

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

*Heleen Demeyer, PT, MSc; Chris Burtin, PhD, PT; Hans Van Remoortel, PhD, PT; Miek Hornikx, PT, MSc; Daniel Langer, PhD, PT; Marc Decramer, MD, PhD; Rik Gosselink, PhD, PT; Wim Janssens, MD, PhD; and Thierry Troosters, PhD, PT*

CHEST 2014; 146(2):318-327

## **e-Appendix 1.**

### **Material and methods**

#### *Study subjects and design*

Patients with COPD referred for outpatient pulmonary rehabilitation at the University hospital Gasthuisberg, Leuven were included in the present study. Inclusion in the rehabilitation program was based on the presence of symptoms of dyspnea combined with one of the following criteria: maximal workload <90 watt, six minutes walking distance <70% of predicted values or quadriceps force <70% of predicted values. Exclusion criteria were the inability of walking without walking aids, orthopedic problems interfering with daily activity, psychiatric or cognitive disorders, progressive neurological or neuromuscular disorders and an hospitalization up until 4 weeks before inclusion. Informed consent was obtained prior to the start of the study.

**Sample size calculation** has been done prior to the start of the study based on the primary research question of the RCT (NCT00948623), namely finding a group difference in the intervention effect. In this secondary analysis the obtained convenience sample size of 57 was available. This sample size was judged to be sufficient to provide a point estimate of the difference and standard deviation. In order to support this statement a sensitivity analysis ('leave-one-out' analysis) was performed leaving random patients out of the analysis (e-Figure 1). Mean, standard deviation and sample size calculation did not change significantly.

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### *Clinical measurements: definition of different activity thresholds*

Different activity thresholds ranging from 1.1 to 3 METs were compared as outcome measurement after rehabilitation. One MET is considered the resting metabolic rate or the energy cost of a person at rest. Sedentary behavior is defined as activities between 1.0 and 1.5 METs, light-intensity as those between 1.6 and 2.9 METs, moderate-intensity between 3.0 and 5.9 METs and vigorous intensity as activities with a metabolic rate of more than 6 METs<sup>1</sup>. Daily minutes of activity above these different thresholds were identified in the minute by minute database of 4 weekdays with at least 8 hours of wearing time and used as outcome measurement after rehabilitation.

### *Data treatment*

#### **Number of days of measurement and impact of weekend days**

Random datasets of 2, 3, 4 and 5 consecutive weekdays were extracted. The impact of the exclusion of weekends was investigated by including the weekend to the analysis of 5 weekdays (1 in e-Figure2). To investigate the number of days of measurement the analyses of 2, 3, 4 and 5 random weekdays (2a in e-Figure2) were compared. To identify the impact of weekly routine the same days at the two time points (ISO DAYS) were analyzed (2b in e-Figure2).

#### **Impact of the used technique of analysis**

The included dataset of analysis depended on the used techniques of analysis: (1) analyze all available minutes of the recorded data (A in e-Figure2), (2) exclude days with low wearing time, with a minimum of 8, 10 and 12 hours (B in e-Figure2), (3) exclude data recorded before 7AM and after 8PM (C in e-Figure2), based on the hypothesis that including this period is sufficient to capture domestic activity and may reduce the impact of duration of daylight.

### **Results**

#### *Influence of the use of different activity threshold*

The use of different activity thresholds had an impact on the needed sample size to achieve a power of 0.8 with a significance level of 0.05. The use of a METs value between 1.3 and 2.2 METs decreased the sample size (e-Table1). Focusing on the activities with a light-intensity (1.6 – 2.9 METs), a gradual increase in the sample size calculation can be seen as of 2.3 METs, when increasing the threshold to a higher METs value (e-Figure3).

### **Discussion**

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The use of a lower threshold instead of the defined moderate physical activity level decreased the needed sample size. When focusing on activities of light intensity, a decreased sample size was shown using minutes of at least 1.6 - 2.3 METs as an outcome measurement after rehabilitation.

Previous literature already indicated that the intensity of activity for patients with COPD should be  $\geq$  2METs and, as activity of light intensity is predominant in these patients, that the evaluation of these activities is very important<sup>2</sup>. Our data reinforce the use of a light intensity threshold instead of the focus on moderate physical activity level, according to the American college of sport medicine<sup>3</sup>, of 3METs. Based on the present study the use of this threshold as an outcome measurement seems out of reach for many patients with COPD and difficult to intervene with in this population. These results can probably explain the higher responsiveness of the daily amount of steps as this measurement reflects particularly lighter activities.

#### References

1. Ainsworth BE, Haskell WL, Herrmann SD et al. 2011 Compendium of Physical Activities: A Second Update of Codes and MET Values. *Medicine and Science in Sports and Exercise*. 2011;43(8):1575-1581.
2. Sugino A, Minakata Y, Kanda M et al. Validation of a Compact Motion Sensor for the Measurement of Physical Activity in Patients with Chronic Obstructive Pulmonary Disease. *Respiration*. 2012;83(4):300-307.
3. Haskell WL, Lee IM, Pate RR et al. Physical activity and public health: Updated recommendation for adults from the American College of Sports Medicine and the American Heart Association. *Medicine and Science in Sports and Exercise*. 2007;39(8):1423-1434.

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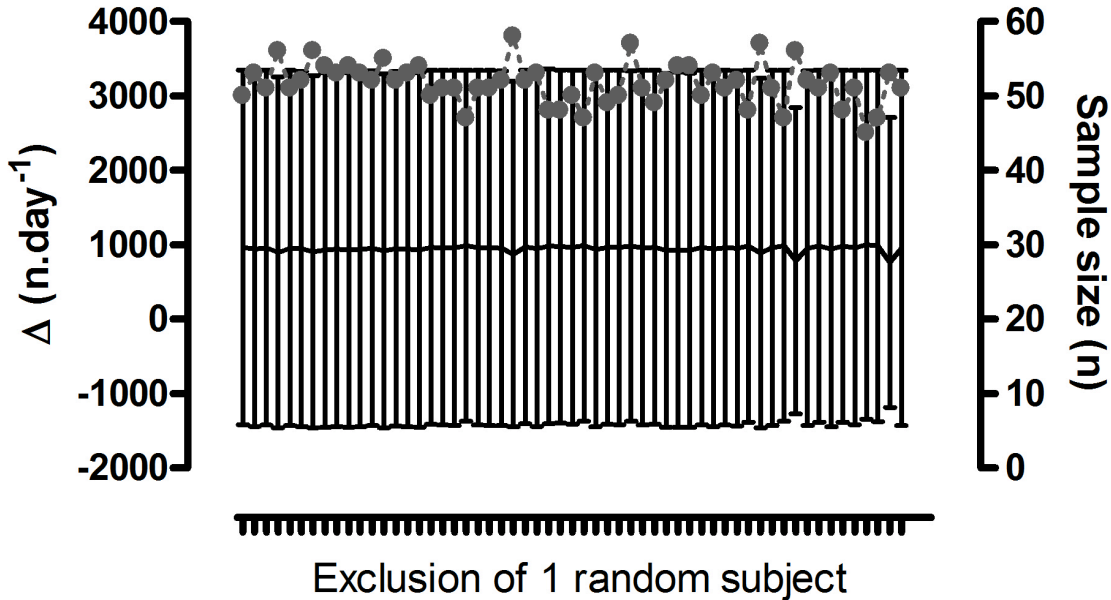
**Tables**

Activity threshold	Baseline	3 months	Δ	P value	SS (n)	<b>e-Table1: Influence of different activity thresholds on the calculated sample size</b>
<b>Time in activity (min)</b>						
1.0 METs	650 ± 217	655 ± 234	5.5 ± 151	0.7860	6015	
1.1 METs	505 ± 194	517 ± 196	12 ± 109	0.4249	695	
1.2 METs	364 ± 174	398 ± 182	34 ± 110	0.0225*	84	
1.3 METs	212 ± 144	250 ± 153	38 ± 110	0.0119*	69	
1.4 METs	94 ± 77	120 ± 99	27 ± 81	0.0157*	74	
1.5 METs	84 ± 70	108 ± 91	24 ± 76	0.0183*	78	
1.6 METs	84 ± 70	108 ± 91	24 ± 76	0.0184*	78	
1.7 METs	84 ± 70	108 ± 91	24 ± 76	0.0185*	78	
1.8 METs	83 ± 70	107 ± 91	24 ± 76	0.0190*	79	
1.9 METs	82 ± 70	106 ± 91	24 ± 76	0.0190*	79	
2.0 METs	80 ± 70	104 ± 91	24 ± 76	0.0189*	79	
2.1 METs	78 ± 71	102 ± 91	24 ± 76	0.0184*	78	
2.2 METs	75 ± 70	99 ± 91	24 ± 76	0.0189*	79	
2.3 METs	72 ± 69	96 ± 91	24 ± 75	0.0215*	82	
2.4 METs	69 ± 68	92 ± 90	23 ± 75	0.0238*	85	
2.5 METs	66 ± 67	88 ± 88	22 ± 74	0.0270*	89	
2.6 METs	63 ± 66	84 ± 87	21 ± 73	0.0310*	94	
2.7 METs	60 ± 64	80 ± 85	20 ± 72	0.0402*	104	
2.8 METs	57 ± 62	76 ± 83	19 ± 70	0.0472*	111	
2.9 METs	53 ± 60	71 ± 80	18 ± 69	0.0557	120	
3.0 METs	50 ± 58	67 ± 78	17 ± 67	0.0684	132	

wearing time); data expressed as mean±SD; SS= predicted sample size to achieve a power of 0.8 with a significance level of 0.05

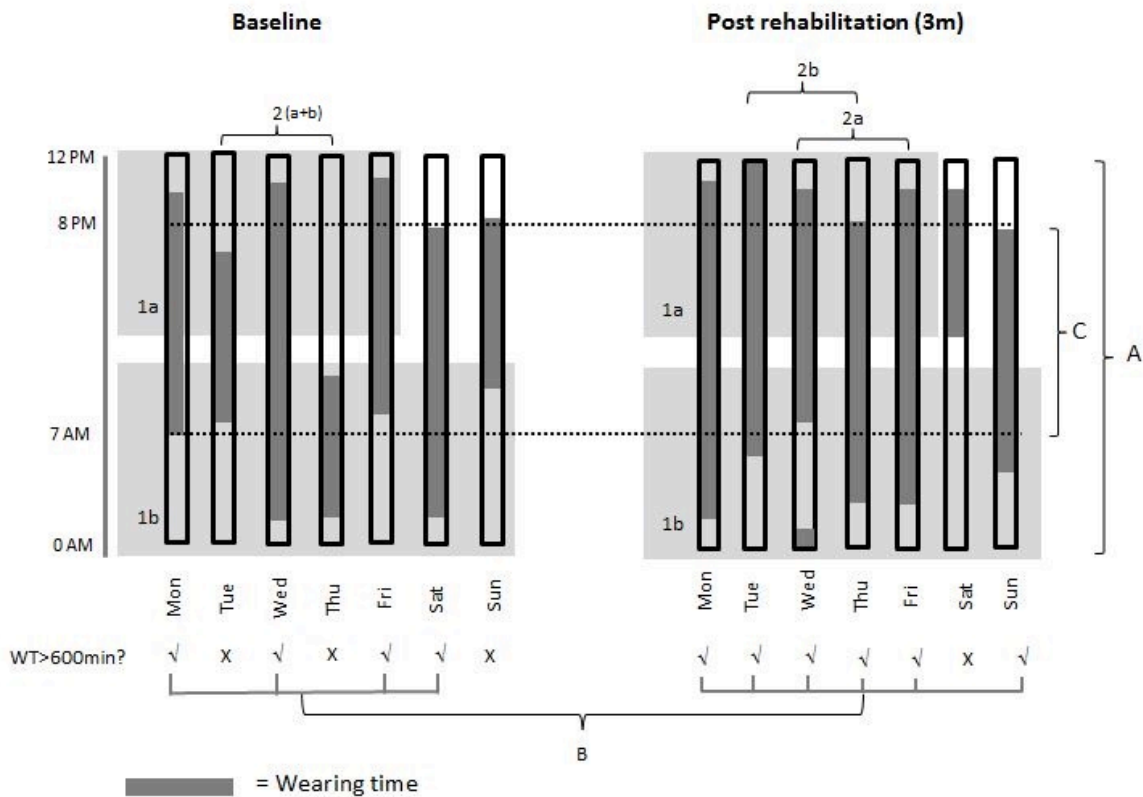
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Figures



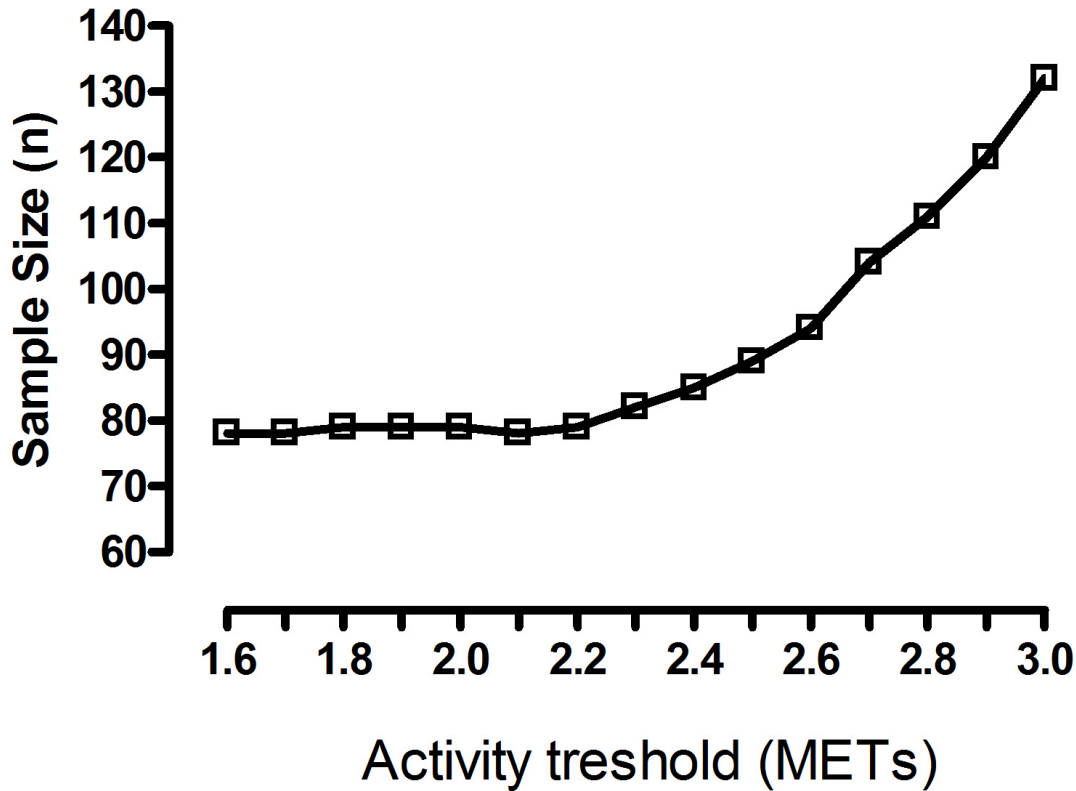
**e-Figure1: Influence of leaving random patients out of the analysis:** Found change in daily stepcount pre-post rehabilitation( $\Delta$ ) on the left y-axis (solid line, data are presented as mean  $\pm$  standard deviation); Sample size calculation to achieve a power of 0.8 presented on the right y-axis (dots)

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**e-Figure2: Example of the different used datasets** (measurement pattern of 1 subject): 1a= Exclude weekends, 1b=Include the whole week; 2a= Compare random days (e.g. 3 days), 2b= Compare overlapping days (e.g. 3 days); A= Include all data; B= Exclude days with a too low wearing time (e.g. 600 min); C= Exclude data before 7AM and after 8PM

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**e-Figure3: Influence of the use of different activity thresholds on the calculated sample size: focus on activities with light intensity;** METs= mean METs level, Sample size= Sample size needed to achieve a power of 0.8 with a significance level of 0.05

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