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Original article

Evaluation of the impact of a nurse-led program of patient self-assessment and self-management in axial spondyloarthritis: results of a prospective, multicentre, randomized, controlled trial (COMEDSPA)

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Abstract

Objective. To evaluate the impact of a nurse-led program of self-management and self-assessment of disease activity in axial spondyloarthritis.

Methods. Prospective, randomized, controlled, open, 12-month trial (NCT02374749). Participants were consecutive axial spondyloarthritis patients (according to the rheumatologist) and nurses having participated in a 1-day training meeting. The program included self-management: educational video and specific video of graduated, home-based exercises for patients; and self-assessment: video presenting the rationale of tight monitoring of disease activity with composite scores (Ankylosing Spondylitis Disease activity Score, ASDAS/Bath Ankylosing Spondylitis Disease Activity Index, BASDAI). The nurse trained patients to collect, calculate and report (monthly) ASDAS/BASDAI. Treatment allocation was by random allocation to this program or a comorbidities assessment (not presented here and considered here as the control group).

Results. A total of 502 patients (250 and 252 in the active and control groups, respectively) were enrolled (age: 46.7 (12.2) years, male gender: 62.7%, disease duration: 13.7 (11.0) years). After the one-year follow-up period, the adherence to the self-assessment program was considered good (i.e. 79% reported scores >6 times). Despite a lack of statistical significance in the primary outcome (e.g. coping) there was a statistically significant difference in favor of this program for the following variables: change in BASDAI, number and duration of the home exercises in

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the active group, and physical activity (international physical activity score, IPAQ).
Conclusion. This study suggests a short-term benefit of a nurse-led program on self-management and self-assessment for disease activity in a young axial spondyloarthritis population in terms of disease activity, exercises and physical activity.

Key words: spondyloarthritis, education, nurse, self-assessment, self-management

Rheumatology key messages

- A nurse-led education intervention had an impact on exercises and physical activity one year later.
- A nurse-led education intervention on self-assessment had an impact on decreasing disease activity one year later.
- Nurses could play a key role implementing recommendations for axSpA management and ASAS quality standards in clinical practice.

Introduction

Recently, two initiatives have proposed recommendations for the management of axial spondyloarthritis (axSpA) (the ASAS/EULAR recommendations [1] and an international task force focusing on the concept of treat-to-target [2]).

Such recommendations can be summarized as follows:

- disease activity should be collected frequently and regularly, using validated composite score (i.e. ASDAS [3] or BASDAI [4]);
  - the patient has to have embarked upon a shared decision concerning the monitoring and treatment strategy;
- NSAIDs have to be considered as the cornerstone of drug therapy in case of active disease;
- tobacco exposure has to be discouraged not only because of its disastrous impact in terms of risk of cancer and/or cardiovascular disease but also because of its negative impact in terms of disease activity and disease severity [5]; and
- physiotherapy including home exercises (for all patients) and physiotherapy under the supervision of a physiotherapist, in case of severe disease, is recommended.

For the evaluation of disease activity, two tools are currently recommended: either ASDAS (preferably) or BASDAI + CRP, and, according to recommendations, the frequency of measurements depends on the level of disease activity with more frequent evaluations in case of high disease activity [1, 2].

However, frequent evaluation might represent a challenge to be implemented in busy clinics for physicians. Several examples in the medical [6, 7], and specifically in the rheumatologic literature [8, 9] suggest that the involvement of the patient in his/her own assessment of disease activity might have a beneficial impact on his/her management by his/her treating rheumatologist. Furthermore, the role of nurses is becoming more and more important in the management of chronic diseases [10]. Many studies and daily practice experiences have clearly shown that nurses have the relevant skills, permitting an optimal education, in particular concerning the best way to perform a self-evaluation of the disease activity [11]. Moreover, nurses are also able to monitor the rheumatic disease by performing physical examinations. In the field of rheumatology, an example could be the joint count in case of peripheral arthritis [12] but also the spinal mobility in case of axial involvement.

Therefore, in the field of axSpA, a nurse intervention might be beneficial for three reasons: (i) to educate a patient in how to calculate and collect an ASDAS/BASDAI; (ii) to detect spinal abnormalities that might require an intensification of physical therapy; and (iii) to educate the patient concerning the importance of physical activity, NSAID intake and/or tobacco exposure.

Based on these remarks, we conducted this study, aiming to evaluate the impact of a nurse- led program of self-management and disease activity self-assessment in patients with axSpA.

Methods

Study design

This was a prospective multicentric interventional randomized controlled open two-groups 12-month trial (COMEDSPA trial, trial registration number: NCT02374749), including 21 secondary and tertiary care centres in France. All patients signed an informed consent. The study was approved by the local ethics committee and was conducted in agreement with good clinical practice procedures.

Participants

Consecutive patients with axSpA according to the rheumatologist, with a disease duration >1 year, and a stable disease. Patients had to be able to understand the questionnaires and the proposed program, and to give their informed consent. Patients were included from March 2015 to October 2016.

Randomization

A computer-generated list (random permuted block design using block sizes of 2, 4 or 6, stratified per centre) was generated by an independent statistician.

Interventions

After written informed consent, patients were randomly allocated (using Clean-Web system) to receive either the educational program (i.e. *education group*) or a comorbidity screening/management program (i.e. *control group*). Both programs were solely led by nurses, with no intervention from physicians during the whole program. All nurses participated in a one-day meeting prior to the start of the study, to be trained on the physical examination of axSpA patients, in particular for the detection of spinal deformities. The program for the active group consisted of two parts: self-management and self-assessment.

Self-management

A video was presented to all patients that explained the disease and the role of NSAIDs as a cornerstone treatment in axSpA (e.g. if tolerated and provided no contraindications, patients were advised to not hesitate to take NSAIDs at an optimal dose for as long as requested) in all patients, including those treated with biologics, as well as the importance of monitoring disease activity, smoking cessation in axSpA and also physical activity and exercise. Afterwards, patients discussed the content of the video with the nurse, who reinforced the main messages of the educational video. A physical examination was performed by the nurse, to check for the presence of definite spinal deformities (i.e. loss of lumbar lordosis, chest wall expansion <4 cm or occiput-wall distance >0 cm) that would suggest a severe disease; in case at least one of these deformities were present, a specific video of home-based exercises for patients with severe disease was projected; if no deformities were present, a specific video for patients with no severe disease was projected. These videos were specifically designed and recorded for this study, and the physical medicine and rehabilitation specialist from the scientific committee specifically insisted on the importance of having separate home-based exercise videos for severe/not severe patients.

Self-assessment

A video explaining the importance of frequent disease activity measurements, and the rationale for the use of composite indices (here, ASDAS and BASDAI) was presented to all patients. Then, the nurse emphasized the importance of disease activity measures collection, and trained patients to calculate BASDAI and ASDAS (with a calculator provided to the patient). Patients were instructed to report the results of the disease activity indices (BASDAI and ASDAS) in a booklet on a monthly basis, considering the last available CRP for ASDAS calculation.

The control group participated in a nurse-led comorbidity screening and management program [13], but did not receive any information about the importance of disease activity monitoring and did not receive any of the disease educational material at the baseline visit.

Data collected

In a dedicated electronic case-report form, the following data were collected:

Data collected at baseline (both groups): Demographics and disease characteristics: patients' characteristics included: age, gender, highest level of education completed, professional status, BMI and smoking status. Disease characteristics such as past history of axial, peripheral articular, enthesitis involvement, dactylitis, non-rheumatological manifestations (e.g. uveitis, psoriasis, IBD), presence of radiographic sacroiliitis (i.e. according to modified New York Criteria) [14] and presence of MRI sacroiliitis according to the ASAS criteria for a positive MRI [15] were collected. All the items allowing for the retrospective calculation of the ASAS criteria for axSpA were collected.

Data collected both at baseline and at the one-year visit (both groups): Coping with the disease during the last 12 months, measured with a numerical rate scale, ranging from 0 to 10 (0 = very well), which was an adaptation of the seventh question of the RAID score [16]: 'Considering the different tools you had access during the last 12 months, how do you evaluate your ability to cope with your disease?'. Disease activity was measured by the ASDAS and the BASDAI. Function was assessed by the BASFI [17], and quality of life with the ASAS Health Index (ASAS-HI) [18]. Past and current medications for axSpA (NSAIDs, glucocorticoids, conventional and biologic DMARDs) were also collected, and the NSAID intake was evaluated using the ASAS-NSAID score over the past 3 months [19]. Home-based exercises: number of sessions per month and duration per session during the last 3 months. Physiotherapy: number of sessions per month during the last 3 months.

Data collected only at the one-year visit in both groups: The International Physical Activity Questionnaire (IPAQ) [20].

Data collected only in the active group at the one-year visit: Number of patients who self-assessed and reported in their booklet the ASDAS or BASDAI during follow-up.

All self-reported questionnaires at baseline and one-year visits were completed by patients in the waiting room right before the nurse visit.

Outcomes

The main outcome was the level of coping (0–10, where 0=very well) after 12 months.

Secondary outcomes were: change over one year on other patient-reported outcomes (BASDAI, BASFI, ASAS-HI), percentage of patients reaching a patient acceptable symptoms status at one year (e.g. PASS, defined by a BASDAI $<4/10$) [21], and disease-activity measures (ASDAS), successful smoking cessation at one year, increase in NSAID intake, number and duration of home-based exercises, number of supervised physiotherapy sessions and the IPAQ (measured at the one-year visit).

Sample size calculation

The sample size was estimated based on the fact that this study was run with two main outcomes (one per group: the main outcome of the comorbidity program group is not presented here). The bilateral testing, used an alpha risk threshold of 2.5% (instead of 5%) to consider the multiplicity induced by two main criteria judgements. The desired power was 80%. To our knowledge there were no data related to this field of research in the literature; thus, a similar study in the field of rheumatoid arthritis (e.g. COMEDRA) was used as a calculation basis. (e.g. COMEDRA [9]). We assumed that similar results in the field of spondyloarthritis would be achieved and we calculated our sample based on the outcome of the other program's outcome (i.e. the screening/management comorbidity program): we hypothesized that 5% of patients not receiving the comorbidity program would undertake actions aimed at preventing comorbidities. Following this estimation, 500 patients (250 patients per group), with an alpha risk of 0.025, and a power of 0.80, our sample size would allow us to detect a difference of 7.8% between groups.

Statistical analysis

Descriptive analysis

Baseline demographics and disease characteristics of patients in both groups were described as means (S.D.) and number (%) for numeric and categorical variables, respectively.

Evaluation of the efficacy of the self-assessment/self-management program:

- Primary endpoint: the level of coping after 12 months was compared in both groups by a T-test.
- Secondary endpoints: all other secondary outcomes were compared in both groups after one year, by a T-test or a Chi-square test, as appropriate.

Evaluation of the adherence to the self-assessment/self-management program

A descriptive analysis on the adherence to the program (e.g. number of reported Patient reported outcomes in the booklet and willingness to continue performing the self-assessment after the end of the study) was performed in the active group at 12 months.

Missing data handling

Only patients attending both the baseline and the one-year visit were included in the analysis. No imputation on missing variables was performed.

Results

Five hundred and two patients were included in the study: 250 and 252 patients were randomly allocated to the education and control groups, respectively.

After one year of follow-up, 232 (92.8%) and 239 (94.8%) patients completed the study in the education and control groups, respectively. In the education group, 11 patients withdrew themselves from the study and seven patients were lost to follow-up; no deaths were observed. In the control group, eight patients withdrew themselves from the study, one patient was lost to follow-up and four patients died (one patient due to acute myeloid leukaemia, one patient from dialysis complications, one patient from cardiac arrest, and for one patient the cause of death was unknown) (Fig. 1).

Fig. 1 Flow chart of the study

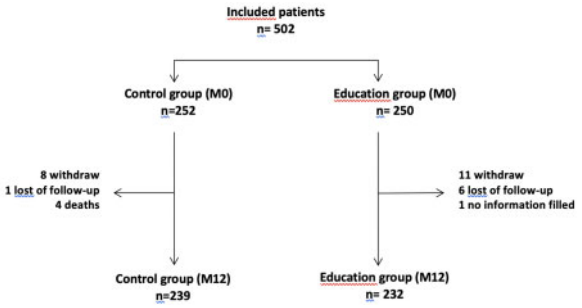


Table 1 Baseline characteristics of patients

Characteristics	Education group $n = 232$	Control group $n = 239$
Age, years[a]	47 (12)	47 (12)
Gender, % male	60	66
Education, % university degree	50	47
BMI $\geq$25 kg/m^2, %	53	54
Smoking status, % current	32	31
HLA-B27, % positive	73	76
Disease duration, years	14 (11)	13 (11)
Radiographic sacroiliitis, %, mNY	63	63
MRI SIJ inflammation, %	69	64
CRP, mg/l	5.0 (7.5)	5.1 (8.2)
ASDAS	1.9 (0.8)	1.9 (0.8)
ASAS-NSAID score (3 months)	22 (46)	19 (40)
Current bDMARDs, %	77	80

[a]Numeric variables are represented as mean (S.D.) and categorical variables as percentages. [b]DMARD: biologic DMARDs; mNY: modified New York criteria; SIJ: sacroiliac joints.

Descriptive analysis

Patients had a mean age of 47 (12) years, were predominantly males (63%), had a mean disease duration of 14 (11) years and more than half of them (53.3%) were overweight or obese (i.e. BMI $\geq$25 kg/m^2). A majority of patients had radiographic sacroiliitis (63%), MRI sacroiliitis 66%, and were under ongoing biologic treatment (78%). At baseline, mean ASDAS-CRP was 1.9 (0.8) and BASFI was 26 (22) (Table 1).

Adherence to the self-assessment/self-management program

After the one-year follow-up period, 174 of the 232 (75.0%) patients from the education group who attended the one-year visit brought their self-assessment booklet: among them, 138 (79.3%) reported their BASDAI or ASDAS >6 times. Furthermore, 146 (62.9%) patients confirmed their willingness to continue self-assessing and reporting disease activity measures after the end of the study.

Evaluation of the efficacy of the self-assessment/self-management program

At the one-year visit, coping was found to be comparable across both groups (2.8 (2.0) *vs* 3.0 (2.1), for the education and control groups, respectively, $P > 0.05$). Successful smoking cessations were more frequent in the education group, but not significantly. NSAID intake decreased after one year, but the change observed was not different between both groups. The change in BASDAI after one year was significantly different in both groups: in the education group, BASDAI decreased while an increase was observed in the control group (−1.2 (15.8) *vs* +1.4 (15.7), respectively $P = 0.03$). The percentage of patients reaching a PASS at the one-year visit was higher in the education group (72.7% *vs* 64.3% in the education and control groups, respectively, $P = 0.06$), but the difference did not meet statistical significance.

Also, a significant increase in the number of the home-exercises per month and duration per session was observed in the education group, along with higher IPAQ score at the end of follow-up (Table 2 and Fig. 2).

Discussion

Our study confirms the efficacy of a nurse-led educational program for self-management and self-assessment in patients with axSpA. Despite the main objective (coping level) not being met, several relevant changes were observed in the 'active group' (e.g. reduction in BASDAI, increase in the number and duration of the home exercises and higher IPAQ).

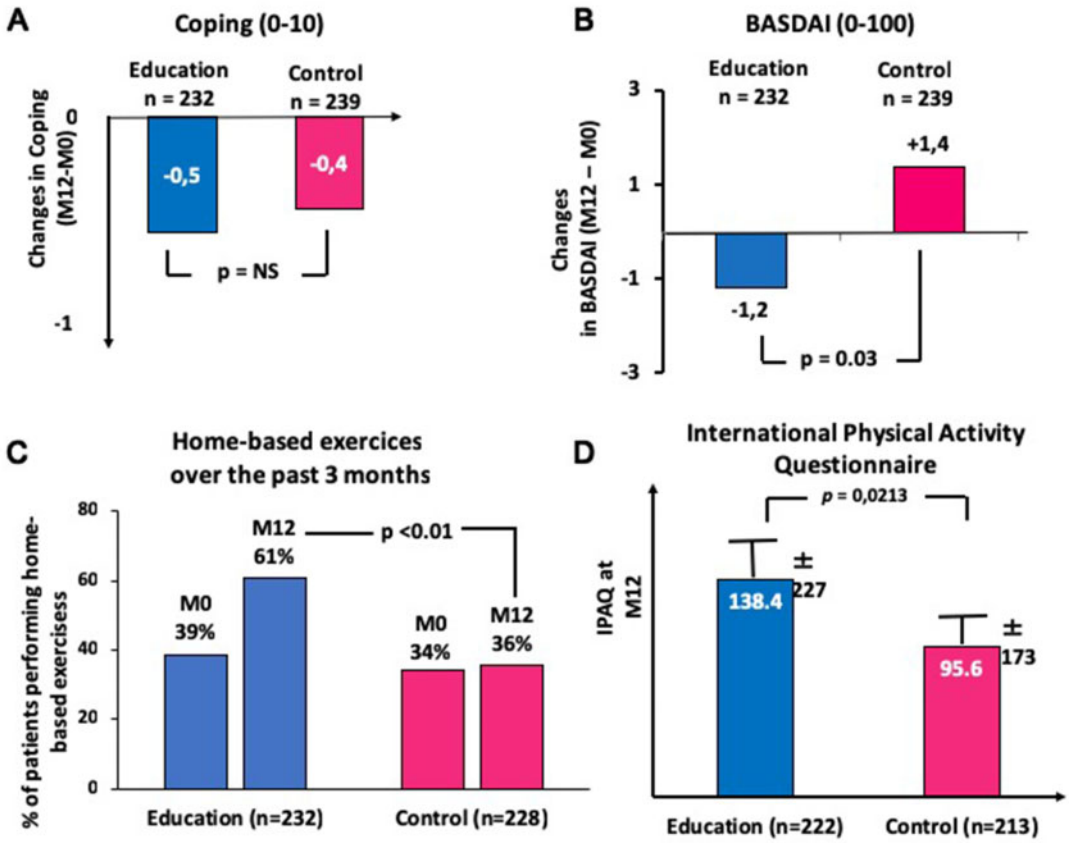
Coping level after 12 months was not different across groups, and this was probably due to a pre-existing better coping level (e.g. floor effect), compared with what has been reported in other studies [22, 23], in these patients with a long-standing and stable disease. It is worth noticing that the adaptation of the coping question for the study was not specifically validated; however the evaluation of coping by a numeric rating scale has been shown to be reliable and sensitive to change [24]. Successful smoking cessations were twice more frequent in the education group, but the difference did not reach a statistical significance, probably due to the low number of events; also, it is worth noticing that patients within the education group were advised to quit smoking with regard to the reported consequences of smoking to disease activity and structural damage [5] but also the

Table 2 Efficacy outcomes

	Education program group			Control group			
	Baseline visit	One-year visit	Δ	Baseline visit	One-year visit	Δ	*P*[a]
Coping (0–10)[b]	3.3 (2.2)	2.8 (2.0)	−0.5 (1.9)	3.4 (2.2)	3.0 (2.1)	−0.4 (2.2)	NS
BASDAI (0–100)	31.3 (19.2)	**30.0 (20.1)**	**−1.2 (15.8)**	30.8 (18.6)	**32.2 (19.6)**	**1.4 (15.7)**	**0.03**
ASDAS	1.9 (0.9)	1.9 (0.9)	0 (0.8)	1.9 (0.8)	1.9 (0.8)	0 (0.7)	NS
BASFI (0–100)	24.4 (20.8)	23 (20.7)	−0.8 (21.4)	26.1 (23.3)	25.8 (23.4)	−0.8 (19.2)	NS
ASAS-HI	6.5 (4.0)	6.2 (3.8)	−0.3 (2.5)	6.6 (3.8)	6.3 (4.1)	−0.3 (2.5)	NS
ASAS-NSAID score (3 months)	22.0 (46.9)	12.7 (27.4)	−9.3 (32.2)	19.2 (40.2)	11.1 (26.5)	−8.1 (28.6)	NS
Successful smoking cessation[c]	—	8/74 (10.8)	—	—	4/74 (5.4)	—	NS[d]
Home-based exercices[e], % yes	38.7	**60.6**	**+21.9**	34.1	**35.6**	**+1.5**	**<0.01**
Home-based exercices[e], sessions/month	5.1(9.3)	**7.3 (9.3)**	**+2.0 (9.6)**	5.2 (9.0)	**5.0 (8.9)**	**−0.1 (8.9)**	**<0.01**
Home-based exercices[e], minutes/session	8.7 (16.3)	**12.9 (16.0)**	—	8.8 (18.3)	**7.2 (13.9)**	—	**<0.01**[d]
Supervised physiotherapy sessions[e], % yes	30.2	33.8	—	33.3	32.6	—	NS[d]
Supervised physiotherapy sessions[e], sessions/month	1.8 (3.4)	1.8 (1.0)	—	2.0 (3.4)	1.6 (0.6)	—	NS
International Physical Activity Questionnaire	—	**138.4 (227.4)**	—	—	**95.7 (173.2)**	—	**0.02**[d]

Significant results are highlighted in bold. [a]*P*-value reflects significance of difference between groups on yearly changes in the variable unless otherwise stated. [b]Numeric variables are represented as mean (S.D.) and categorical variables as percentages. [c]Among the active smokers at baseline. [d]*P*-value reflects significance between groups in the variable at the 1-year visit. [e]Over the last 3 months. Δ: change over the 1-year follow-up; ASAS-HI: ASAS Health Index.

Fig. 2 Efficacy outcomes



M0: baseline visit; M12: one-year visit. (**A**) Changes in coping over the one-year follow-up; (**B**) changes in BASDAI on a 0 to 100 scale over the one-year follow-up; (**C**) percentage of patients performing home-based exercises over the 3 months preceding the study visit (baseline and M12); (**D**) International Physical Activity Questionnaire at the 1-year visit.

control group underwent a comorbidity screening and management program where they were potentially also advised to quit smoking for the cardiovascular and cancer consequences; this may have hampered the results on this outcome. The decrease in NSAID intake during the one-year follow-up is easily explained in the control group because of the comorbidity program. However, the decrease also observed in the self-management/self-assessment group is more difficult to explain; one hypothesis could be that the benefit of an increase in the frequency and duration of home-based exercises and their physical activity in general (e.g. measured by the IPAQ) resulted in a decrease in the requirement of NSAID treatment.

Identically, a change in the BASDAI was observed after one year, with a decrease in the education group, and the percentage of patients reaching the PASS for BASDAI was also higher in the education group. This difference of BASDAI change and PASS based on the BASDAI status between groups could have been explained by the increase of exercise, as both physical activity in general [25–27] and axSpA-specific home-based exercises [28] have been associated with an BASDAI improvement. This might be the explanation of a change in the BASDAI but not in the ASDAS, which does not include the item 'fatigue' (potentially improved by increased physical activity). Furthermore, it is worth noticing that these changes (e.g. on physical activity, BASDAI and NSAID intake) were observed one year after the nurses' intervention, who did only give patients the booklet and exercises videos, but did not perform any follow-up telephonic/email reminder to exercise.

Another reason behind the one-year decrease of BASDAI in the education group might be related to the understanding of the questionnaire: in this group, nurses took the time to explain the importance of collecting the BASDAI, but also to explain the purpose of each of the questions of the BASDAI. Some have suggested that the understanding of some of the BASDAI's questions can be difficult, and agreement between patients and physicians is not perfect, in particular for question 4 (which was related to tender areas, e.g. enthesitis) [29].

This study has some limitations worth noticing, but also some strengths. Firstly, the main outcome was not

met, i.e. coping level was not better in the education group compared with controls after one year. This was probably because of the long-standing disease and this suggests that potentially it would have been needed to select a population with room for improvement (i.e. with a low level of coping) with regard to the main outcome. Nevertheless, in both groups coping did improve during the year of follow-up, suggesting that participation in this study, regardless of the group of treatment had a beneficial impact on the patients coping with the disease for a long time already.

Secondly, some of the endpoints were not met (e.g. successful smoking cessation) because of the potential impact of the program performed in the control group; however, this reflects both the difficulties of successful smoking cessation, but also the beneficial impact of the other program that resulted also in some successful smoking cessations. Furthermore, significant increases were observed in the physical activity and home-based exercises in patients receiving the self-management program, and were not observed in the comorbidities program, suggesting that a specific program had more impact than the general recommendations of physical activity that were advised in the comorbidity program.

Thirdly, only secondary and tertiary care rheumatology departments (i.e. settings in which a rheumatology nurse could lead the study) have participated in this study. This ensured the feasibility of this study, but it may have induced a selection bias, as reflected by the high proportion of patients with ongoing biologic treatment at baseline, and their long-standing disease. We did not collect for how long patients were already treated in the same centre prior to the study and it is possible that many of these patients were already followed-up in these centres for years. Nevertheless, in our opinion, the fact that some of outcomes improved in these patients with the nurse intervention, reinforces even more the importance of this initiative even in patients with long-standing disease.

Furthermore, four deaths were observed during the follow-up in the control arm, while none was observed in the education arm. Causes of death were acute myeloid leukaemia, dialysis complications, and cardiac arrest (for the forth patient, the cause of death was unknown), and are highly unlikely to be related to the program the patients received.

Moreover, no shared decision-making process was performed during this study. Shared decision-making includes the provision of evidence-based information about options, outcomes and uncertainties, the decision support counselling and implementing patients' informed preferences at the individual level [30], while during the study the same identical program was administered to all patients (except for the type of home-based exercises, but the difference was based on the presence/absence of spine deformities, not patients' preferences) and no consensual-tailored management program was proposed. This may have hampered the results of the main outcome, as some have reported that shared decision-making improves coping as compared with classic education [31].

Finally, our findings are in perfect agreement with the new ASAS quality standards, which include a specific quality standard on education and self-management [32], and emphasizes that health-care professionals (e.g. nurses) can support a patient's ability to self-manage their disease.

To summarize, this study suggests a short-term benefit of a nurse-led program on the self-management and self-assessment for disease activity in a young axSpA population in particular with regard to the frequency and the duration of home exercises, but also in terms of disease activity, assessed by the BASDAI. Further studies aiming to evaluate the long-term benefit of such programs are needed to confirm (or not) our findings.

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Supplementary data

Supplementary data are available at *Rheumatology* online.

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