Rheumatol Int (2016) 36:333–339
DOI 10.1007/s00296-015-3399-6

Rheumatology INTERNATIONAL

ORIGINAL ARTICLE - CLINICAL TRIALS

Favorable effect of rehabilitation on balance in ankylosing spondylitis: a quasi-randomized controlled clinical trial

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Received: 1 July 2015 / Accepted: 16 November 2015 / Published online: 7 December 2015

Abstract Balance impairment is a frequent and undertreated manifestation in ankylosing spondylitis, leading to increased risk of falls and lower quality of life. Our aim was to assess supervised training and home-based rehabilitation efficacy on balance improvement in ankylosing spondylitis subjects on biologic agents. This was a single-blinded, quasi-randomized parallel study in a single outpatient Rehabilitation Clinic of a tertiary referral center. Subjects with ankylosing spondylitis on biologic agents were assigned either to supervised training and home-based rehabilitation program (rehabilitation group) plus educational–behavioral therapy, or to educational–behavioral therapy alone (educational groups). The same therapist provided therapy. Outcome measures were assessed at baseline (T0), end of treatment (T1) and at 7-month follow-up (T2). Rheumatologic outcomes were Bath Ankylosing Spondylitis Metrology Index, Bath Ankylosing Spondylitis Functional Index and Bath Ankylosing Spondylitis Disease Activity Index. Balance parameters (anterior–posterior oscillation, latero-lateral oscillation, sway area, sway density and sway path) were evaluated by stabilometry in a condition of open and closed eyes. Forty-six subjects (36 M, 10 F) were enrolled. Demographic data and clinical status at baseline were comparable between the two groups (22 rehabilitation group, 20 educational group). Primary outcome was sway density that improved both at T1 (SDy: open eyes $p = 0.003$, closed eyes $p = 0.004$) and at T2 (SDx: open eyes $p = 0.0015$, closed eyes $p = 0.032$). A trend toward improvement in the rehabilitation group rather than in the educational group emerged for balance parameters, especially those measured with closed eyes ($0.004 < p < 0.048$ at T1 and $0.004 < p < 0.036$ at T2). Supervised training and home exercise lead to balance improvement in people with ankylosing spondylitis. Eyes-closed trials show a more marked trend toward improvement, and this may suggest a positive effect of rehabilitation on proprioception.

Keywords Supervised training · Home-based training · Stabilometric platform · Rheumatological disease

Introduction

Ankylosing spondylitis is characterized by chronic and progressive inflammation of the axial, sacroiliac and peripheral joints, leading to ankylosis and posture modifications. Extra-articular manifestations including audio-vestibular dysfunction [1–3] may contribute to balance impairment which is often underdiagnosed [4–7]. This may affect up to a third of individuals with the condition [2]. Physical therapy is a mainstay therapy in ankylosing spondylitis. A metanalysis suggested better functional outcome after supervised group physiotherapy in comparison with individual, home or spa therapy [8]. Most of the reported studies were in people not on biologic agents, but two recent reports suggested marked efficacy of physical therapy also in subjects treated with these drugs [9, 10].

We hypothesis that physical therapy, acting synergistically with pharmacological treatment, could improve balance

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impairment in ankylosing spondylitis. We aim to evaluate the efficacy of a specific exercise protocol [11] on balance quantitative parameters in subjects on biological agents.

Methods

This was a single blinded, quasi-randomized controlled clinical trial. The study was approved by the local ethical committee.

Subjects with a diagnosis of ankylosing spondylitis according to the modified New York criteria were enrolled at a single unit. Inclusion criteria were: age 18–65 years taking infliximab, etanercept or adalimumab for at least 9 months and with a stable Bath Ankylosing Spondylitis Disease Activity Index for the last 6 months. Exclusion criteria were: having participated to other rehabilitation programs in the previous 6 months, having complete spine ankylosis or other medical conditions leading to physical disability. Changes to therapy during the study or withdrawal of consent would lead to drop out from the study.

Intervention and data collection

Participants were alternatively allocated, according to a quasi-randomized study design, to rehabilitation therapy or to educational–behavioral program alone. Rehabilitation consisted of supervised training and home-based rehabilitation plus educational–behavioral training. The educational–behavioral program consisted of group discussions, problem solving, and disease-specific lectures held twice with a two-week interval in between [9–11] ("Appendix"). The rehabilitation group received a previously validated exercise protocol [9–11]. It was developed by an interdisciplinary team (physical medicine doctor, rheumatologist, physiotherapist and psychologist). Twelve twice-weekly sessions lasting 60 min were provided by the same trained physiotherapist. The full protocol is reported in Table 1. At completion of the supervised exercise program, a handout with detailed home exercises was given to each participant. A diary was also provided to record exercise at home. Adherence to the program was monitored by regular follow-up phone calls by a researcher, supplemented by checks of the diaries.

Demographic and disease-related data including age, sex, time since diagnosis, symptom activity, erythrocyte sedimentation rate, reactive C protein, visual analog pain scale, and drugs were collected at baseline.

Primary outcome was sway density improvement. Secondary outcomes were the following quantitative balance and rheumatologic parameters. Rheumatologic and balance outcome measures were recorded at baseline, end of treatment (T1) and at 7-month follow-up (T2). Rheumatologic evaluation included: Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), and Bath Ankylosing Spondylitis Metrology Index (BASMI). Fatigue and morning stiffness were obtained as sub-items of the BASDAI. Stabilometric analysis provided balance data, including anterior–posterior oscillation, latero-lateral oscillation and sway density. Subjects were allowed to choose their preferred foot position over the force plate during the protocol with feet comfortably apart. The deflections of the center of pressure (CoP) along the lateral (x) and anterior–posterior (y) axes were recorded with a force platform (ARGO, RGMD, Italy) [6]. A proprietary software provided sway area, measuring the area encompassed by CoP, sway density, measuring the entity of oscillations, and sway path, measuring the total length of CoP trajectory.

Each balance parameter was analyzed both with open and closed eyes. Each trial was separated by a 15-min rest interval to minimize fatigue.

Outcome measurements were assessed by the same examiner blinded to treatment.

Statistical analysis

A pre-study sample size calculation predicted that, with an alpha of 5 % and a power of 90 %, a total number of 66 subjects would be needed. The study followed the ITT (intention-to-treat) analysis approach in line with the CONSORT statements [12] (Fig. 1).

Baseline characteristics of the groups were compared by unpaired t tests for independent samples (continuous data). Before–after training improvements (intra-group analysis) were tested with Wilcoxon matched-pairs test at T1 and T2. Mann–Whitney U test tested differences between the two groups (inter-group analysis) in score gains on balance and rheumatologic parameters. Treatment effects were analyzed stratifying by treatment (infliximab, etanercept or adalimumab) with Kruskal-Wallis test. Statistical significance was set at $p < 0.05$. Statistics were processed using SPSS version 20.0 (SPSS Inc., Chicago, Illinois).

Results

Participants

Participants were enrolled from September 2012 to March 2013. Last follow-up was in October 2013. Sixty-six individuals were screened (46 males). Of these, 46 enrolled (eleven refused consent; nine did not meet inclusion criteria). Four did not complete the full evaluation. A total of 22 (17 males) enrolled in educational and 20 (15 males) in the rehabilitation group, and all these were fully evaluable (Fig. 1).

Table 1 Detailed exercise protocol of the supervised training and home-based rehabilitation program

		First period (FP)				Second period (SP)				Third period (TP)			
1° week	2° week	3° week		4° week		5° week		6° week		7° week		8° week	
Tuesday	Tuesday	Tuesday	Thursday	Tuesday	Thursday	Tuesday	Thursday	Tuesday	Thursday	Tuesday	Thursday	Tuesday	Thursday
1° Educational session pre FKT	2° Educational session pre FKT	1° FKT session	2° FKT session	3° FKT session	4° FKT session	5° FKT session	6° FKT session	7° FKT session	8° FKT session	9° FKT session	10° FKT session	11° FKT session	12° FKT session
Pathophysiology of AS, affected anatomical structures, physiopathology and prognosis; therapy aim	Information was provided on the relationships between pain, muscle tension, stress, and depression. Cognitive strategies of pain management were outlined. Extensive information was provided on relaxation as a method of pain management Identification of problem-solving techniques to overcome barriers	**Information on exercises (10 min)** Illustrated-description of exercises (exercises check from the 2° session) **Warm-up (15 min)** 1. Respiratory exercises and cardiorespiratory fitness (2 series of 10 repetitions): deep breathing and chest expansion 2. Stretching exercises for the posterior and anterior muscle chain of the spine (2 series of 10 repetitions) **Main period (25 min)** 1. Exercises to mobilize the back and limbs (2 series of 10 repetitions): *Cervical* and *thoracolumbar district*: lateral flexion and rotation, flexion–extension. Shoulder and upper limb side: ab/adduction, flexion, elevation, and circumduction. *Coxofemoral*, knee and ankle district: add/adduction, rotation and flexo-extension 2. Stretching exercises for the anterior and posterior pelvic girdle muscle chain and muscles of lower limbs (2 repetitions for 30/40 s) **Cool-down (10 min)** 1. Respiratory exercises; spine and limbs stretching exercises				**Information on exercises (10 min)** Illustrated description of exercises **Warm-up (15 min)** 1. Respiratory exercises and cardiorespiratory fitness (2 series of 10 repetitions) thoracic breathless, expiratory breathless (+FP warm-up exercises) 2. Stretching exercises for the posterior and anterior muscle chain of the spine (2 series of 10 repetitions) **Main period (25 min)** 1. Aerobic exercises for progressive duration on the basis of the patient's functional capacity (10 min cycling or walking 2 km/h) 2. Stretching of anterior and posterior muscles of lower limbs (1 + FP warm-up exercises) (2 series of 10 repetitions) 3. Strengthening and muscle chain of the spine, respiratory muscle and anterior–posterior muscles of lower limbs (+FP main period exercises to mobilize the back and limbs) (2 repetitions for 30/40 s) **Cool-down (10 min)** 1. Respiratory exercises; spine and limbs stretching exercises			**Information on exercises (10 min)** Illustrated description about exercises to learn and to perform at home **Warm-up (15 min)** 1. Respiratory exercises and cardiorespiratory fitness (2 series of 10 repetitions): Abdominal control and diaphragmatic breathing exercises and exercises for scapular girdle muscle (+FP and SP warm-up exercises) 2. Stretching exercises for the posterior and anterior muscle chain of the spine (2 series of 10 repetitions) **Main period (25 min)** 1. Aerobic exercises for progressive duration on the basis of the patient's functional capacity (10 min cycling or walking 4 km/h) (+FP main period exercises and SP main period strengthening and muscle chain of the spine, respiratory muscle and anterior–posterior muscles of lower limbs) **Cool-down (10 min)** 1. Respiratory exercises; spine and limbs stretching exercises		

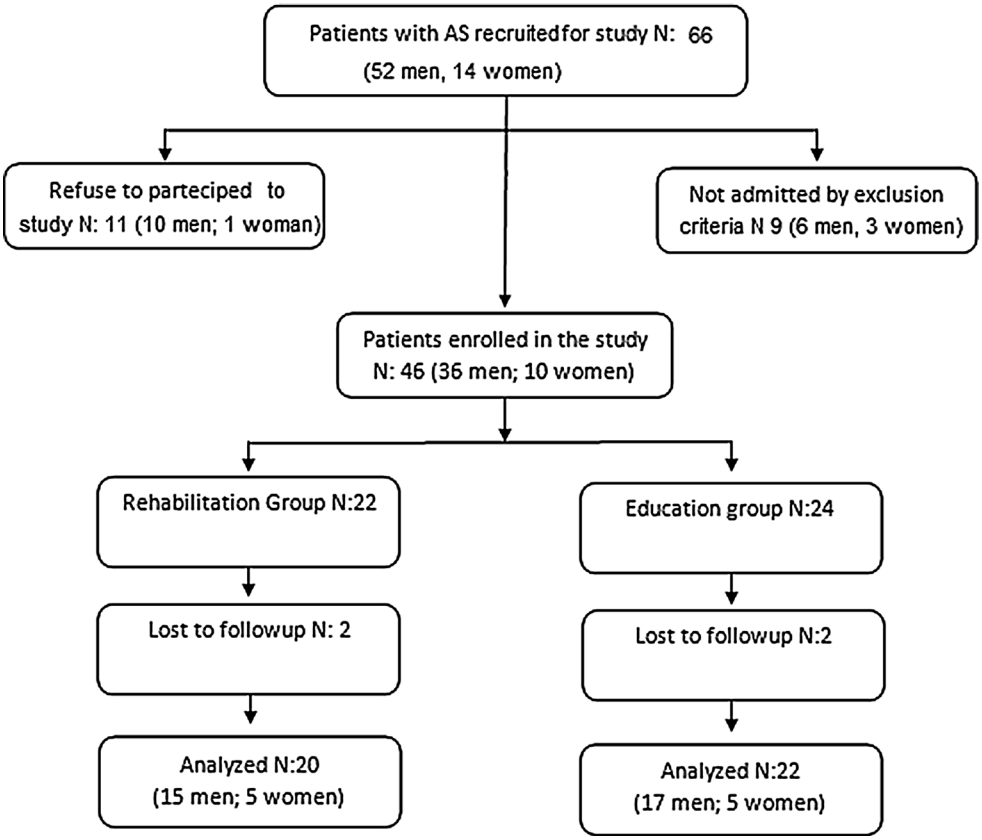

Fig. 1 Patients enrolled for the trial

Participants' characteristics at baseline

No significant differences in demographics, pain or rheumatologic and balance parameters were detected (Table 2). Adherence to the program based on diary checking suggested that this was high, with home exercises carried out on a daily basis by 79 % of participants and at least 5 day per week by another 10 %.

Balance parameters

Intra-group analysis in the rehabilitation group demonstrated a reduction in closed-eyes oscillations and sway parameters at T1 and T2. Open-eyes parameters, despite not statistically different at the end of rehabilitation treatment, improved at 7-month follow-up compared to baseline (Table 3). In the educational group, open-eyes anterior–posterior oscillation, and open- and closed-eyes sway density improved at end of the rehabilitation program. Open-eyes sway Area improved only at 7-month follow-up (Table 3).

Inter-group comparison suggested better results in the rehabilitation group for latero-lateral oscillations ($0.01 > p > 0.009$) and some sway parameters ($0.003 < p < 0.019$), both with open and closed eyes at T1 (Table 3). At follow-up, the rehabilitation group maintained these results, with additional improvement on closed-eyes latero-lateral oscillations ($p = 0.004$) and all sway measures ($0.015 < p < 0.046$) (Table 3). The rehabilitation group showed no significant differences between the end of treatment and 7-month follow-up on balance parameters differentiating for drug ($0.093 < p < 0.111$) and years from diagnosis of ankylosing spondylitis ($0.9 < p < 0.14$).

Rheumatologic parameters

Intra-group analysis in the rehabilitation group showed Bath Ankylosing Spondylitis Disease Activity Index, Bath Ankylosing Spondylitis Functional Index and Bath Ankylosing Spondylitis Metrology Index improvement at end of rehabilitation program and at follow-up. In the educational–behavioral group, only Disease Activity Index improved at end of treatment, and Functional Index at follow-up (Table 3).

Inter-group comparison yielded better scores for the Metrology Index ($p = 0.049$ and 0.008) and the Disease Activity Index ($p = 0.022$ and 0.010) at end of treatment and follow-up in the rehabilitation group. The rehabilitation group showed no differences between end of treatment and 7-month follow-up on rheumatologic parameters differentiating for drug ($0.093 < p < 0.111$) and years from diagnosis of ankylosing spondylitis ($0.9 < p < 0.14$).

Table 2 Baseline evaluation

Characteristic	Rehabilitation group	Educational group	*p*
Age	49.30 (±11.33)	45 (±8.45)	0.182
Time since diagnosis	9.10 (±7.51)	8.12 (±4.5)	0.598
ESR	90 (7.0–17.5)	11.0 (0–17.0)	0.873
RCP	0.9 (0.3–3.1)	0.5 (0.1–1.5)	0.649
VAS cervical	29.0 (12.0–50.2)	29.0 (0.5–60)	0.926
VAS lumbar	29.0 (8.0–60.5)	27.5 (1.7–50.0)	0.950
Fatigue	4.5 (2.2–6.0)	3,.5 (2.0–6.3)	0.756
Level of morning stiffness	27.0 (13.5–37.5)	30.0 (8.5–42)	0.897
BASDAI	3.0 (2.2–2.4)	2.6 (2.2–3.9)	0.102
BASFI	2.4 (1.8–3.9)	2.8 (1.8–3.5)	0.315
BASMI	4.3 (3.4–5.8)	3.6 (2.6–5.2)	0.069
Adherence to at home program	79 % daily 10 % 5 days/w	Nihil	
Sway area CE	46.6 (24.9–63.4)	31.8 (25.4–56.5)	0.110
Sway area OE	14.7 (12.2–31.9)	15.7 (9.4–19.2)	0.175
OscAntPost OE	18.4 (16.2–24.6)	18.1 (13.8–24.4)	0.985
OscAntPost CE	32.0 (19.7–42.0)	28.3 (22.3–42.0)	0.260
OscLatLat OE	17.9 (14.4–27.4)	14.5 (12.2–21.1)	0.071
OscLatLat CE	29.1 (20.1–39.76)	25.0 (18.7–27.2)	0.241
SDx OE	3.7 (3.1–4.7)	3.2 (2.5–4.0)	0.108
SDx CE	5.6 (3.7–7.0)	4.2 (3.7–5.4)	0.175
SDy OE	3.4 (2.9–5.0)	3.3 (2.8–4.6)	0.352
SDy CE	5.7 (3.3–7.4)	5.2 (3.6–6.4)	0.084
Sway path CE	20.9 (14.5–31.9)	16.0 (14.7–22.5)	0.108
Sway path OE	10.2 (8.3–15.6)	9.5 (8.9–12.0)	0.110

Results are expressed as median (upper and lower quartiles). Age and time since diagnosis are expressed as mean and standard deviation

OE opened eyes, *CE* closed eyes, *OscAntPost* Anterior–posterior oscillation, *OscLatLat* latero-lateral oscillation, *SDx* sway density, coordinate x, *SDy* sway density, coordinate y. *BASDAI* Bath Ankylosing Spondylitis Disease Activity Index, *BASMI* Bath Ankylosing Spondylitis Metrology Index, *BASFI* Bath Ankylosing Spondylitis Functional Index, *ESR* erythrocyte sedimentation rate, *RCP* reactive C protein, *VAS* visual analog scale

Discussion

Rehabilitation treatment seems effective on posture control in ankylosing spondylitis in a population taking biological agents, suggesting that there might be a synergistic effect of drugs and rehabilitation on balance. Current guidelines advise the association of physical and pharmacological treatment [13]. Due to recruitment problems, we did not reach the expected power but a clear trend was seen. This is in line with previous findings [8, 11] of a beneficial effects on spine mobility, pain and physical function in a similar population undergoing the same rehabilitation protocol.

This approach provides long-lasting benefits, highlighted by the persistence of improved balance parameters at follow-up. Eyes-closed trials showed a trend to improvement, and this may suggest a positive effect of rehabilitation on proprioception.

Postural control theory considers balance as the product of integrated inputs, and the body as a mechanical system that interacts with the nervous system in a continuously changing environment [14]. In ankylosing spondylitis, the biomechanical system, movement strategies and sensory strategies are likely to be impaired, due to the pathognomonic bone deformities, enthesitis and postulated vestibular dysfunction [1–3, 5].

Pathophysiologically, the observed beneficial results of rehabilitation training could be attributed not only to partial posture correction, but also to effects on vestibular dysfunction [1–3] and diffuse enthesitis [15]. While vestibular dysfunction produces a clear-cut, often asymmetric, disequilibrium, enthesitis, as an inflammatory process of the sites where tendons or ligaments insert into the bone, affects articular capsule nerve endings and Golgi organs. Chemosensitive nociceptor excitation in vertebral joints, muscles and tendons may alter the sensitivity of the muscle spindles by reflex activation of fusimotor neurones, leading to a decreased proprioceptive acuity.

Our study has limitations. Firstly, the expected power was not achieved, which may have prevented us reporting statistically significant results. Our initial hypothesis could not be confirmed but a clear trend for the efficacy of rehabilitation emerges. These results warrant replication on larger samples to confirm our findings.

Another limitation is the lack of enthesitis indexes. Given that correlations between the enthesitis indices and ankylosing spondylitis disease activity measures, participants global assessment and BASMI metrology are reported to be moderate to weak [16], enthesitis indexes were not considered a crucial measurement in the study design.

Another point is that the observed modification of BASDAI is not clinically significant, preventing us to conclude that also disease activity and progression were modified.

The single-blinded nature of the design needs to be considered a minor bias, although we cannot rule out the psychological component of the stricter follow-up and care received by the rehabilitation group. Lastly, the short follow-up may have masked possible relapses.

Despite these limitations, the study offers promising results: although our hypothesis was not fully confirmed, rehabilitation programs in ankylosing spondylitis suggest a benefit also on a neglected symptom such as balance impairment. Trials on larger population samples are needed to confirm these findings.

Table 3 Intergroup analysis

Outcome	Rehabilitation group (T1)	Educational group (T1)	Rehabilitation group (T2)	Educational group (T2)
VAS cervical	11.0 (3.5–23.7)	20.0 (0.0–39.2)	10.0 (0.0–13.7)	17.5 (0.0–29.7)
VAS lumbar	17.5 (2.5–29.7)	25.0 (0.0–40.0)*	7.5 (0.0–20.0)*	30.0 (2.5–38.7)
Fatigue	3.0 (1.6–4.0)	3.2 (1.2–6.0)	2.25 (1.0–3.0)*	3.0 (2.0–5.2)
Morning stiff	12.0 (6.0–34.5)	33.0 (6.0–42.0)	12 (6.0–34.5)	230.0 (6.0–40.5)
BASDAI	2.5 (1.0–3.5)*	2.4 (1.5–3.4)	2.4 (0.5–3.0)*	2.4 (1.7–4.0)
BASFI	1.6 (1.0–2.9)	1.4 (0.6–4.5)	1.1 (0.7–2.0)	1.7 (1.0–4.1)
BASMI	3.7 (2.5–4.7)*	3.8 (2.6–4.8)	3.1 (2.4–3.8)**	4.0 (2.8–4.9)
Sway area CE	14.6 (11.1–25.1)	45.3 (17.8–57.3)*	12.7 (8.3–4.0)*	28.3 (16.1–56.9)
Sway Area OE	13.4 (12.4–17.6)*	16.9 (9.2–21.8)*	24.8 (13.4–1.3)	14.3 (9.7–24.1)
OscAntPost OE	16.8 (13.0–22.3)	24.5 (16.1–30.4)	19.9 (14.2–8.8)	25.5 (17.1–29.5)
OscAntPost CE	23.8 (20.2–32.0)	31.7 (25.1–35.8)	25.5 (18.7–5.1)	25.7 (19.8–39.1)
OscLatLatOE	20.11 (17.8–.2)**	18.2 (15.6–24.9)	17.6 (12.2–3.4)**	19.1 (14.3–28.3)
OscLatLatCE	24.8 (20.7–33.3)*	21.9 (16.5–35.8)	20.8 (13.6–1.7)*	22.2 (17.7–32.0)
SDx OE	3.65 (3.0–4.3)	3.2 (2.8–4.9)	3.0 (2.2–4.1)*	3.2 (2.5–4.06)
SDx CE	5.3 (3.9–6.3)	4.2 (3.2–6.0)	3.6 (2.5–5.5)*	4.3 (3.2–5.7)
SDy OE	3.3 (2.5–4.6)**	4.7 (3.5–5.4)	3.7 (2.6–4.9)	5.7 (4.5–6.4)
SDy CE	4.5 (3.3–6.1)**	5.4 (4.3–7.6)*	4.4 (3.4–6.0)	6.6 (4.9–8.6)*
SwayPath OE	11.1 (9.7–14.6)	11.3 (8.0–13.1)	8.5 (87.1–11.1)*	9.5 (8.4–12.3)
SwayPath CE	16.2 (14.1–27.6)*	18.9 (11.9–24.7)	14.8 (10.9–22.8)*	14.6 (10.5–24.2)

Comparison between supervised training and home based rehabilitation group (RG) and Educational–behavioral group (EG) at the Mann–Whitney *U* test *p* values at the end of therapy and at 7-month follow-up. Results are expressed as median (25th–75th percentile). Intergroup statistical significance for each test was indicated by asterisk ($p < 0.05$) or double asterisk ($p < 0.01$)

OE opened eyes, *CE* closed eyes, *OscAntPost* Anterior–posterior oscillation, *OscLatLat* latero-lateral oscillation, *SDx* sway density, coordinate x, *SDy* sway density, coordinate y. *BASDAI*: Bath Ankylosing Spondylitis Disease Activity Index, *BASMI*: Bath Ankylosing Spondylitis Metrology Index, *BASFI* Bath Ankylosing Spondylitis Functional Index

Transfer of these results to clinical practice should be implemented by incorporating a physical medicine doctor and a physiotherapist in the rheumatology clinic team.

Compliance with ethical standards

Conflict of Interest The authors declare that they have no conflict of interest to declare in relation to this work.

Appendix

See Table 4.

Table 4 Educational–behavioral program

Educational–behavioral program	
1° session	2° session
Content of meeting:	Content of meeting:
Pathophysiology of ankylosing spondylitis (AS)	Information about the relationships between pain, muscle tension, stress and depression
Physical structures involved	Outline of cognitive methods of pain management
Physiopathology and course	Information on relaxation as a method of pain management
Objective of medication today	Identification of problem-solving techniques to overcome barriers
	Description of exercise training program (objectives and expected results)

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