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UNIVERSITE CÔTE D'AZUR

ANNEE 2020



THESE D'EXERCICE DE MEDECINE

Pour l'obtention du diplôme d'Etat de Docteur en Médecine

**IMPACT ON DISEASE ACTIVITY OF THE USE OF A WEARABLE
ACTIVITY TRACKER IN SPONDYLOARTHRITIS : A RANDOMIZED
CONTROLLED TRIAL**

Présentée et soutenue le 8 septembre 2021,

A la faculté de Médecine de Nice

Par Guillaume Labat

Né le 11 janvier 1994 à Metz (57)

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Liste des abréviations

WAT : WEARABLE ACTIVITY TRACKER

PA : PHYSICAL ACTIVITY

TG : TRACKER GROUP

NTG : NON-TRACKER GROUP

SPA : SPONDYLARTHRITE

TNF : TUMOR NECROSIS FACTOR

CRP : PROTEINE C REACTIVE

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Introduction

La spondylarthrite et ses traitements (médicamenteux ou non)

La spondylarthrite (SpA) est un rhumatisme inflammatoire chronique fréquent, dont la prévalence en Europe est estimée à 0.54% de la population [1]. L'âge moyen au diagnostic est de 26 ans [2]. Cette pathologie est caractérisée par des rachialgies inflammatoires pouvant conduire à une ankylose rachidienne, responsable d'une réduction de mobilité.

Le pronostic de la SpA a été transformé par l'arrivée des biothérapies, les anti-TNF α , dans les années 2000. Les recommandations actuelles de l'ASAS [3] et de la SFR [4] pour la prise en charge des spondyloarthrites donnent des directives claires pour les thérapies médicamenteuses. En l'absence de traitement efficace, cette pathologie est responsable d'une altération de la qualité de vie, voire d'une diminution de l'espérance de vie [5,6].

Mais, la prise en charge actuelle des SpA ne repose pas uniquement sur une prise en charge médicamenteuse. Les recommandations rappellent également les mesures associées, telles que la physiothérapie ou la médecine thermique. Un programme comprenant de la médecine thermique, de la physiothérapie ou des exercices à domicile a montré son efficacité sur la douleur, la raideur, la mobilité de la colonne vertébrale, la fonction physique et l'évaluation globale du patient [7].

Spondylarthrite et activité physique

L'activité physique est définie par l'Organisation mondiale de la santé comme « tout mouvement corporel produit par les muscles squelettiques nécessitant une dépense d'énergie ». Pour la population générale, il est recommandé d'effectuer 150 minutes par semaine d'activité aérobie d'intensité modérée ou 75 minutes par semaine d'exercice aérobie d'intensité vigoureuse. L'Eular a émis des recommandations pour la promotion de l'activité physique dans le cadre de la prise en charge des rhumatismes [8]. L'activité physique tient une place importante dans la prise en charge de la pathologie [9]. La pratique régulière d'activités physiques ou sportives protège contre les maladies cardio-vasculaires [10]. Le sur-risque cardiovasculaire dans les rhumatismes inflammatoires est maintenant bien connu. En effet, l'inflammation chronique constitue un facteur de risque cardio-vasculaire indépendant. La pratique régulière d'activités physiques ou sportives par des patients atteints de SpA pourrait avoir des bénéfices individuels qui dépassent le simple cadre de l'activité de la maladie [11]. L'inflammation chronique entraîne également une diminution de la masse musculaire [12], probablement dépendante du Tumor Necrosis Factor (TNF) [13]. La pratique régulière

d'activités physiques ou sportives pourrait permettre de lutter contre la perte musculaire notamment en diminuant le taux sanguin de protéine C réactive (CRP), marqueur de l'inflammation [14, 15]. Les patients présentant une SpA ont également une augmentation du risque d'ostéoporose [16], une diminution de la densité minérale osseuse [17] et augmentation du risque de fractures ostéoporotiques [18]. Or, l'activité physique permet un maintien du capital osseux [19]. Les patients souffrant de SpA ont généralement une diminution de la qualité de vie [20]. La pratique régulière d'activités physiques ou sportives pourrait contribuer à l'amélioration des paramètres de qualité de vie. En effet, l'amélioration de l'activité de la maladie et de la qualité de vie pourrait aussi permettre aux patients de garder des activités professionnelles et sociales. Mais encore, le coût des traitements médicamenteux ne cessant de croître dans la prise en charge des rhumatismes inflammatoires chroniques [21], l'ajout d'une activité physique pourrait diminuer leur consommation [22]. De plus, la sédentarité est un problème de santé publique qui n'épargne pas les rhumatismes inflammatoires dont les SpA. Les patients ont parfois des problèmes de surpoids liés à la sédentarité et à la prise de certains médicaments voire à l'arrêt du tabac. La pratique d'activité physique permet une meilleure régulation de son poids. D'ailleurs, une étude a montré une diminution nette de la pratique d'activité physique chez les patients souffrant de SpA en surpoids [23]. En dépit des nombreux bénéfices de l'activité physique pour les patients atteints de SpA, ces derniers sont insuffisamment actifs au regard des recommandations et en comparaison de leurs homologues sains [24]. Les rhumatologues constatent quotidiennement lors de leurs consultations que peu de patients atteints de SpA ont une activité physique régulière malgré leurs conseils [25]. Les principales barrières expliquant ce manque d'engagement dans l'activité physique concernent des limitations physiques (douleur, fatigue, handicap). En revanche, le temps, la motivation, une pratique adaptée et la stabilité de la maladie apparaissent comme des facilitateurs [26]. Une problématique actuelle concerne donc l'adhésion et l'engagement durable dans l'activité physique des patients atteints de SpA, ce qui s'est traduit par différentes propositions de stratégies de promotion et d'intervention. Il faut dans un premier temps que les rhumatologues soient informés des effets bénéfiques de l'activité physique et que ces derniers en fassent la promotion. Le fait que la pratique de l'activité physique soit supervisée est une chose importante car cela permet d'obtenir un gain de motivation. Une méta-analyse récente a mis en lumière que l'efficacité sur l'activité de la maladie d'une activité physique supervisée est supérieure à une activité physique réalisée seul à la maison [27].

Hypothèse de recherche : les objets connectés.

Les outils connectés peuvent être des aides utiles dans la promotion de l'activité physique et renforcer ainsi l'adhérence à cette pratique [28]. En effet, ils suscitent de plus en plus d'intérêt dans le domaine médical ces dernières années et les études les concernant se multiplient dans diverses spécialités, notamment en rhumatologie mais aussi en cardiologie, oncologie, endocrinologie, pneumologie [29, 30, 31, 32].

Par ce projet, nous allons essayer de démontrer qu'utiliser des objets connectés pour effectuer une activité physique peut avoir un impact sur l'activité clinique de la maladie en amenant les sujets qui présentent une SpA à effectuer une activité physique. Nous montrerons de plus, que l'utilisation d'objets connectés a aussi de meilleures chances de faire adhérer les patients présentant une SpA à une pratique d'activité physique régulière qu'une simple recommandation.

Nous avons décidé dans notre étude de montrer que l'utilisation d'objets connectés combinée à l'envoi hebdomadaire de SMS de rappel d'activité visant à garantir le maintien d'une activité physique chez des sujets présentant une spondyloarthrite permet de réduire le nombre de poussées de la maladie à 12 semaines.

RÉFÉRENCES

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ORIGINAL ARTICLE

Title: Impact of a wearable activity tracker on disease activity in spondyloarthritis: A randomized controlled trial

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ABSTRACT

Objective

To evaluate the impact of a wearable activity tracker (WAT) used to encourage physical activity on disease activity in patients with spondylarthritis.

Methods

In this randomized controlled trial consisting of three 12-week steps, patients with spondylarthritis were randomized into a tracker group (TG), or a non-tracker group (NTG). Disease activity, performance (6-Minute Walk Test), and quality of life (SF36) were assessed at 12, 24, and 36 weeks. The primary endpoint was the evolution of flares between baseline and 12 weeks.

Results

Altogether, 108 patients were included in the study. At 12 weeks, both groups presented an improvement in the number of flares mean change (Δ), -0.32 [95% CI -0.66;0.02] in the TG and Δ , -0.38 [95% CI -0.68;60.09] in the NTG, but the between-group evolution differences were not significant ($p = 0.87$). The 6MWT improved in both groups at 12, 24, and 36 weeks ($p < 0.01$, and $p < 0.001$, respectively). We observed an improvement in different dimensions of SF36 at 12 weeks ($p < 0.01$).

Multivariate analysis showed an improvement over time in moderate flares ($p < 0.01$) and performance ($p < 0.01$) without the influence of a WAT ($p = 0.29$, and $p = 0.66$).

Conclusions

Use of a WAT did not show any effect on the number of flares, performance, or quality of life in patients with spondyloarthritis. This study confirmed the benefits of physical activity on disease activity, quality of life, and physical performance in patients with spondyloarthritis.

Keywords: Physical activity; Wearable activity tracker; Spondyloarthritis; Disease activity, flare; Patient-reported outcomes

1. INTRODUCTION

Physical activity (PA) is important in the management of patients with spondyloarthritis [1, 2]. The benefits of PA are multiple; it improves disease control, pain, joint mobility, and quality of life [3 - 5]. Regular PA may contribute to decreased inflammation, as measured by serum C-reactive protein levels [6–8]. Indeed, PA seems crucial in decreasing the number of cardiovascular events in patients with ankylosing spondylitis, whose risk is increased compared to that of the general population [9,10].

Most spondyloarthritis patients do not appear to engage in regular PA, despite specific advice given [11,12]. It seems that they perform less PA than patients who do not have rheumatism [13]. Pain, fatigue, and disability are the main barriers to this lack of involvement in PA, whereas availability, adapted practice, stability of disease, and motivation appear to be facilitators [14].

It is important that PA prescription and adherence to a PA program is evaluated [15]. Therefore, many innovative health promotion and intervention strategies have been proposed [16, 17]. Among these, the latest studies have focused on new technologies [18]. Indeed, adherence to a PA program and motivation could be promoted by tools such as connected applications and devices [19]. Monitoring PA through a connected device appears to be accessible and acceptable by patients suffering from chronic inflammatory rheumatism [20]. In fact, the use of a wearable activity tracker (WAT) combined with PA advice has been studied in other chronic rheumatological diseases and may increase PA [21,22]. Frequent remote patient monitoring could lead to early identification of disease flares, early intervention for patients requiring

treatment adaptation, or reduction in appointment frequency for stable patients [23]. It could become a useful tool to monitor flares and disease activity in patients suffering from chronic inflammatory rheumatism [18, 20]. Furthermore, monitoring PA through a connected WAT is linked to identifying disease flares [24]. The assessment of these flares is important in clinical practice to understand more clearly disease status and treatment efficacy [25]. Spondylarthritis is characterized by alternating periods of flares and stable disease activity [26]. The presence of persistent flares is useful for identifying patients with severe disease activity [27].

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 spondyloarthritis and to assess longitudinally the effect of a WAT on performance and quality of life.

2. METHODS

2.1 Study design

We conducted an interventional, single-center, randomized, open-label controlled clinical trial at NICE University hospital. The patients were randomized into a tracker group (TG) wearing a tracker or a free-of-tracker group (NTG) (Figure 1).

2.2 Subjects

We included inpatients or outpatients recruited from the Rheumatology Department of Nice University Hospital, between February and May 2018.

Individuals were eligible if they were over 18 years of age, understood the objectives and constraints of the study, had a diagnosis of spondylarthritis according to the Assessment of SpondyloArthritis International Society criteria, lived in Nice or the surrounding 20 km, and

they were certified as having no contraindication to the practice of a sports activity 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, those who were unable to attend the activity venue, if they were already undergoing supervised PA in a club or with a sports coach, and were pregnant or breastfeeding. Exclusion criteria during the study were serious adverse events, withdrawal of consent, and protocol violation. All patients provided written informed consent for participation in the study. 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).

2.3 Data collection

2.3.1 Medical data

Patient characteristics collected at baseline included: sex, age, weight, height, ongoing pharmacological treatment (including non-steroidal anti-inflammatory drugs, disease-modifying anti-rheumatic drugs, and biologics), and comorbidities using the Charlson Comorbidity Index (0 = no comorbidity; ≥ 1 one or more comorbidities) [28].

2.3.2 Patient-reported outcomes

The number of flares in the last seven days was evaluated at the end of each 12-week step. The primary outcome was the number of flares that evolved between baseline and week 12. The presence and duration of flares were reported each week by patients in a notebook. They provided information on the duration of each flare and flares were categorized into moderate (less than 3 days) and severe (more than 3 days).

For assessment of disease activity, we collected information on the number of flares and the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) by self-evaluation, whereas performance was assessed by the 6-Minute Walk Test (6 MWT) and evaluated by a physiotherapist [29].

Quality of life was evaluated using the Short Form 36 Health Survey Questionnaire (SF36) and the personality of patients using the Big Five test [30,31]. Levels of PA were evaluated using the International Physical Activity Questionnaire (IPAQ) [32].

The patient-reported outcome questionnaires (IPAQ, SF36) were completed at baseline and at 12, 24, and 36 weeks during their sessions at the center.

2.3.3 Physical activity measurement

All patients were given instructions at baseline on the practice of PA and were free to practice a PA of their choice. We asked them to schedule two weekly sessions of PA. The participants were randomized to the tracker group (TG) or to the non-tracker group (NTG) in a 1:1 allocation ratio. Patients in the TG were monitored by a WAT: a bracelet (Garmin Vívofit 4) combined with weekly sending of activity reminder SMS messages. Patients in the NTG group did not receive a WAT. At the end of the 12th week, the WAT was removed from the 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 one hour per week of coach-supervised PA, in addition to the two weekly sessions organized independently. At the end of the 36-week period the patients in the TG returned their WAT to the study organizers.

Physical performance was assessed using the 6 MWT and the IPAQ questionnaire at baseline and at 12, 24, and 36 weeks.

2.3.4 Statistical analysis

In univariate analysis, categorical variables were compared using the chi-square test or Fisher test, and continuous variables were compared using Student's t-test or Wilcoxon's non-parametric test for independent group comparisons. We used the paired Student's t-test or Wilcoxon's S-rank test to compare the evolution of the outcomes of interest between baseline and 12, 24, and 36 weeks for each group.

For 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, 12 weeks, 24 weeks, and 36 weeks) and intercept random effects for patients. Sex, age, and the wearing of the WAT, were also included as covariates (fixed effect).

We performed an intent-to-treat analysis.

2.3.5 Sample size estimate

With a sample size of 118 (59 per group) and an alpha level of 0.05, we would have 90% power to detect a 60% decrease in the number of flares. We estimated the percentage of patients with questions unanswered at 15%. Therefore, 70 patients were required per group for a total of 140 patients.

2.3.6. Role of the funding source

The study was supported by a grant from Novartis and Pfizer. They have no involvement in study design, in the collection, analysis and interpretation of data; in the writing of the report; and in the decision to submit the article for publication.

3. RESULTS

Between February and May 2018, 108 patients were included in the study. Among them, 55 patients were randomized to the TG and 53 patients to the NTG. 22 patients were lost to follow up at 12 weeks, 8 (14.6%) patients in the TG, and 14 (26.4%) in the NTG ; 45 patients were lost to follow up at 24 weeks, 18 (32.7%) patients in the TG, and 27 (50.9%) in the NTG ; 52 patients were lost to follow up at 36 weeks, 23 (41.8%) in the TG and 29 (54.7%) in the NTG.

The baseline characteristics of the population were well balanced across both groups (Table 1). Of note, the mean (\pm standard deviation [SD]) number of flares was 0.7 ± 1.1 in the TG and 0.5 ± 0.8 , with no significant difference between the groups ($P = 0.12$). The mean (SD) number of severe flares was 0.6 ± 1.3 in the TG and 0.5 ± 0.8 in the NTG, with no significant difference between the two groups ($P = 0.61$).

3.1 Evolution of flares between baseline and 12 weeks

We found no differences in the number of moderate and persistent flares that evolved between baseline and week 12 between the two groups ($P = 0.87$, moderate flares; $P = 0.80$ for severe flares).

The mean number of moderate and persistent flares decreased in both groups; Δ (difference between endpoint and baseline) -0.32 [95% confidence interval (CI) $-0.66, 0.02$] ($P = 0.09$) for moderate flares and $\Delta, -0.30$ [95% CI $-0.70, 0.10$] ($P = 0.24$) for persistent flares in the TG, and $\Delta, -0.38$ [95% CI $-0.68, -0.09$] ($P = 0.02$) for moderate flares and $\Delta, -0.08$ [95% CI $-0.33, 0.17$] ($P = 0.68$) for persistent flares in the NTG. (Table 2)

3.2 Evolution of BASDAI, 6 MWT at 12 weeks

We found a non-significant decrease in BASDAI in the two groups between baseline and week 12, without significant differences between the two groups ($P = 0.58$). (Table 2) We found a significant increase in 6 MWT in the two groups between baseline and week 12, without differences between the two groups ($P = 0.22$). (Table 2)

3.3 Evolution of flares, BASDAI, 6 MWT at 24 weeks

We found no differences in moderate and persistent flare evolution between baseline and week 24 between the two groups ($P = 0.81$, moderate flares; $P = 0.18$, severe flares). (Table 3). The same was observed in the BASDAI evolution ($P = 0.39$). (Table 3) We found a significant increase in 6 MWT in the two groups between baseline and week 24, without differences between the two groups ($P = 0.72$). (Table 3)

3.4 Evolution of flares, BASDAI, 6 MWT at 36 weeks

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

3.5 Confounding factors on flare progression, physical performance, and BASDAI at 12, 24, and 36 weeks

Multivariate analysis showed a significant time effect on the number of flares ($P < 0.01$). (Table 5) From baseline to 12 weeks, there was a decrease in the number of flares Δ , -0.34 [95% CI $-0.54, -0.13$]. This time effect was also observed in the 6 MWT with a linear increase in performance of 157.1 meters between 36 weeks and baseline [95% CI 138.1, 176.2] ($P < 0.01$).

Concerning the 6 MWT, we also noticed a significant age effect ($P = 0.03$). There was a significant effect of sex on the number of flares and BASDAI scores ($P = 0.03$, $P < 0.01$, respectively). We did not find a significant effect of the activity tracker on moderate flares ($P = 0.66$), persistent flares ($P = 0.42$), BASDAI ($P = 0.11$), or 6 MWT ($P = 0.28$).

3.6 SF-36 score

We observed an improvement in different dimensions of SF36, mainly in physical functioning ($P < 0.01$, $P < 0.01$, $P = 0.06$), role physical ($P = 0.06$, $P = 0.03$, $P < 0.01$), role emotional ($P < 0.01$, $P < 0.01$, $P = 0.03$), mental health ($P = 0.03$, $P < 0.01$, $P = 0.01$) at 12, 24, and 36 weeks, respectively and general health ($P < 0.01$) and bodily pain ($P < 0.01$) at 12 weeks. No differences were observed in the between-group comparison at different times (Appendix, Figure S1).

4. DISCUSSION

We did not show the ability of an activity tracker to improve disease activity in patients with spondyloarthritis. Given the importance of PA in the management of spondyloarthritis, 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 impact of WAT use on disease activity in spondyloarthritis.

In the ActConnect study, which investigated the use of a connected device in a population with rheumatoid arthritis and spondyloarthritis, the authors showed that a WAT had the ability to measure disease activity through the assessment of PA [18]. In addition, the link between PA and disease activity was observed longitudinally. Other studies have shown the ability of a WAT to improve PA in different rheumatic diseases [21,22]. Thus, we would have expected

that a WAT would have improved disease activity in spondyloarthritis given the importance, as described in the literature, of PA in this disease [1, 2].

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 spondylorathritis [24, 35]. Our results were consistent with these findings. We showed a non significant improvement in disease activity as measured by flares and BASDAI in both groups. These improvements seems 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 initial information encouraging them to engage in PA. In recent rheumatology studies, an increase in PA was found in groups wearing activity trackers, particularly in patients with knee osteoarthritis, rheumatoid arthritis, or systemic lupus erythematosus [21,22]. 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 with patients who did not receive these aids. Indeed, the benefits attributed to the WAT are inseparable from the physical therapy and PA advice that accompanies them. Thus, the impact 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 on their disease. It is possible that the influence of the WAT alone is insufficient to make a difference in disease activity.

There was an improvement in physical performance in both the wearable tracker and non-wearable tracker groups. Moreover, we observed an even greater 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 one hour per week of PA supervised by a coach, in addition to the two weekly sessions organized independently. These results appear to be consistent with a

recent meta-analysis that found that short-term supervised exercise programs may be more effective than home-based exercises in decreasing disease activity in patients with spondyloarthritis [33]. The absence of a difference between the two groups suggests that PA advice might be sufficient to reduce the number of flares, reduce disease activity, and improve physical performance in patients with spondyloarthritis.

Our study provides interesting information on the number of flares in patients with spondyloarthritis. We found more persistent flares in our population than those reported by Gossec et al. in their studies (80% versus 79 for moderate, 60% versus 21% for persistent flares ; for our study and the Gossec et al. study, respectively). It is possible that the higher number of persistent flares in our study was due to patients with more severe disease and is part of the reason for the lack of effect of the WAT. The impact of PA on disease activity is likely to be less in patients with high disease activity. Indeed, flares may lead to poor outcomes, including low quality of life and poor function [26, 37 ,38]. However, the feasibility and use of a WAT seems to be easier in patients with better baseline health [39].

For patients with spondyloarthritis, PA improves quality of life [40], and our study confirmed the effect of PA on different SF36 dimensions, such as physical functioning, role physical, role emotional, and mental health. However, it is possible that the effect decreases over time, which seems to be observed in our study, since the general health and bodily pain dimensions were only improved at 12 weeks.

Unfortunately, we did not have an objective measure of PA in our study. Data on PA were collected using the IPAQ self-questionnaire. The IPAQ is an internationally validated self-administered questionnaire that assesses weekly frequency, duration, and type of PA in three

domains (vigorous, moderate, and walking). Very few patients answered this questionnaire correctly, so 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 [18], the decreased number of flares during we observed could reflect an increase in PA.

Another limitation of our study is that the number of subjects that needed to be included (n = 140) was lower than expected (n = 108), which probably resulted in a lack of power. Encouraging PA in spondyloarthritis is difficult with several important obstacles linked to the disease, the time available in these active subjects, and motivational aspects [11]. 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 be a trigger for the patient to engage in PA.

The high dropout rate at 36 weeks is comparable to other studies of WAT use, in which it appears that patients who dropped out had worse baseline scores on exercise capacity, quality of life, and depression compared with those who completed the study [39]. This could be an explanation given that in our study, patients had high disease activity at baseline.

Our study showed no effect of WAT use on disease activity in patients with spondyloarthritis, whether the PA was free 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 spondyloarthritis.

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Table 1. Characteristics of the baseline population

	Total population	TG	NTG	P
	n = 108	n = 55	n = 53	
Age, mean (SD)	51.5 (+/- 13.8)	52.3 (+/- 13.6)	50.7 (+/- 14)	0.55
Women, n (%)	76 (70.4)	40 (72.7)	36 (67.9)	0.58
BMI, mean (SD)	25.2 (+/- 4.8)	25 (+/- 4.9)	25.4 (+/- 4.7)	0.61
Charlson Comorbidity Index = 0, n (%)	81 (77.9)	43 (79.6)	38 (76)	0.41
NSAIDs, n (%)	47 (51.7)	10 (11)	3 (3.3)	0.05
Biological therapy, n (%)	62 (68.1)	24 (52.2)	38 (84.4)	0.01
DMARDs, n (%)	11 (12.4)	8 (9)	3 (3.4)	0.14
BASDAI, mean (SD)	4.6 (+/- 2.3)	4.4 (+/- 2.4)	4.3 (+/- 2.1)	0.37
TM6, mean (SD)	415.6 (+/- 51.5)	420.5 (+/- 52)	410.4 (+/- 51)	0.31
Number of flares				
1-3 day flares, mean (SD)	0.8 (+/- 1.2)	0.7 (+/- 1.1)	0.5 (+/- 0.8)	0.12
>3 day flares, mean (SD)	0.6 (+/- 1.1)	0.6 (+/- 1.3)	0.5 (+/- 0.8)	0.61

Abbreviations: TG, tracker group; NTG free-of-tracker group; SD, standard deviation; NSAIDs, non-steroidal anti-inflammatory drugs; DMARDs, disease-modifying antirheumatic drugs; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; TM6

Table 2: Comparison of the evolution of patient-reported flares, BASDAI, and 6 MWT between baseline and week 12

	Tracker group (TG)				Non-tracker group (NTG)				P+	
	Baseline (SD)	Week 12 (SD)	Δ (95% CI)	P*	Baseline (SD)	Week 12 (SD)	Δ (95% CI)	P*		
1-3 day flares, mean (SD)	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, mean (SD)	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, mean (SD)	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	
6 MWT, mean (SD)	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	

P*: comparison between baseline and week 12

P+: comparison between two groups at week 12

Abbreviations: SD, standard deviation; CI, confidence interval; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; 6 MWT, 6-Minute Walk Test

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

	Tracker group (TG)				Non-tracker group (NTG)				P+	
	Baseline (SD)	Week 24 (SD)	Δ (95%CI)	P*	Baseline (SD)	Week 24 (SD)	Δ (95% CI)	P*		
1-3 day flares, mean (SD)	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, mean (SD)	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, mean (SD)	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	
6 MWT, mean (SD)	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	

P*: comparison between baseline and week 24

P+: comparison between two groups at week 24

Abbreviations: SD, standard deviation; CI, confidence interval; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; 6 MWT, 6-Minute Walk Test

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

	Tracker group (TG)				Non-tracker group (NTG)				P+
	Baseline (SD)	Week 36 (SD)	Δ (95% CI)	P*	Baseline (SD)	Week 36 (SD)	Δ (95% CI)	P*	
1-3 day flares, mean (SD)	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, mean (SD)	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, mean (SD)	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
6 MWT, mean (SD)	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

P*: comparison between baseline and week 36

P+: comparison between two groups at week 36

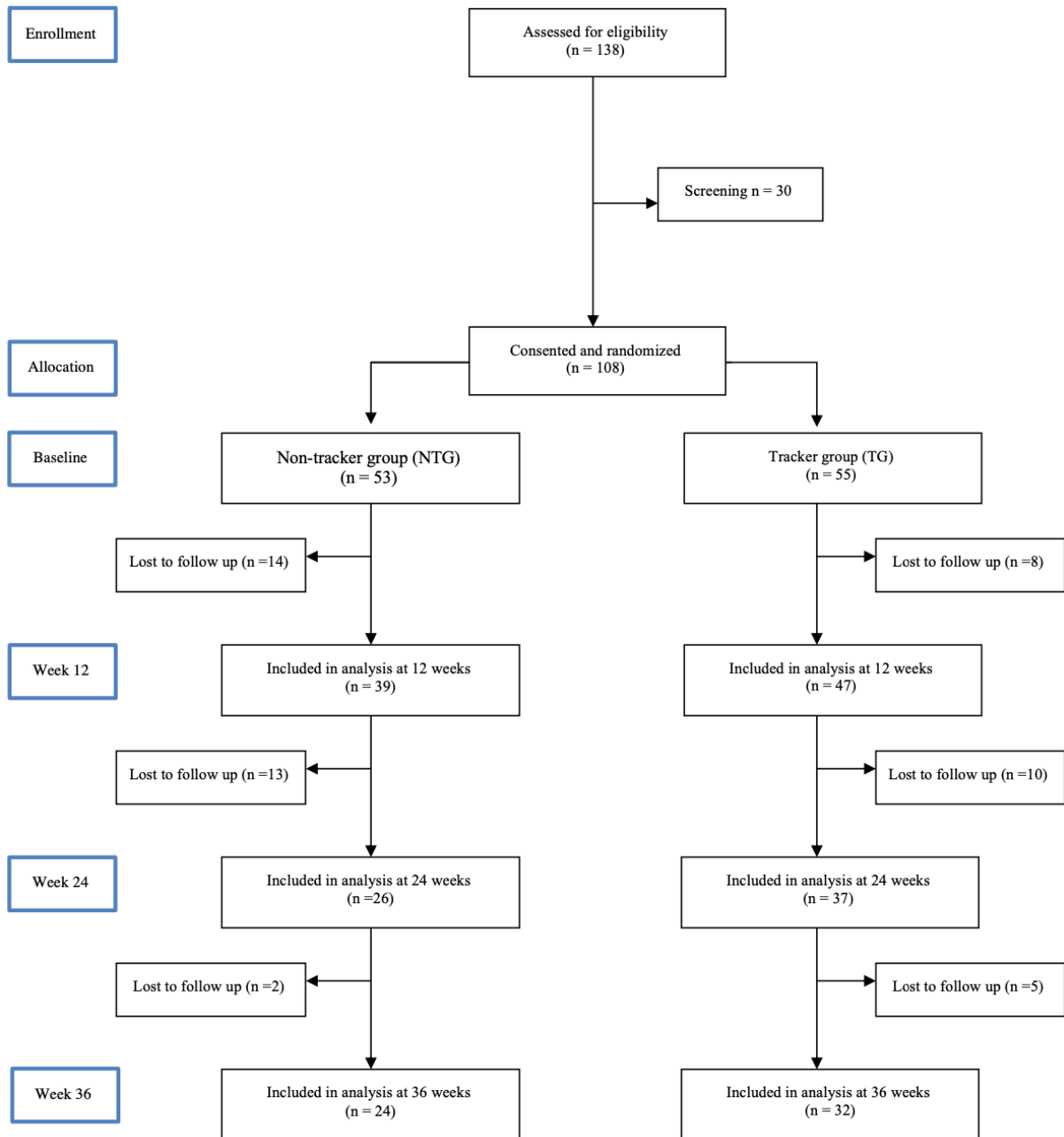
Abbreviations: SD, standard deviation; CI, confidence interval; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; 6 MWT, 6-Minute Walk Test

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

	1-3 day flares	>3 day flares	BASDAI	6 MWT
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 (P)	<0.01	0.32	0.08	<0.01
Sex effect (P)	0.03	0.76	<0.01	0.07
Age effect (P)	0.12	0.84	0.15	0.03
Tracker effect (P)	0.66	0.42	0.11	0.29
Coefficient estimation and 95% CI in linear mixed model				
12 weeks vs baseline	-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 vs baseline	-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 vs baseline	0.10 (-0.29 / 0.48)	-0.22 (-0.47 / 0.03)	-0.49 (-0.96 / -0.02)	157.1 (138.1 / 176.2)

Abbreviations: BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; 6 MWT, 6-Minute Walk Test; CI, confidence interval

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) flowchart



Serment d'Hippocrate

Au moment d'être admis(e) à exercer la médecine, je promets et je jure d'être fidèle aux lois de l'honneur et de la probité.

Mon premier souci sera de rétablir, de préserver ou de promouvoir la santé dans tous ses éléments, physiques et mentaux, individuels et sociaux.

Je respecterai toutes les personnes, leur autonomie et leur volonté, sans aucune discrimination selon leur état ou leurs convictions.

J'interviendrai pour les protéger si elles sont affaiblies, vulnérables ou menacées dans leur intégrité ou leur dignité.

Même sous la contrainte, je ne ferai pas usage de mes connaissances contre les lois de l'humanité.

J'informerai les patients des décisions envisagées, de leurs raisons et de leurs conséquences.

Je ne tromperai jamais leur confiance et n'exploiterai pas le pouvoir hérité des circonstances pour forcer les consciences.

Je donnerai mes soins à l'indigent et à quiconque me les demandera. Je ne me laisserai pas influencer par la soif du gain ou la recherche de la gloire.

Admis(e) dans l'intimité des personnes, je tairai les secrets qui me seront confiés. Reçu(e) à l'intérieur des maisons, je respecterai les secrets des foyers et ma conduite ne servira pas à corrompre les mœurs.

Je ferai tout pour soulager les souffrances. Je ne prolongerai pas abusivement les agonies. Je ne provoquerai jamais la mort délibérément.

Je préserverai l'indépendance nécessaire à l'accomplissement de ma mission. Je n'entreprendrai rien qui dépasse mes compétences. Je les entretiendrai et les perfectionnerai pour assurer au mieux les services qui me seront demandés.

J'apporterai mon aide à mes confrères ainsi qu'à leurs familles dans l'adversité.

Que les hommes et mes confrères m'accordent leur estime si je suis fidèle à mes promesses ; que je sois déshonoré(e) et méprisé(e) si j'y manque.