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Standardizing the Analysis of Physical Activity in Patients With COPD Following a Pulmonary Rehabilitation Program

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BACKGROUND: There is a wide variability in measurement methodology of physical activity. This study investigated the effect of different analysis techniques on the statistical power of physical activity outcomes after pulmonary rehabilitation.

METHODS: Physical activity was measured with an activity monitor armband in 57 patients with COPD (mean ± SD age, 66 ± 7 years; FEV_1, 46 ± 17% predicted) before and after 3 months of pulmonary rehabilitation. The choice of the outcome (daily number of steps [STEPS], time spent in at least moderate physical activity [TMA], mean metabolic equivalents of task level [METS], and activity time [ACT]), impact of weekends, number of days of assessment, post-processing techniques, and influence of duration of daylight time (DT) on the sample size to achieve a power of 0.8 were investigated.

RESULTS: The STEPS and ACT (1.6-2.3 metabolic equivalents of task) were the most sensitive outcomes. Excluding weekends decreased the sample size for STEPS (83 vs 56), TMA (160 vs 148), and METS (251 vs 207). Using 4 weekdays (STEPS and TMA) or 5 weekdays (METS) rendered the lowest sample size. Excluding days with < 8 h wearing time reduced the sample size for STEPS (56 vs 51). Differences in DT were an important confounder.

CONCLUSIONS: Changes in physical activity following pulmonary rehabilitation are best measured for 4 weekdays, including only days with at least 8 h of wearing time (during waking hours) and considering the difference in DT as a covariate in the analysis.

TRIAL REGISTRY: ClinicalTrials.gov; No.: NCT00948623; URL: www.clinicaltrials.gov

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ABBREVIATIONS: DT = duration of daylight time; ICC = intraclass correlation coefficient; METs = metabolic equivalents of task; METS = mean metabolic equivalents of task level; STEPS = daily number of steps; TMA = time spent in at least moderate physical activity

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In patients with COPD, physical inactivity is believed to play a crucial role in the development of comorbidities (ie, skeletal muscle weakness, osteoporosis, depression, exercise intolerance, cardiovascular disease).[1-3] Moreover, physical inactivity is an independent predictor of adverse outcome[4,5] and affects quality of life.[6,7] Increasing physical activity has become a patient-centered goal for the treatment of patients with COPD. Unfortunately, the literature suggests that after following a pulmonary rehabilitation program, an enhancement of physical activity is not guaranteed.[8,9] The lack of statistically significant improvements can be due to a failure of interventions to achieve behavioral changes or to the conduct of underpowered studies unable to account for the variability in the outcome measure.

Physical activity is characterized by large variability because it is measured under unstandardized conditions. Recommendations identify the need for optimal activity monitor schedules in field research.[10] Factors affecting standardization are related to intrinsic differences in physical activity levels from day-to-day, extrinsic variability (ie, climatologic conditions, seasons[11,12]); the measurement itself (ie, the monitor, the number of days of assessment, the number of hours of measurement); and postprocessing (ie, days and time use in the analysis). Minimizing the noise around the measure of physical activity can enhance the statistical power of studies, whereas minimizing the number of days and hours of assessment reduces the burden to patients, which may contribute to study compliance.

The aim of the present study was to find a standardized method of physical activity measurement and data analysis to improve the power of physical activity-related outcomes, predominantly by reducing the variability of the outcomes and optimizing the effect size. We explored the following research questions: What is the impact of (1) the chosen outcome, (2) the exclusion of weekends, (3) increasing the number of days of assessment, and (4) altering the postprocessing analysis techniques (eg, time set used, definition of valid days according to wearing time, correction for daylight time)?

We hypothesized that the variability in physical activity can be reduced by excluding weekends, using more assessment days, comparing the same days of the week at both time points, using a fixed time frame for physical activity analysis (eg, 7:00 AM-8:00 PM), and omitting days with a low monitor wearing time. Previous studies[13-17] identified the number of days of assessment through cross-sectional data analysis. The present study compared the impact of different techniques of analysis on the intervention effect after rehabilitation.

Materials and Methods

Study Subjects and Design

The baseline and 3-month data of a rehabilitation study (Clinical Trials registry No.: NCT00948623; approved by UZ Leuven Medical Ethics Committee [B32220095599]) were used to investigate variability in physical activity. Patients with stable COPD[2] (no exacerbations in preceding 4 weeks) referred for outpatient pulmonary rehabilitation were randomly assigned to a conventional rehabilitation group (described in detail elsewhere[18]) or a conventional rehabilitation plus counseling group. In the present analysis, both groups are combined. The sample size calculation of the original study was based on the primary aim of the rehabilitation study; hence, the present sample should be seen as a convenience sample and was judged to be appropriate for the present (sub)analysis. This judgment was based on a sensitivity analysis where random patients were left out of the analysis, which showed no change in mean and SD of the effect (e-Appendix 1). In addition, the present study sample is one of the larger samples analyzing the (objectively measured) physical activity of patients undergoing pulmonary rehabilitation.[9] Fifty-seven of the subjects already had accelerometer data files both at baseline and after 3 months. These data were retrieved for this investigation. Informed consent was obtained prior to the start of the study. More information can be found in e-Appendix 1.

Clinical Measurements

All subjects underwent spirometry (Jaeger MasterScreen Body; CareFusion Corp) according to European Respiratory Society and American Thoracic Society standards. The results were referred to the predicted normal values proposed by Quanjer et al.[19] A 6-min walk test was performed in a 50-m corridor, and the best of two tests was used.[20]

Physical activity was measured before and immediately after rehabilitation for 7 consecutive days with the SenseWear Pro armband (BodyMedia, Inc), which detects wearing time directly by skin contact.[21] The SenseWear Pro armband has been thoroughly validated.[22-24]

Subjects were asked to wear the monitor whenever awake. They refrained from their rehabilitation program in the week of the physical activity assessment. The minute-by-minute output of the number of steps and metabolic equivalents of task (METs) was exported for further analysis using SenseWear Professional, version 6.0 software (BodyMedia, Inc).

The variables chosen for this analysis were the total daily number of steps (STEPS); daily time spent in at least moderate physical activity (TMA), defined as any activity ≥ 3 METs[25]; and daily mean METs level (METS). Active time was also defined at lower thresholds (between 1 and 3 METs) using a 0.1-MET increase (e-Appendix 1).

Data Treatment

The full analysis set comprised all available minute-by-minute data before and after rehabilitation. From the full analysis set, several datasets were constructed to test various hypotheses (e-Appendix 1).

Duration of daylight time (DT) has been suggested as a proxy for seasonality. DT of each measured day was predicted using the CSIRO (Commonwealth Scientific and Industrial Research Organisation) Biosphere model, with a day length coefficient of 0.8333 and latitude of 50.78° (Fig 1).[26]

Statistics

Minute-by-minute datasets were analyzed with SAS, version 9.3 (SAS Institute Inc) statistical software. Two different approaches were used to identify the impact of standardization:

1. Similar to previous cross-sectional research,[13-17] the intraclass correlation coefficient (ICC) of the baseline measurement was used to assess reliability and identify the optimal number of days of measurement. The usually desired ICC value for multiple days is 0.80.[17] In addition, the repeatability coefficient of the baseline measurement was calculated as a measure of absolute reliability.[27]
2. Based on data of the intervention effect, robustness of the measurement was expressed as the sample size needed to achieve a power of 0.8 with a significance level $\alpha = .05$. Sample size calculation (two-tailed) was done with an a priori power calculation using G*Power 3.1.3.[28]

To identify a difference between the analysis techniques, a paired *t* test was performed. The influence of a difference in DT on the intervention effect was studied using a mixed-model analysis. The corrected intervention and interaction effects ($\Delta PA \times \Delta DT$ [where PA = physical activity]) were retrieved. $P < .05$ was considered statistically significant.

Results

Subjects

Fifty-seven subjects with COPD were analyzed. The subject characteristics are shown in Table 1.

Impact of Outcome Used

A summary of the effect and variability of the intervention is provided in Table 2. The choice of the physical activity outcome used (STEPS, TMA, METS) had important implications in identifying intervention effects. Use of a 7-day measurement (mean effect compared with baseline, 21% for STEPS, 29% for TMA, and 4% for METS) resulted in a calculated sample size of 83 subjects for STEPS, 160 for TMA, and 215 for METS. The use of an activity threshold between 1.3 and 2.3 METs lowered the sample size (lowest at 1.3 METs, 69 subjects) (e-Appendix 1).

Impact of Days of Assessment

Excluding weekends did not have an impact on the intervention effect but did decrease the sample size to achieve the intended power (Fig 2) (33% [56 subjects vs 83 subjects] for STEPS, 4% [207 subjects vs 215 subjects] for METS, and 8% [148 subjects vs 160 subjects] for TMA) because of a reduction of the SD of the effect (Table 2). The sample size decreased gradually until 4 days of measurement for STEPS and TMA and until 5 days for METS (Fig 2). Comparing the same weekdays prerehabilitation and postrehabilitation did not enhance the robustness for any of the outcome measurements and resulted in a loss of subjects with no valid comparable data before and after intervention.

Solely based on achieving an acceptable reliability (ICC > 0.8), one would conclude that 2 days for STEPS (ICC = 0.85), TMA (ICC = 0.87), and METS (ICC = 0.89) would be sufficient. The ICC further increased up until 5 weekdays of measurement (STEPS, 0.93; TMA, 0.93; METS, 0.93) but slightly worsened when including the weekend days (STEPS, 0.90; TMA, 0.92; METS, 0.92) for all outcomes (Fig 2). Analysis of the repeatability coefficient showed a comparable result with a gradual decrease from 2 to 5 weekdays (STEPS, 1,157 steps/d vs 497 steps/d; TMA, 66 min vs 41 min; METS, 0.25 vs 0.19 METs).

$$\theta = 0.2163108 + 2\tan^{-1}[0.9671396\tan[0.00860 * (J-186)]]$$

$$\phi = \sin^{-1}[0.39795\cos\theta]$$

$$D = 24 - \frac{24}{\pi}\cos^{-1}\left[\frac{\sin\left(\frac{p\pi}{180}\right) + \sin\left(\frac{L\pi}{180}\right)\sin\phi}{\cos\left(\frac{L\pi}{180}\right)\cos\phi}\right]$$

J = day of the year
p = daylength coefficient (degrees)
L = latitude (degrees)
θ = revolution angle (radians)
ϕ = sun's declination angle (radians)
D = daylength (hours)

Figure 1 – *Formula used to calculate daylight time based on the day of the year and latitude (CSIRO [Commonwealth Scientific and Industrial Research Organisation] Biosphere model).[26] A day length coefficient of 0.8333° (US government definition of day length) and a latitude of 50.78° (Belgium) were used to predict the daylight time. Northern latitudes are positive, southern latitudes are negative, and daylight time is calculated in hours (and converted to minutes).*

TABLE 1] Baseline Subject Characteristics

Characteristic	Baseline Value
Sex	
Male	47 (82)
Female	10 (18)
Age, y	66 ± 7
BMI, kg/m^2	26 ± 7
FEV_1, L	1.28 ± 0.46
FEV_1, % predicted	46 ± 17
FVC, L	3.10 ± 0.79
FVC % predicted	88 ± 22
FEV_1/FVC, %	41 ± 11
GOLD stage	
I	4 (7)
II	15 (26)
III	29 (51)
IV	9 (16)
6MWD, m	427 ± 105
6MWD, % predicted	67 ± 17

Data are presented as No. (%) or mean ± SD. 6MWD = 6-min walk distance; GOLD = Global Initiative for Chronic Obstructive Lung Disease.

TABLE 2] Influence of the Outcome Used, Exclusion of Weekends, and Number of Days of Measurement on the Calculated Sample Size

Outcome	Baseline	3 mo	Δ	p5-p95	*P* Value
STEPS, No./d					
2 d	4,038 ± 2,783	4,837 ± 3,333	799 ± 2,625	−2,683 to 7,629	.0253
3 d	3,989 ± 2,639	4,814 ± 3,222	824 ± 2,495	−2,126 to 4,815	.0156
4 d	3,966 ± 2,636	4,932 ± 3,381	967 ± 2,505	−1,775 to 5,212	.0051
5 d	3,931 ± 2,566	4,846 ± 3,257	916 ± 2,392	−1,599 to 4,948	.0055
7 d	3,892 ± 2,656	4,692 ± 3,284	800 ± 2,560	−1,771 to 9,183	.0218
TMA, min/d					
2 d	51 ± 64	62 ± 64	11 ± 67	−116 to 134	.2199
3 d	50 ± 58	64 ± 77	14 ± 69	−76 to 176	.1309
4 d	50 ± 58	66 ± 78	16 ± 67	−67 to 161	.0784
5 d	50 ± 55	64 ± 75	15 ± 63	−58 to 158	.0855
7 d	49 ± 52	63 ± 76	14 ± 63	−66 to 153	.0976
METS					
2 d	1.333 ± 0.28	1.375 ± 0.33	0.042 ± 0.29	−0.445 to 0.478	.2792
3 d	1.331 ± 0.26	1.379 ± 0.34	0.048 ± 0.31	−0.417 to 0.464	.2447
4 d	1.332 ± 0.26	1.388 ± 0.35	0.056 ± 0.30	−0.402 to 0.401	.1640
5 d	1.327 ± 0.26	1.383 ± 0.34	0.055 ± 0.28	−0.371 to 0.485	.1450
7 d	1.319 ± 0.24	1.374 ± 0.35	0.055 ± 0.29	−0.271 to 0.424	.1524

Data are presented as mean ± SD. Δ = found intervention effect; METS = mean metabolic equivalents of task level; p5-p95 = percentile 5 to percentile 95 of the found intervention effect; STEPS = daily number of steps; TMA = time spent in at least moderate physical activity.

Difference in Postprocessing Analysis

Subjects were most active between 7:00 AM and 8:00 PM (Fig 3A). During this period, 84% of steps were captured (Fig 3B). The influence of the various analysis techniques is shown in Table 3. Altering the postprocessing technique had little to no impact on the statistical significance of the intervention's effect for any of the outcomes.

Excluding data recorded before 7:00 AM and after 8:00 PM reduced the sample size needed for METS. Analyzing days with a valid wearing time (a minimum of 480 min) reduced the sample size needed for STEPS (Table 3).

Excluding days of < 12 h wearing time had no further impact on the sample size but resulted in the loss of seven subjects (12%) who lacked valid days of assessment in this scenario.

Sixteen subjects (28%) started in winter, 19 (33%) in spring, 16 (28%) in summer, and six (11%) in autumn, with a mean DT measurement of 758 ± 180 min at baseline and 731 ± 167 min at 3 months. For all outcome measurements, the difference in DT had a significant influence on the intervention effect. The impact of DT remained in all scenarios of postprocessing. Correcting

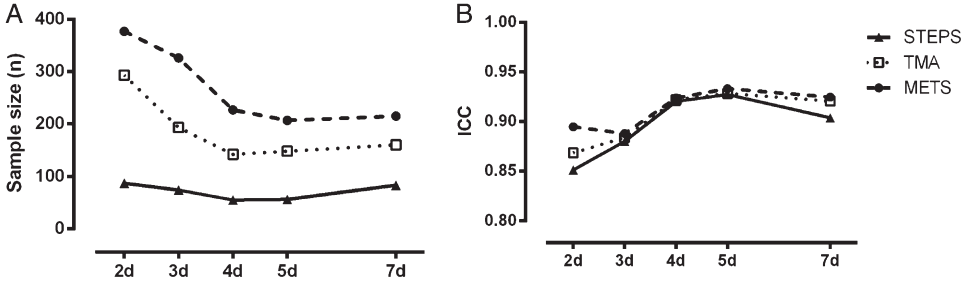

Figure 2 – *Influence of the number of days of measurement and exclusion of weekend days on the calculated sample size and ICC. A, Sample size needed to achieve a power of 0.8 with a significance level of .05 (STEPS, TMA, and METS) in 2 to 5 (random) weekdays and a whole week of measurement. B, ICCs (STEPS, TMA, and METS) in 2 to 5 (random) weekdays and a whole week of measurement. ICC = intraclass correlation coefficient; METS = mean metabolic equivalents of task level; TMA = time spent in at least moderate physical activity; STEPS = daily number of steps.*

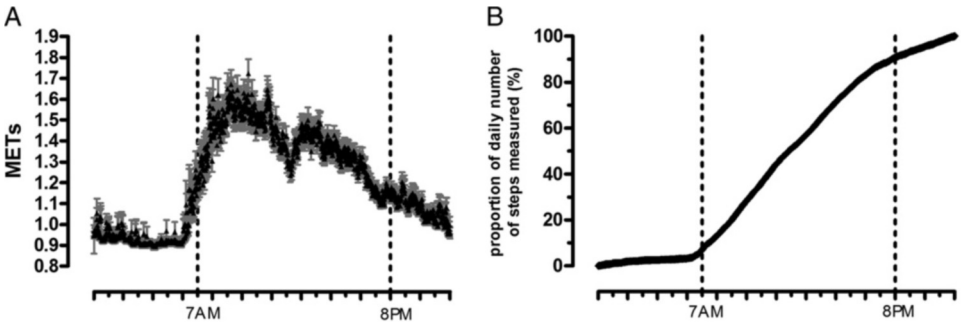

Figure 3 – *Whole-day physical activity pattern. Mean min-by-min physical activity pattern (all data, 7 d) of all patients. A, Mean METs per minute, presented as mean ± SEM (gray). B, Proportion of total number of steps measured presented min by min. METs = metabolic equivalents of task.*

for the difference in DT resulted in slightly larger intervention effects, which further reduced the sample size requirements (Table 4).

Discussion

The present study showed that the choice of outcome and the processing of physical activity data had important implications for the statistical significance of the results. These methodologic choices, thus, affect the number of subjects required in a study. Excluding weekends improved the robustness, as did the inclusion of more weekdays. A difference in DT had an important influence on the observed change in physical activity. We hypothesized that this effect would be counteracted by limiting the assessment time to between 7:00 AM and 8:00 PM, but this was not the case. The methodology of data processing has a significant impact on the outcome and estimates of effect, which was also highlighted by the American College of Sports Medicine.[10]

Data provided by activity monitors are commonly used to measure daily physical activity. In patients with COPD, validation studies highlighted the usability and validity of measures of physical activity compared with a gold standard methodology.[23,24] Promoting physical activity has become an increasingly important part of the treatment of patients with COPD. The measurement of physical activity, therefore, is of indisputable clinical importance. Activity monitor-based counseling programs are proven to have a beneficial effect in patients with chronic diseases,[29] and clear physical activity guidelines for promoting health are widely used.[30] For clinicians, standardization of measurements, as proposed in the present study, can provide a clear benchmark of normal and abnormal physical activity and can be used for clinical comparisons before and after interventions. In some paradigms (eg, coaching patients toward a more active lifestyle), full data including weekends may be valuable. The main outcome chosen for the present study was the sample size needed to achieve a power of 0.80. The statistical power is the probability that the null hypothesis will be rejected when it is truly false (type II error).[28] Analyzing the power of a study depends on the significance level α, the sample size, and the effect size. The latter depends on the average difference and the variability of the measurement. The present study took several approaches into account to reduce variability.

Comparing the same days (ie, Monday to Monday) was hypothesized to control for differences in patients' weekly routines and, hence, decrease the variability. The data suggest that a systematic day-to-day pattern is absent, similar to observations in healthy subjects comparably aged[31] and patients with COPD.[32] Therefore, we confidently suggest that correcting for weekly routines is not necessary. The exclusion of weekends could decrease the variability of the physical activity measurement and did not affect the intervention effect.

Previously, at least 2,[14] 3,[15,16] 5,[17] and 7[13] days of assessment were suggested for physical activity measurement. These cross-sectional studies were mainly based on the obtained ICC and assumed the reliability of the baseline measurement only. Similarly, we would have concluded a minimum of 2 days of measurement needed for reliable data (ICC $>$ 0.8). In a longitudinal design, however, including more days clearly enhanced the robustness. The reliability coefficient is a useful index for quantifying absolute reliability using the same units as the measurement tool.[27] The reliability coefficient is also referred to as the smallest real difference and shows that more days of measurement can halve the minimal detectable difference needed to prove that an effective intervention can increase the number of steps.

In healthy adults, at least 3 weekdays are needed to achieve a sufficient ICC for physical activity level, and

TABLE 3] Influence of Various Analysis Techniques on the Calculated Sample Size (Measurement Based on 5 Weekdays)

Technique	Baseline	3 mo	Δ	p5-p95	*P* Value	Sample Size
STEPS, No./d						
All data	3,931 ± 2,565	4,846 ± 3,257	916 ± 2,392	−1,599 to 4,948	.0055	56
7:00 AM-8:00 PM	3,664 ± 2,456	4,529 ± 3,143	866 ± 2,298	−1,430 to 4,963	.0062	58
>480 min	3,981 ± 2,602	4,927 ± 2,364	946 ± 2,364	−1,631 to 4,948	.0038	51
>600 min	4,026 ± 2,666	4,988 ± 3,253	962 ± 2,445	−1,631 to 4,948	.0044	53
Combination	3,711 ± 2,464	4,652 ± 2,272	941 ± 2,272	−1,352 to 4,963	.0028	48
TMA, min/d						
All data	50 ± 55	64 ± 74	15 ± 63	−58 to 158	.0855	148
7:00 AM-8:00 PM	48 ± 53	61 ± 69	13 ± 60	−58 to 115	.0957	158
>480 min	50 ± 56	65 ± 75	15 ± 63	−61 to 158	.0873	150
>600 min	51 ± 57	66 ± 76	15 ± 65	−61 to 158	.0895	152
Combination	48 ± 53	62 ± 69	14 ± 60	−58 to 115	.0903	153
METS						
All data	1.327 ± 0.26	1.375 ± 0.34	0.055 ± 0.28	−0.445 to 0.478	.1450	207
7:00 AM-8:00 PM	1.395 ± 0.29	1.466 ± 0.36	0.071 ± 0.30	−0.428 to 0.626	.0763	140
>480 min	1.330 ± 0.26	1.387 ± 0.34	0.057 ± 0.29	−0.371 to 0.485	.1349	197
>600 min	1.330 ± 0.26	1.388 ± 0.34	0.058 ± 0.29	−0.371 to 0.488	.1418	204
Combination	1.395 ± 0.29	1.467 ± 0.36	0.072 ± 0.30	−0.428 to 0.626	.0780	141
Wearing time, min/d						
All data	890 ± 808	916 ± 812	…	…	…	…
No. d	4.75	4.37	…	…	…	…
7:00 AM-8:00 PM	689 ± 62	680 ± 83	…	…	…	…
No. d	4.72	4.37	…	…	…	…
>480 min	901 ± 223	924 ± 255	…	…	…	…
No. d	4.67	4.25	…	…	…	…
>600 min	912 ± 233	932 ± 256	…	…	…	…
No. d	4.53	4.09	…	…	…	…
Combination	698 ± 57	697 ± 65	…	…	…	…
No. d	4.58	4.12	…	…	…	…

Data are presented as mean ± SD unless otherwise indicated. 7:00 AM-8:00 PM = data exclusion before 7:00 AM and after 8:00 PM; >480 min = exclusion of days with ≤480 min of wearing time; >600 min = exclusion of days with ≤600 min of wearing time; combination = included data between 7:00 AM and 8:00 PM of days with minimum of 480 min of wearing time in this period. See Table 2 legend for expansion of other abbreviations.

5 weekdays are needed for STEPS.[21] The present results showed no difference in ICC among the various outcomes. Based on the sample sizes, the most sensitive outcome to find differences is STEPS, which is explained by (1) a reasonable change (20% vs only 5% in average METs) and (2) a manageable SD. It seems that motion-related outcomes (ie, number of steps) better reflect changes in physical activity following rehabilitation compared with other physical activity outcomes (ie, energy expenditure). The use of a light-intensity activity threshold (1.6-2.3 METs) instead of the defined moderate physical activity level reduced the needed sample size and almost approached the sample size needed for STEPS. TMA is an outcome measurement that is difficult to alter and is probably out of reach for many patients with COPD, even following rehabilitation (e-Appendix 1).

Because of the association with mortality and morbidity in patients with chronic diseases (often independent of physical activity levels) increasing attention is given to the measurement of sedentary behavior.[33,34] Sedentary behavior has been defined as any waking behavior characterized by an energy expenditure of ≤ 1.5 METs while

TABLE 4] The Influence of Daylight Time on the Intervention Effect and Calculated Sample Size (Measurement Based on 5 Weekdays)

	Intervention Effect (Δ) Unadjusted[a]		Interaction Effect[b]	Intervention Effect (Δ) Adjusted[c]		
Technique	Mean ± SD	*P* Value	*P* Value	Mean ± SD	*P* Value	Sample Size
STEPS, No./d						
All data	916 ± 2,392	.0055	.0129	990 ± 2,291	.0019	44
7:00 AM-8:00 PM	866 ± 2,298	.0062	.0217	932 ± 2,219	.0025	47
> 480 min	946 ± 2,364	.0038	.0079	1,024 ± 2,247	.0011	40
> 600 min	962 ± 2,445	.0044	.0023	1,055 ± 2,276	.0009	39
Combination	941 ± 2,272	.0028	.0203	1,007 ± 2,192	.0010	40
TMA, min/d						
All data	15 ± 63	.0855	.0016	17 ± 58	.0314	94
7:00 AM-8:00 PM	13 ± 60	.0957	.0030	16 ± 56	.0395	99
> 480 min	15 ± 63	.0873	.0014	17 ± 59	.0316	97
> 600 min	15 ± 65	.0895	.0006	18 ± 59	.0284	87
Combination	14 ± 60	.0903	.0027	16 ± 56	.0361	99
METS						
All data	0.055 ± 0.28	.1450	.0101	0.065 ± 0.27	.0767	138
7:00 AM-8:00 PM	0.071 ± 0.30	.0763	.0028	0.080 ± 0.28	.0297	99
> 480 min	0.057 ± 0.29	.1349	.0092	0.067 ± 0.27	.0696	130
> 600 min	0.058 ± 0.29	.1418	.0052	0.068 ± 0.28	.0686	136
Combination	0.072 ± 0.30	.0780	.0024	0.083 ± 0.28	.0298	92

See Table 2 and 3 legends for expansion of abbreviations.
[a]Uncorrected intervention effect.
[b]Interaction effect (intervention effect × Δ daylight time).
[b]Corrected intervention effect for Δ daylight time, using mixed-model analysis.

in a sitting or reclining posture.[35] The SenseWear armband does not record information on changes in posture; therefore, the results discussed in the present study only relate to physical activity measurement and not to standardization of sedentary behavior data collection. In healthy elderly people, more days of measurement are needed to reliably (ICC > 0.80) assess sedentary data (7 days) in cross-sectional analyses.[31,36] Thus, we hypothesize that more days and hours of wearing time are needed to analyze sedentary behavior in patients with COPD, which is a direction for future studies.

DT and weather conditions affect physical activity levels in elderly people.[12] The difference in DT as a marker of the measured season influences the effects on physical activity seen in repeated measures and can be included as a confounder in intervention studies. This is in line with previous literature showing that seasonal variation has an important impact on the change in physical activity after rehabilitation[11] and concluding that season affects the change in STEPS.[37] This finding may be less relevant to certain regions, such as equatorial Brazil where the mean temperature difference in winter compared with summer is less pronounced than in most European countries, seasonal effects have been shown to be less present,[38] and differences in DT are less pronounced compared with Belgium (latitude 51°N).

The present study confirms that patients with COPD perform most activities between 7:00 AM and 8:00 PM.[14] Compliance with wearing an activity monitor is a prerequisite for obtaining an accurate physical activity measurement. Research has concluded an excellent compliance with wearing the monitors day and night, supporting feasibility.[39] In overweight adults, reliable and comparable results were observed with 8, 10, and 12 h of assessment.[40] This finding can be explained by the very low activity pattern of the studied population, which is also common in the present COPD population.[41] When physical activity is only measured during waking hours, we recommend defining days as noncompliant when wearing time is < 8 h. If data are available during night and day, we propose defining valid days as those with a minimum of 8 h of wearing time between 7:00 AM and 8:00 PM. Exclusion of days

with < 12 h of wearing time is not recommended because of the large drop in the number of subjects.

Aside from decreasing the variability of the measurement, increasing the effect size (and subsequently the power) of the study can be achieved by increasing the magnitude of the intervention effect itself. The fact that enhanced physical activity is not guaranteed after pulmonary rehabilitation programs can be due to a lack of effective behavior change. This behavior change probably needs more-specific interventions aimed at an increase in physical activity instead of exercise programs that primarily aim for an increase in functional capacity. More research on these programs is warranted, but pilot data using a combination of a step counter and online feedback seem promising.[42] Various strategies of processing physical activity data have implications for the perceived impact of an intervention but do not change the magnitude of the effect itself. The latter is limited because no minimal clinically important difference has been established yet.

A few limitations should be considered when interpreting the present data. First, the SenseWear armband provides accurate information on identifying minutes of moderate to intense activity but is less reliable as a step counter.[22] This multisensory activity monitor, worn at the arm and validated against both indirect calorimetry and doubly labeled water, is less accurate in identifying the number of steps. When expressed as the difference between steps measured by an activity monitor vs actual steps measured by manual counting, accelerometers worn at the arm less accurately represent the actual step count compared with leg activity monitors.[22,43] The number of steps measured in the present study may be underestimated, but although this may affect cross-sectional values, it is not likely to affect the interventional changes or the conclusions. Second, the activity measurement was restricted to 7 days. Whether more days of measurement could have further decreased the sample size is not known. Increasing the assessment time is not feasible because patients may refuse to wear the monitors for longer periods. The majority of patients appear to be willing to wear activity monitors for up to 1 week.[23] In addition, measurement data at 5 days was almost identical to that at 4 days, so it is unlikely that longer periods would have changed the present conclusions. Third, it should be highlighted that through the proposed standardized way of measuring physical activity, we attempted to provide an optimal analysis of activity data from a statistical standpoint, but this does not necessarily provide a more accurate representation or validation of the outcomes. Finally, although the main findings apply to pulmonary rehabilitation, the proposed way of analyzing physical activity data likely will also be applicable to studies of other interventions because the measurement methods mainly had an effect on the SD. Similarly, we suggest that our way of analysis can be generalized to other validated activity monitoring devices, in as far as their activity outcomes, (eg, step count), are validated.

Conclusions

Outcome measurements of number of steps and time in light activity (1.6-2.3 METs) assessed on at least 4 weekdays with a minimum of 8 h of monitor wearing time (during waking hours) with proper correction for a difference in DT reduce the noise in physical activity data and improve intervention responsiveness. These findings have implications for trial design and data processing and would potentially be cost saving for researchers on the one hand and helpful in measuring physical activity in the clinical routine for clinicians on the other hand by reducing the burden on patients.

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Additional information. The e-Appendix can be found in the Supplemental Materials section of the online article.

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