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Community based physiotherapeutic exercise in COPD self-management: A randomised controlled trial

Tanja Effing [a,b,*], Gerhard Zielhuis [c], Huib Kerstjens [d], Paul van der Valk [a], Job van der Palen [a,e]

[a] Medisch Spectrum Twente, Department of Pulmonology, Enschede, The Netherlands
[b] Repatriation General Hospital, Department of Respiratory Medicine, Daw Park, South Australia, Australia
[c] Radboud University Nijmegen, Department of Epidemiology, Biostatistics and HTA, Nijmegen, The Netherlands
[d] University Medical Center Groningen, and University of Groningen, Department of Pulmonology, Groningen, The Netherlands
[e] Department of Research Methodology, Measurement and Data Analysis, University of Twente, Enschede, The Netherlands

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Summary
Little is known about effects of community-based physiotherapeutic exercise programmes incorporated in COPD self-management programmes. In a randomised trial, the effect of such a programme (COPE-active) on exercise capacity and various secondary outcomes including daily activity as a marker of behaviour change was evaluated.

All patients attended four 2-h self-management sessions. In addition the intervention group participated in the COPE-active programme offered by physiotherapists of private practices, consisting of a 6-month "compulsory" period (3 sessions/week) and subsequently a 5-month "optional" period (2 sessions/week). Because COPE-active was intended to change behaviour with regard to exercise, one session/week in both periods consisted of unsupervised home-based exercise training.

Of 153 patients, 74 intervention and 68 control patients completed the one-year follow-up. Statistically significant between-group differences in incremental shuttle walk test-distance (35.1 m; 95% CI (8.4; 61.8)) and daily activity (1190 steps/day; 95% CI (256; 2125)) were found in favour of the intervention group. Over the 12-month period a significant difference of the chronic respiratory questionnaire (CRQ) dyspnoea-score (0.33 points; 95% CI (0.01; 0.64)) and a non-significant difference of the endurance shuttle walk test (135 m (95% CI (−29; 298)) was found. No differences were found in the other CRQ-components, anxiety and depression scores and percentage of fat free mass.

* Corresponding author. Repatriation General Hospital, Department of Respiratory Medicine, Daws Road, Daw Park SA 5041, Australia. Tel.: +61 8 8275 1189; fax: +61 8 8275 1195.
E-mail address: tanja.effing@health.sa.gov.au (T. Effing).

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This study demonstrates that a community-based reactivation programme improves exercise capacity in patients with moderately to severe COPD. Even more important, the programme improves actual daily activity after one-year which indicates behaviour change with regard to daily exercise.

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Introduction

The natural course of COPD includes a progressive decline in functional capacity and health-related quality of life (HRQoL)[1] and imposes a significant burden in terms of disability[2] and of costs.[3] Therefore, optimisation of treatment is an important goal. Treatment currently consists of pharmacological interventions complemented by hospital-based pulmonary rehabilitation, oxygen therapy in the more severe patients, and attempts at life-style interventions. Self-management programmes directed towards behaviour change are recommended in COPD patients,[4] but there is still lack of clarity about the appropriate content and effects of the various components of self-management programmes.

Firm evidence exists for multi-disciplinary rehabilitation programmes,[5] however less is known about physiotherapeutic exercise programmes as an extension of self-management programmes. Studies reported divergent effects.[4] A recent study reported similar positive effects of an in-hospital and a home-based exercise programmes in addition to a self-management programme on quality of life and cycle endurance time, but not on walking distance.[6]

Community-based physiotherapeutic exercise programmes, executed by local physiotherapists working in private physiotherapy practices, are common in the Netherlands. When proven effective, these programmes would be a perfect extension to a self-management programme because of their good accessibility. Nevertheless, very few of these programmes have been evaluated in randomised controlled trials and therefore this intervention has not yet been demonstrated to be effective.[7,8]

Besides physical progress, physiotherapeutic exercise programmes within self-management programmes should aim on behavioural change towards exercise in daily life. Therefore, we evaluated the effects of a community-based physiotherapeutic exercise programme (COPE-active) incorporated in a self-management programme, compared to self-management only, on exercise capacity and daily activity (as an indicator of behavioural change) using a randomised controlled trial.

Material and methods

Patients

From November 2004 to July 2006, 159 patients were recruited from the outpatient pulmonary clinic of Medisch Spectrum Twente hospital at Enschede, The Netherlands. Patients had to meet the following criteria; (1) a clinical diagnosis of COPD according to the GOLD criteria;[1] (2) no exacerbation in the month prior to enrolment; (3) $\geq$3 exacerbations, defined as respiratory problems that required a course of oral corticosteroids and/or antibiotics, or one hospitalisation for respiratory problems in the two years preceding study entry; (4) (ex) smoker; (5) age 40—75 years; (6) post-bronchodilator FEV_1 25—80% of predicted; (7) able to understand and read Dutch; and (8) written informed consent from the subject prior to participation. Patients were excluded if they had: (1) serious other disease with a low survival rate; (2) other diseases influencing bronchial symptoms and/or lung function (e.g., cardiac insufficiency, sarcoidosis); (3) severe psychiatric illness; (4) uncontrolled diabetes mellitus during a COPD exacerbation in the past or a hospitalisation for diabetes mellitus in the two years preceding the study; (5) need for regular oxygen therapy ($>$16 h/day or $pO_2<7.2$ kPa); (6) maintenance therapy with antibiotics; (7) known α1-antitrypsine deficiency; (8) disorders or progressive disease seriously influencing walking ability (e.g., amputation, paralysis, progressive muscle disease). The hospital's medical ethics committee approved the study.

Study design

A two-by-two factorial design was used, meaning that two independent interventions (self-treatment of exacerbations and a community-based physiotherapeutic exercise programme) were evaluated using one design (Table 1). This paper compares the effect of a self-management programme including COPE-active (intervention group) with a self-management programme only (control group). Patients receiving guidelines for self-treatment of exacerbations were equally distributed over the intervention and control group. This design assumes that both interventions do not interact with each other which needs to be verified before the final analyses. Patients were randomised into two study groups, using a minimisation programme,[9] minimising differences between groups in gender, current smoking, FEV1 predicted ($\leq$ or $>$50%), use of inhaled corticosteroid, and current participation in a regular physiotherapy programme. In the first month self-management sessions were offered to all patients, followed by the start of the COPE-active programme in the intervention group in the second month. During the whole study period, patients in the control group were allowed to attend regular, non-COPE-active physiotherapy sessions if this was prescribed as part of regular care. Measurements were performed at baseline, and after 7 and 12 months.

Self-management sessions

Smokers were offered a smoking cessation programme, the Lung Minimal Intervention Strategy (LMIS),[10] prior to the group-allocation. Smoking cessation was attempted

Table 1 Description of the design of the COPE-II study, including the two interventions (self-treatment of exacerbations and COPE-active) and the measurements at baseline, 7, and 12 months.

Time schedule	Interventions	Intervention group (=COPE-active group) $n = 77$		Control group $n = 76$	
		Subgroup 1 ($n = 40$)	Subgroup 2 ($n = 37$)	Subgroup 3 ($n = 37$)	Subgroup 4 ($n = 39$)
Month 0	Baseline measurement	X	X	X	X
Month 1	Self-management sessions	X	X	X	X
Month 1—12	Self-treatment of exacerbations	X	—	X	—
Month 2—7	COPE-active: 'compulsory'	X	X	—	—
Month 7	Measurement	X	X	X	X
Month 8—12	COPE-active: 'voluntary'	X	X	—	—
Month 12	Measurement	X	X	X	X

individually (by a specialised nurse) during a 3-month period. It included three individual sessions (one 60-min intake and two 30-min sessions in week 2 and 3) and three telephone contacts (at "quitting" day and in week 4 and 13). Pharmacological support was recommended during LMIS counseling, but the use was voluntary and at the patients' costs.

After randomisation, all patients and their partners (from both the intervention and control group) were offered four weekly 2-h small-group (approximately 5 patients) self-management sessions given by a respiratory nurse and a physiotherapist. The intention was to change patient's disease behaviour by increasing their knowledge, confronting them with consequences of specific behaviour, and helping patients acquire and practice skills to deal with different components of their disease. Half of the patients, distributed equally over the intervention and control group (see Table 1), were educated in early recognition of exacerbations and were taught when to start a course of oral prednisolone by using an action plan that was linked to a daily diary. Methods and results of this intervention have been described elsewhere.[11] Four, 13, and 26 weeks after the last session, the respiratory nurse contacted the patients by phone with the goal to recall the items addressed during the self-management sessions. Patients were supplied with a booklet with the content of sessions (regarding COPD; medication; nutrition & weight; exacerbations; exercise, relaxation & sputum mobilisation; and communication).

COPE-active programme

For the development of the COPE-active programme the most problematic activities of a sample of 15 COPD patients were identified with help of the Canadian Occupational Performance Measure[12] and subsequently incorporated in the programme: bicycling, walking, climbing stairs, and lifting weights. Exact descriptions of the different training activities and the used training schemes can be found in an online supplementary file. Home exercises included: walking or cycling, and strength exercises for the upper and lower extremities.

The 16 participating private physiotherapy practices were situated in the catchment area of our hospital. All physiotherapists had already attended a national COPD course prior to the COPE-II study and were experienced in caring for COPD patients. At start of this study, they had to participate in an addition three-session course (11 h in total) to refresh their knowledge about COPD in general and to standardise the content of the COPE-active-programme. In order to tailor the intensity of the programme to the individual, we provided the physiotherapist with detailed information about the individual patient at baseline: results of the incremental maximal cycle ergometry test, incremental shuttle walk test, lung function, and fat free mass.

The 11-month training period per patient was divided in two parts: a 'compulsory' 6-month and a subsequent optional but recommended 5-month period. Besides improvement of physical condition in the first period and preservation of these gains in the second period, behaviour change towards exercise was strived for during the whole period. Frequency of training sessions (first period: 3 times/week; second period: 2 times/week) and intensity of the exercises within the programme are in line with the latest rehabilitation recommendations.[13] During the 11-month period, one training session per week was performed at home (unsupervised) to facilitate behaviour change towards exercise. Training was given in small groups (2—3 patients).

For the home-based sessions, a diary including training information and illustrations of how to perform the exercises was provided to increase the patient's compliance with the programme. Patients had to record whether they had executed these exercises, their feelings during the exercises, and their fatigue afterwards. Besides evaluation of the appropriateness of the training intensity of the different home-based exercises, physiotherapists went through the diaries with the patients every week.

Outcome measures

The primary outcome was maximal exercise capacity measured with the incremental shuttle walk test according to the protocol of Singh et al.[14] using a 10-min course.

A practice walk was performed before the baseline measurement. The minimal important difference for individual change is 47.5 m.[15]

Endurance capacity was measured with the endurance shuttle walk test using a 10-min course[16] and a walking speed of 85% of the maximal incremental test walking speed. HRQoL was measured with help of the self-administered Chronic Respiratory Questionnaire standardised (CRQ-SAS).[17] The minimal important difference for individual change is 0.5/domain (dyspnoea, fatigue, emotional functioning, mastery).[18] Health status was evaluated by the self-administrated Clinical COPD Questionnaire (CCQ).[19] A change of 0.4 represents the minimal important difference at individual level.[20] Anxiety and depression was measured with the Hospital Anxiety and Depression Scale (HADS).[21] This instrument produces separate scores for anxiety and depression ranging from 0 to 21. A score over 10 is judged to be a predictor of a clinical diagnosis of anxiety and depression. Body composition was estimated using single-frequency bioelectrical impedance analysis (Bodystat 1500, Bodystat Ltd., Douglas, Isle of Man, UK). Fat free mass was calculated from COPD- and gender specific regression equations.[22] Finally, daily activity was assessed by the number of steps measured with the Yamax Digi-Walker SW-200 (Tokyo, Japan) during 7-day periods at baseline, 7, and 12 months.

Statistical analyses

We calculated that 64 evaluable patients per treatment group were required to detect a difference of 50 m (SD 100 m) on the incremental shuttle walk test between both groups with 80% power and a two-sided 0.05 α-level test. We used intention-to-treat principles for all analyses. Between-group differences in continuous variables over time were assessed by analysis of repeated measurements (SPSS procedure for mixed models, version 12.0). Baseline values were subtracted from follow-up values to correct for baseline differences. Additional analyses were performed using Chi-square statistics for categorical variables.

Results

Of the 421 eligible patients, 159 patients were assigned to the intervention ($n = 80$) or the control group ($n = 79$) (Fig. 1). Between the inclusion and the baseline measurements three patients dropped out in each study group (Fig. 1). Table 2 shows the baseline characteristics of the remaining 153 patients.

The study groups were similar with respect to all measured prognostic factors. Twenty-six patients took part in the smoking cessation programme prior to the group allocation. The self-reported quitting rate was 27% ($n = 7$). The "quitters" were equally distributed over the two study groups (COPE-active: $n = 3$; control group: $n = 4$).

During the year after the baseline measurements, three patients dropped out in the intervention group, as did eight patients in the control group (see Fig. 1).

The three patients who dropped out of the intervention group during the one-year follow-up all dropped out directly after the baseline measurements before the start of COPE-active. In addition seven patients assigned to the intervention group refused to participate in the COPE-active programme (transport problems ($n = 2$); too busy ($n = 3$); disagreement with protocol ($n = 1$); co-morbidity ($n = 1$)) but they completed the follow-up measurements. So, 67 patients (87.0%) participated in the COPE-active programme. After the first 6-month period, 11 patients decided not to continue with COPE-active as was allowed according to the protocol. Therefore, 56 patients (72.7%)

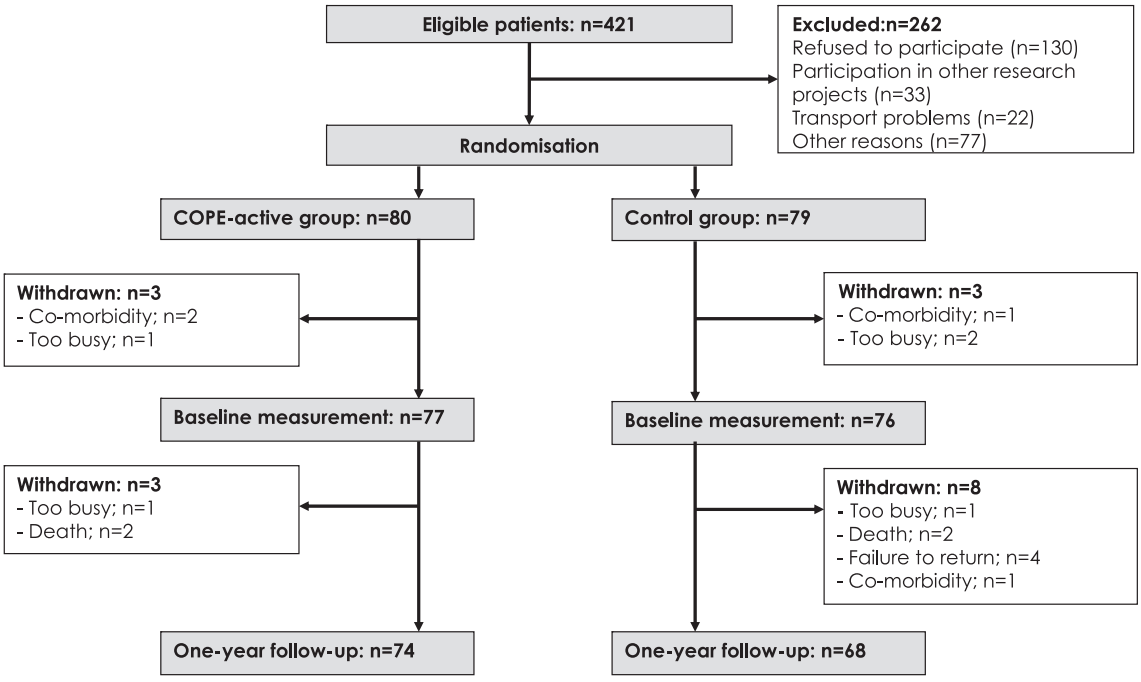

Figure 1 Flow diagram of subject progress through the COPE II-study.

Table 2 Baseline characteristics of the two treatment groups.

Number of patients	COPE-active $n = 77$	Control $n = 76$
Age (mean ± SD; years)	62.9 ± 8.1	63.9 ± 7.8
Male (%)	58.4	57.9
Body mass index (mean ± SD; kg/m2)[a]	26.1 ± 5.0	26.8 ± 4.4
Medical research council dyspnoea scale (mean ± SD)	2.25 ± 1.05	2.50 ± 1.15
Smokers (%)	35	34
Lung function post bronchodilation (mean ± SD)		
FEV1 (L)	1.43 ± 0.54	1.40 ± 0.53
FEV1% predicted value	49.6 ± 14.2	50.5 ± 17.0
VC (L)	3.78 ± 1.05	3.47 ± 0.84
Inhaled corticosteroid use (%)	85.7	88.2
Incremental shuttle walk test (mean ± SD; m)[b]	388 ± 164.5	341 ± 152.4
Endurance shuttle walk test (mean ± SD; m)[b]	679 ± 553.1	630 ± 554.1

[a] Mean values were based on 77 and 75 patients in the COPE-active and control group respectively.
[b] Mean values were based on 77 and 74 patients in the COPE-active and control group respectively.

completed the whole 11-month training period. Twenty-five patients (32.9%) in the control group received usual care physiotherapy (non-standardised) during the 12-month follow-up.

Results of the repeated measurements analysis of the incremental shuttle walk test are presented in Fig. 2 and Table 3. During the first 7 months of the follow-up period, the intervention group showed a slight increase in walking distance that remained stable until the end of the one-year follow-up period. Conversely, the control group showed a steady decline in walking distance over the whole follow-up period. A significant between-group difference of 35.1 m was found after 12 months (Table 3).

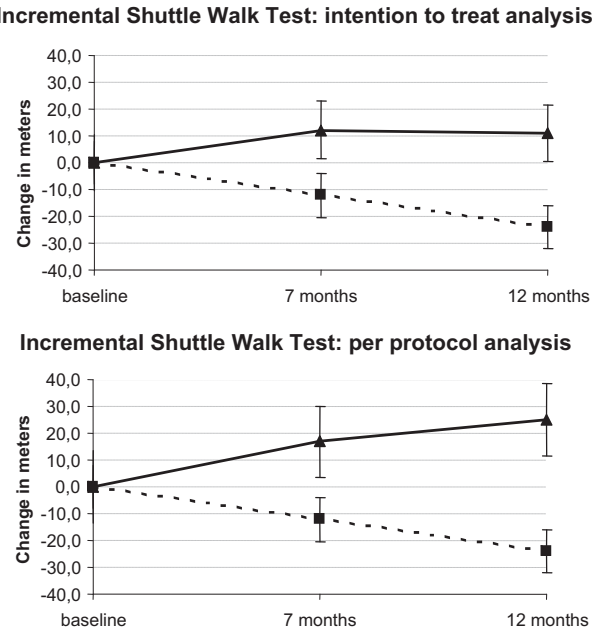

Figure 2 Mean change (SE) from baseline in incremental shuttle walk test walking distance (m) at 7 and 12 months after baseline measurements of the COPE-active (▲) and control (■) group using an intention to treat analysis (number of patients at baseline: COPE-active: 77; control: 74) and a per protocol analysis (number of patients at baseline: COPE-active: 51; control: 74).

The probability of an improved walking distance by 47.5 m (the minimal important difference) or more after one year was 1.91 times higher (95% CI 0.97—3.78) in the intervention group compared to the control group. Similarly, the probability of a decreased walking distance by 47.5 m or more after one year was 1.56 times higher (95% CI 0.92—2.70) in the control group compared to the intervention group.

In addition, a per protocol analysis was performed, for which 26 patients (34%) were omitted because of an attendance of less than 70% of the physiotherapeutic sessions (11-month period: <50 sessions; 6-month period: <36 sessions). The major reasons for this lack of attendance were not starting COPE-active ($n = 10$) and new co-morbidity ($n = 4$). With this analysis a between-group difference of 48.9 m was found ($p < 0.01$) (Fig. 2).

Results of the secondary outcomes are presented in Table 3. The COPE-active group showed an improvement of daily activity (steps/day) after 7 months that increased further during the second period. Daily activity of the control group decreased progressively. The mean between-group difference over the whole period was 877 steps/day ($p = 0.028$), the between-group difference at 12 months was even higher (1190 steps/day). An increase in the endurance shuttle walk test in comparison with baseline was seen at 7 and 12 months in the intervention group. The walking distance of the control group diminished progressively over the whole follow-up. A non-significant between-group difference of 145.8 m was found after 12 months ($p = 0.11$). The CRQ dyspnoea-score was 0.33 points higher in the COPE-active group compared to control ($p = 0.04$). No between-group differences were found in the other CRQ-components and CCQ (sub)-scores, the HADS scores, and percentage of fat free mass and no unexpected adverse events occurred.

Discussion

This randomised controlled trial evaluated the effects of a one-year community-based physiotherapeutic exercise

Table 3 Mean (SD) baseline scores, the mean differences (SE) from baseline at 7 months and 12 months after baseline, the between-group difference at 12 months, and the overall mean difference between both study groups with the corresponding 95% confidence interval (95% CI).

Measures[a]		COPE-active			Control						
		Difference with baseline[b]			Difference with baseline[b]			Treatment effect COPE-active - control			
		Baseline mean (SD)	7 months mean (SE)	12 months mean (SE)	Baseline mean (SD)	7 months mean (SE)	12 months mean (SE)	Δ 12 months	95% CI (Δ at 12 months)	Δ overall[b]	95% CI (Δ overall)[b]
ISWT	Nr of patients	$n = 77$	$n = 68$	$n = 69$	$n = 74$	$n = 60$	$n = 66$				
	Distance (m)	387.7 (164.5)	12.2 (10.6)	11.1 (10.6)	341.4 (152.4)	−12.1 (8.4)	−24.0 (8.2)	35.1	8.4; 61.8	30.4	5.1; 55.7
ESWT	Nr of patients	$n = 77$	$n = 68$	$n = 68$	$n = 74$	$n = 60$	$n = 66$				
	Distance (m)	678.9 (553.1)	106.1 (67.4)	53.3 (67.4)	629.5 (554.1)	−15.9 (55.6)	−92.5 (54.5)	145.8	−26.2; 317.8	134.5	−29.0; 298.0
CRQ	Nr of patients	$n = 77$	$n = 68$	$n = 71$	$n = 76$	$n = 63$	$n = 68$				
	Dyspnoea	4.40 (1.44)	0.37 (0.13)	0.30 (0.13)	4.52 (1.38)	0.04 (0.12)	−0.02 (0.12)	0.32	−0.03; 0.67	0.33	0.01; 0.64
	Fatique	4.55 (1.24)	0.15 (0.15)	0.15 (0.15)	4.13 (1.28)	0.03 (0.17)	0.06 (0.16)	0.09	−0.34; 0.52	0.10	−0.29; 0.50
	Emotional function	5.14 (1.19)	−0.02 (0.11)	0.18 (0.11)	4.90 (1.02)	−0.05 (0.12)	0.08 (0.12)	0.10	−0.22; 0.42	0.07	−0.21; 0.34
	Mastery	5.35 (1.15)	0.13 (0.12)	0.33 (0.12)	5.30 (1.09)	0.14 (0.12)	0.22 (0.11)	0.11	−0.21; 0.43	0.12	−0.18; 0.41
CCQ	Nr of patients	$n = 77$	$n = 67$	$n = 70$	$n = 74$	$n = 60$	$n = 66$				
	Symptoms	2.35 (1.02)	−0.06 (0.12)	−0.11 (0.12)	2.92 (1.22)	−0.06 (0.14)	−0.17 (0.14)	0.06	−0.30; 0.42	0.03	−0.29; 0.34
	Functional state	2.14 (1.17)	0.03 (0.12)	−0.06 (0.12)	2.33 (1.29)	−0.03 (0.12)	0.06 (0.12)	0.00	−0.46; 0.22	−0.03	−0.34; 0.28
	Mental state	0.93 (0.98)	−0.06 (0.11)	−0.14 (0.11)	1.03 (1.09)	0.08 (0.15)	−0.12 (0.14)	−0.02	−0.37; 0.33	−0.08	−0.40; 0.23
	Total	1.80 (0.89)	−0.03 (0.08)	−0.10 (0.08)	2.09 (0.95)	−0.01 (0.10)	−0.08 (0.10)	−0.02	−0.27; 0.23	−0.03	−0.26; 0.20
HADS	Nr of patients	$n = 76$	$n = 67$	$n = 69$	$n = 76$	$n = 62$	$n = 68$				
	Anxiety	4.26 (3.74)	−0.17 (0.32)	−0.66 (0.32)	5.38 (3.60)	−0.28 (0.38)	−0.61 (0.36)	0.05	−1.00; 0.90	0.02	−0.79; 0.84
	Depression	3.96 (3.66)	−0.37 (0.33)	−0.71 (0.33)	5.24 (3.87)	−0.48 (0.32)	−0.30 (0.31)	−0.41	−1.31; 0.49	−0.16	−0.94; 0.62
Pedometer	Nr of patients	$n = 62$	$n = 59$	$n = 55$	$n = 65$	$n = 52$	$n = 55$				
	Steps (per day)	4472 (2715)	478.1 (348.5)	815.6 (358.6)	5224 (3464)	−87.3 (313.6)	−374.8 (306.4)	1190.4	255.6; 2125.2	876.6	95.4; 1657.7
FFM	Nr of patients	$n = 77$	$n = 68$	$n = 70$	$n = 75$	$n = 62$	$n = 67$				
	Fat free mass (%)	34.7 (7.32)	1.1 (0.44)	0.8 (0.43)	35.2 (6.28)	−0.1 (0.40)	0.2 (0.39)	0.6	−0.55; 1.75	0.1	−0.5; 0.6

[a] ISWT: incremental shuttle walk test; ESWT: endurance shuttle walk test; CRQ: chronic respiratory questionnaire; CCQ: clinical COPD questionnaire; HADS: hospital anxiety and depression scale (HADS); FFM: percentage of fat free mass.

[b] Intention to treat analyses: results were obtained with repeated measurements analyses (SPSS), the "overall difference" is in contrast with the "Δ 12 month" also influenced by the 7-month measurement.

programme (COPE-active) incorporated in a self-management programme compared to self-management alone. The intervention group showed an improved maximal exercise capacity and a positive change in daily activity, which was used as a marker of behaviour change in comparison with the control group.

The COPE-active group experienced a clear improvement in maximal exercise capacity compared to the steady decline in the control group. A 35 m larger mean shift in the intervention group than in the control group is rather impressive as a group level effect, knowing that there will always be patients who do not respond to exercise interventions.[23] In fact, patients in the intervention group were almost twice as likely to improve their walking distance with a magnitude of at least the recently publicised MID of 47.5 m.[15]

In contrast to many other studies (e.g., Ref.[24–27]), we used an 'intention to treat' – principle for our primary analyses, meaning that all patients who were assigned to the intervention group at baseline were included in the analysis. As expected, applying a per protocol analysis (with potential bias due to incomparable groups[28]) led in our study to a larger between-group difference in favour of the intervention group.

The study population comprised relatively severe COPD patients with a median one-year exacerbation rate of 3 in both study groups. This relatively high exacerbation rate might explain the deterioration in exercise capacity in the control group and also the relatively small increase of exercise capacity in the intervention group because exacerbations do not only lead to a reduced walking distance during an exacerbation, but walking distance remains reduced also after the exacerbation.[29]

Besides the changes in exercise capacity, we intended to change behaviour with regard to exercise with our relatively long lasting programme.[30] The fact that only 11 of the 67 patients who started the training decided not to continue after the first 6-month training period seems to indicate at least a high motivation to continue exercising under guidance of the physiotherapist. Moreover, we found a between-group difference (1190 steps/day) in daily activity in favour of the intervention group. Baseline scores of patients in the COPE-active and control group were 4472 and 5224 steps/day respectively, which places the difference of almost 1200 steps in more perspective, i.e., an improvement of approximately 25%. We believe that these results indicate behavioural change with regard to levels of daily activity.

A positive trend, though not significant, was seen in endurance capacity. The change in endurance exercise capacity showed the same trend as the change in maximal (incremental) exercise capacity, but the substantial between-group difference at 12 months of 145.8 m did not reach significance. The latter is explained by a large standard deviation, and by a ceiling effect (i.e., 12 COPE-active and 14 controls already walked the maximum 20 min at baseline).

A statistically significant between-group difference of the CRQ-dyspnoea domain was found over the 12-month period. This is in line with our expectations, because desensitisation to dyspnoea seems to be an important mechanism in improving the exercise tolerance of COPD.[7] Because no significant nor clinically relevant effects were detected in the other CRQ-domains, we can conclude that our HRQoL-results do not match results from the literature.[31] Lack of power and relatively high CRQ-baseline scores are possible explanations. Finally, no changes in anxiety and depression were found, but average baseline scores were so low that expecting a further decrease might not be reasonable.

In literature scant information is available about the effects of community-based physiotherapeutic reactivation programs in general,[8,9] and even less about their effect on daily activity. These programmes have a great accessibility and could therefore be an excess value for the COPD community in addition to in-hospital and home-based rehabilitation programmes that are already proven effective.[5,7] We have demonstrated effects of such a programme on exercise capacity and daily activity. But, before a decent decision about implementation can be made, cost-effectiveness data need to be evaluated to properly balance the effects and costs against each other, which we will do in an additional paper.

Probably larger effects of this intervention can be expected in a more exercise naive population for several reasons. First, our included patients were not "fresh" patients. The majority of the patients was under supervision of our chest physicians for years already. Therefore, aspects as e.g., the importance of exercising were brought to their attention many times before. Also, we designed our study to evaluate whether the positive effects of a proactive and mandatory training programme would surpass the effects of variable and less strict exercise programmes in usual care. Hence, patients were allowed to receive physiotherapy at the time of inclusion and control patients were allowed to receive physiotherapy during the study as part of their usual care. Between-group effect might have been diminished by the latter and by the fact that for intervention patients with previous experience in physiotherapy, the programme might only have acted as a maintenance programme with limited effects as a result. Finally, all patients received self-management instructions on exercising as part of the life style advices. This might also have slightly diminished the room for improvement in the active arm compared to the control arm, even though the effects of self-management in this sense have not been found to be very large.[4]

Using a two-by-two factorial design confers the theoretical risk of interaction between both interventions. Since the proportion of patients receiving physiotherapy was the same in both study groups, possible (additional) effects of the COPE-active programme will have affected both study groups and will thereby not directly influence the between-group differences. Before the final analysis we have checked for interaction between both interventions and we concluded that interaction was not present.

We conclude that a community-based reactivation programme is valuable in patients with moderate to severe COPD and improves exercise capacity. Even more important, the programme improves actual daily activities after one-year which indicates behaviour change with regard to daily exercise.

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Conflict of interest

The authors TE, HK, PV, GZ and JP have declared no conflict of interest including involvement with any organisation with a direct financial, intellectual, or other interest in the subject of the manuscript (e.g., an author is an employee, consultant, shareholder, or paid expert witness of the organisation).

Supplementary data

The supplementary data associated with this article can be found in the on-line version at doi:10.1016/j.rmed.2010.09.017.

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