (BASFI). Although there was no significant between-group difference for the BASFI, over 6 months, the p value of 0.08 was approaching significance. Possibly a larger subject group would be required to show a statistically significant change in BASFI. Alternatively, a long disease duration (i.e., ≥ 20 years) may have affected the lack of significant change in function, indicating that a younger cohort with a shorter disease duration would show greater improvement in BASFI. It is also plausible that levels of exercise increased from already moderate levels would not mediate changes in function, suggesting that patients with low baseline exercise levels may benefit from function improvement.

Similarly, the BASDAI and BAS-G showed no between-group differences by 6 months. It is possible that the increase in exercise levels from baseline, although significant, are not substantial enough to affect BASDAI or BAS-G.

In summary, our exercise intervention package improves self-reported exercise levels and self-efficacy for exercise, while between-group differences for BASFI, BASDAI, and BAS-G and the SES could not be detected.

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