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Original Article

Six-month home-based exercise and supervised training in patients with ankylosing spondylitis

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Abstract: Objective: To evaluate the effect of six-month home-based exercise and supervised training on patients with ankylosing spondylitis. Methods: Subjects were allocated randomly to an exercise group (EG) and a control group (CG). Patients in EG received home-base flexibility exercises and exercise therapy supervised by a physiotherapist for six months, while those in CG received conventional treatment. The Bath Ankylosing Spondylitis Metrology Index (BASMI), the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), the Bath Ankylosing Spondylitis Functional Index (BASFI) and quality of life measured by SF-36V2 were assessed at baseline and 6 months. Results: Compared with baseline, BASMI, BASDAI, BASFI and PF, RP, BP, GH, VT and MH of SF-36V2 scores were improved in EG ($P < 0.05$), while only BASDAI and VT in CG ($P < 0.05$). At 6 months, compared with CG, the EG exhibited significant differences in PF, RP, BP, GH, VT, SF and MH: PF13.656 (4.320~22.991), RP 16.741 (4.968~28.515), BP 14.242 (1.990~26.493), GH 11.853 (2.095~21.611), VT 9.373 (3.145~15.602), SF 11.276 (0.465~22.087), MH9.330 (0.902-17.758). Conclusion: The home-based exercise and supervised training can improve the spinal mobility, physical function and quality of life in patients with ankylosing spondylitis.

Keywords: Ankylosing spondylitis, exercise therapy, exercise, quality of life

Introduction

Ankylosing spondylitis (AS) is a systemic rheumatic disease which often results in pain, fatigue, joint destruction, deformity, even disability, loss of joint function [1, 2]. Pharmacological management can control or relieve symptoms, however, its side effects and high cost often cause drug discontinuation [3, 4]. Therefore, ASAS/EULAR recommends pharmacological management and non-pharmacological management as two basic treatments of AS [5]. Non-pharmacological treatment such as electrotherapy, manual therapy and spa therapy and exercise therapy [6]. It has been confirmed that exercise therapy on the basis of drug treatment can improve pain, joint function and activities in AS patients [7-9]. However, a unified standard has not formed in terms of the content, intensity and duration of the current exercise therapies and their effects vary greatly [6, 10]. Meanwhile, the outcome measures in these studies mostly are disease-specific indicators [11] and the effect of exercise therapy on patients' quality of life is rarely studied. This study investigated the six-month's effects on mobility, physical function and quality of life of combined home-base exercises and supervised training for patients with AS in Mainland China.

Methods

The study included AS patients who were treated in a hospital in Guangzhou, China between November 2012 and October 2014. They were allocated to the exercise group and the control group randomly. Numbers and the groups (EG, CG) were generated by a computer randomly for random allocation. This study was approved by the ethics committee of the hospital and all patients signed the informed consent.

All subjects must meet the following inclusion criteria: 1) AS was confirmed according New

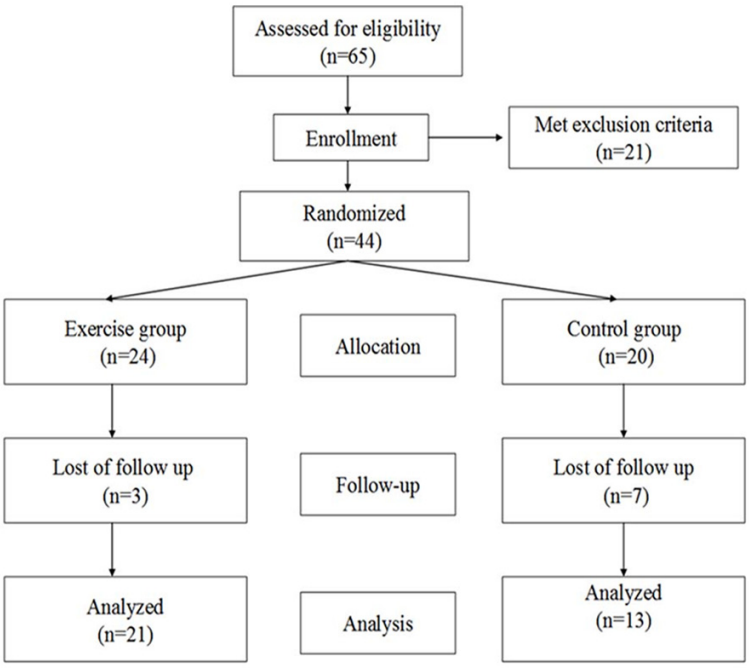

Figure 1. Flow of participants through the randomized controlled pilot study. 65 patients met the inclusion criteria, among which 21 patients were excluded according to the exclusion criteria, so 44 patients participated in the study, 24 patients in EG and 20 patients in CG. In the process of the intervention, 10 patients (3 patients in EG and 7 patients in CG) failed to receive follow-up according to the study program and were unable to get in touch, so they withdrew from the study, therefore, a total of 34 patients completed the study (21 in EG and 13 in CG).

York criteria revised in 1984 [12]; 2) 16-60 years old; 3) the female patients with childbearing potential promised to use contraceptives during the study period and until the last treatment; 4) have some ability to read and understand and can complete the study program; 5) disease in well-controlled condition and disease lasting at least 6 months. Exclusion criteria were as follows: 1) Pregnant or become pregnant and lactating women; 2) In the past year, the affected joints have obvious trauma or receive a surgery; 3) Fibromyalgia, local pain caused by the lumbar or cervical spine oppression, accompanied with moderate to severe pain of nerve root or other parts; 4) The patients with heart failure, multiple sclerosis, severe chronic obstructive pulmonary disease, recurrent infection, lymphoma or other malignancies as well as a history of tuberculosis; 5) The patients with mental diseases or the patients who cannot regularly go to the clinic for subsequent visits and result in insufficient information, affecting the efficacy or safety judgment.

All patients treated with drugs, and there were no restrictions with regard to type of non-pharmacological intervention, or to dose, duration or route of administration. In the exercise group, on the basis of drug therapy, the patients received home-based flexibility exercises combined exercise therapy supervised by a physiotherapist.at least three times a week 6 months. Each exercise lasted about 60 minutes. According to the recommendations from American College of Sports Medicine, the specific contents included: [13] 1) warm-up exercises: forward head flexion, backward extension, lateral flexion, rotation around, neck movement; lumbar flexion, extension and rotation, lumbar spine movement. Each action maintained for 10 seconds, and the entire exercise was repeated 5 times. 2) chest exercise: both elbows were parallel to the shoulders, put both hands together before the chest and expanded both hands to both sides respectively for 10 seconds and repeated 5-10 times. 3) muscle exercise of lumbar spinal cord: be prone with a pillow under the abdomen, put forth your strength to rise the head and the upper body, maintain 5-10 seconds and repeat 10 to 15 times. 4) abdominal exercise: be prone with both hands supporting the upper body, rise the head and lean back for 10 seconds. And then, four limbs support the trunk, stretch the elbows straightly, try to lower the head to the position between the two arms, while rise the back as far as possible. And then, rise the head with the back and waist down as far as possible. Repeat 5 times. 5) Waist muscle group exercise: go down the legs, lay on the 50 to 60 cm fitness ball with one side, bend in sideways direction as far as possible, stretch waist muscle group to have tight feeling, maintain 30 seconds and repeat 4 times. The same exercises are carried out for the opposite waist muscle group. The patients

Table 1. Baseline descriptive of all patients, exercise group and control group

	Exercise group, n=21	Control group, n=13
Age, years, mean (SD)	26.62 (4.72)	26.46 (6.78)
Gender		
Male, n (%)	17 (81)	13 (100)
Female, n (%)	4 (19)	0 (0)
Family history, n (%)	3 (14.3)	4 (30.8)
Disease duration, years, mean (SD)	4.56 (3.92)	4.88 (3.50)
Drug usage		
NSAIDs, n (%)	20 (95.2)	13 (100)
Biologics, n (%)	12 (57.1)	10 (76.9)
Others, n (%)	12 (57.1)	9 (69.2)

NSAIDs: non-steroidal anti-inflammatory drugs.

went to the hospital once a month and received one-to-one exercise training under the guidance of the physiotherapist since the study began. And then, the patients did exercise according to the exercise prescription at home. At baseline and 6 months, BASMI, BASDAI, BASFI and SF-36V2 were evaluated by an evaluator. The patients were followed up by telephone by a nurse every two weeks, 15-30 minutes a time, including whether the patients complete self-exercises, the occurrence of adverse reactions, answering the questions raised by the patient, guidance of daily self-management including drugs and disease education and encouraging the patient to adhere to exercise training. The physiotherapist, the evaluator and the follow up nurse didn't participate in any other research.

In the control group, on the basis of drug treatment, the patients received the doctor's guidance on conventional drugs and disease education including the guidance of home-based exercise training, but not one-to-one exercise therapy Basic demographic data and basic disease characteristics of the patients were recorded before treatment. The outcome was evaluated at baseline and 6 months, including disease-specific indicators and quality of life. Evaluation methods included filling out the questionnaire and physical examination, and the questionnaire was filled out by the patients themselves and physical examination was conducted by rehabilitation therapists.

Disease-specific indicators

BASMI [12] reflects spinal mobility, five indicators, including ear wall distance, neck rotation, lumbar scoliosis, lumbar flexion and intermalleolar distance are measure, each indicator is scored as 0, 1, 2 according to the measured values, and the total score is the sum of the score of five indicators and is 0-10 points. The lower the score is, the better spinal mobility is.

BASDAI [14] reflects the degree of disease activity, including fatigue, axial and peripheral joint pain, morning stiffness and tendon pain, and six problems should be answered by the patients to know their symptoms in the last week. The former 5 questions are completed with 10 cm VAS method and the maximum score is 10 points, and the last problem is scored according to the duration of morning stiffness. Duration of morning stiffness is divided into 0, 30, 60, 90 and 120 minutes, respectively, and the score is 0, 2.5, 5, 7.5 and 10 points. The total score is calculated with the formula, $0.2 \times [A + B + C + D + (E + F) / 2]$. Total score is 0 to 10 points, the higher the score is, the more active the disease is.

BASFI [15] is used to evaluate the comprehensive functional status of patients with AS. A total of 10 questions are prepared and 10 cm VAS method is used for recording, the score of each question is 0 to 10 points, and the total score is the average score of each question, the higher the total score is, the worse the function is.

The Chinese version of SF-36v2 of QualityMetric Incorporated was used to measure the quality of life. The scale has been used in the Chinese population and gained a proven reliability and validity [16, 17]. The scale includes a total of 36 items, among which an item is used to evaluated the overall change in health status (Reported Health Transition, HT), the other 35 items include eight indicators, physical functioning (PF), role-physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE) and mental health (MH). According to the scoring rules of the scale, the score of each indicator is calculated. The higher the score is, the better the quality of life is.

SPSS16.0 software was used for statistical analysis. Descriptive analysis was performed

Table 2. Effects of combined home-based exercise and supervised training on BASMI, BASDAI, BASFI and SF36 v2

	Exercise group, n=21 Mean (SD)		Control group, n=13 Mean (SD)		Estimated mean group difference (95% CI)	*P*-value
	Baseline	6 months	Baseline	6 months		
BASMI	1.62 (1.94)*	1.19 (1.66)*	2.31 (2.06)	2.00 (1.87)	-0.264 (-0.828, 0.299)	0.346†
BASDAI	2.66 (1.69)*	1.21 (1.54)*	3.19 (1.29)*	2.00 (1.64)*	-0.444 (-1.349, 0.461)	0.325†
BASFI	1.35 (1.74)*	0.24 (0.75)*	2.05 (2.26)	1.63 (2.24)	-0.694 (-1.682, 0.294)§	0.162§
SF36 v2						
PF	77.62 (17.72)*	90.48 (11.17)*	75.38 (20.36)	75.77 (20.80)	13.656 (4.320, 22.991)	0.006†,#
RP	67.86 (27.11)*	82.44 (12.59)*	71.15 (19.35)	66.35 (22.03)	16.741 (4.968, 28.515)	0.007†,#
BP	57.14 (21.46)*	79.89 (19.76)*	59.83 (21.05)	66.67 (16.36)	14.242 (1.990, 26.493)	0.024†,#
GH	33.09 (18.19)*	54.29 (17.19)*	41.92 (12.34)	46.92 (11.46)	11.853 (2.095, 21.611)	0.019†,#
VT	59.52 (17.19)*	73.21 (9.91)*	51.44 (9.59)*	61.06 (9.25)*	9.373 (3.145, 15.602)	0.004†,#
SF	72.62 (28.94)	83.93 (15.88)	62.50 (20.41)	70.19 (15.76)	11.276 (0.465, 22.087)	0.041†,#
RE	72.62 (22.38)	82.54 (18.62)	67.31 (21.09)	67.95 (20.08)	12.616 (-0.173, 25.406)	0.053†
MH	61.67 (17.05)*	73.81 (13.68)*	56.54 (15.73)	62.31 (12.85)	9.330 (0.902, 17.758)	0.031†,#

Note: *P < 0.05 for paired t test when the values after the intervention were compared with the baseline values; †*P* value of ANCOVA with the baseline values as covariables; #indicated that the difference tested with ANCOVA was statistically significant between the two groups in term of the values after intervention; §indicated that when the results of analysis of covariance showed the homogeneous slopes, independent-sample t test was carried out for the difference between the two group before and after the intervention. BASMI: The Bath Ankylosing Spondylitis Metrology Index; BASDAI: the Bath Ankylosing Spondylitis Disease Activity Index; BASFI: The Bath Ankylosing Spondylitis Functional Index; SF36 v2: The Medical Outcomes Survey 36-item short-form survey version 2; PF: Physical Functioning; RP: Role-Physical; BP: Bodily Pain; GH: General Health; VT: Vitality; SF: Social Functioning; RE: Role-Emotional; MH: Mental Health.

for all variables, the mean and standard deviation were described for quantitative data and the percentage was described for qualitative data. Baseline demographics and disease characteristics were compared between the two groups. independent-samplet test was carried out for quantitative data and chi-square test was carried out for qualitative data. Paired t test was carried out of the scores of BASMI, BASDAI, BASFI and SF-36 in every group before and after treatment. The normal test was done before t test. The baseline scores of BASMI, BASDAI, BASFI and SF-36 were used as covariables, the scores of BASMI, BASDAI, BASFI and SF-36 after treatment were used as dependent variables, homogeneity test was performed for the slope, and if the slope was homogeneous, ANCOVA was performed, and LSD test was used for comparison between groups, and 95% confidence interval of the difference between the two groups was calculated; if the slope was not homogeneous, independent-sample t test was carried out for the difference between the two groups before and after treatment. For all tests, *P*-values < 0.05 were considered to be statistically significant.

The number of participators and their absent reasons are as followes (**Figure 1**).

The average age, sex, average duration of disease, whether use drugs of the two groups have been done in **Table 1**.

Results

Compared with baseline values, the scores of BASMI, BASDAI and BASFI were improved in the exercise group after treatment (P < 0.05), however, only BASDAI scores was improved (P < 0.05) in the control group (**Table 2**).

At baseline, there were no significant differences in BASMI and BASDAI between the two groups. According to the ANCOVA, at 6 months, it's no difference in term of the scores of BASMI and BASDAI (P > 0.05) between the two groups, and the 95% confidence intervals were -0.828~0.299, -1.349~0.461, respectively (**Table 2**).

At baseline, the two groups are different in BASFI. Independent-sample t test for the difference in BASFI before and after treatment between the two groups showed no significant difference, and the 95% confidence interval was -1.682~0.294 (**Table 2**).

Compared with baseline values, except for the two indicators SF and RE, the other 6 indicators

PF, RP, BP, GH, VT and MH were improved in the exercise group after treatment, and the differences were statistically significant ($P < 0.05$), however, only VT was improved in the control group ($P < 0.05$) (**Table 2**).

At baseline, there were no significant differences in all indicators of SF36 between the two groups. At 6 months, the indicators of PF, RP, BP, GH, VT, SF and MH (except for RE) were higher in the exercise group, and the difference was statistically significant by ANCOVA ($P < 0.05$). After treatment, the mean differences and 95% confidence intervals for PF, RP, BP, GH, VT, SF and MH were 13.656 (4.320~22.991), 16.741 (4.968~28.515), 14.242 (1.990~26.493), 11.853 (2.095~21.611), 9.373 (3.145~15.602), 11.276 (0.465~22.087), 9.330 (0.902~17.758) (**Table 2**).

Discussion

This study aimed to investigate the effects of exercise therapy in AS and provided evidence that exercise therapy was effective as a treatment to improve the quality of AS patients. Exercise therapy was one of the main non-pharmalogical treatment methods of AS. Although many studies have been researched, there were no significant differences in efficacy, the main outcome measures were disease-specific indicators, such as BASMI, BASDAI, BASFI and so on [6, 10, 11]. However, patients with AS not only show changes in disease-specific physiological indicators, but also their quality of life [2, 18, 19]. Therefore, the quality of life should also be used as an indicator to judge the efficacy. Combined with drug treatment, the study used the exercise program to intervene some patients with AS in Mainland China, and used disease-specific symptoms and functional indicators and quality of life indicators to evaluate its efficacy.

Because AS mainly affected axial joints, exercise therapy mainly focused on improving spinal mobility, and flexibility exercise [10]. Exercise program used in this study was based on flexibility exercise and the objective to improve the flexibility of the spine and activity. During exercise training, the intensity, number of times, frequency and duration of each action were strictly controlled to ensure the effect of exercise.

The results of the study showed that the scores of BASMI, BASDAI and BASFI in the exercise group after treatment was lower than those before treatment, and for the six indicators of quality of life, PF, RP, BP, GH, VT and MH (except for SF and RE) the scores were higher than that before treatment, however, only the scores of two indicator BASDAI and quality of life VT were improved after six-month treatment compared with baseline values in the control group. It suggested that home-based exercise would help to improve physical function and spinal mobility in patients with AS and improve the quality of life of patients. And compared with the control group, seven indicators of quality of life PF, RP, BP, GH, VT, SF and MH in the exercise group were higher than those in the control group after treatment, indicating the exercise group was superior to the control group in term of the improvement of quality of life. These results agreed with the results of other studies [20-22]. However, there was no statistically significant difference between the two groups in terms of the scores of BASMI, BASDAI and BASFI score after six-month treatment, indicating that the conclusion that the exercise group was superior to the control group cannot be drew in term of the improvement of BASMI, BASDAI and BASFI.

Maybe our research report are less accurate, one reason is the patients in the two groups ommunicated with each other ,and practiced by themselves, the other is lack of medcial resources in Mainland China. Meanwhlie the compliance of AS, such as drug therapy, not only dosage, accuracy and individualization but also patient compliance can also impact the effect of exercise. But in our subsequent visit, we ensured the quality of home-based exercise and the feasibility of supervised exercise program.

In this study, we called the patients every two weeks during exercise program to solve their problems, urge the patients to adhere to exercise programs and improved the compliance of the patient.

Sampling techniques used in the studies are important to assure the quality of data. Only 34 patients actually completed the study, of which only 13 patients in the control group, resulting in insufficient sample size and the numbers of subject in the two groups were imbalanced.

Secondly, 10 patients failed to receive follow-up, aslo leading to insufficient sample size. Meanwhile, as a progressive disease, the analysis of structural changes of individual with AS is different over years. Therefore, it impossible to carry out in-depth analysis for the effect of the intervention. But further studies with large sample sizes and the strict controlled compliance of exercise therapy needed to be carried out in Mainland China.

BASMI, BASDAI and BASFI were used to evaluate the therapeutic effect of exercise on patients with AS, but the studies completed by Rosaline, etc show that, the current exercises showed greatly different effects on improving BASMI, BASDAI and BASFI [11] and the results of some studies were also similar to the results of this study [9].

The results suggested that combined with drug treatment, home-based exercise program and exercise therapy directed by professional staff can improve the spinal mobility, physical function and quality of life in patients with ankylosing spondylitis.

Disclosure of conflict of interest

None.

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