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"Take home" message: mHealth intervention does not improve or maintain physical activity in COPD patients after pulmonary rehabilitation.

Abstract

Physical inactivity in patients with Chronic Obstructive Pulmonary Disease (COPD) is associated with poor health status and increased disease burden. The present study aims to test the efficacy of a previously developed mHealth intervention to improve or maintain physical activity (PA) in patients with COPD after pulmonary rehabilitation (PR).

A randomized controlled trial was performed in 32 physiotherapy practices in the Netherlands. COPD patients were randomized into an intervention (I) or usual care group (U). The intervention consisted of a smartphone application for the patients and a monitoring website for the physiotherapists. Measurements were performed at 0, 3, 6 and 12 months. PA, functional exercise capacity, lung function, health-related quality of life, and body mass index were assessed.

157 patients started and 121 completed the study. There were no significant positive effects of the intervention on PA (0 months: I:5824±3418 U:5717±2870; 12 months: I:4819±2526; U:4950±2634 steps/weekday; p=0.811) or on the secondary endpoints. There was a significant decrease over time in PA (p<0.001), lung function (p<0.001), and mastery (p=0.017), but not in functional exercise capacity (p=0.585).

Although functional exercise capacity did not deteriorate, our mHealth intervention did not improve or maintain PA in patients with COPD after a period of PR.

Introduction

Persons with Chronic Obstructive Pulmonary Disease (COPD) demonstrate reduced daily physical activity (PA) compared to healthy age-matched controls [1]. Both the amount and the intensity of PA is reduced [2], and data suggest that their PA is reduced early in the course of the disease [3]. Physical inactivity worsens over time [4], has important clinical consequences, and undoubtedly complicates the course of the disease [3,5].

Functional exercise capacity is known to improve in COPD patients during a pulmonary rehabilitation (PR) program[6], but this effect declines over time [7] when patients do not continue to exercise after finalizing the program [8].
The effect of PR on PA yields inconsistent results [3,6]. A 24-week duration of PR seems beneficial compared with 12 weeks and an exercise program of 18 months resulted in greater improvements than a 12-week program [9,10]. However, most PR programs only last for 8 to 12 weeks [11], and structured aftercare programs are often lacking [5]. Hence, there is a need for effective interventions aiming to improve, and subsequently maintain, PA in patients with COPD during and particularly after PR [12]. Of the various interventions aimed to prolong the beneficial effects of PR none has unequivocally been shown to work [13]. There is some evidence that health technology can help to facilitate PA behavior change [14]. It is expected that the developments in information and communication technology and the proficiency of future patients will have a significant impact [5], making mobile-health support programs accessible to patients. The inclusion of accelerometers in mobile phones and the increasing availability of mobile technology further facilitates such developments.

This study aims to test the efficacy of a previously developed mHealth intervention [15] in a randomized controlled trial. The primary aim is to study whether this mHealth intervention, started after discharge of a 12 week PR program, will enhance or maintain PA compared to usual care in patients with COPD. The secondary aim is to study whether these improvements would affect functional exercise capacity, health related quality of life (HRQoL), and body mass index (BMI).

Methods

Design
This was a multicenter, investigator-blinded, randomized controlled trial with an intervention duration of 6 months. Participants were randomized into an intervention or a usual care group. All participants gave written informed consent and continued to receive usual care according to the guidelines of the Dutch College of General Practitioners [16]. The study was approved by the Utrecht Medical Ethical Research Board (research protocol 11/279).

Participants
Physiotherapists (PTs) in primary care physiotherapy practices with expertise in COPD were recruited at random throughout the Netherlands via the the Utrecht network for COPD PTs and an advertisement in a national physiotherapy journal (FysioPraxis). The PTs subsequently

recruited patients from their practice that were diagnosed with COPD, GOLD stage 2 or 3 (30% ≤ FEV1 < 80%, FEV1/FVC < 70% after bronchodilatation), aged >40 years, who had completed a PR program of 3 months within the last 6 months and lived independently. Persons were not included in the trial if they were suffering from a comorbidity that greatly influences PA, using an assistive device for PA (e.g., walker, mobility scooter), intermittently ceased the PR program, and/or experienced an exacerbation resulting in a hospital admission in the 6 months previous to the study commencement.

Randomization and intervention

The patients included in the study were randomly assigned to the intervention or usual care group, independent of physiotherapy practice, based on a random number sequence generated in Excel (Microsoft, Redmond, WA, USA) *before* enrollment. These numbers ranged between 0 and 1. The values were categorized into 0 (= usual care) and 1 (= intervention), based on a ≥0.5 threshold. Subsequently, each newly recruited participant was given the first available number and enrolled in the corresponding group. Patients with and without long-term physiotherapy after PR (some form of continued, though significantly reduced, supervised exercise training for 1-2 sessions a week vs. no physiotherapy continuance) were separately randomized via stratification because this was seen as a confounder.

All subjects received individual face to face (and written) instructions on the design of the study. Subjects in the usual care group solely performed the assessments at the four measurement time points.

The intervention consisted of two components: 1. a smartphone application (online supplement figure 1), and 2. a website for the PTs (online supplement figure 2) [15]. The application showed PA in real time in quantitative and qualitative form, measured by the accelerometer embedded in the smartphone (HTC desire A8181 smartphone). Subjects were persuaded to obtain their personalized PA goal by automated persuasive messages and an emoticon (pictorial representation of an emotion). The PT could monitor their patients via the (secure) website, which showed both the PA data from all the participants from their practice and a more detailed view of individual patients. The PT was able to adjust each patient's PA goal and sent group or individual text messages. No automated adjustments of the PA goal were performed. PTs received an individual face to face (and written) instruction on the functionalities of the website. The intervention group received a smartphone, a phone/internet contract, and an individual face to face (and written) instruction on the use of the smartphone and the application. The subjects in the intervention group were instructed to wear the smartphone in a pouch on their belt and use it as their usual phone. Those subjects in the possession of mobile phones were asked to transfer their SIM card into the study smartphone. For the first week of the study, PA goals were not set, and subjects were instructed to perform their day-to-day activities as usual. Afterwards, initial personal PA goals were calculated with data from this baseline week as follows: 1. average steps/day + 20% as daily step goal; 2. Daily, the number of steps during the 30 most intensive minutes were averaged. These steps were averaged into a value for a week. This latter value + 20% was set as the minimum required number of steps in one minute to account for an intensive minute of PA; and 3. 30 minutes of intensive minutes performed per day, according to the Dutch healthy exercise norm [17]. After this initial PA goal setting, PTs were given responsibility for

PA goal adjustment. They could reduce or increase the amount and intensity of the PA goal via the website based on the individual ability of their patient over time.

Assessments

Measurement time points were at 0, 3, 6 and 12 months (T0, T3, T6, and T12, respectively). Assessments were performed by two researchers that were blinded for group allocation.

Lung function

Forced expiratory volume in 1 second (FEV1) and forced vital capacity (FVC) were measured with a Spiromed 2000 (Medikro, Finland). Spirometry was performed according to ATS-ERS guidelines [18], and the results were compared to normal values of Quanjer et al. [19].

Functional exercise capacity

The modified six minute walk test (6 MWT) was performed on a 10 meter course using methodology suggested for primary care [20]. Six MWTs were performed twice each measurement time point (with a period of rest in between), and the best score was used for analysis. The results were expressed as percentage of the predicted normal values for the Dutch population [21].

HRQoL

Subjects filled out the self-administered standardized chronic respiratory questionnaire (crq-sas). The questionnaire has been found to be a reproducible, reliable, and stable measure of health status [22]. Additionally, it has been found to be reliable and valid in the Dutch Language [23].

Physical Activity

Each subject was provided an accelerometer validated in patients with COPD (SenseWear PRO or MF-SW mini armband, Body Media, Pittsburgh, USA) [24]. This device was worn following the manufacturer's instructions. Subjects were asked to wear the armband during waking hours (except for water-related activities) for seven successive days after each measurement time point. Physical activity was analyzed using proprietary software (SenseWear v7.1).

BMI

Height was measured only at baseline. Weight was measured at all visits.

Weather

For each assessment humidity, atmospheric pressure and temperature of a meteorological point nearest to the location of the physiotherapy practice were written down from a Dutch meteorological website [25].

Statistical analysis

Descriptive statistics include the mean (with standard deviation) or frequencies, where appropriate. Power calculations revealed the need for 70-80 subjects per group to be sufficient to achieve a satisfactory power (see online supplement A).

Average steps/weekday was the main outcome measure and was computed as suggested by Demeyer et al. [26]. Using repeated measures linear mixed modelling (LMM), we assessed the

differences between groups, the effects of measurement time points, and whether group differences were dependent on measurement time points (=group by time interaction). If this latter group by time interaction is not significant, then the development of the outcome measure over time is similar in both groups, and there is no effect of the intervention. The chosen approach was a random intercept, random slope method with an unstructured covariance matrix. The primary explanatory parameters were the measurement time points (T0-12) and the group allocation (I/U). These two parameters constitute the basic model. Subsequently, other parameters were added to see if they improved the model. Online supplement B describes the LMM analysis in more detail. This analysis process was repeated with the six-minute walk distance (6 MWD), Average Metabolic Equivalent of Task (Average METs), CRQ-SAS outcomes, and BMI as outcome measures.
Adherence to the intervention was measured as percentage of days the intervention was used, and as percentage of days the PA goal was obtained. Analyses were carried out using SPSS (IBM®, PASW Statistics, version 23.0, Chicago, IL, USA) for Windows.

Results

One hundred and fifty-seven subjects started the study, and 121 subjects completed all four measurements (**figure 1**). Subjects were recruited from from 32 physiotherapy practices throughout the Netherlands; 14 within and 18 outside of the Province of Utrecht. Baseline characteristics of the subjects in the intervention (I) and the usual care (U) group can be found in **table 1**. Results on weather can be found in online supplement C.

Table 1. Baseline characteristics and demographics.

	I (N=84)	U (N=73)
Age (years)	62 ± 9	63 ± 8
Females/Males	42/42	37/36
Body mass index		
Underweight (<18.5 kg/m^2)	1 (1%)	2 (3%)
Normal (18.5-24.9 kg/m^2)	24 (30%)	27 (37%)
Overweight (25-29.9 kg/m^2)	31 (38%)	22 (30%)
Obese (≥30 kg/m^2)	25 (31%)	22 (30%)
Forced expiratory volume in 1 second (liters)	1.67 ± 0.59* (59 ± 20% predicted)	1.48 ± 0.43 (53 ± 15% predicted)
Forced vital capacity (liters)	3.6 ± 0.98 (101 ± 20 % predicted)	3.48 ± 0.98 (99 ± 19% predicted)
6-minute walking distance (meters)	465 ± 87 (80 ± 15% predicted)	459 ± 73 (79 ± 12% predicted)
CRQ-SAS (score 1-7)		
Dyspnea	4.8 ± 1.3	4.8 ± 1.3
Fatigue	4.3 ± 1.1	4.2 ± 1.2
Emotional function	5.0 ± 1.1	4.8 ± 1.2
Mastery	5.4 ± 1.1	5.3 ± 1.1
Average steps/day (weekday)	5824 ± 3418	5717 ± 2870
Average steps/day (weekend)	5219 ± 3696**	5328 ± 3424**
Average METs	1.48 ± 0.39	1.55 ± 0.41
Long term physiotherapy (N)	69 (82%)	58 (79%)

Data are presented as N or mean ± SD or number. I: intervention group; U: usual care group; BMI: 3 missing values for I; *significantly higher than U; **significantly lower than weekdays at p<0.001.

Average personal PA goal was 6124 ± 2819 steps/day at the start of the study and 5968 ± 2442 steps/day at the end of the intervention period. The intervention was used on 89 ± 18.5% of the study days. The personal PA goal was obtained on 34 ± 16% of these days (**figure 2**). On average, subjects achieved 10 ± 25% steps/day fewer than indicated in their PA goal. PTs sent 362 personal and 10 group messages to their patients. The patients returned 162 messages to the PT. In the intervention group, FEV1 decreased at an average of 56 ml over the one year follow-up period (p=0.162) and in the usual care group with 98 ml (p=0.001). There was no group by time interaction (p=0.508) meaning that the decline in FEV1 over time was not significantly different between the groups.

The effect sizes of the measurement time points and added parameters that significantly improved the models can be found in online supplement C. **Table 2** shows the results of the LMM analyses for the outcome measures (additional information on the outcomes is shown in table 11 of online supplement C).

Primary outcome

On average, subjects wore the armband for 6.6 ± 0.76 days/week. Overall, PA as assessed by steps per weekday, decreased over time ($p<0.001$), but no group by time interaction ($p=0.811$) nor group effect was observed ($p=0.934$). These data show that both groups declined over time in a similar way (**figure 3**). There was no group by time interaction between subjects with long-term physiotherapy after PR and those subjects without long-term physiotherapy ($p=0.266$) meaning that this did not have any effect on the results in this study.

There was no significant decrease in Average METs over time ($p=0.07$), and no differences between the groups ($p=0.22$). The group by time interaction was also non-significant ($p=0.36$).

Secondary outcomes

Functional exercise capacity

The 6-minute walking distance (6 MWD) did not show a significant group by time interaction ($p=0.585$), no significant decrease over time ($p=0.53$), and no group effect ($p=0.485$).

HRQoL

Only fatigue showed a significant group by time interaction, whereas the other variables did not. However, this was probably caused by great variability in the data rather than the intervention (see **figure 4**). No significant differences were found between the groups at each individual measurement time point (T0-12) for fatigue. There was significantly less dyspnea at T3 ($p=0.01$), and a lower emotional function at T0 ($p=0.04$) and T6 ($p=0.02$) compared with T12. Mastery significantly diminished over time ($p=0.017$) but fatigue did not. There were no significant group differences for all CRQ-SAS outcomes.

BMI

The group by time interaction of BMI was not significant. BMI was significantly higher at T6 ($p=0.02$), but this was not clinically relevant. There were no differences between the groups.

Table 2. Results of the outcome measures.

	T0	Change at T3	Change at T6	Change at T12	N with ≥20% improvement at T3/T6/T12	N with ≥20% worsening at T3/T6/T12	Group*time interaction p-values
Average steps/weekday							0.811
I	5717 ± 418	-512 [-1003:-21]	-593 [-1058:-128]	-1225 [-1712: -738]	18/16/8 (25/24/13%)	24/22/28 (34/33/45%)	
U	6011 ± 402	-635 [-1074:-156]	-833 [-1315:-352]	-1148 [-1651:-644]	9/12/12 (13/19/20%)	22/23/27 (32/35/45%)	
Average METs							0.364
I	1.5 ± 0.05	-0.061 [-0.15:0.03]	-0.057 [-0.15:0.04]	-0.055 [-0.15:0.04]	8/9/4 (11/13/7%)	8/10/5 (11/15/8%)	
U	1.57 ± 0.05	-0.061 [-0.15:0.03]	0.021 [-0.09:0.13]	-0.105 [-0.22:0.01]	5/6/5 (7/9/8%)	6/3/5 (9/5/8%)	
6 MWD (in meters)							0.585
I	456 ± 14	4.1 [-2.8:11.1]	4.8 [-3.9:13.5]	0.8 [-8.8:10.3]	2/2/3 (2.8/3/4.8%)	0/0/1 (0/0/1.6%)	
U	461 ± 8	1.9 [-4.1:7.9]	3.3 [-2.9:9.6]	4 [-2.4:10.3]	-	0/0/1 (0/0/1.7%)	
Dyspnea (1-7)							0.179
I	4.84 ± 0.15	0.17 [-0.45:0.38]	0.11 [-0.14:0.35]	-0.17 [-0.44:0.09]	11/14/12 (16/21/19%)	5/10/17 (7/15/27%)	
U	4.79 ± 0.15	0.01 [-0.21:0.23]	-0.13 [-0.33:0.08]	-0.08 [-0.3:0.14]	16/7/9 (24/11/15%)	9/7/6 (13/11/10%)	
Fatigue (1-7)							0.018
I	4.35 ± 0.1	0.05 [-0.15:0.26]	-0.19 [-0.39:0.01]	-0.14 [-0.35:0.07]	14/10/7 (20/15/11%)	7/13/14 (10/19/22%)	
U	4.2 ± 0.13	-0.06 [-0.28:0.17]	0.13 [-0.12:0.37]	-0.12 [-0.37:0.13]	10/12/13 (15/19/22%)	8/11/12 (12/17/20%)	
Emotional function (1-7)							0.590

I	4.93 ± 0.09	0.01 [-0.14:0.16]	-0.03 [-0.18:0.12]	0.09 [-0.07:0.24]	9/8/7 (13/12/11%)	4/10/8 (6/15/13%)	
U	4.76 ± 0.13	0.11 [-0.04:0.27]	0.04 [-0.11:0.19]	0.19 [0.04:0.34]	10/12/10 (15/19/17%)	5/8/5 (7/12/8%)	
Mastery (1-7)							0.154
I	5.42 ± 0.09	-0.03 [-0.22:0.16]	-0.14 [-0.32:0.06]	-0.1 [-0.31:0.11]	7/9/7 (10/13/11%)	5/13/9 (7/19/15%)	
U	5.35 ± 0.09	-0.06 [-0.21:0.08]	0.03 [-0.13:0.19]	-0.23 [-0.39:-0.06]	6/8/6 (9/12/10%)	5/3/8 (7/5/13%)	
BMI (kg m^{-2})							0.458
I	27.7 ± 0.58	0.08 [-0.11:0.26]	0.12 [-0.14:0.37]	-0.05 [-0.37:0.27]	-	-	
U	26.7 ± 0.6	0.06 [-0.13:0.26]	0.32 [0.07:0.57]	0.09 [-0.2:0.39]	-	-	

Data are presented as N, the mean ± SE, and change with baseline values. I = intervention group, U = usual care group. Group*time interaction=effect of the intervention.

Discussion

The present study shows that an mHealth intervention using a smartphone with support from a primary care PT did not improve or maintain PA in patients with COPD following PR. The intervention also did not affect functional exercise capacity, HRQoL outcomes (dyspnea, fatigue, mastery, and emotional function), or BMI. Our hypothesis that subjects with the intervention would improve or maintain their PA through the benefit of real-time PA biofeedback, goal setting, and motivational support from their PT could not be confirmed. We found nine other studies that examined the effect of personalized feedback based on real-time objective data on PA in patients with COPD [12,27-32]. All studies used external pedometers as a source of feedback on PA, and most of these studies were pilot studies with a short duration of intervention, which makes it difficult to draw any evidence-based conclusions on their long-term effectiveness. There were two larger studies with a long-term follow-up [33,34]. Although both studies showed short term effects, these were not maintained at the one year assessment. PA level in COPD is consistently associated with mortality and exacerbations [35] stressing the importance of continuation of studies that are finding ways to improve or maintain PA in this patient group.

Potential reasons for ineffectiveness of the intervention

Smartphone as an interface and as a pedometer. Adherence in wearing the smartphone was high, at 89%. However, on average, subjects only obtained their PA goal on 34% of the days they wore the smartphone and came 10% short of their PA goal throughout the intervention period. The interface of the smartphone to intermediately get feedback on the actual PA level may not have been optimal or its accuracy may have been insufficient. This could have reduced subjects' motivation to adhere to the PA goal. Other forms of eHealth, such as telehealthcare, might offer better results with respect to PA. However, this remains unclear as heterogeneity of studies is high and only few report on PA outcomes [36].

PTs involvement. PTs were instructed to monitor patients, send stimulating text messages or adjust PA goals when necessary. However, patients might have received insufficient support from their PTs to adhere to the personalized PA goals. For example, PTs did not sent a lot of stimulating text messages. On the other hand, when indicators of website usage and PT characteristics were added to the LMM analyses, the model did not improve significantly (online supplement B). Furthermore, there was no difference in steps per weekday between subjects with long-term physiotherapy after PR, thus receiving more attention from their PT, and those without long-term physiotherapy.

Digital and self-management skills. With a complex disease like COPD, mHealth interventions could be a valuable addition to the whole of multidisciplinary care offered to these patients. Strong self-management skills including the ability to act on incentives could improve the efficacy of these interventions. Digital skills and the aid of health care practitioners will also help in this regard. It is plausible that a large number of subjects in this study might have lacked the skill-set that is needed to fully benefit from our mHealth intervention. It might be interesting to see if these skill-sets can be measured in individual patients and taught in a personally tailored form. Learning self-management skills only during PR does not seem to be sufficient [6], thus we should pay attention to how these skills can be maintained in the long-term. It is nevertheless plausible that during the PR program time can be set aside to learn how to use the mHealth application and take appropriate actions when prompted. This was not done in the present study.

Subject selection. The intervention might have yielded different results in patients that did not complete a PR program. As there could be more room for improvement, PA levels could have gone up. This has been shown in previous pedometer studies [12,32]. Nevertheless, as the intervention was not succesfull in maintaining PA in patients after PR, the questions remains whether it is capable in improving PA in patients without PR.
PA significantly decreased over time as well as lung function and mastery. PA decreased by 889 average steps/weekday over the one-year study duration, which is more than double what was found in previous reports [4]. It is possible that patients had increased their PA by the end of the three-month outpatient rehabilitation program preceding the study [26] and subsequently decreased their activity back to their pre-rehabilitation PA. In any case, our intervention could not prevent this from happening. A study that followed patients during 12 months after a PR program showed that, similar to our study, PA declined. Past exercise habits, 6MWD, and barriers to exercise were determinants that desciminated between patients that declined significantly during follow-up, and those that remained at a high, or a low activity level [37]. These outcomes might be able to discriminate between patients that are in need of additional attention from a PT and patients that are able to maintain their PA with less support.

Surprisingly, functional exercise capacity remained unchanged over the study duration of one year. This is in contrast to other studies where the 6 MWD deteriorated over time in post rehabilitation COPD patients [38-40]. Our results indicate that subjects remained at the same capacity level but became less active during daily life; this holds true for patients with and without long-term physiotherapy after PR.

eHealth is a relatively new area in health care, and it has many potential benefits. Nonetheless, this study shows that in a population of patients with COPD, mHealth interventions are not always effective and expectations have to be adjusted. Future studies should try to identify those factors that influence the usability and efficacy of mHealth interventions. It is not only important to look at disease specific factors but also at individual factors as the population of COPD patients is comprised of a wide variety of persons with varying needs, abilities, and wishes.

Limitations

Subjects. Drop-out in the intervention group was higher (39% in the intervention group vs. 27% in the usual care group) and also higher among women. Initial worries about the telephone contract (linked to a personal bank account) and fear of losing the device were reasons for patients to drop out of the study. After the consent form was adjusted to state explicitly that there would not be any financial ramifications, the drop-out decreased.
There were patients who still had trouble using the smartphone, even after the individual face-to-face (and written) instructions and the availability of a help desk. Because smartphones are becoming more common, this probably will be less of a problem in the future.
Patients with GOLD stage 4 were not included in the study resulting in a sample not fully similar to other PR studies. This was done because their low PA level renders an intervention effect improbable.

PTs. After initial instruction the PTs were no longer prompted to use the mHealth intervention (they did have access to a help center). This was done by design to see how the intervention

would work in practice. As an indication, PTs were told to monitor the website at least once a week. Multiple instructions/more prompting might have increased monitoring/stimulation from PTs and subsequently positively influenced patient outcomes.

Conclusion

Compared to usual care, no differences were observed in PA, functional exercise capacity, HRQoL outcomes, or BMI in patients with COPD using a consumer smartphone-based mHealth intervention geared to enhance PA with support from a primary care PT following PR. There was a significant decrease over time in PA, mastery, and lung function, but not in functional exercise capacity. Our mHealth intervention did not succeed in enabling patients with COPD to prevent a decrease in PA.

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