Promoting Physical Activity in COPD:

Insights from a Randomized Trial of a Web-Based Intervention and Pedometer Use

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Online Data Supplement

Supplementary Methods

Participants and Study Design

Subjects were at their baseline clinical status with no acute exacerbations ≤ 4 weeks prior to enrollment. All subjects received medical clearance for participation from a healthcare provider. Subjects provided detailed information about medical history, demographics, comorbidities, and medication and oxygen use.

Pedometer Accuracy Testing

At the enrollment visit, subjects were instructed to walk 800 feet along a pre-determined course at their usual speed while wearing the Omron pedometer. Manual step counts were obtained simultaneously during this walk to confirm that the Omron achieved >90% accuracy in each subject.

Outcome Assessments

The wear day criterion (≥8 hours/day and ≥100 steps) identified days when the pedometer was not worn by the subject. Based on our prior experience showing that even the most inactive subject compliant with wearing the pedometer walks at least 100 steps per day, our definition does not exclude subjects who have low PA [1]. Baseline daily step count was the average of all wear days (minimum ≥ 5 days) during the 7 days prior to randomization. We chose ≥3 days per week during the study as a pragmatic way to balance including as many subjects in the analysis as possible while having an accurate representation of PA for the week under consideration for each participant. The definition of a wear day and calculation of baseline and follow-up step counts were similarly applied to both groups.

The 6MWT distance and questionnaires were secondary outcomes assessed in person in the clinic. Subjects missing any of the secondary outcomes data were not excluded from the entire study, only from analyses involving that variable. HRQL was assessed with the St. George's Respiratory Questionnaire (SGRQ) [2]. Scores range from 0-100 with lower scores indicating better HRQL. A change of 4 units is the minimum clinically important difference for the SGRQ-TS [2]. Dyspnea was assessed with the modified Medical Research Council (MMRC) scale with responses ranging 0-4 with 4 being the most dyspneic [3], and depression with the 24-item Beck Depression Inventory-II [4] where higher scores indicate more depressive symptoms.

We administered the Bristol COPD Knowledge Questionnaire to test what patients learn and understand about COPD. The 65 items cover topics such as symptoms, exacerbations, smoking, vaccination, and medication use [5] with higher scores indicative of increased knowledge. The Exercise Self-Regulatory Efficacy Scale (Ex-SRES) for persons with COPD measures exercise self-regulation, and incorporates items from Resnick's self-efficacy scale for older adults and McCauley's self-efficacy questionnaire for sedentary adults [6]. The 16-item questionnaire has been shown to be reliable and valid in COPD with higher scores indicative of increased self-efficacy [6]. The Medical Outcome Study (MOS) Social Support survey [7] assesses social support, with higher score indicative of greater support. Participants also answered two questions using a 0 (not at all) to 10 (extremely) response scale: "Overall, how motivated are you to exercise each day?" and "Overall, how confident are you that you can exercise each day?" We have previously shown that responses to these 2 questions are related to daily step counts [8]. Changes in outcomes were calculated as the difference of values obtained at baseline and end-of-study.

Statistical Analysis

The assumption for the mixed effects models is that the distribution of change in step count is Gaussian (normal). This was a reasonable approximation of the distribution of the observed data. To evaluate the effect of the pedometer plus website and the impact of season on change in PA, generalized linear mixed effects models for repeated measures using an auto-regressive covariance matrix (PROC MIXED, SAS v9.4, Cary, NC) were constructed with change in daily step count as the dependent variable and randomization group, FEV_1 % predicted (chosen *a priori* as a marker of disease severity), and season of study week as the independent variables. Study week was included as a categorical variable. The final model tested was:

[Change in step count (week)] = [Randomization group] + [FEV_1 %] + [Season of study week] + [Study week (categorical)] + [Randomization group]*[Study week (categorical)]

The least squares means solutions from each multivariate model provided adjusted values for change in daily step count at weekly time points. Because the between-group difference at end-of-study (week 13) was the *a priori* endpoint, corrections for multiple testing were not made.

Supplementary Results

Change in daily step count by study week

Supplementary Table 1. Change in daily step count by study week, and randomization group

	Pedometer plus Website		Pedometer Alone	
Study Week	Change in daily step count	p-value*	Change in daily step count	p-value*
1	253.9 (± 225.7)	0.26	3.3 (± 235.8)	0.99
2	355.3 (± 229.8)	0.12	240.9 (± 235.9)	0.31
3	523.1 (± 232.3)	0.02	313.2 (± 235.0)	0.18
4	585.7 (± 231.9)	0.01	147.7 (± 236.7)	0.53
5	700.7 (± 232.5)	2.6×10^{-3}	139.3 (± 234.5)	0.55
6	573.7 (± 232.5)	0.01	-1.7 (± 234.8)	0.99
7	435.6 (± 234.3)	0.06	22 (± 236.1)	0.92
8	652.5 (± 233.9)	5.4×10^{-3}	-149.4 (± 240.6)	0.53
9	710.6 (± 233.1)	2.4×10^{-3}	63.6 (± 243.6)	0.79
10	480.5 (± 232.7)	0.04	80.5 (± 244.4)	0.33
11	573.8 (± 234.5)	0.01	-160 (± 248.9)	0.52
12	590.2 (± 234.0)	0.01	-1.8 (± 251.5)	0.99
13	581.3 (± 240.4)	0.02	-222.9 (± 263.3)	0.4

Data are expressed as mean (±SE).
*p-values test the hypothesis that mu = zero (no change)
Values are derived from least square means solutions for change in daily step count from a generalized linear mixed-effects model for repeated measures, adjusting for FEV_1 % predicted and season of study week.

Effects of Season

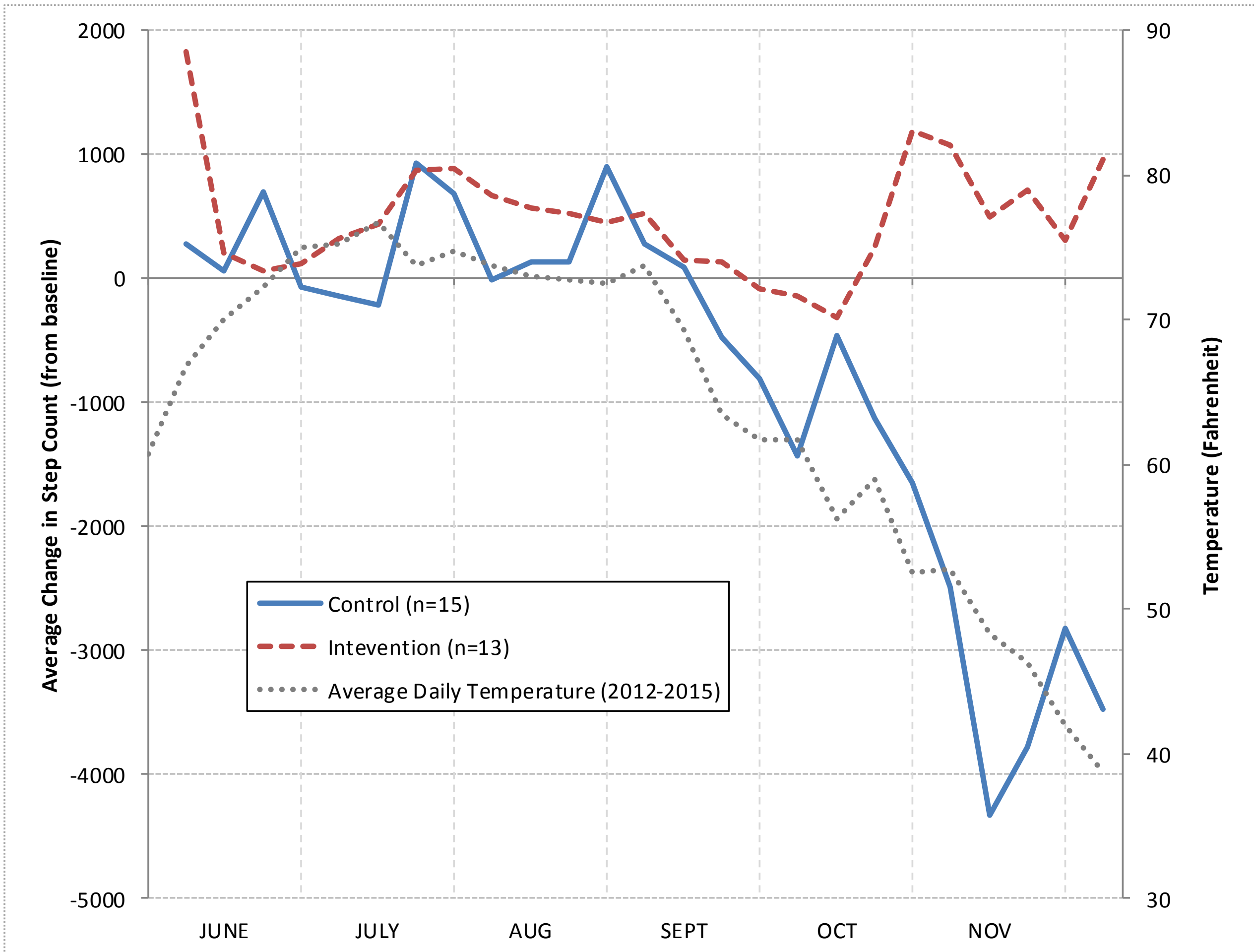
Season was a significant predictor of change in step count in the primary model. Effect estimates for each season ("winter" as reference) are shown in Supplementary Table 2.

Supplementary Table 2. Effect estimates of each season (categorical) in primary model

Season	Effect	SE	p-value
Spring (March, April, May)	621.2	202.3	0.0030
Summer (June, July, August)	497.0	202.8	0.0166
Fall (September, October, November)	276.5	166.6	0.1010
Winter (December, January, February) [reference]			

Using historical data from weatherunderground.com, we graphed the average daily temperature (by week) recorded at Boston's Logan International Airport for the periods of June through the first week in December for 2012-2015 (during the period of study enrollment). Supplementary Figure E1 shows that average temperatures decline dramatically during the second week in September. Data from subjects included in Figure 3 were plotted as the average change in step count by calendar month (instead of study week), illustrating the decline in daily step count in September among the pedometer alone group which coincides with the onset of cooler temperatures. This sharp decline in daily step count was not observed in the pedometer plus website group.

Supplementary Figure E1. Change in daily step count and average daily temperature by calendar month (for subjects enrolled during summer)

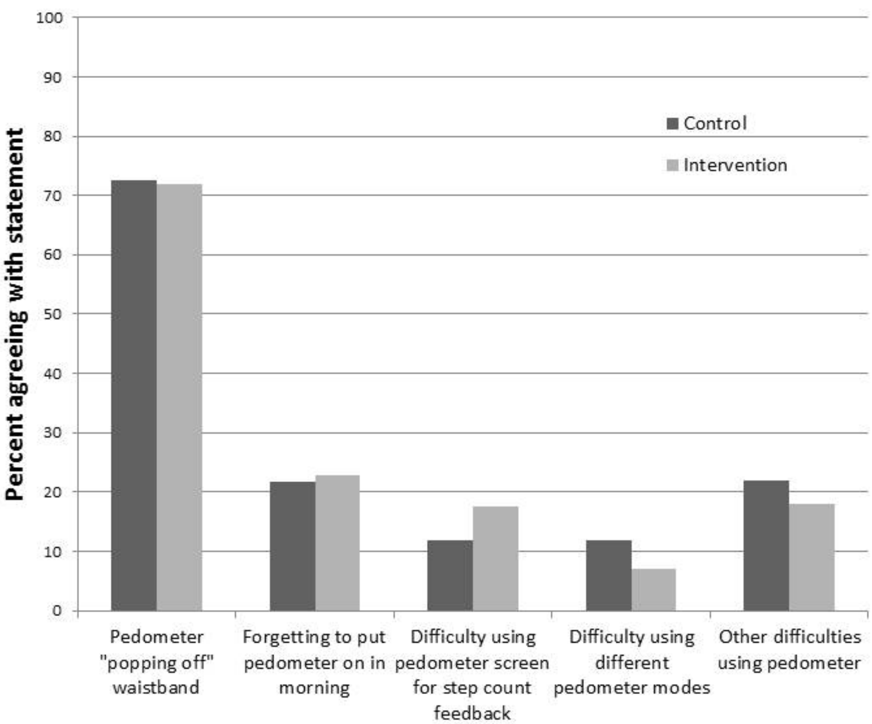


Average change in daily step count for the pedometer alone (control – solid blue line) and pedometer plus website (intervention – dashed red line) groups by calendar month (x-axis) are shown superimposed on a plot of average daily temperatures at Boston's Logan International Airport during the years of study recruitment (2012-2015). Subjects in the control group demonstrate a decline in daily step count from baseline which coincides with the decrease in average daily temperature. Historical temperature data from weatherunderground.com (www.weatherunderground.com; accessed March 16, 2017).

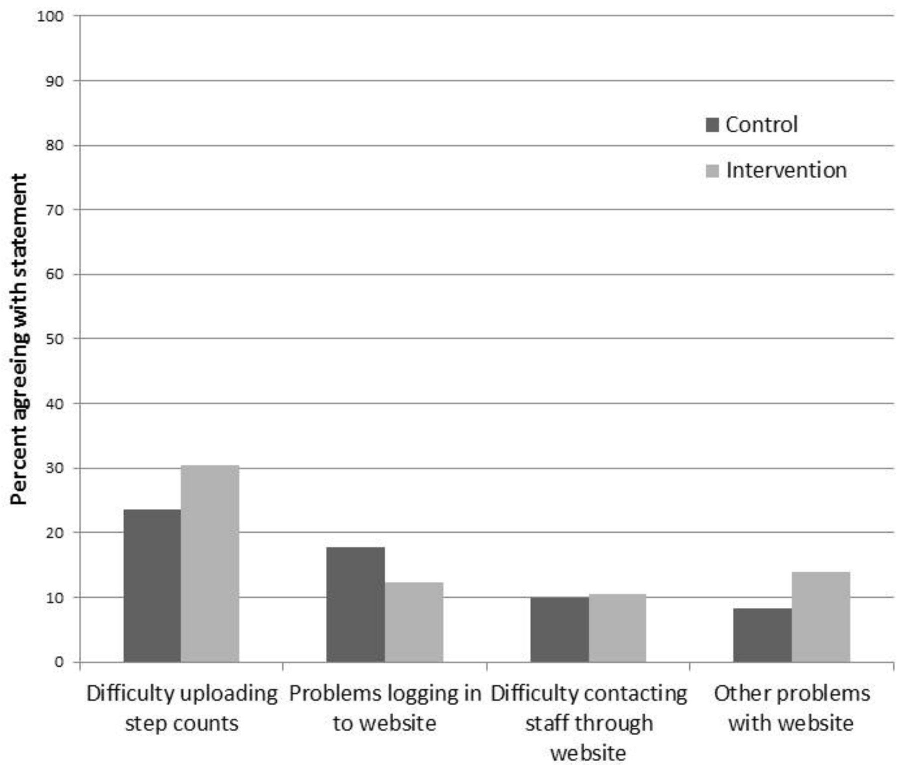
Among subjects enrolled during the summer, 6 pulmonary events (pneumonia or acute exacerbations) were reported by 5 individuals (3 pedometer alone, 2 pedometer + website). Four of the six pulmonary events occurred in the fall/winter (defined as occurrence on or after September 1^{st} each year); two pulmonary events occurred in each group. Thus, increased occurrence of pulmonary events in the fall/winter was unlikely to account for the decrease in daily step count observed in the pedometer alone group.

Supplementary Figure E2. Subject-reported technical difficulties

(a) Pedometer difficulties



(b) Website difficulties



Supplementary References

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