

Impact of a Wearable Activity Tracker on Disease Flares in Spondyloarthritis: A Randomized Controlled Trial

Guillaume Labat¹ , Meggy Hayotte² , Laurent Bailly³, Roxane Fabre³, Olivier Brocq⁴, Pauline Gerus², Véronique Breuil¹, Manuella Fournier-Mehouas⁵, Raphaël Zory², Fabienne D'Arripe-Longueville², and Christian H. Roux⁶

ABSTRACT. Objective. To evaluate the impact of a wearable activity tracker used to encourage physical activity, on disease flares in patients with spondyloarthritis (SpA).

Methods. This randomized controlled trial involved randomizing 108 patients with SpA into tracker and nontracker groups. The participants were then subjected to assessments of disease activity, performance (6-minute walk test), and quality of life (QOL; 36-item Short Form Health Survey) at the 12th, 24th, and 36th week. The primary outcome was the change in the frequency of flare episodes (categorized as no flare, flare in ≤ 3 days, and flare in > 3 days) between baseline and 12 weeks.

Results. The results of the study showed that at the 12th week, the mean change (Δ) of the number of flares improved in both groups: -0.32 (95% CI -0.66 to 0.02) and -0.38 (95% CI -0.68 to -0.09) in the tracker and nontracker group, respectively. However, the between-group differences were insignificant ($P = 0.87$). Performance scores improved in both groups at the 12th, 24th, and 36th week (all $P < 0.01$). The different dimensions of QOL also improved at the 12th week ($P < 0.01$). Conversely, moderate flares ($P < 0.01$) and performance ($P < 0.01$) improved over time; however, the influence over time of a wearable activity tracker was not significant ($P = 0.29$ and $P = 0.66$, respectively).

Conclusion. The use of a wearable activity tracker did not affect the number of flares, performance, or QOL of patients with SpA. Nevertheless, this study confirmed the benefits of physical activity on flares, disease activity, QOL, and physical performance in patients with SpA. (Move Your Spondyl "Better Live Its Rheumatism With the Physical Activity"; ClinicalTrials.gov: NCT03458026)

Key Indexing Terms: activity trackers, patient-reported outcome measures, physical functional performance, spondyloarthritis

Ankylosing spondylitis (AS) is a painful and progressive inflammation of the axial skeleton that mainly affects the spine and sacroiliac joints.¹

Physical activity (PA) is important in the management of patients with spondyloarthritis (SpA).^{2,3} PA has multiple benefits as it is known to improve a patient's disease control, pain tolerance, joint mobility, and quality of life (QOL).⁴⁻⁶ Regular PA

may contribute to decreased inflammation, as measured by serum C-reactive protein levels.⁷⁻⁹ Since patients with AS are known to have an increased risk of developing cardiovascular events, PA plays a crucial role in the prevention of these sequelae.^{10,11}

Despite medical advice, most patients with SpA do not appear to engage in regular PA.^{12,13} In fact, they engage in less PA than patients who do not have rheumatism.¹⁴ Pain, fatigue, and disability are the main barriers to the lack of involvement in PA, whereas availability, adapted practice, stability of disease, and motivation appear to encourage engagement in PA.¹⁵

It is important that PA prescription and adherence to a PA program are evaluated.¹⁶ Therefore, many innovative health promotion and intervention strategies have been proposed.^{17,18} Among these, the latest studies have focused on new technologies as it has been found that adherence to a PA program and motivation could be promoted by tools such as connected applications and devices.^{19,20} Monitoring PA through a connected device appears to be accessible and acceptable to patients with chronic inflammatory rheumatism.²¹ In fact, the use of a wearable activity tracker (WAT) combined with PA advice has been studied in other chronic rheumatic diseases and has been noted to increase engagement in PA.^{22,23}

¹G. Labat, Dr med, V. Breuil, Prof Dr, Université Côte d'Azur, Rheumatology Department, CHU de Nice, France; ²M. Hayotte, P. Gerus, R. Zory, Pr, F. D'Arripe-Longueville, Pr, LAMHESS, Université Côte d'Azur, Nice, France; ³L. Bailly, Dr med, R. Fabre, Department of Public Health, University Hospital Centre Nice, Université Côte d'Azur, Nice, France; ⁴O. Brocq, Dr med, Rheumatology Department, CHPG Monaco, Monaco City, Monaco; ⁵M. Fournier-Mehouas, Prof Dr, Physical and rehabilitation medicine, Nice University Hospital, Nice, France; ⁶C.H. Roux, Prof Dr, Université Côte d'Azur, Rheumatology Department, CHU, LAMHESS, and, IBV CNRS IMR 7277 INSERM U1091 UNS, University Côte d'Azur, Nice, France.

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Address correspondence to Dr. C.H. Roux, Rheumatology Department, CHU de Nice, Hospital Pasteur 2, 30 voie Romaine, 06000 Nice, France.

Email: roux.c2@chu-nice.fr

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Additionally, frequent remote patient monitoring could also assist in the early identification of the disease flares, and subsequently leads to early intervention for patients requiring treatment adaptation. Likewise, this may also aid in formulating decisions regarding the reduction in the frequency of appointments for stable patients.²⁴ Therefore, remote patient monitoring could become a useful tool in monitoring flares and disease activity in patients with chronic inflammatory rheumatic disease.^{19,21} Further, monitoring PA through a connected WAT has been linked to identifying disease flares.²⁵ The assessment of these flares is important in clinical practice as they aid clinicians in understanding disease status and treatment efficacy more clearly.²⁶ SpA is characterized by alternating periods of flare and remission.²⁷ The presence of persistent flares is useful in identifying patients with severe disease activity.²⁸ These flares have a known effect on the QOL of patients with SpA and PA improves the QOL of these subjects.²⁹ However, to our knowledge and to date, no data exist on the effect of WAT use on the QOL of subjects with SpA.

We hypothesized that the use of a WAT to encourage PA decreases disease activity by increasing PA. The aim of this study was to evaluate the impact of a WAT on patient-reported flares in SpA and to longitudinally assess the effect of a WAT on performance and QOL.

METHODS

Study design. We conducted a single-center randomized controlled clinical trial at the Rheumatology Department of University Hospital Centre Nice between February and May 2018. The patients were randomly allocated to either the tracker group (TG) or a nontracker group (NTG) at a ratio of 1:1 using computer-generated numbers (Figure). The allocation could not be hidden considering that it was the use, or lack thereof, of the WAT.

Ethics and consent. The protocol was approved by the local ethics review board and was performed according to the International Conference on Harmonization Good Clinical Practice Guideline and the Declaration of Helsinki. This trial was registered with ClinicalTrials.gov (NCT03458026). All patients provided written informed consent for participation in the study.

Sample size calculation. The number of participants required for this study was 118, with an error rate α to 0.05 (2-tailed test), with 90% power, or 60 subjects in each group. To account for a 15% loss to follow-up, the global sample size was set at 140 patients. The primary analysis compared the change in the frequency of flares between TG and NTG at the 12th week. We noted that in the study by Jacquemin et al,¹⁹ which looked at the relationship with physical activity measured with a connected activity tracker, patients had an average of 25 flares. Thus, in our study, the objective was a 60% reduction in the number of flares.

Study participants. Individuals were considered eligible for the research if they were aged > 18 years, understood the objectives and constraints of the study, were diagnosed with SpA according to the Assessment of SpondyloArthritis international Society criteria, lived in Nice or the surrounding 20-km area, and were certified as having no contraindication to perform physical activities such as swimming or Nordic walking. We excluded people who had coronary artery disease, moderate-to-severe heart failure, uncontrolled hypertension, myocarditis, pericarditis or endocarditis, lung disease, any contraindication to PA, were unable to go to the activity venue, were already undergoing supervised PA in a club or with a sports coach, and were pregnant or breastfeeding. Further, the participants were also excluded if during the study they experienced serious adverse events, withdrew their consent, and conducted

any protocol violation. As such, all patients provided written informed consent prior to participating in the study.

Medical data. The patient characteristics collected at baseline included sex, age, weight, height, ongoing pharmacological treatment (including use of nonsteroidal antiinflammatory drugs [NSAIDs], disease-modifying anti-rheumatic drugs [DMARDs], and biologics), and comorbidities using the Charlson Comorbidity Index (0 = no comorbidity; ≥ 1 = one or more comorbidities present).³⁰

Patient-reported outcomes. The number of flares experienced in the last 7 days was recorded at baseline and through 36 weeks. The primary outcome was measured in terms of the change in the frequency of flares experienced between baseline and week 12.

As used in previous studies, the disease flares were assessed based on the patient's perspective with the question^{21,25}: "Has your disease flared up since the last assessment?" The flares were then categorized into no flare, moderate (≤ 3 days), and persistent (> 3 days).

In terms of assessing disease activity, we collected information on the frequency of flares by self-assessment with the use of the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI). Performance was assessed using the 6-minute walk test (6MWT) and was evaluated by a physiotherapist.³¹

In addition, the QOL of the participants was evaluated using the 36-item Short Form Health Survey (SF-36). Moreover, the PA levels were evaluated using the International Physical Activity Questionnaire Short Form (IPAQ-SF).³² Here, the patient-reported outcome questionnaires (IPAQ-SF, SF-36) were completed at baseline and during the sessions at weeks 12, 24, and 36 at the center.

PA measurement. At baseline, all patients were given instructions on how they should perform the PA of their choice, with Nordic walking encouraged. The instructions were discussed in the presence of physiotherapists and doctors knowledgeable on the rehabilitative management of patients with SpA. Training was provided to avoid positions or activities that could be counterproductive in the context of this pathology. Likewise, the training was also designed to maximize the expected benefits of performing PA.

The participants were asked to schedule 2 weekly PA sessions. The patients in the TG were monitored by a WAT, also known as a bracelet (Garmin Vivofit 4), with weekly activity SMS reminders. The WAT allowed for the tracking of the number of steps, distance covered, and calories burned. Each individual participant was also able to set a personalized daily step goal. On the other hand, patients classified under NTG did not receive a WAT. At the end of the 12th week, the WAT was removed from patients in the TG.

At the end of the 24th week, the patients in the TG were given their WAT again and both groups received 1 hour of coach-supervised PA per week in addition to the 2 independent weekly sessions organized in their own time. At the end of the 36-week period, the patients in the TG returned their WAT to the study organizers.

The participants' physical performance was assessed using the 6MWT and IPAQ-SF questionnaires administered during baseline and at the 12th, 24th, and 36th week.

Statistical analysis. This is an intention-to-treat analysis wherein subjects were analyzed according to whether they belonged to the randomized group, and whether they followed the protocol correctly. In this context, subjects who were lost to follow-up were not accounted for. Additionally, imputation for missing data was not done. In the univariate analysis, categorical variables were compared using the chi-square test or Fisher exact test, whereas the continuous variables were compared using t test or Wilcoxon nonparametric test for independent group comparisons. We used the paired t test or Wilcoxon signed-rank test to assess for changes in the outcomes of interest between baseline and at the 12th, 24th, and 36th week for each group. The characteristics of patients lost to follow-up were also compared to those of patients who completed the study. The data from those lost to follow-up were used for intergroup comparison.

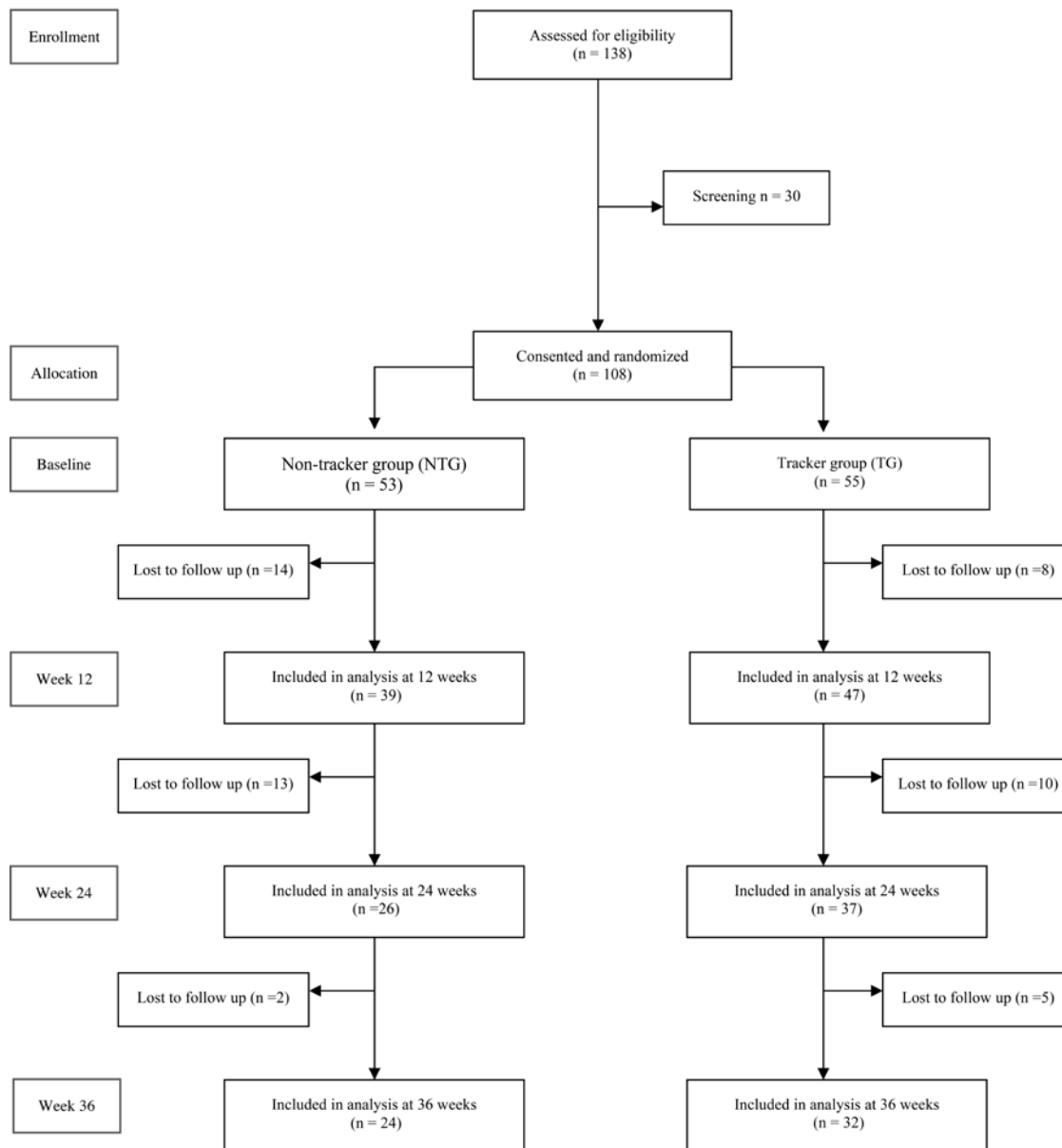


Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flowchart. NTG: nontracker group; TG: tracker group.

As for the longitudinal analysis, primary and secondary outcomes were analyzed using a linear mixed model to account for repeated measures. All models included fixed effects for time (baseline, 12th week, 24th week, and 36th week) and intercept random effects for patients. Sex, age, and the presence of a WAT were also included as covariates (fixed effects).

The statistical analysis was performed using SAS Enterprise 7.1 (SAS Institute).

RESULTS

The study included 108 patients. Among them, 55 patients were randomized to the TG and 53 to the NTG (Figure).

The baseline characteristics of the population were well balanced across both groups (Table 1). Of note, the mean (SD) number of moderate flares was 0.7 (1.1) in the TG and 0.5 (0.8) in the NTG, with no significant difference between groups

($P = 0.12$). The mean (SD) number of persistent flares was 0.6 (1.3) in the TG and 0.5 (0.8) in the NTG, with no significant difference between the groups ($P = 0.61$). Finally, the mean (SD) 6MWT was 420.5 (52.0) in the TG and 410.4 (51.0) in the NTG, with no significant difference between the groups ($P = 0.31$). However, we noted a difference in the use of medication, with 10 (18.2%) patients noted to use NSAIDs in the TG compared to 3 (5.7%) in NTG, producing a significant difference between the 2 groups ($P = 0.01$). Additionally, a difference was also observed in terms of the number of patients who used DMARDs, specifically, 8 (14.5%) in the TG and 3 (5.6%) in the NTG ($P = 0.14$). It should also be noted that more patients were on biologic therapy in the NTG (38 [71.7%]), compared to 24 (43.6%) in the TG ($P = 0.01$).

Table 1. Baseline characteristics of the included patients.

	Total Population, N = 108	TG, n = 55	NTG, n = 53	P
Age, yrs	51.5 (13.8)	52.3 (13.6)	50.7 (14.0)	0.55
Women, n (%)	76 (70.4)	40 (72.7)	36 (67.9)	0.58
BMI	25.2 (4.8)	25.0 (4.9)	25.4 (4.7)	0.61
CCI = 0, n (%)	81 (75)	43 (78.2)	38 (71.7)	0.41
NSAIDs, n (%)	13 (12)	10 (18.2)	3 (5.7)	0.05
Biologics, n (%)	62 (57.4)	24 (43.6)	38 (71.7)	0.01
DMARDs, n (%)	11 (10.2)	8 (14.5)	3 (5.6)	0.14
BASDAI	4.6 (2.3)	4.4 (2.4)	4.3 (2.1)	0.37
6MWT	415.6 (51.5)	420.5 (52.0)	410.4 (51.0)	0.31
No. of flares				
1-3 days	0.8 (1.2)	0.7 (1.1)	0.5 (0.8)	0.12
> 3 days	0.6 (1.1)	0.6 (1.3)	0.5 (0.8)	0.61

Values are mean (SD) unless indicated otherwise. 6MWT: 6-minute walk test; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; CCI: Charlson Comorbidity Index; DMARD: disease-modifying antirheumatic drug; NSAID: nonsteroidal antiinflammatory drug; NTG: nontracker group; TG: tracker group.

Change in the number of flares between baseline and 12 weeks. Between the 2 groups, there were no differences found in terms of the number of moderate and persistent flares that occurred at baseline and at week 12 ($P = 0.87$, moderate flares; $P = 0.80$, persistent flares).

The mean number of moderate and persistent flares were also noted to decrease in both groups. The mean differences between the endpoint and baseline (Δ) were -0.32 (95% CI -0.66 to 0.02 ; $P = 0.09$) for moderate flares and -0.30 (95% CI -0.70 to 0.10 ; $P = 0.24$) for persistent flares in the TG, and -0.38 (95% CI -0.68 to -0.09 ; $P = 0.02$) for moderate flares and -0.08 (95% CI -0.33 to 0.17 ; $P = 0.68$) for persistent flares in the NTG (Table 2).

Changes in BASDAI and 6MWT at 12 weeks. There was a nonsignificant decrease in BASDAI in both groups between baseline and at week 12, but this difference was not statistically significant ($P = 0.58$; Table 2). We also found a significant increase in 6MWT in both groups between baseline and week 12, but there were no differences between the 2 groups ($P = 0.22$; Table 2).

Changes in flares, BASDAI, and 6MWT at the 24th week. Table 3 presents the comparison of changes in patient-reported flares, PA, and performance between baseline and week 24. There were no differences in terms of the changes in the frequency of moderate

and persistent flares between baseline and week 24 between the 2 groups ($P = 0.81$, moderate flares; $P = 0.18$, persistent flares). The same trend was also observed in their BASDAI scores ($P = 0.39$). Although a significant increase in 6MWT in the 2 groups between baseline and week 24 was also found, there were no differences between the 2 groups ($P = 0.72$).

Evolution of flares, BASDAI, 6MWT at 36 weeks. No differences in flares ($P = 0.80$, moderate flares; $P = 0.62$, persistent flares) and BASDAI ($P = 0.36$) were found between baseline and week 36 between the 2 groups (Table 4). However, we found a significant increase in 6MWT in the 2 groups between baseline and week 36, without differences between the 2 groups ($P = 0.56$; Table 4).

Confounding factors on flare progression, physical performance, and BASDAI at 12th, 24th, and 36th week. Multivariate analysis showed a significant effect of time on the number of moderate flares ($P < 0.01$; Table 5). From baseline to the 12th week, there was a decrease in the number of flares ($\Delta = -0.34$, 95% CI -0.54 to -0.13). This time effect was also observed in the 6MWT, depicted by a linear increase in performance of 157.1 m between 36th week and baseline (95% CI 138.1-176.2; $P < 0.01$). Concerning the 6MWT, we also noticed a significant effect of age ($P = 0.03$). There was also a significant effect of sex on the

Table 2. Comparison of the changes in patient-reported flares, BASDAI, and 6MWT between baseline and week 12.

	TG				NTG				P**
	Baseline, Mean (SD)	Week 12, Mean (SD)	Δ (95% CI)	P*	Baseline, Mean (SD)	Week 12, Mean (SD)	Δ (95% CI)	P*	
1-3 day flares	0.7 (1.1)	0.5 (0.5)	-0.32 ($-0.66, 0.02$)	0.09	1.0 (1.3)	0.5 (0.8)	-0.38 ($-0.68, -0.09$)	0.02	0.87
> 3 day flares	0.6 (1.3)	0.4 (0.5)	-0.30 ($-0.70, 0.10$)	0.24	0.6 (1.0)	0.5 (0.8)	-0.08 ($-0.33, 0.17$)	0.68	0.80
BASDAI	4.4 (2.4)	4.1 (2.0)	-0.45 ($-0.99, 0.08$)	0.24	4.8 (2.2)	4.3 (2.1)	-0.50 ($-1.14, 0.14$)	0.13	0.58
6MWT	420.5 (52.0)	513.4 (64.6)	91.9 (73.4, 110.5)	< 0.01	410.4 (51.0)	495.4 (68.8)	80.8 (55.2, 106.4)	< 0.01	0.22

Δ : Mean change. * Comparison between baseline and week 12. ** Comparison between the 2 groups at week 12. 6MWT: 6-minute walk test; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; NTG: nontracker group; TG: tracker group.

Table 3. Comparison of the changes in patient-reported flares, BASDAI, and 6MWT between baseline and week 24.

	TG				NTG				P**
	Baseline, Mean (SD)	Week 24, Mean (SD)	Δ (95% CI)	P*	Baseline, Mean (SD)	Week 24, Mean (SD)	Δ (95% CI)	P*	
1-3 day flares	0.7 (1.1)	0.6 (0.7)	-0.03 (-0.35, 0.29)	0.95	1.0 (1.3)	0.6 (1.4)	-0.31 (-0.58, -0.03)	0.06	0.81
> 3 day flares	0.6 (1.3)	0.4 (0.5)	-0.24 (-0.65, 0.16)	0.27	0.6 (1.0)	0.6 (0.8)	0.08 (-0.24, 0.40)	0.81	0.18
BASDAI	4.4 (2.4)	3.8 (2.0)	-0.73 (-1.41, -0.05)	0.06	4.8 (2.2)	4.2 (1.9)	-0.13 (-0.70, 0.47)	0.47	0.39
6MWT	420.5 (52.0)	529.9 (74.5)	104.1 (80.6, 127.7)	< 0.01	410.4 (51.0)	535.4 (68.1)	121.0 (99.5, 142.5)	< 0.01	0.72

Δ: Mean change. * Comparison between baseline and week 24. ** Comparison between the 2 groups at week 24. 6MWT: 6-minute walk test; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; NTG: nontracker group; TG: tracker group.

Table 4. Comparison of the changes in patient-reported flares, BASDAI, and 6MWT between baseline and week 36.

	TG				NTG				P**
	Baseline, Mean (SD)	Week 36, Mean (SD)	Δ (95% CI)	P*	Baseline, Mean (SD)	Week 36, Mean (SD)	Δ (95% CI)	P*	
1-3 day flares	0.7 (1.1)	0.9 (1.3)	0.34 (-0.21, -0.90)	0.14	1.0 (1.3)	0.8 (1.6)	-0.08 (-0.51, 0.35)	0.65	0.80
> 3 day flares	0.6 (1.3)	0.4 (0.7)	-0.25 (-0.70, -0.20)	0.43	0.6 (1.0)	0.5 (0.8)	-0.13 (-0.48, 0.22)	0.61	0.62
BASDAI	4.4 (2.4)	4.2 (2.3)	-0.48 (-1.38, 0.42)	0.22	4.8 (2.2)	3.7 (1.5)	-0.16 (-0.85, 0.53)	0.72	0.36
6MWT	420.5 (52.0)	573.7 (79.5)	146.4 (114.2, 178.7)	< 0.01	410.4 (51.0)	584.9 (64.2)	164.2 (137.5, 190.8)	< 0.01	0.56

Δ: Mean change. * Comparison between baseline and week 36. ** Comparison between the 2 groups at week 36. 6MWT: 6-minute walk test; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; NTG: nontracker group; TG: tracker group.

Table 5. Longitudinal analysis of the number of flares, BASDAI, and 6MWT adjusted for time effect, age, sex, and the wearable tracker.

	1-3 Day Flares	> 3 Day Flares	BASDAI	6MWT
Mean				
Baseline	0.83	0.62	4.55	415.6
12 weeks	0.50	0.44	4.18	505.2
24 weeks	0.62	0.48	3.99	531.6
36 weeks	0.89	0.42	3.97	578.5
Test of fixed effects in linear mixed model, P value				
Time effect	< 0.01	0.32	0.08	< 0.01
Sex effect	0.03	0.76	< 0.01	0.07
Age effect	0.12	0.84	0.15	0.03
Tracker effect	0.66	0.42	0.11	0.29
Coefficient estimation and 95% CI in linear mixed model, vs baseline				
12 weeks	-0.34 (-0.54, -0.13)	-0.18 (-0.39, 0.04)	-0.41 (-0.81, -0.01)	88.1 (73.9, 102.3)
24 weeks	-0.17 (-0.43, 0.08)	-0.14 (-0.36, 0.08)	-0.49 (-0.90, -0.09)	113.3 (97.5, 129.1)
36 weeks	0.10 (-0.29, 0.48)	-0.22 (-0.47, 0.03)	-0.49 (-0.96, -0.02)	157.1 (138.1, 176.2)

6MWT: 6-minute walk test; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index.

number of flares and BASDAI scores ($P = 0.03$ and $P < 0.01$, respectively).

IPAQ-SF. Data on patient activity were missing. Indeed, even when focusing on the IPAQ-SF questions, fewer than half of the patients in both groups had answered the questions at week 12 and even fewer at weeks 24 and 36.

SF-36 score. We assessed the change in SF-36 scores over time in each group (Supplementary Figure S1, available from the authors upon request). For each group, we compared the change in the average SF-36 scores between the aforementioned 3 timepoints and baseline.

Concerning physical functioning, we found an increase in scores of 3.3 (SD 1.5; $P = 0.07$) at the 12th week, of 5.53 (SD 6.2; $P = 0.04$) at the 24th week, and of 1.1 (SD 3.8; $P = 0.68$) at the 36th week in the TG. On the other hand, in the NTG, we found an increase in scores of 7.43 (SD 2.4; $P < 0.01$) at the 12th week, 5.65 (SD 3.5; $P = 0.06$) at the 24th week, and 8.1 (SD 5.7; $P = 0.03$) at the 36th week (Supplementary Figure S1, available from the authors upon request).

Concerning role limitation (physical), we found an increase in scores of 7.7 (SD 3.8; $P = 0.15$) at week 12, of 8.1 (SD 1.2; $P = 0.12$) at week 24, and of 13.5 (SD 0.1; $P = 0.10$) at week

36 in the TG. In the NTG, we found an increase of 6.1 (SD 9.9; $P = 0.25$) at week 12, 12.5 (SD 8.3; $P = 0.12$) at week 24, and 27.6 (SD 1.1; $P < 0.01$) at week 36 (Supplementary Figure S1, available from the authors upon request).

Concerning role limitation (emotional), we found an increase in scores of 18.8 (SD 6.4; $P < 0.01$) at week 12, of 14.9 (SD 6.9; $P = 0.06$) at week 24, and of 13.8 (SD 0.4; $P = 0.08$) at week 36 in the TG. In the NTG, we found an increase of 9.6 (SD 0.2; $P = 0.15$) at week 12, 15.4 (SD 0.3; $P = 0.06$) at week 24, and 10 (SD 4.4; $P = 0.21$) at week 36 (Supplementary Figure S1, available from the authors upon request).

Concerning mental health, we found an increase in score of 3.1 (SD 1.1; $P = 0.07$) at week 12, of 4.2 (SD 1.7; $P = 0.03$) at week 24, and of 2.4 (SD 8.5; $P = 0.14$) at week 36 in the TG. In the NTG we found an increase of 2 (SD 0.7; $P = 0.26$) at week 12, 0.3 (SD 2.9; $P = 0.89$) at week 24, and 3.6 (SD 8.0; $P = 0.05$) at week 36 (Supplementary Figure S1, available from the authors upon request).

Concerning general health, in the TG, we found an increase in scores of 3.0 (SD 0.2; $P = 0.07$) at week 12, then a decrease of -0.06 (SD 1.3; $P = 0.98$) at week 24 and of -1.7 (SD 0.3; $P = 0.40$) at week 36. On the other hand, for NTG, we found an increase of 3.4 (SD 9.3; $P = 0.03$) at week 12, of 2 (SD 1.9; $P = 0.46$) at week 36, and a decrease of -1.3 (SD 4.1; $P = 0.65$) at week 24 (Supplementary Figure S1, available from the authors upon request).

Concerning bodily pain, we found an increase in scores of 11.5 (SD 3.1; $P < 0.01$) at week 12, of 5.1 (SD 4.0; $P = 0.20$) at week 24, and of 4.6 (SD 5.8; $P = 0.35$) at week 36 in the TG. In the NTG, we found an increase of 9.7 (SD 2.2; $P < 0.01$) at week 12, 4.6 (SD 6.2; $P = 0.34$) at week 24, and 4.8 (SD 2.3; $P = 0.34$) at week 36 (Supplementary Figure S1, available from the authors upon request).

Concerning social function, we found an increase in scores of 0.4 (SD 3.7; $P = 0.92$) at week 12, of 2.7 (SD 7.4; $P = 0.35$) at week 24, and a decrease of -2.5 (SD 7.7; $P = 0.48$) at week 36 in the TG. In the NTG, we found an increase of 2.7 (SD 1.7; $P = 0.45$) at week 12, 1.9 (SD 2.8; $P = 0.67$) at week 24, and 0.8 (SD 6.2; $P = 0.82$) at week 36 (Supplementary Figure S1, available from the authors upon request).

DISCUSSION

The results of the study show that the activity tracker did not improve the frequency of flares in patients with SpA. Given the importance of PA in the management of SpA, finding a way to get or keep patients physically active is a major challenge. To the best of our knowledge, our study is the first to explore the effect of WAT use on the frequency of flares measured using PA in patients with SpA.

In the ActConnect study, which investigated the use of a connected device in a population with rheumatoid arthritis (RA) and SpA, the authors found that a WAT had the ability to measure disease activity through the assessment of PA.¹⁹ In addition, the link between PA and disease activity was observed longitudinally. Other studies have also shown the ability of a WAT to improve PA in different rheumatic diseases.^{22,23} Thus,

given the described importance of PA in SpA, we would expect that a WAT would improve disease activity in patients with this disease.^{2,3}

PA improves disease activity in rheumatic diseases, but most of the studies are cross-sectional^{33,34} and only a few longitudinal studies have confirmed this in SpA.^{25,35} Our results were consistent with these findings. Indeed, we found no significant improvement in disease activity as measured by flares and BASDAI in both groups. These improvements seem to show that the initial advice to practice PA was adhered to by both groups.

One explanation for these results is that both groups received an initial 1 hour briefing encouraging them to engage in PA. In previous rheumatology studies, an increase in PA was found in groups wearing activity trackers, particularly in patients with knee osteoarthritis, RA, or systemic lupus erythematosus.^{22,23} However, in these studies, patients who received a PA program, including the use of a WAT coupled with physical therapy sessions and PA advice, were compared to patients who did not receive these aids. Indeed, the benefits attributed to the WAT are inseparable from those stemming from the physical therapy and PA advice that accompany them. Thus, the effect of PA advice alone is difficult to assess in these studies. In our study, patients in both groups were instructed on PA and its benefits for their disease. It is possible that the influence of the WAT alone is insufficient to make a difference in disease activity.

Additionally, in the present study, there was an improvement in physical performance in both TG and NTG. Moreover, we observed an improvement in the physical performance in the last 12 weeks of the study in both groups. Indeed, at the end of week 24, both groups benefited from 1 hour of PA per week supervised by a coach, in addition to the 2 weekly sessions organized in their own time. These results appear to be consistent with a previous metaanalysis that demonstrated short-term, supervised exercise programs may be more effective than home-based exercises in decreasing the disease activity in patients with SpA.³⁶ The absence of a difference between the 2 groups suggests that PA advice might be sufficient to reduce the number of flares and disease activity, and to improve physical performance in patients with SpA. During the period without WAT (12-24 weeks), we observed that the gain in PA was maintained, thus reinforcing the beneficial effect of the instructions.

Our study provides interesting information on the number of flares in patients with SpA. We found more persistent flares in our population than those reported by Gossec et al (80% vs 79% for moderate, 60% vs 21% for persistent flares, for our study and the Gossec et al study, respectively).²⁵ It is possible that the higher number of persistent flares in our study was because of the inclusion of patients with more severe disease, which may partly explain the lack of effect of the WAT. However, the higher rate of NSAID use at baseline in the TG and the higher number of lost to follow-up in the NTG are also indirect markers that might suggest a beneficial effect of trackers. The impact of PA on disease activity is likely to be less pronounced in patients with high disease activity. Indeed, flares may lead to poor outcomes, including low QOL and poor function.^{27,37,38} However, the

feasibility and use of a WAT seem to be easier in patients with better health at baseline.³⁹

For patients with SpA, PA improves QOL.²⁹ Our study confirmed the effect of PA on different SF-36 dimensions, such as physical functioning, role limitations (physical and emotional), and mental health. However, it is also possible that this effect may decrease over time—a trend that was observed in our study—since the general health and bodily pain dimensions were improved only at week 12.

The present study has some limitations. Unfortunately, we did not have an objective measure of PA in our study. Data on PA were collected using the IPAQ-SF self-questionnaire. The IPAQ-SF is an internationally validated self-administered questionnaire that assesses weekly frequency, duration, and type of PA in 3 domains (vigorous, moderate, and walking). Very few patients answered this questionnaire correctly; therefore, analysis of these data could not be performed. However, since a link between increased PA and decreased disease activity has been demonstrated by previous studies,¹⁹ the decreased number of flares that we observed could reflect an increase in PA. Patients in the TG had a pedometer, which may have encouraged them to be more physically active because of the nature of the WAT.

Another limitation of our study is that the number of subjects that needed to be included ($n = 140$) was higher than the number of those actually enrolled ($n = 108$). This could have potentially resulted in a lack of power. Encouraging PA in SpA is difficult, with several important obstacles linked to the disease such as the subjects' availability and motivation.¹² However, it is interesting to note that at 12 weeks, there were fewer dropouts in the TG than in the NTG; thus, WAT use could also be considered as a trigger for the patients to engage in PA.

The high dropout rate seen at 36 weeks is comparable to that seen on other studies on WAT use, in which it appears that patients who dropped out had worse baseline scores for exercise capacity, QOL, and depression as compared to those who completed the study.³⁹ Again, this could be related to the high baseline rate of disease activity presented by the subjects in this study.

To conclude, our study showed no effect of WAT use on disease flares in patients with SpA, whether the PA was unsupervised or supervised by a coach. However, a supervised PA program with or without a WAT could improve physical performance over time and help maintain PA in patients with SpA.

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