The Effects of Custom-made Foot Orthoses on Foot Pain, Foot Function, Gait Function and Freeliving Walking Activities in Psoriatic Arthritis (PsA) Patients: a Pre-experimental Trial

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Research Article

Keywords: Psoriatic arthritis, custom foot orthoses, foot pain, foot function, spatiotemporal parameters, Freeliving walking activities

Posted Date: November 30th, 2021

DOI: https://doi.org/10.21203/rs.3.rs-978469/v1

Abstract

Introduction: Foot involvement is a major concern in psoriatic arthritis (PsA) as it can lead to severe levels of foot pain and disability as well as reduced mobility and quality of life. Previous studies have shown moderate efficacy in reducing foot pain and disability in rheumatoid arthritis patients with the use of custom-made foot orthoses (CFO). However, evidence on the efficacy of CFO in PsA patients is lacking.

Objectives: Explore the effects of CFO on foot function, foot and lower limb pain, gait function, and freeliving walking activities (FWA) in PsA patients.

Methods: A Pre-experimental study including 20 PsA patients (mean age: 54.10 ± 9.06 y and disease duration: 11.53 ± 10.22 y), was conducted. All the participants received and wore CFO for a 7-week period. Foot and lower limb pain and foot function were measured before and after the intervention using the numerical rating scale (NRS) and the foot function index (FFI). Gait function was assessed from gait spatiotemporal parameters (STPs) extracted during a 10-meter walk test with an gait analysis system (Mobility Lab). Freeliving walking activities (step count, freeliving cadence, time spent in different ambulatory physical activities (APA)) were recorded over 7 days using accelerometer data collected from an instrumented sock worn during waking hours.

Results: PsA patients reported severe baseline levels of foot pain (54.46 ± 14.58 %) and disability (46.65 ± 16.14%) on the FFI. Statistically and clinically significant improvements with large effect sizes (Cohen's effect size > 1, $p<0.005$) in foot pain and foot function were observed after 7 weeks of CFO use. A significant correlation ($r=-0.64$, $p<0.01$) between CFO wear time after the adaption period and foot function on the FFI at 7 weeks was observed. However, no significant changes were demonstrated for gait STP nor for free-living walking activities after 7 weeks of CFO use.

Conclusion: Results support the clinical and biomechanical plausibility of using CFO with PsA patients to reduce pain and improve foot function. Larger and controlled studies are needed to confirm these findings and a multidisciplinary approach including the prescription of exercise therapy and physiotherapy in combination with CFO could be relevant to improve STP and promote APA in PsA patients.

Study registration: ClinicalTrials.gov, NCT05075343, Retrospectively registered on 29 September 2021.

Background

Psoriatic arthritis (PsA) is a chronic inflammatory arthropathy and a complex disease that frequently associates skin psoriasis, musculoskeletal manifestations including axial and/or peripheral arthritis, and several comorbidities such as cardiovascular disease, diabetes and obesity [1]. Foot and ankle problems are very common in PsA and are sometimes the first and most important musculoskeletal manifestation of the disease [2]. Several inflammatory features can be observed in the foot and ankle such as toe dactylitis, also known as sausage-like toes [3], as well as enthesitis of the Achille's tendon and the plantar fascia [4, 5]. Synovitis is also commonly observed at the metatarsophalangeal and distal interphalangeal

joints [6, 7], whereas tenosynovitis affects most commonly the tibialis posterior, common peroneal sheath, and at the ankle, the long flexor tendons of flexor digitorum longus and flexor hallucis longus [2, 7]. All foot compartments can consequently be affected by PsA causing pain, swelling, stiffness, tenderness, and in later stages, deformities leading to severe foot disability, reduced mobility and quality of life [2, 8, 9, 10].

Quantitative gait analysis including spatiotemporal, kinematic, and kinetic parameters assessment, has been proven useful in the evaluation of gait function, disease progression and/or a given intervention's effect on patients' mobility [11, 12]. Gait spatiotemporal parameters (STP) in particular, are key metrics in gait function evaluation [13] and are associated with gait adaptations in patients with inflammatory arthritis [14]. Instrumented gait analysis studies in PsA patients demonstrated gait STP impairments, including reduced cadence, gait speed, stride length, and increased double support time, indicating impaired gait function and ultimately implying difficulties in walking activities [15–17].

Walking activities however, involve moving in diverse situations and environments (e.g. the patient's usual environment). A major part of daily living activities including transport/commuting, recreation, and domestic/occupational activities depend mostly on walking. Walking is also the most practical, accessible, and prevalent form of physical activity (PA) and it is the most frequently prescribed activity to meet the recommendations of the international guidelines for PA [18, 19, 20]. Inherently, gait and walking are closely intertwined. For instance, a reduced gait speed is a significant predictor of decreased daily walking activity and it could therefore have major daily life and PA impacts [21, 22]. The impact of PA and walking on health outcomes is well established [23, 24]. It has also been reported that PA may be beneficial on disease activity, muscle strength, fatigue, pain, and quality of life in PsA patients [25]. However, a recent systematic review demonstrated low PA levels in PsA patients, which could be detrimental on PsA associated comorbidities (i.e. cardiovascular health) and on the disease per se [25]. Importantly, a close relationship between foot pain and gait function defeciencies has been demonstrated [28, 29]. This suggests that interventions aiming at improving foot pain and function could eventually improve gait function and consequently promote walking activity and overall PA in PsA patients.

PsA management is mainly based on pharmacological treatments including disease-modifying antirheumatic drugs (DMARDs), Janus Kinase inhibitors (JAKi) and biological therapies which have been proven efficient on symptoms control and disease activity reduction [30–32]. Remarkably, inflammation and foot pain as well as the related disability can still be observed in a large proportion of patients on pharmacological therapy [15, 17][33–35]. From a physiopathological perspective, mechanical stress and trauma have been suggested as joints and soft tissues inflammation triggers in PsA [36–38]. This could partly explain the high prevalence and persistence of foot and ankle problems, considering the weight bearing function and the continuous mechanical stress applied to the foot during daily living activities [39]. In this context, experts stress out the need for targeted therapies addressing biomechanical abnormalities in the foot to reduce mechanically triggered inflammation and pain in PsA patients with persistent foot problems.

Among such therapies, custom foot orthoses (CFO) are medical devices designed specfically to correct the foot position, realign the lower limb articulations, redistribute pressures, and offload painful structures [40]. CFO are common practice in patients with foot problems associated to rheumatic diseases. In patients with rheumatoid arthritis (RA), a disease characterized by high prevalence and severity of foot problems similar to those reported in PsA, the use of CFO showed positive effects on foot pain and disability [41–46]. However, to our knowledge, there are no records in the literature on the efficacy of CFO in PsA patients. In addition, despite the similarities of foot problems, RA and PsA are different entities with different clinical presentations making direct extension of results from RA to PsA inadequate [47]. Therefore, the primary objective of this study is to explore the effects of a 7-week CFO use period on foot function in PsA patients. The secondary objectives are to explore the effects of CFO on foot pain, the relationship between the CFO wearing time and foot pain and function, and the effects of CFO on gait function (STP) and free-living walking activities (FWA) in PsA patients.

Methods

Study design and participants

A pre-experimental study with pre-test/post-test design was conducted. Twenty-two PsA patients were recruited from the rheumatology out-patient clinics at the *Université de Sherbrooke Hotel Dieu* University Hospital (CHUS). Inclusion criteria were: between 20 and 70 years of age, a confirmed diagnosis of PsA by a trained rheumatologist, moderate to severe and recurrent foot pain and stable medication over three months preceding the recruitment. Patients with diabetes, neurological disease or any musculoskeletal disease that could impact the normal gait pattern, who received an intra-articular corticosteroid injection or any conservative foot treatment such as foot orthoses/footwear intervention within the past three months were excluded. The study was approved by the CIUSSS de l'Estrie-CHUS Ethics Board, and all the participants gave their informed consent prior to data collection.

Data collection procedure

Demographic and baseline characteristics were assessed on a first data collection session (T1) at Sherbrooke's Research Center on Aging. Foot and lower limb pain, global pain, and foot function were then measured using self-reported questionnaires. Afterwards, participants were fitted with inertial measurement units (IMUs) and performed a 10 meters gait test at a self-selected speed. Participants were then examined by a podiatrist who performed foot casts and designed the CFO. At the CFO delivery visit (T2), the participants' foot and lower limb pain, and foot function were evaluated for a second time. This second pre-intervention measurement was planned considering the T1 - T2 delay as well as the fluctuating nature of PsA patients' pain. CFO were then dispensed and adjusted if necessary, to improve fit and comfort. The participants were then directed to wear the CFO for a 7-week period. They were provided with a diary to record daily CFO wearing time, weekly foot pain intensity and any changes in medication during the intervention period. At a final follow up visit at the end of the 7-week period (T7), foot and lower limb pain and foot function were re-assessed and the instrumented 10 meters gait test was repeated. Free walking activities (FWA) were recorded over seven consecutive days before the CFO

first use, and after the seven-week intervention period using an instrumented sock (inertial sensors module positioned at the ankle and embedded in a sock) worn daily during waking hours by the participants.

Intervention

Functional foot orthoses were custom-made for each participant. The CFO were designed by the same experienced podiatrist (GBC) based on a detailed clinical and biomechanical assessment. Foot scans were obtained with the Occipital Structure Sensor 3D scanner (Occipital Inc), the patient in a prone position while the subtalar joint was held in a neutral position. The obtained scan was edited and smoothed using the MSoft software (Techmed3d Inc, Levis, QC, Canada). The prescriptions/corrections were defined by the podiatrist before manufacturing. Three-quarter length CFO were 3D printed in a rigid material (Nylon) using a MultiJet Fusion 3D printer (HP, Palo Alto, CA, USA). The thickness of the CFO ranged between 2 and 3.4 mm depending on the participants' medial arch weight and height. Most of the orthoses included a medial arch support, a heel stabilizer and a metatarsal pad. The degrees and types of corrections added to the CFO were determined specifically for each participant based on the clinical examination and were adjusted at the CFO delivery according to each patient's comfort and tolerance. The participants were taught to wear the CFO progressively during the first two weeks to allow for the lower limbs' muscles and structures to adjust to the CFO, and to wear the orthoses for the next 5 weeks, 7 days a week as often as they could. To document adherence to the CFO, all the participants completed a diary to report the daily wearing time in hours. In addition, the participants were advised to wear the CFO with adapted shoes after the general characteristics (e.g. heel height, malleability of the sole etc.) of such shoes were explained.

Outcomes measures

Sociodemographic, baseline characteristics and control variables: Sex, age, body mass index, professional occupation, and previous history of foot injuries were assessed using a self-reported questionnaire. Disease duration and C-reactive protein levels (CRP) at baseline were obtained from the patients' medical records. Foot type, foot deformities and foot pain sites were obtained from the podiatrist clinical examination records. Changes in medication that occurred during the CFO intervention period were recorded by the participant in a diary.

Foot function: Foot function was measured using the Foot function index (FFI). The FFI is a valid, reliable and responsive self-reported questionnaire widely used in studies of foot and ankle disorders previously used to evaluate CFO effects on foot function [48, 49]. The FFI is composed of 23 items divided into three subscales measuring foot pain (FFI-P), foot disability (FFI-D) and foot-related activity limitation (FFI-AL). Each item of the FFI is recorded on a 0 to 10 numeric rating scale (NRS) allowing for subscale and total scores calculation. A sub-scale score is obtained by totaling the sub-scale items' scores and dividing the total by the sub-scale maximum possible total [48]. The total score is obtained by adding all subscales final percentages and dividing by the total number of subscales. The values reported are presented as percentages ranging between 0 and 100 %, with higher values indicating greater pain, disability, and

activity limitation. The minimal clinically important difference (MCID) for the FFI total score was found to be 7 points in patients with plantar fasciitis [50].

Foot pain: The intensity of foot pain was measured using a zero-to-ten NRS considered a valid, reliable, and responsive tool for pain intensity assessment [51]. The MCID for patients with chronic pain is a 2 points change [52]. Participants were asked to circle the number between 0 and 10 that better matched their average foot pain intensity in the seven days preceding data collection. Foot pain was assessed more in detail (e.g. pain walking with foot orthoses, pain walking with shoes, pain at the end of the day etc.) with the FFI pain sub-scale. To monitor the evolution of weekly foot pain intensity during the intervention period, the patients were asked to record it at the end of each week, in a diary using 0 to 10 NRS. Foot pain and foot function were measured at three time points, at first data collection (T1), at CFO delivery (T2), and after the 7-week intervention period (T7). As there were no statistical differences in the FFI and NRS scores between T1 and T2, the average of these two time points was used as a baseline measure while the last time point (T7) represented the final measure.

CFO wearing time: CFO wearing time was assessed by asking the participants to record it in hours in a diary covering the 7-week intervention period. The CFO wearing time is reported as the average reported time per week.

Global and Lower limb pain: Global pain and pain at the knee, hip, and lower back pain, were measured at T1, T2 and T7 using the NRS (0, no pain – 10, worst imaginable pain). Similarly to foot pain and foot function, data obtained during the first two time points was used as baseline.

Gait function: Gait function was assessed using an instrumented gait analysis system. Gait spatiotemporal parameters (STPs) including cadence, gait cycle duration, gait speed, stride length, double support, swing time, foot strike angle, and stride time variability, were recorded using the Mobility Lab system (APDM Wearable Technologies) during 10 meters walk test (10MWT). Mobility Lab is a research grade system proven to accurately and reliably estimate STP [53–55]. Mobility Lab uses a set of six OPAL inertial measurement units (IMUs) and a software that allows for an automated and easy extraction of STP. All the participants performed three 10MWT trials over a 14-meters straight walkway with the Mobility lab's IMUs fixed with elastics straps on the chest, the lower back, both wrists and feet. The 10MWT trials were performed at the participants' comfortable speed and the average of the three trials was calculated.

Freeliving walking activities (FWA): FWA including step count, freeliving cadence, and time spent in ambulatory physical activity (APA) intensity-based categories were measured using an instrumented sock (Sensoria Inc, Redmond, WA, USA) with an embedded 9 axis IMU positioned at the ankle. The instrumented sock connects automatically, without any manipulation needed from the participants, via Bluetooth to a smartwatch (Apple Watch, series 3) where the raw inertial measures of motion (3D accelerometer) are stored and then transferred for data reduction and processing to extract walking activities specific outcomes (see Additional file for signal processing and steps identification description). Step count was assessed as the total number of steps per day. Besides, to describe the steps

accumulation pattern throughout the day, the number of steps was also assessed for each of the following active events' categories determined based on the number of consecutive steps within each category: 0 to 20 steps, 20 to 60 steps, 60 to 120 steps, 120 to 300 steps, 300 to 600 steps, and more than 600 steps. Free-living cadence included cadence averaged for total wearing time (mean cadence/day). Moreover, as cadence may vary depending on the number of consecutive steps performed, it was also assessed for each of the above active events' categories. APA intensity-based categories were determined using cadence data and included stepping activities (0 to 59 steps/min), slow walking (60 to 79 step/min), medium walking (80 to 99 step/min), moderate intensity APA (MAPA) (100 to 119 step/min) and vigorous APA (VAPA) (> 120 step/min), as previously defined [56, 57]. The time spent in each of the last three categories was calculated only for more than 60 steps events referred to as purposeful walking. Free-living walking activities were assessed over a 7 consecutive days period before and after the intervention during which, the participants were instructed to wear the instrumented sock during waking hours while they perform daily activities. Only valid days defined as days with at least 8 hours of recordings, and only valid participants with a minimum of one valid day were included in the analyses. Adherence to the instrumented sock use was tested by the system itself and by asking the participants to record the daily wearing time in a diary. To avoid influencing the participant's physical activity, they were only told that the study would assess the effects of CFO on foot pain, foot function and gait STP.

Sample size and statistical analysis

Given the exploratory nature of this study, the sample size was calculated assuming a large effect size (0.8) for the pre-post differences in the FFI total score. Using a two tailed paired T-test, a significance level α of 5%, a power of 90%, and assuming a 15% dropout rate, a total sample size of 22 participants was required. The Shapiro-Wilk test was used to examine data distribution and parametric and non parametric statictical tests were used depending on data distribution. Paired t-tests (or the Wilcoxon signed-rank test) were used to assess the differences in foot pain, foot function, global and lower limb pain between baseline and T7 and Cohen's effect size was calculated to quantify the magnitude of these differences. A one-way repeated measures ANOVA was conducted to determine whether there was a statistically significant difference in weekly recorded foot pain intensity and CFO wearing time over the 7-week intervention period. Spearman correlation coefficients were calculated to assess the relationships between the CFO wearing time, foot pain and foot function at T7. As a two-week adaptation period was required, correlation analyses were performed using the average CFO wearing time per week calculated for the last 5 weeks of the intervention period. Correlation coefficients were considered weak, moderate, and strong for values between 0.1 and 0.3, 0.3 and 0.5, and > 0.5, respectively [58]. The pre-post differences in gait function and freeliving walking activities were assessed using the Wilcoxon signed-rank test. The significance level was set at 0.05. The statistical analyses were performed using SPSS Version 26 (IBM statistics Corporation, Armonk, NY).

Results

Demographic and baseline clinical characteristics: Of twenty-two PsA patients initially recruited for the study, one patient was excluded after podiatry examination because the CFO was considered not clinically appropriate. Another patient was excluded because of an acute outbreak during follow up. The remaining 20 participants were included in the analyses. Demographic and baseline clinical characteristics are presented in Table 1. The study sample was composed of 5 males and 15 females with a mean age of 54.10 ± 9.06 years, a mean BMI of 29.3 ± 4.5 kg/m^2 and a mean disease duration of 11.53 ± 10.22 years. The CRP baseline levels were within the normative ranges for 75 % of the patients. Two participants recorded changes in medication during the intervention period (Table 1). The first participant started taking NSAIDs at the end of the fourth week for generalized body pain, and the second received a new biological therapy starting at week 4.

Foot function, global and lower limb pain: Figure 1 presents the FFI (1a) and NRS (1b) scores at baseline and after 7 weeks of using the CFO. All the FFI sub-scores and total score decreased at T7 indicating a significant improvement in foot pain (54.46 ± 14.58 % at baseline, and 34.01 ± 18.94 at T7), foot disability (46.26 ± 19.91 % at baseline, and 24.13 ± 18.84 at T7) and foot related activity limitation (41.54 ± 31.35 % at baseline, and 12.26 ± 17.57 at T7). The mean pre-post difference in the FFI total score was 22.30 ± 24.76 % (p= 0.004) and a large effect size (d= 1.25) was reported. A significant improvement of foot pain was also demonstrated through the NRS score which decreased by 2.30 ± 2.98 points and a large effect size was reported (d= 1.19, p=0.004). Global pain was also significantly decreased with a mean difference of 1.95 ± 2.77 and a large effect size (d= 0.90, p=0.006). In regard with lower limb pain, while there were no significant changes in knee and lower back pain, hip pain significantly improved after the 7-week intervention period and a moderate effect size was reported (d= 0.67, 0.031) (Table 2).

Seventeen participants recorded the weekly foot pain intensity and CFO wearing time using the provided diaries. The CFO daily wearing time and the evolution of foot pain are presented in Figure 2a and 2b. As it can be observed, there was a tendency for foot pain to decrease during the first 4 weeks, a plateau was observed after this period. The same tendency was also observed for wear time which increased progressively during the first 4 weeks and remained almost stable afterwards. The one-way repeated measures ANOVA showed statistically significant changes in weekly foot pain intensity F (2.13, 32.02) = 20.28, p= 0.001 and CFO wearing time F (2.27, 34.17) = 5.92, p= 0.005 over time. Post hoc tests (with Bonferroni adjustment) showed no significant differences in foot pain between the different time points. However, the differences between week 1 and week 7 (Mean difference = 1.81, p=0.09) and week 2 and week 7 (Mean difference= 1.43, p= 0.06) were almost significant. Regarding CFO wearing time, post hoc analysis showed that there was significant decrease between the first week and all the other time points ($p < 0.05$). Correlation coefficients showed significant correlations between the CFO wearing time (hours/week) and foot pain (r= -0.57, p= 0.023), disability (r= -0.68, p= 0.005), limitation (r= -0.49, p=0.047) and FFI total score (r= -0.64, p=0.01) at T7 (Figure 3).

Gait function: Spatiotemporal gait parameters measured before and after the intervention period are presented in Table 2. Results show slight but significant increase and decrease in double support time and swing time, respectively, at T7. However, for all the remaining STP including cadence, gait cycle

duration, gait speed, stride length, and foot strike angle, there were no significant differences at T7 compared to baseline. Similarly, no significant changes were reported for effects of CFO on stride time variability.

Table 1
Demographic and baseline characteristics.

Variables	PsA
	Mean ±SD / Number (%)
AGE (years)	54.10 ± 9.06
BMI	29.3 ± 4.5
SEXE (M : F)	5 : 16
DISEASE DURATION (years)	11.53 ± 10.22 (Median = 6)
CRP (mg/l)	
o Normal	15 (75 %)
o High	2 (10 %)
Employment	
o YES	47.6 %
o NO	52.4 %
History of foot and ankle injury	
o YES	57 %
o NO	43 %
DMARDs	35 %
Biological	25 %
DMARDs and Biological	36.8 %
DMARD AND/OR Biological therapy	91 %
Change in medication during the study	2 (10 %)
Foot type	
o Normal foot	5 (25 %)
o Pes cavus	8 (40 %)
o Pes planus	7 (35%)

Variables	PsA
Deformities	
o **Rearfoot valgus**	13 (65 %)
o **Hallux valgus**	5 (25 %)
o **Hallux rigidus**	5 (25 %)
o **Hammer toes**	14 (70 %)
Pain site	
o **Toes**	16 (80 %)
o **Metatarsus**	16 (80 %)
o **Heel**	11 (55 %)
o **Ankle**	17 (85 %)

Values are mean ± standard deviation and percentages for categorial variables. BMI: body mass Index, M: males, F: females, CRP : c-reactive protein, DMARD: disease-modifying antirheumatic drugs.

Table 2

Spatiotemporal parameters pre (baseline) and post intervention.

Variables	Pre	Post	p
	Mean ± SD	Mean ± SD	
Cadence (step/min)	108.63 ± 10.87	107.54 ± 9.44	0.126
Gait cycle duration (s)	1.12 ± 0.14	1.13 ± 0.11	0.104
Gait speed (m/s)	1.09 ± 0.23	1.07 ± 0.18	0.295
Stride length (m)	1.19 ± 0.18	1.19 ± 0.13	0.55
Double support (% GCT)	21.48 ±3.95	22.25 ± 3.19	*0.014
Swing time (% GCT)	39.25 ± 2.00	38.92 ± 1.56	*0.03
Foot strike angle (degrees)	25.18 ± 3.91	25.89 ± 3.25	0.279
Stride Time variability (%)	4.10 ± 3.74	3.89 ± 1.64	0.167

Values are mean ± standard deviation. * Significant difference (p values < 0.05). SD: standard deviation, GCT: gait cycle time.

Freeliving walking activities (FWA): Freeliving walking activities are presented in Figures 4, 5 and 6. Out of the 20 participants, four were excluded from the FWA analyses because they didn't accumulate at least

one valid day of recordings (i.e., recording time > 8 hours) at baseline and T7. Consequently, the results presented in this section include data from 16 participants. On average, the patients accumulated a total of 10.79 ± 1.18 hours and 9.99 ± 1.02 hours of recorded time at baseline and T7, respectively, with no significant differences between baseline and T7 (p=0.09). The average active time was 3.9 ± 1.7 hours at baseline and 3.5 ± 1.6 hours at T7 (p=0.08). The average number of steps per day was 6460 ± 2818 step/day at baseline, and 5836 ± 3079 step/day at the end of the intervention period with no significant differences between the two time points (p=0.18) (Figure 4. a). The pattern of accumulating these steps is presented in Figure 4. b. As it can be observed, the total number of steps was accumulated in short active events composed of 20 to 300 consecutive steps (Figure 4. b). The daily average freeliving cadence was 96.68 ± 5.85 steps/min and 96.03 ± 5.58 steps/min before and after the intervention, respectively (p=0.79) (Figure 5. a). Results show that cadence increases considerably for active events of more than 20 steps compared to those of less than 20 steps (Figure 5. b). For active events composed of 20 to 600 consecutive steps, the mean cadence was 96.65 ± 1.10 step/min at baseline, and 96.38 ± 1.02 step/min at T7. Results also show that cadence reaches and crosses 100 step/min only for active events composed of more than 600 consecutive steps, for an average of 100.94 ± 11.06 step/min at baseline, and 101.75 ± 8.73 step/min at T7 with no significant differences between the two time points (p= 0.44).

Figures 6 presents minutes spent in APA intensity-based categories including stepping activities (Figure 6a) and slow, medium, brisk walking and vigorous APA (Figure 6b). At baseline, out of 234.1 min of active time, 183.7 min (78 %) were spent in stepping activities and 50.4 min (22 %) were spent in purposeful walking. This same pattern was observed at T7: out of 210.2 min of active time, 164.3 min (78 %) were spent in stepping activities and 45.0 min (22%) spent purposeful walking with no significant differences between the two time points. Participants accumulated 25.9 ± 19.4 min and 18.7 ± 11.6 min of medium and brisk walking at baseline, and 21.5 ± 15.0 19 min and 19.1 ± 13.9 min at T7. Time spent in vigorous APA was 1.2 ± 2.0 minutes at baseline and 0.8 ± 1.4 minutes at the final follow-up (p=0.52).

Discussion

The primary purpose of this study was to explore the effects on foot function of wearing CFO for a 7-week period in PsA patients. As a secondary objective we sought to assess the effects of CFO on foot pain, gait function (instrumented gait STP analysis) and FWA, and to assess the relationship between the CFO wearing time, foot pain and function in PsA patients with foot involvement.

Foot pain and foot function: The main findings showed a significant improvement in foot pain (NRS and FFI) and foot function (FFI) after the use of CFO for a 7-week intervention period. The FFI total score decreased by 22.30 % and a large effect size (d= 1.25) was reported. Interestingly, this improvement was above the MCID reported for the FFI total score meaning that the improvement was clinically significant and it was observed after only 7 weeks of wearing time.

Research in rheumatoid arthritis (RA) patients has shown some efficacy of CFO on foot pain which is consistent with our findings [41, 42, 43]. However, conflicting results regarding the of CFO effects on foot

function have been reported. Indeed, while some studies endorsed the effectiveness of CFO on foot function [44, 46], others reported no significant effects for this outcome[59–61]. Several factors could explain such discrepancies. First, the type of orthoses can differ between the studies according to the targeted therapeutical aim (e.g. palliative vs functional). Moreover, foot casting and manufacturing materials and techniques can significantly vary from one study to another depending on the latest advances in technologies and on the national practice guidelines making between-studies comparison difficult. In our study, we used *functional CFO* in all the participants. The materials and techniques of foot casting and manufacturing were standardized for all the participants. However, the degrees and types of corrections were specific for each participant's needs and tolerance. The CFO were also adjusted at delivery and during the following two weeks if needed, to increase comfort and acceptance. This could explain the positive effects on pain and foot function observed in this study. Furthermore, there was no consensus regarding the intervention durations and the control conditions in the previous studies. Some trials used placebo orthoses while others used shoes only as a control condition. As the former are usually made from thick and cushioned materials they cannot be considered as having no therapeutic effects, thereby attenuating the CFO effects. In contrast, using shoes-only as control could overestimate the effect of CFO [62].

Importantly, CFO wearing time was not documented in all the previous studies which can compromise their conclusions as a lack of effectiveness could partially be related to insufficient use of the orthoses. In our study, a sufficient wearing time (8hours/day) was reported and a strong correlation between the CFO wearing time and the FFI total score was demonstrated. These findings are similar to those reported in the few studies in RA patients that did report wearing time [44, 46, 60]. This observation highlights the relevance of monitoring this variable in future studies and the importance of continuous and regular wearing of the CFO.

Also of note, the intervention characteristics, sampling groups and individual characteristics such as age, sex distribution, disease duration, and baseline levels of foot pain and disability are also important considerations as they may influence the effectiveness of CFO. For instance, data from a previous study [63] showed that shorter disease duration, younger age and higher baseline values of foot pain and disability predicted outcomes after CFO use. In our study, the participants had a mean age of 54.10 ± 9.06, a median disease duration of 6 years, a high prevalence of foot pain and severe levels of disability at baseline. It is therefore not unexpected that the CFO was helpful relieving pain and improving perceived foot function. In addition to foot pain and disability, the findings showed a significant decrease in global and hip pain, with large and medium effect sizes reported for these variables, respectively. Knee and lower back pain also improved but the differences did not reach the significance level. Although there is evidence that CFO could have beneficial effects on lower limb pain [64–67], further studies using specific tools to assess knee, hip and lower back pain in details, are needed to confirm the beneficial effects of CFO on these variables.

Gait function: Gait STPs are indicators of functional capacity, overall health and autonomy, which makes them the mostrelevant and most often measured biomechanical parameters for gait analysis in healthy

and pathological populations [13, 73]. We noticed a lack of scientific evidence regarding the effects of CFO on gait STPs in patients with arthritic foot diseases. For instance, studies in RA patients, showed only a minimal or no effect of CFO for increasing gait speed, cadence and stride length [43, 70, 71] and some other studies involving RA patients showed that wearing CFO allowed for an improvement of gait stability [46, 72].

Our findings showed that gait STPs were altered compared to the normative values reported for healthy adults [73, 74]. However, there were no significant changes in STP and gait stability after 7 weeks of CFO use with the exception for a negligible effect on double support and swing time. These results could be potentially attributed to short-term nature of our intervention period and the long disease duration reported in this study. In fact, gait impairments demonstrated in PsA patients may be acquired over years and as the disease progresses, the patients can develop antalgic walking strategies that would necessitate longer intervention periods to improve. Aditionnaly, the patients could have developed fear-avoidance beliefs which have been reported as significant predictors of poorer response to CFO in other patient populations [75]. Another possible explanation for the lack of STP response could be that PsA is responsive to CFO treatment in earlier stages of the disease. Therefore, long-term studies including patients with early disease would be more relevant to properly assess the effects of CFO on gait STP.

Additionally, although the 10MWT is reliable and responsive in patients with major gait impairments secondary to neurological disease such as stroke and Parkinson [76], it might have not been responsive in this study because of the relatively milder gait impairment related to PsA and the short duration of the intervention and follow up period [77]. Longer time/distance tests should also be considered when assessing gait in PsA patients as gait impairements reported in this population could be attributed to commun features of inflammatory arthritis patients such as muscle weakness, reduced range of motion, and deformities [78, 79, 80] and may be more evident during sustained walking activities.

Freeliving walking activities: The benefits of physical activity on health are undeniable. Results from a recent systematic review [25] suggest that physical activity may have positive effects on disease activity, muscle strength, fatigue, pain, quality of life and cardiovascular risk in PsA patients. Therefore, promoting physical activity in this population should be a health care priority. Among physical activities, walking is a practical, accessible and low skill mode of physical activity that also plays a major role in occupational and social activities in everyday living [81]. The findings of this study reported decreased step counts with large standard deviaitions (6460 steps/day at baseline, and 5836 steps/day at T7) which are below the recommended 10000 steps/day [82]. Similarly, the daily averaged freelving cadence was 96.67 ± 5.85 steps/min at baseline, and 96.03 ± 5.85 steps/min at T7 which is below the naturally selected freeliving walking speed (100 steps/min) reported for healthy individuals [57, 83]. Besides, the reported time spent in brisk walking didn’t achieve the minimum of daily 30 min of moderate-intensity physical activity recommended by the international guidelines for PA activity [84]. Theses results indicate decreased PA levels in PsA patients which is consistent with what is reported in a previous systematic review [25].

We postulated that by alleviating pain, the use of CFO would impact positively on walking activities in PsA patients. Nevertheless, neither the number of steps/day, free-living cadence, or the time spent in intensity-based APA changed after the use of CFO. Again, the short-term nature of this study could have not fully reflected the effects of CFO. Besides, free-living cadence is a measure of ambulatory behavior [57] that could be influenced by psychoaffective factors that has not been assessed in this study. In a previous study in PsA patients, beliefs about PA (e.g. fear of exacerbating pain) have been shown to be associated with activity level [85]. This suggests that future studies should adress the patient's behavior which is a complex task and may require using a multidisciplinary approach to promote physical activity in PsA patients including behavioral change strategies, advice, education, and prescription of exercise therapy in addition to CFO. In addition, as this study was carried over nearly two years, natural environmental factors such as seasons /weather, and the occurrence of the COVID19 pandemic, might have influenced the patients PA [86, 87].

Lastly, it should be mentioned that only 16 participants were included in the FWA analyses and there might be not enough power to detect significant changes. Also, the average recorded time was nearly 1 hour lower at T7 compared to baseline (10.79 hours vs 9.99). This could have contributed to our results. To our knowledge only one study investigated the effects of CFO on physical activity [88] in a population of RA patients. Using a self-reported questionnaire, their results showed that a 6-month CFO use improved light intensity physical activity but not moderate and vigorous-intensity activities [88]. However, these findings cannot be compared to ours because of the different approaches used for PA measurement since using self-reported measures could overestimate PA compared to objective measurements [89].

This study has limitations that should be mentioned. First, there was no control group to minimize the placebo effect and to control for the natural evolution of the disease. However, as this is the first study to assess the effects of CFO in patients with RP, the results are just exploratory but encouraging for performing RCTs. Second, the follow-up duration may have been too short to show changes in outcomes such as gait parameters and FWA that may necessitate longer time to improve. Moreover, the small sample size and the high proportion of female participants which is not representative of the gender distribution usually seen in PsA, would compromise the generalizability of our findings.

Conclusion

The use of CFO for 7-week period improved foot pain and related disability in PsA patients. This suggests that CFO may be used in conjunction with pharmacological therapy to relief pain and improve perceived foot function. However, the results should be confirmed in larger and controlled studies. The effects of CFO on gait function and freeliving walking activities were not obvious in this study due to the small sample size, short follow-up period and environmental factors that have not been measured. Future RCTs with lager sample sizes and longer intervention durations are needed for any conclusions to be drawn.

Abbreviations

APA: ambulatory physical activity; BMI: body mass index, CRP: c reactive protein; CFO: Custom foot othoses; DMARD: disease-modifying anti-rheumatic drugs; FFI: foot function index; FWA: Freeliving walking activities; GCT: gait cycle time; MCID: minimal clinically important difference; NRC: numerical rating scale; PA: physical activity; PsA: psoriatic arthritis; STPs: spatiotemporal parameters; 10MWT: 10-meter walk test.

Declarations

Ethics approval and consent to participate

The study was approved by the the Institutional Review Board of the CIUSSS de l'Estrie-CHUS (2019-3182), and all the participants gave their informed consent to participate in the study.

Consent for publication

Not applicable

Availability of data and materials

The dataset used and analyzed during the current study is available from walha.roua@usherbrooke.ca on reasonable request.

Competing interests

The authors declare no conflict of interest. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript, or in the decision to publish the results.

Funding

This research was funded by the Canadian MSK Rehab Research Network and supported through a donation from Janssen Pharmaceutical compagnies to *Fondation pour la recherche et l'enseignement en orthopédie de Sherbrooke.*

Authors' contributions

RW and PB conceived the study. RW collected and analyzed the data and wrote the first full draft of the manuscript. PB assisted with the analysis of data. PB, GBC, PD and NG all reviewed the manuscript drafts. All authors read and approved the final manuscript.

Acknowledgment

The authors would like to thank the rheumatologists of the CHU Hôtel Dieu of Sherbrooke for their contribution to the participants' recruitment.

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Figures

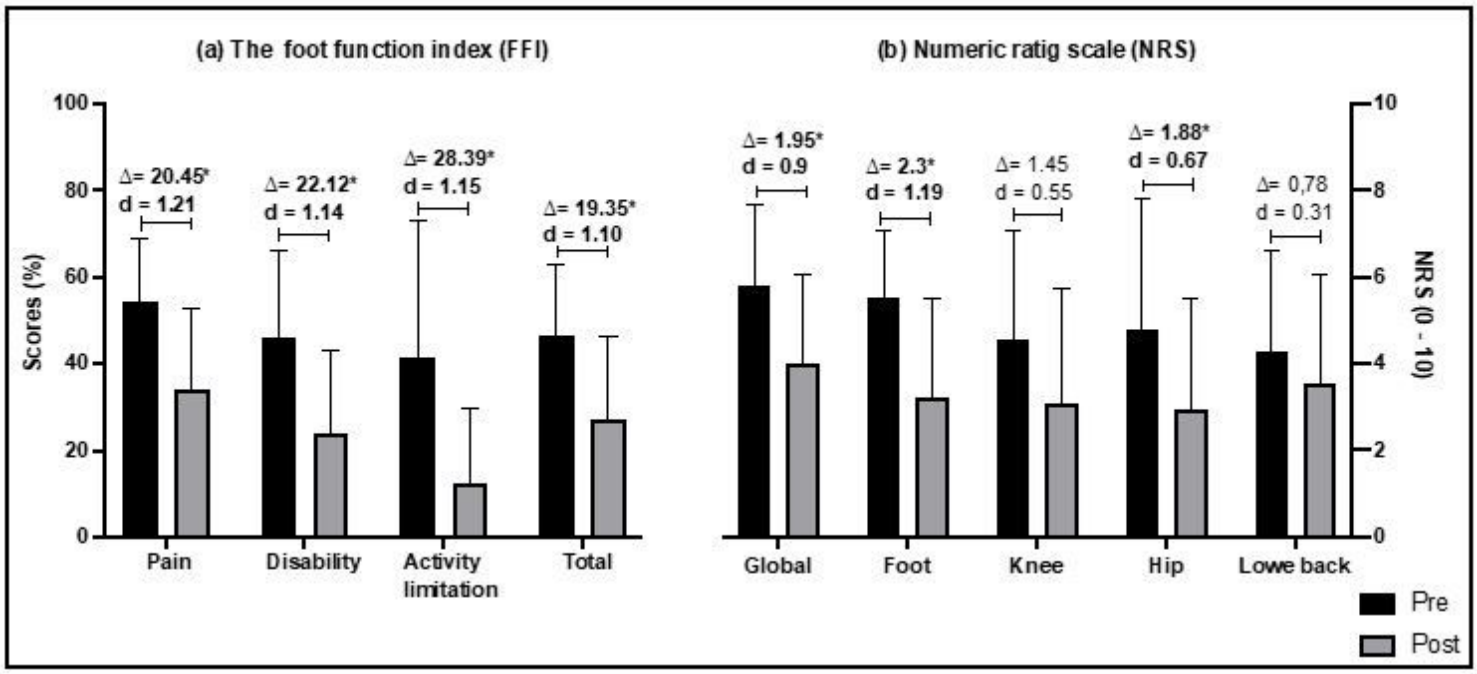

Figure 1

(a) Foot function and (b) global and lower limb pain pre (baseline) and post intervention period. * Significant differences (p values < 0.05) in mean values between baseline and final follow up. FFI: Foot function index, NRS: numerical rating scale, d: Cohen's effect size.

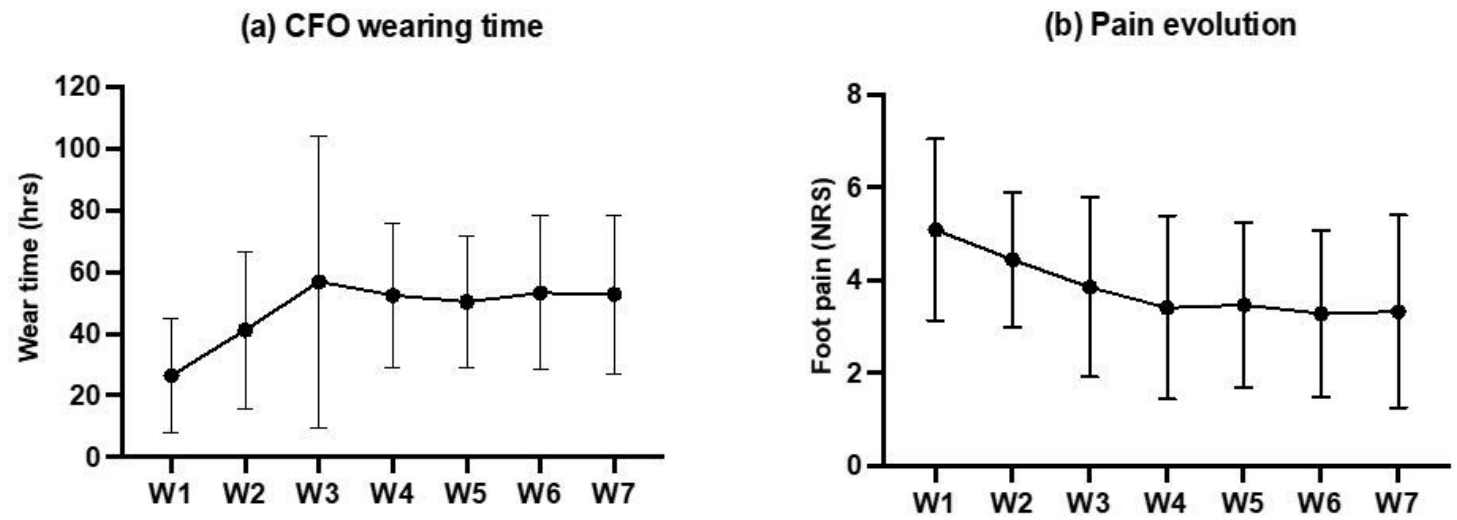

Figure 2

(a) Weekly CFO wearing time and (b) weekly foot pain intensity recorded in the patients' diaries using the NRS.

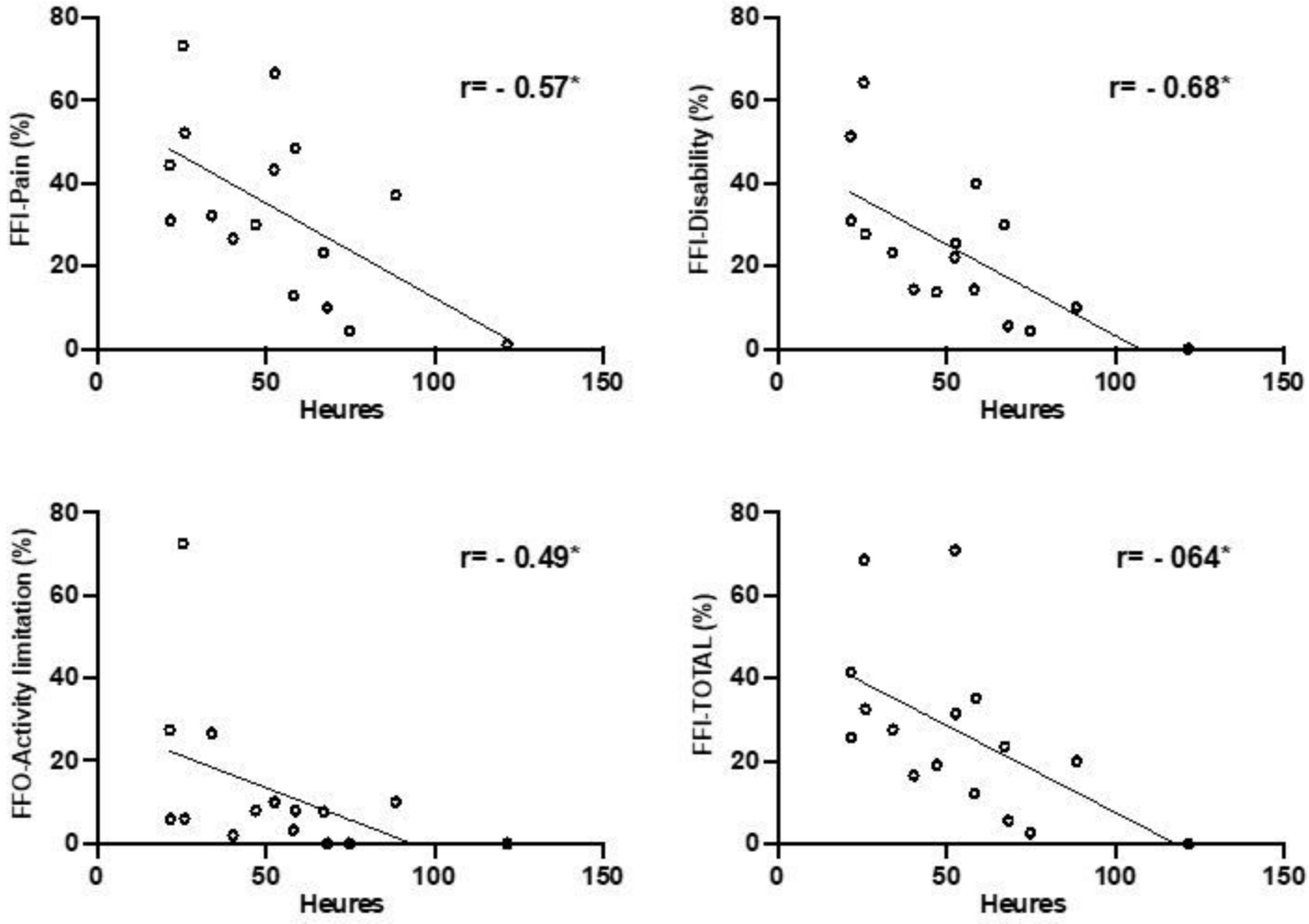

Figure 3

Correlation between weekly CFO wearing time averaged for the last 5 weeks of the intervention period and the FFI subscales and the total score recorded at T7.

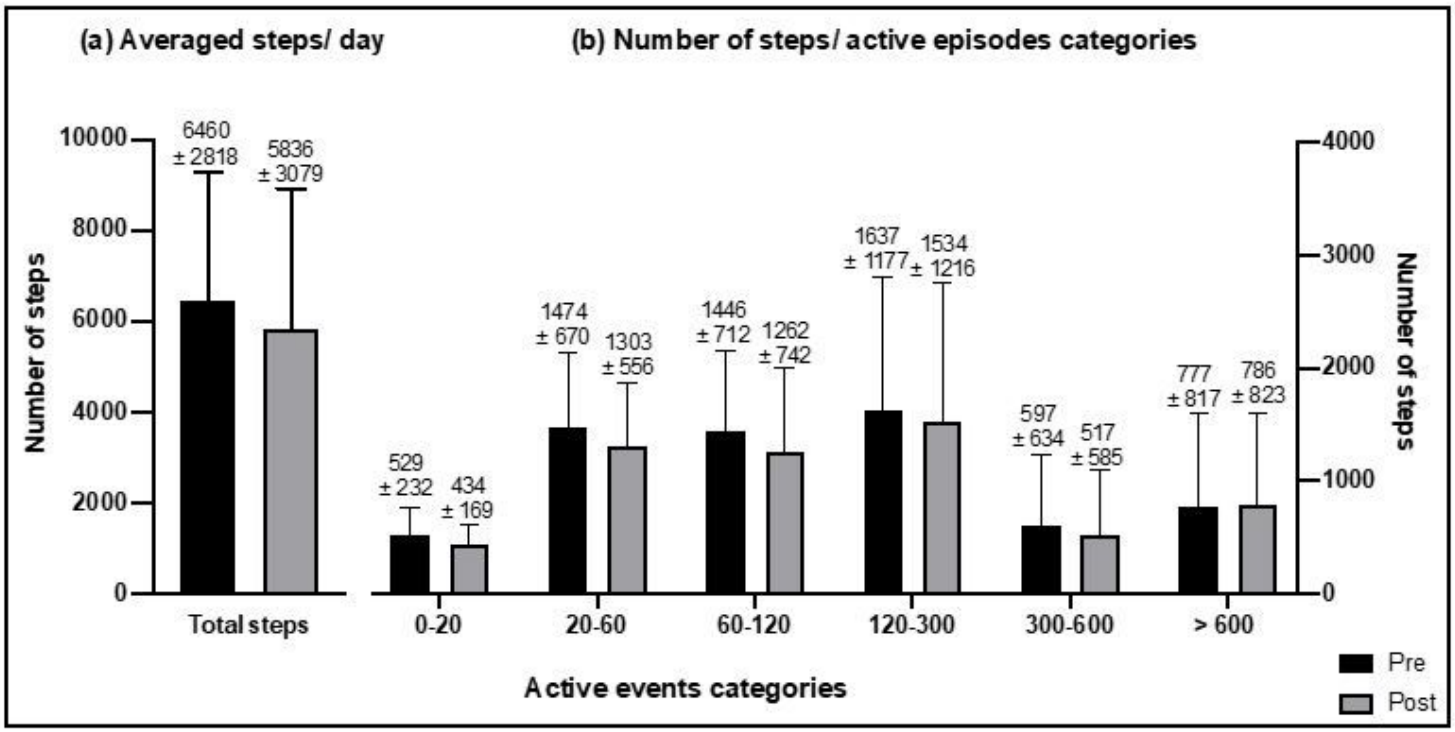

Figure 4

Step count. (a) Daily averaged steps and (b) number of steps the different step-based active episodes categories.

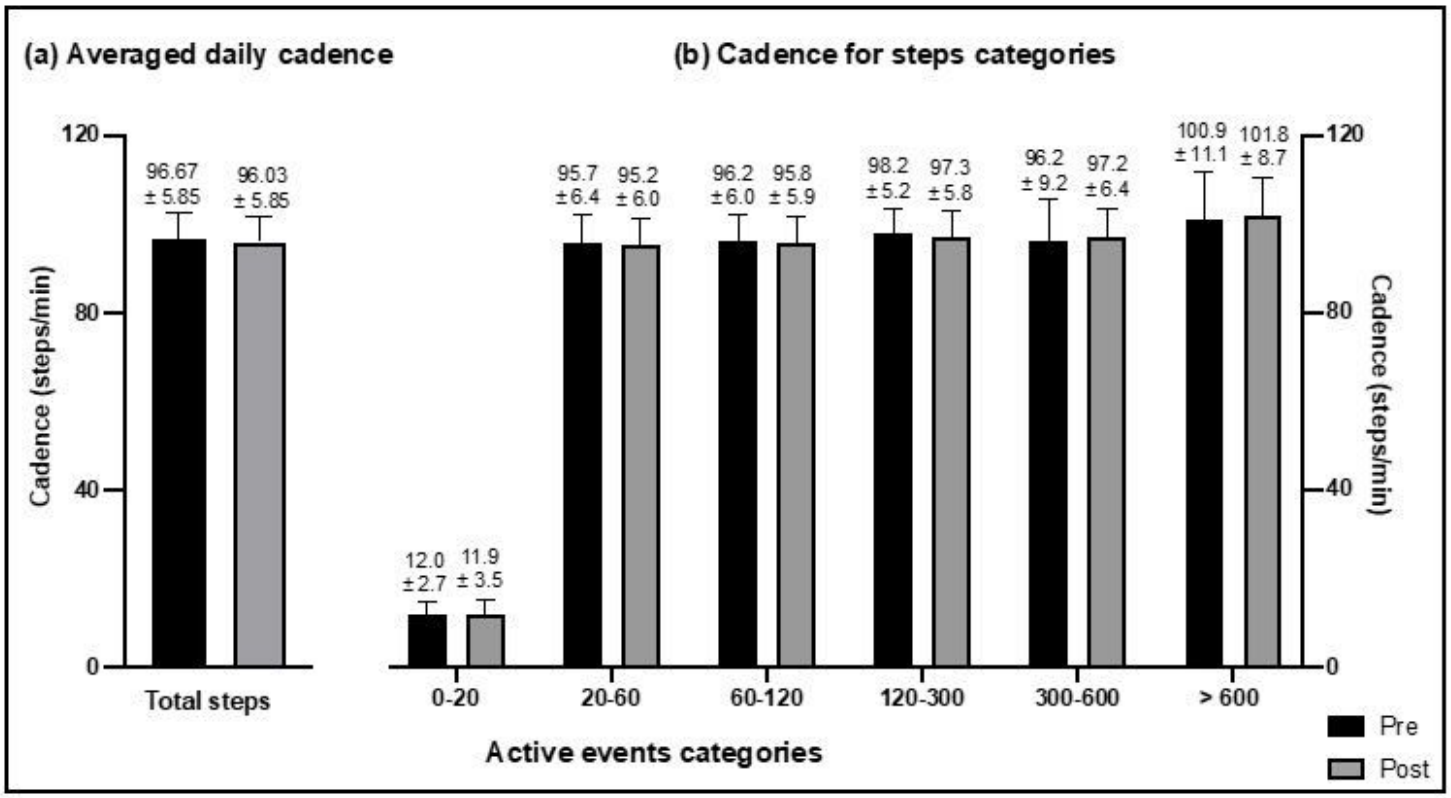

Figure 5

Freeliving cadence. (a) Freeliving daily averaged cadence and (b) cadence for the different step-based active episodes categories.

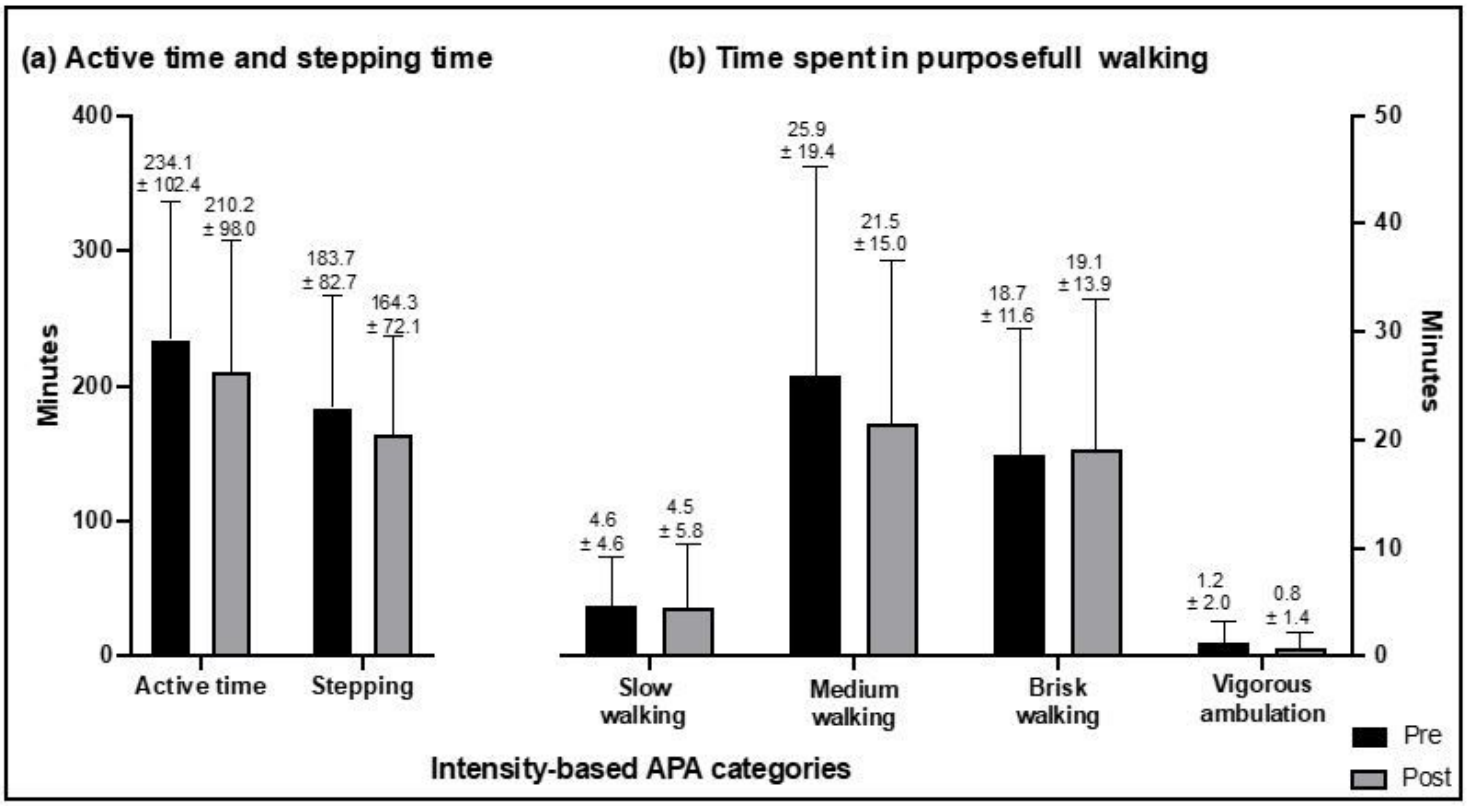

Figure 6

Time spent in APA intensity-based categories (a) Total active time and time spent in stepping activities and (b) Time spent in purposuful walking including only active events of more than 60 steps.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- CFOSupplementalmaterialv15102021.docx