



Maintaining benefits following pulmonary rehabilitation: a randomised controlled trial

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ABSTRACT: The aim of this study was to determine if weekly, supervised, outpatient-based exercise plus unsupervised home exercise following an 8-week pulmonary rehabilitation programme would maintain functional exercise capacity and quality of life at 12 months better than standard care of unsupervised home exercise training.

Chronic obstructive pulmonary disease (COPD) subjects completed an 8-week pulmonary rehabilitation programme, were randomised to an intervention group (IG) of weekly, supervised, exercise plus home exercise or to a control group (CG) of unsupervised home exercise and followed for 12 months. Outcome measurements at baseline (after pulmonary rehabilitation), and 3, 6 and 12 months included the 6-min walk test and St George's Respiratory Questionnaire (SGRQ).

59 subjects with moderate COPD (Global Initiative for Chronic Obstructive Lung Disease stage II) were recruited and 48 subjects completed the study. 12-month mean difference showed no significant change from baseline in 6-min walk distance (IG -11 m, 95% CI -21–10 m; CG -6 m, 95% CI -34–11 m) or total SGRQ score (IG 3, 95% CI -0.8–7; CG -3, 95% CI -7–3).

12 months following pulmonary rehabilitation both weekly, supervised, outpatient-based exercise plus unsupervised home exercise and standard care of unsupervised home exercise successfully maintained 6-min walk distance and quality of life in subjects with moderate COPD.

KEYWORDS: Chronic obstructive pulmonary disease, exercise, maintenance, pulmonary rehabilitation

Chronic obstructive pulmonary disease (COPD) is a preventable and treatable disease with significant extrapulmonary effects that contribute to the severity of symptoms in individual patients [1]. By 2020, it is estimated that COPD will be fifth in the worldwide burden of disease [1]. Management of COPD involves optimising medical therapy, commencing smoking cessation and participating in pulmonary rehabilitation [2].

Pulmonary rehabilitation programmes, involving at least 4–6 weeks of exercise training with or without education, have been shown to improve functional exercise capacity and quality of life, and to reduce dyspnoea and hospital length of stay [3]. These benefits have been shown to last for up to 9 months [4–6]; however, the benefits appear to decline by 12 months [7, 8].

Recently, there has been increased interest in ways to maintain exercise capacity and quality of life following pulmonary rehabilitation. Randomised controlled studies have included exercise interventions [7–10], as well as interventions to promote adherence to exercise, such as telephone calls [7, 8], activity monitors [11] and cell phone paced walking [12].

The maintenance exercise interventions used in previous studies have varied in frequency from supervised exercise once per week [9, 13], three times per week [10] or once per month [7, 8]. Although supervised exercise three times per week maintained exercise capacity and quality of life [10], this could be considered a continuation of pulmonary rehabilitation that may not be feasible for many centres. The studies that evaluated supervised monthly exercise [7, 8] showed a decline in exercise capacity at 12 months, indicating that this frequency of supervised exercise training was insufficient to maintain improvements. Two studies have shown that supervised exercise once per week [9, 13] maintained exercise capacity and quality of life; however, one of these studies [9] utilised an initial pulmonary rehabilitation programme of 6 months, which is much longer than commonly available [3], and the other study [13] was not a randomised trial.

It remains unclear whether supervised weekly exercise following a standard 8-week pulmonary rehabilitation programme [3] would be effective in maintaining exercise capacity and quality of life in the long term. Advantages of supervised exercise once per week include the provision of

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regular patient support and encouragement, early detection of exacerbations and the opportunity to progress exercise training.

The aim of this study was to determine if weekly, supervised, outpatient-based exercise training plus unsupervised home exercise following an 8-week pulmonary rehabilitation programme would maintain functional exercise capacity and quality of life to 12 months better than standard care of unsupervised home exercise training. The hypothesis was that weekly supervised exercise would maintain exercise capacity and quality of life better than unsupervised home exercise.

METHODS

Subjects

The study was a longitudinal randomised controlled trial. COPD subjects with a forced expiratory volume in 1 s (FEV₁) to forced vital capacity (FVC) ratio <70% and FEV₁ <80% predicted [1, 2] were consecutively recruited to the study following the successful completion of an 8-week pulmonary rehabilitation programme. The detailed methods for this paper have been published previously [14]. The study was performed in the Pulmonary Rehabilitation Physiotherapy Gymnasium and in the Dept of Respiratory Medicine, Royal Prince Alfred Hospital Sydney (Sydney, Australia).

Subjects were excluded if they had experienced an exacerbation of COPD in the previous month, required supplemental oxygen or had comorbidities, such as severe cardiovascular, neurological or musculoskeletal conditions, that would prevent them performing functional exercise tests. Subjects received written and verbal information explaining the study and written consent was obtained from all subjects. Ethics approval to conduct the study was obtained from the ethics committee of Sydney South West Area Health Service (SSWAHS). The study was registered with the Australian New Zealand Clinical Trials Registry ACTRN012605000678695.

Intervention and control groups

The intervention group (IG) performed supervised, outpatient-based exercise 1 day per week in the Pulmonary Rehabilitation Physiotherapy Gymnasium, where they had completed their initial programme, plus unsupervised home exercise on four other days. On the day subjects attended the gymnasium, they performed the same exercise regimen as during the pulmonary rehabilitation programme. This included 20 min walking (track or treadmill), 20 min cycling, 10 min arm cycling, and upper and lower limb strength training exercises using weight equipment and free weights. Unsupervised home exercise consisted of 30 min of walking plus 30 min of upper and lower limb strengthening exercises using free weights and body weight. The home exercises were practised during the pulmonary rehabilitation programme and all subjects had an illustrated home exercise booklet to guide them, plus a diary for recording sessions completed. The control group (CG) performed unsupervised home exercise 5 days per week and also received the home exercise booklet and diary.

Assessment times

Primary and secondary outcomes were measured at baseline (immediately following pulmonary rehabilitation), and at 3, 6 and 12 months following pulmonary rehabilitation.

Primary outcome measures

6-min walk test

Subjects performed two 6-min walk tests (6MWTs) at each assessment time. Instructions and encouragement were standardised according to the American Thoracic Society Guidelines [15]. Tests were performed in the physiotherapy gymnasium on a 32-m continuous track and the better of the two tests was recorded.

St George's Respiratory Questionnaire

Subjects completed the St George's Respiratory Questionnaire (SGRQ), a valid and reliable measure of quality of life in people with COPD [16]. The SGRQ consists of 50 items, 76 weighted responses and three component scores (symptoms, activities and impacts). The total score was calculated from all three components with zero indicating the best health and 100 the worst.

Secondary outcome measures

Lung function tests

Spirometry was performed in accordance with American Thoracic Society standards [17]. FEV₁ and FVC were measured using a mass flow sensor (Sensormedics Vmax 20 Pulmonary Spirometry Instrument; Sensormedics Corporation, Yorba Linda, CA, USA). The spirometer was calibrated immediately before each test using a 3-L calibrating syringe. The highest value for FEV₁ and FVC after three reproducible trials was recorded and compared to predicted normal values [18]. Lung volumes were performed in accordance with American Thoracic Society standards [19] using a body plethysmograph (Sensormedics V6200 Autobox Body Plethysmograph; Sensormedics Corporation). Results were compared to predicted normal values for lung volumes [20].

Incremental shuttle walk test and endurance shuttle walk test

Subjects performed the incremental shuttle walk test (ISWT) and endurance shuttle walk test (ESWT) at each assessment time according to the protocols described by SINGH *et al.* [21] and REVILL *et al.* [22], respectively. A 10-m track was used with cones placed 9 m apart. Subjects were asked to walk around the cones keeping in time with the beeps from the compact disk. Two ISWTs and two ESWTs were performed at each assessment time and the better of the two tests was recorded.

Oxygen saturation, heart rate (pulse oximeter; RAD-5v Masimo Corp, Irvine, CA, USA) and dyspnoea (modified Borg scale, category ratio 0–10 scale) [23] were measured at the end of each of the walk tests.

Hospital anxiety and depression scale

Subjects were asked to complete the hospital anxiety and depression (HAD) scale, a self-administered questionnaire consisting of 14 items (seven each for anxiety and depression). From a total score of 42, a score of eleven or more in either the anxiety or depression domains was taken to indicate a clinically significant case of anxiety or depression [24].

Hospital admissions, length of stay and exacerbations

Information on emergency department and hospital admissions, as well as length of stay, was recorded over two time periods. The first time period was the year prior to the completion of the pulmonary rehabilitation programme

(including time in pulmonary rehabilitation). The second time period was the 12 months following the completion of the pulmonary rehabilitation programme. Subjects were asked for a verbal report on admissions and length of stay and this was verified using the hospital medical record database that included surrounding hospitals within SSWAHS. Subjects were also asked to report the number of exacerbations that they experienced during the 12-month period. For the purposes of this study an exacerbation was described as a period of worsening symptoms that required antibiotics and/or prednisone.

Exercise diary

Each subject was asked to complete a home exercise diary. Subjects were asked to tick a box to indicate if they had performed exercise on a particular day and to leave it empty if they had not performed any exercise. The diaries were sited at assessment times and whether the subjects had used the diary was recorded and, if they had, how many days they ticked as having exercised as recorded. The maximum number of ticks (days) for a subject compliant with the protocol was 60 at 3 months and 120 at 12 months.

Randomisation and allocation

Randomisation (performed using computerised number generation) was concealed in opaque envelopes and prepared by an investigator not directly involved in the study. The assessor and subjects were not blind to group allocation.

Sample size

The sample size calculation was based on detecting a difference in 6-min walk distance (6MWD) of 48 m [3] between the IG and CG at 12 months and using a baseline standard deviation of 59 m [9]. 48 m was chosen as it represented the effect size for the 6MWD reported in a meta-analysis of 16 randomised controlled trials of exercise training in COPD [3] and could be expected to be the difference if exercise capacity was maintained in the IG but not in the CG. 48 m is also in the range of reported clinically worthwhile differences in 6MWD, as it is within the 95% confidence interval of the minimum clinical important difference reported by REDELMEIER *et al.* [25] and greater than the 35 m reported by PUHAN *et al.* [26]. 48 subjects (24 per group) were sufficient to provide 80% power to detect a 48-m difference in 6MWD as significant, at the (two-sided) 5% level. To allow for a 20% loss to follow-up, 58 participants (29 per group) were considered necessary.

Statistics

Data were analysed using SPSS (version 16; SPSS Inc., Chicago, IL, USA). For the primary and secondary outcome measures, the mean results plus 95% confidence intervals (95% CI) were determined using repeated measures analysis with polynomial regression. The results for the initial pulmonary rehabilitation programme were also reported for 6MWD and SGRQ. The data were analysed using paired t-tests. All results were considered significant if $p < 0.05$. Intention to treat analysis was used.

RESULTS

Data for all outcome measures were collected at baseline (immediately following pulmonary rehabilitation), and at 3, 6

and 12 months. The subject flow reflected the recommendations from the Consolidated Standards of Reporting Trials (CONSORT) statement (fig. 1) [27]. Baseline characteristics for all subjects are described in table 1.

Effects of 8 weeks pulmonary rehabilitation

Prior to recruitment, all subjects completed pulmonary rehabilitation and showed a significant improvement in the mean 6MWD and total SGRQ score, as follows. 6MWD: IG 60 m, 95% CI 39–82, $p < 0.001$; CG 65 m, 95% CI 45–85, $p < 0.001$; and SGRQ: IG -9, 95% CI -15– -4, $p = 0.002$; CG -5, 95% CI -9– -0.2, $p < 0.05$.

24 subjects in the IG and 24 subjects in the CG completed the 12-month study (fig. 1). The total number who withdrew from the study was 11 (18.6%) out of 59 subjects: seven in the IG and four in the CG. There was no significant differences in age ($p = 0.65$), body mass index ($p = 0.4$), FEV₁/FVC ($p = 0.9$), FEV₁ ($p = 0.25$) and 6MWD ($p = 0.8$) between the subjects who completed the study and those who withdrew (table 1).

Primary outcomes

6MWT results are reported in table 2 and figure 2. For both the IG and the CG, there was no significant change in 6MWD from baseline to 12 months. SGRQ results are reported in table 2 and figure 3. For both the IG and the CG, there was no significant change in total SGRQ score from baseline to 12 months. For both the 6MWD and the total SGRQ score there was no significant difference between the groups in the change from baseline to 12 months.

Secondary outcomes

There was no significant change from baseline (immediately following pulmonary rehabilitation) to 12 months for lung function, ISWT, ESWT, HAD Score, hospital admissions or length of hospital stay in either group (table 3). There was also no significant difference between the groups in the change from baseline to 12 months for these outcomes. The mean \pm SD number of exacerbations during the 12 months was 2.3 ± 3 in the IG and 1.4 ± 1.8 in the CG, with no difference between the groups at 12 months (mean difference 0.9, 95% CI 0.4– -2).

Diary use and attendance

At 3 months, 67% of the IG and 61% of the CG used the exercise diaries and at 12 months this had decreased to 30% in both the IG and CG. Of the subjects who reported using the exercise diaries, the mean \pm SD number of ticks at 3 months out of a possible 60 ticks was 52 ± 13 in the IG and 28 ± 18 in the CG. At 12 months, the mean number of ticks out of a possible 120 ticks was 91 ± 38 in the IG and 87 ± 24 in the CG. 22 of the subjects in the IG attended $>80\%$ of the supervised exercise sessions for the period of the study and two subjects attended $<50\%$ of sessions.

Adverse events

There were no adverse events reported from the exercise interventions or from the testing.

DISCUSSION

In this study, the IG of supervised, weekly, outpatient-based exercise plus unsupervised home exercise successfully maintained exercise capacity and health-related quality of life for

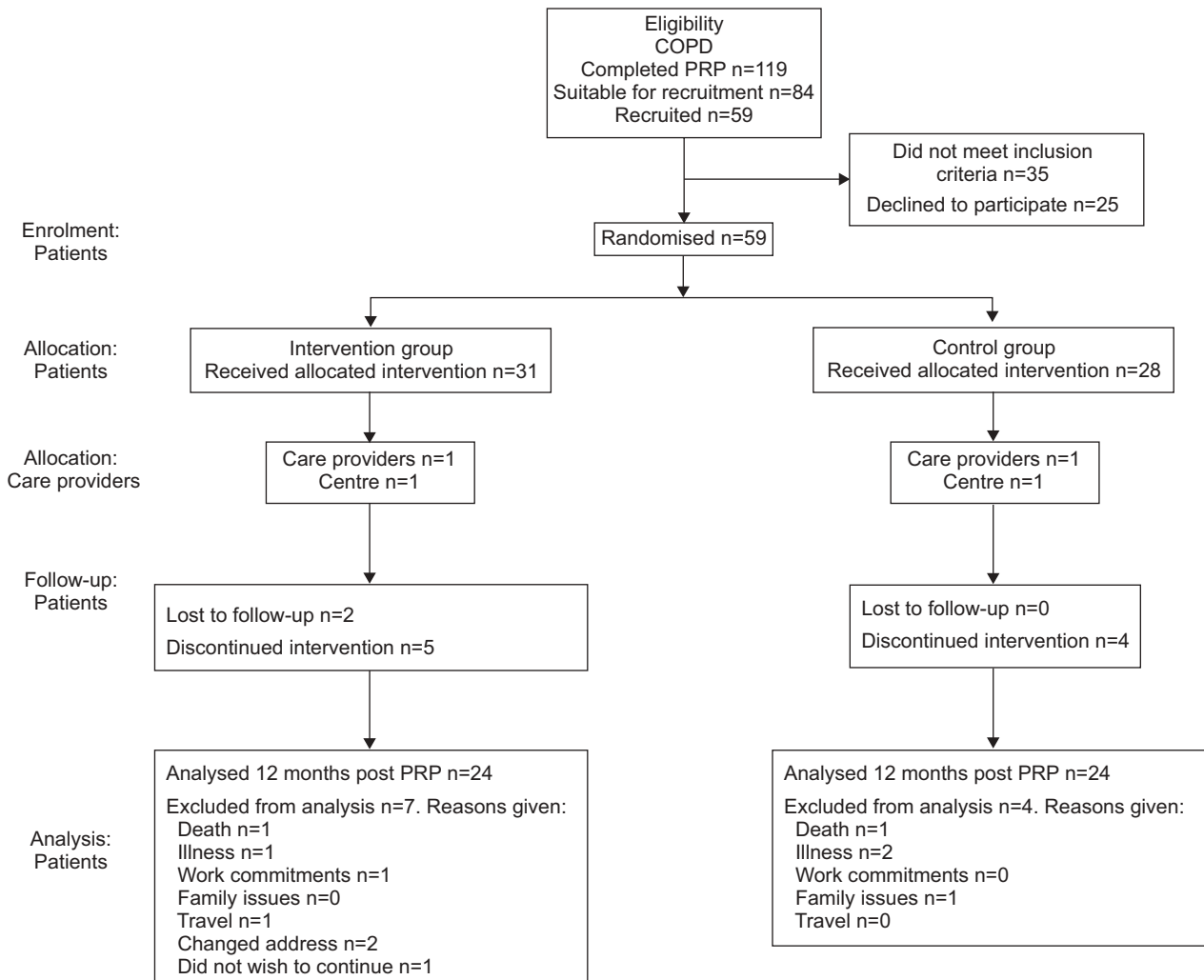


FIGURE 1. Consort flow diagram. COPD: chronic obstructive pulmonary disease; PRP: pulmonary rehabilitation programme.

12 months following pulmonary rehabilitation. Similar outcomes were observed in the CG, in which patients were asked to adhere to unsupervised home exercise. These findings are

	IG	CG	Excluded [#] mean
Subjects n	24	24	11
Males/females n	10/14	12/12	5/6
Age yrs	65±8	67±7	68±10
BMI kg·m⁻²	25±5	27±7	24±5
Current smokers n	6	5	4
FEV₁/FVC %	51±11	54±11	52±14
FEV₁ % pred	57±21	60±16	50±23
6MWD m	523±107	530±86	514±97

Data are presented as mean ± SD, unless otherwise stated. IG: intervention group; CG: control group; BMI: body mass index; FEV₁: forced expiratory volume in 1 s; FVC: forced vital capacity; % pred: % predicted; 6MWD: 6-min walk distance. [#]: excluded from analysis as per figure 1.

important because they show that it is possible for subjects with moderate COPD to maintain the benefits gained from an 8-week pulmonary rehabilitation programme if they continue to exercise regularly and this can be achieved with both supervised and unsupervised exercise in either an outpatient or home setting.

The intervention of supervised exercise once per week and advice to exercise on four other days maintained 6MWD and quality of life for 12 months in subjects with moderate COPD (Global Initiative for Chronic Obstructive Lung Disease (GOLD) stage II) [1] following an 8-week pulmonary rehabilitation programme. To our knowledge, this is the first study to demonstrate these results. Previous studies that used supervised exercise once per week to maintain the benefits following pulmonary rehabilitation either had an initial pulmonary rehabilitation programme of duration 6 months [9] or did not have a randomised control group [13]. In contrast, less frequent supervised exercise of once per month in subjects with severe COPD (GOLD stage III) [1] did not maintain 6MWD and quality of life for 12 months [7, 8].

A unique finding in our study was that the CG, to which advice was given to exercise unsupervised at home five days

TABLE 2 Exercise capacity and quality of life

	Pre-PRP		Baseline		3 months		6 months		12 months		Mean difference (baseline to 12 months)		Mean difference between groups
	IG	CG	IG	CG	IG	CG	IG	CG	IG	CG	IG	CG	
	6MWT m	463±111	465±76	523±108*	530±85*	524±100	523±94	525±96	527±78	512±109	524±79	-11 (-21-10)	-6 (-34-11)
Total SGRQ %	43±16	44±19	34±13*	39±15*	32±14	36±16	35±13	38±15	37±15	36±18	3 (-0.8-7)	-3 (-7-3)	5 (-2-11)
SGRQ symp.	52±24	57±21	38±19*	48±19*	40±19	40±22	41±23	46±24	46±22 [#]	43±24	8 (0.3-15)	-5 (-14-4)	12 (0.2-23) [†]
SGRQ activity	58±19	57±23	53±19	54±21	51±20	54±20	50±20	55±18	53±19	52±24	0 (-5-4)	-2 (-9-5)	2 (-8-10)
SGRQ impact	31±16	32±19	21±11*	27±16	21±12	25±17	24±11	26±17	25±14	25±19	4 (-0.2-9)	-2 (-7-4)	4 (-9-5)

Data are presented as mean±SD or mean (95% CI). PRP: pulmonary rehabilitation programme; IG: intervention group; CG: control group; 6MWT: 6-min walk test; SGRQ: St George's Respiratory Questionnaire; symp.: symptom. *: significantly different to pre-PRP, p<0.05; [#]: significantly different to baseline (post-PRP), p<0.05; [†]: significant difference between groups, p<0.05.

per week, maintained exercise capacity and quality of life at 12 months. This result was similar to the IG, which had the additional support of supervised exercise 1 day per week, shown to be important in a previous study [28]. Previous randomised controlled trials have reported a decline in exercise capacity and quality of life in control groups that received advice to continue home exercise after a pulmonary rehabilitation program [7, 8]. The initial pulmonary rehabilitation programme in these studies was of 6–8 weeks duration; however, in both studies subjects had severe COPD (FEV₁ 46% pred and 32% pred), which may have contributed to the decline in outcomes. Subjects who had severe COPD and successfully maintained exercise capacity at 18 months had an initial pulmonary rehabilitation programme of 6 months followed by advice to continue home exercise [29]. The length of the initial programme may have allowed subjects time to adopt new behaviours of independent home exercise, therefore impacting on long-term outcomes. Interestingly, our initial pulmonary rehabilitation programme of 8 weeks followed by

advice to exercise 5 days each week at home (CG) was successful in maintaining exercise capacity at 12 months in subjects with moderate COPD.

There are a number of possible reasons for the maintenance of exercise capacity and quality of life in the CG in our study. Firstly, it may be related to the regular follow-up testing. Despite no supervised training in the CG, the regular re-testing may have encouraged and motivated subjects to continue the home exercise programme [28, 30, 31]. In a previous study, COPD subjects reported that follow-up and monitoring was an important factor that helped adherence to an exercise programme [30]. Regular support and follow-up was provided in our study by the same physiotherapist who was experienced in pulmonary rehabilitation. This intermittent contact may have aided adherence to the long-term unsupervised home exercise programme.

Further possible reasons for the maintenance of exercise capacity in the CG may be related to the amount of

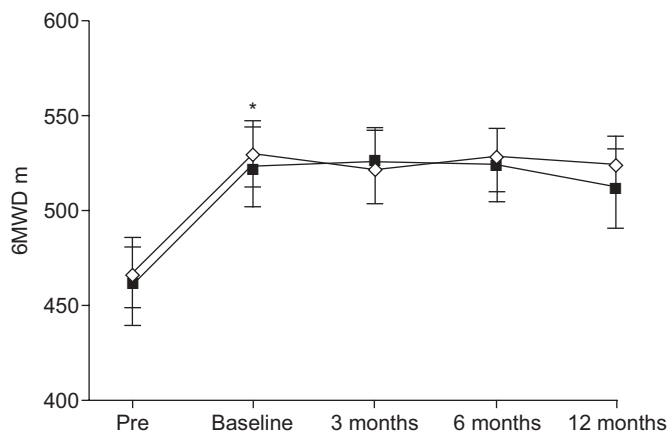


FIGURE 2. Results for 6-min walk distance (6MWD). Data are presented as mean values with error bars representing standard errors. ◇: control group; ■: intervention group. Pre: before pulmonary rehabilitation; baseline: following the completion of pulmonary rehabilitation. *: significant improvement from before rehabilitation in both groups, p<0.05.

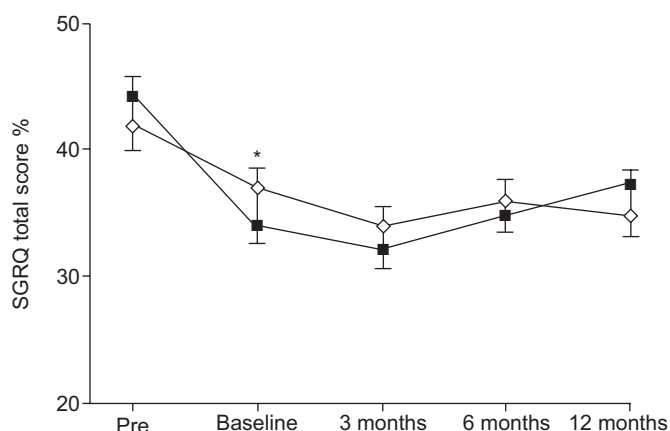


FIGURE 3. Results for the St George's Respiratory Questionnaire (SGRQ) total score. Data are presented as mean values with error bars representing standard errors. ◇: control group; ■: intervention group. Pre: before pulmonary rehabilitation. *: significant improvement from before rehabilitation in both groups, p<0.05.

TABLE 3 Exercise capacity, anxiety and depression, hospital admissions and length of stay (LOS)

	Baseline		3 months		6 months		12 months		Mean difference (baseline to 12 months)		Mean difference between groups
	IG	CG	IG	CG	IG	CG	IG	CG	IG	CG	
ISWT m	391 ± 117	416 ± 117	407 ± 116	415 ± 133	419 ± 124	423 ± 128	409 ± 129	415 ± 118	18 (-89–280)	-1 (-278–226)	20 (-9–48)
ESWT s	526 ± 404	774 ± 414	648 ± 474	756 ± 437	640 ± 479	807 ± 452	583 ± 470	758 ± 438	57 (-154–271)	-16 (-209–177)	68 (-147–284)
ESWT m	732 ± 550	1062 ± 639	948 ± 664*	1020 ± 629	925 ± 664	1080 ± 641	837 ± 668	1036 ± 620	105 (-422–431)	-26 (-6–278)	122 (-180–424)
Anxiety	6 ± 3	6 ± 3	6 ± 4	7 ± 4	5 ± 3	6 ± 3	5 ± 3	5 ± 4	-1 (-2–0.8)	-1 (-3–0.4)	0.5 (-1–2)
Depression	4 ± 2	5 ± 3	4 ± 3	6 ± 5	4 ± 3	5 ± 4	4 ± 3	5 ± 3	0 (-1.4–0.6)	0 (-2–1)	0.13 (-2–2)
Hosp. admissions	0.3 ± 0.8	0.6 ± 0.1	NA		NA		0.3 ± 1	0.5 ± 1	0 (-0.5–0.6)	-0.1 (-0.4–0.2)	0.2 (-0.7–0.4)
Hosp. LOS days	5 ± 20	4 ± 10	NA		NA		1.4 ± 5	3 ± 7	3.6 (-11–5)	1 (-5–2)	1.6 (-5–2)

Data are presented as mean ± SD or mean (95% CI). IG: intervention group; CG: control group; ISWT: incremental shuttle walk test; ESWT: endurance shuttle walk test; hosp.: hospital; NA: not applicable to this time point; *: significantly different to baseline, $p < 0.05$.

improvement in exercise capacity achieved in the initial pulmonary rehabilitation programme and the level of disease severity of this group. The subjects had moderate COPD (GOLD stage II) [1] that was preserved throughout the study. Also, subjects had completed an 8-week pulmonary rehabilitation programme prior to recruitment to the study and those randomised to the CG had significantly improved in exercise capacity (6MWD: 65 m increase) and quality of life (total SGRQ: -5 points improvement). Other studies that maintained exercise capacity and quality of life in the longer term also had large improvements in 6MWD of between 52 m and 80 m from the initial pulmonary rehabilitation programme [9, 10, 29]. Conversely, studies that failed to show maintenance of exercise capacity and quality of life at 12 months showed only small improvements in 6MWD of 14 m [8] and 23 m [7] despite significant improvements in quality of life [7].

A number of other factors may have aided long-term exercise adherence in our study. The home exercise programme was largely a walking programme that could be easily integrated into daily life [11]. In addition, adherence can be affected by belief about one's disease [32], satisfaction with outcomes [30, 33], psychological state [30, 34], disease exacerbations [28] and supervision [28]. The subjects in the CG may have gained positive attitudes towards exercise training following their substantial improvements in 6MWD from the initial pulmonary rehabilitation programme [30]. The subjects had stable lung function throughout the study, no detectable anxiety or depression (according to the HAD score) and relatively few exacerbations. These factors may have contributed to long-term adherence in the CG.

A further unique feature of this study was that the ISWT and the ESWT were used to measure exercise capacity at each time point. Results from the ISWT and the ESWT mirrored the findings of the 6MWT in that exercise capacity measured by these tests was maintained for 12 months. Although the 6MWT is a more widely used outcome measure in long-term exercise studies, it appears from this study that the ISWT and the ESWT are also useful tools for measuring functional exercise capacity following pulmonary rehabilitation.

During the 12 months of the maintenance study, the number of hospital admissions and length of stay were not significantly different compared to the 12 months prior to recruitment. One study that used exercise as a maintenance intervention also reported little change to the number of hospital admissions but a reduction in the length of hospital stay [5]. The smaller subject numbers in our study may have reduced the ability to detect changes in hospital length of stay. In addition, subjects in our study had less severe disease with a better level of functional exercise capacity than that reported by GRIFFITHS *et al.* [5], which may have resulted in the much lower rate of hospital admissions in our study.

A limitation of the study was that the assessor was not blinded to group allocation. However, all measurements were strictly standardised with the aim of minimising assessor bias. In addition, although evaluating exercise adherence was not a primary aim of the study, the poor rate of completion of home exercise diaries reduced our ability to comment on adherence to home exercise training. Diary completion at 3 months was 67% for IG and 61% for CG and at 12 months was only 30% in both groups. A number of subjects who verbally reported exercising at home did not continue with diary entries over the 12 months. One report was "I knew the exercises off by heart and did not need to use the exercise booklet and diary any more". The use of exercise diaries has been shown to increase adherence to short-term (2-week) unsupervised home exercise [31]; however, few studies report the results of long-term use of exercise diaries.

In conclusion, subjects with moderate COPD who completed an 8-week pulmonary rehabilitation programme and who showed good improvement in both 6MWT and SGRQ were able to maintain exercise capacity and quality of life for 12 months by following either supervised weekly outpatient-based exercise or unsupervised home exercise.

CLINICAL TRIALS

The study was registered with the Australian New Zealand Clinical Trials Registry ACTRN012605000678695.

STATEMENT OF INTEREST

None declared.

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