

Maintaining benefits following pulmonary rehabilitation: a randomised controlled trial.

Spencer LM^{1,2}, Alison JA^{1,2,3} & McKeough ZJ²

¹ Physiotherapy Department, Royal Prince Alfred Hospital, Sydney, Australia

² Discipline of Physiotherapy, Faculty of Health Sciences, University of Sydney, Australia

³ Department of Respiratory Medicine, Royal Prince Alfred Hospital, Sydney, Australia

Corresponding author

Lissa Spencer

Physiotherapy Department

Royal Prince Alfred Hospital

59 Missenden Rd Camperdown 2050, NSW Australia

Phone: 612 9515 9857

Fax: 612 9515 9751

Email: spencl@email.cs.nsw.gov.au or david.g.spencer@bigpond.com

Running title: Maintenance exercises in COPD

Key words: COPD, exercise, maintenance, pulmonary rehabilitation

Australian Clinical Trials Registry ACTRN012605000678695

Abstract

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

Methods: COPD subjects completed an eight-week pulmonary rehabilitation program, 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 twelve months. Outcome measurements at baseline (post PR), 3, 6 and 12 months included the six-minute walk test (6MWT) and St George's Respiratory Questionnaire (SGRQ).

Results: Fifty-nine subjects with moderate COPD (GOLD Stage II) were recruited and 48 subjects completed the study. Twelve month mean difference (95%CI) showed no significant change from baseline in 6MWD [IG = -11m (-21 to 10); CG = - 6 m (-34 to 11)] or total SGRQ score [IG = 3 (-0.8 to 7); CG = -3 (-7 to 3)].

Conclusion: Twelve months following pulmonary rehabilitation both weekly, supervised, outpatient-based exercise plus unsupervised home exercise and standard care of unsupervised home exercise successfully maintained six-minute walk distance and quality of life in subjects with moderate COPD.

BACKGROUND

Chronic Obstructive Pulmonary Disease (COPD) is a preventable and treatable disease with significant extra-pulmonary effects that contribute to the severity of symptoms in individual patients [1]. By 2020, COPD is estimated to 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 programs, involving at least four to six weeks exercise training with or without education, have been shown to improve functional exercise capacity, quality of life, reduce dyspnoea and hospital length of stay [3]. These benefits have been shown to last for up to nine months [4, 5, 6], however, the benefits appear to decline by twelve 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, 8, 9, 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 program of six 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 eight-week pulmonary rehabilitation program [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 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 eight-week pulmonary rehabilitation program would maintain functional exercise capacity and quality of life to twelve 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 an $FEV_1/FVC < 70\%$ and $FEV_1\%$ predicted $< 80\%$ [1, 2] were consecutively recruited to the study following the successful completion of an eight-week pulmonary rehabilitation program. The detailed methods for this paper have been published previously [15]. The study was performed in the Pulmonary Rehabilitation Physiotherapy gymnasium and in the Department of Respiratory Medicine, Royal Prince Alfred Hospital Sydney, Australia.

Subjects were excluded if they had experienced an exacerbation of COPD in the previous month, if they required supplemental oxygen, or had co-morbidities 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 Group

The Intervention Group (IG) performed supervised, outpatient-based exercise one day per week in the Pulmonary Rehabilitation Physiotherapy gymnasium where they had completed their initial program 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 program. This included 20 minutes

walking (track or treadmill), 20 minutes cycling, 10 minutes arm cycling, upper and lower limb strength training exercises using weight equipment and free weights.

Unsupervised home exercise consisted of 30 minutes of walking plus 30 minutes of upper and lower limb strengthening exercises using free weights and body weight.

The home exercises were practised during the pulmonary rehabilitation program 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 five 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), 3, 6 and 12 months following pulmonary rehabilitation.

Primary Outcome Measures

Six-Minute Walk Test (6MWT)

Subjects performed two 6MWTs at each assessment time. Instructions and encouragement were standardised according to the American Thoracic Society Guidelines [16]. Tests were performed in the physiotherapy gymnasium on a 32 metre continuous track and the better of the two tests was recorded.

St George's Respiratory Questionnaire (SGRQ)

Subjects completed the St George's Respiratory Questionnaire, a valid and reliable measure of quality of life in people with COPD [17]. 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 [18]. Forced expiratory volume in one second (FEV₁) and forced vital capacity (FVC) were measured using a mass flow sensor (Sensormedics Vmax 20 Pulmonary Spirometry Instrument; Sensormedics Corporation, Yorba Linda, California USA).

The spirometer was calibrated immediately before each test using a three-litre calibrating syringe. The highest value for FEV₁ and FVC after three reproducible trials was recorded and compared to predicted normal values [19]. Lung volumes were performed in accordance with American Thoracic Society Standards [20] using a body plethysmograph (Sensormedics V6200 Autobox Body Plethysmograph; Sensormedics Corporation, Yorba Linda, California, USA). Results were compared to predicted normal values for lung volumes [21].

Incremental Shuttle Walk Test (ISWT) & Endurance Shuttle Walk Test (ESWT)

Subjects performed the ISWT and ESWT at each assessment time according to the protocols described by Singh [22] and Reville [23] respectively. A 10-metre track was used with cones placed 9 metres 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) [24] were measured at the end of each of the walk tests.

Hospital Anxiety and Depression (HAD) Scale

Subjects were asked to complete the 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 [25].

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 program (including time in pulmonary rehabilitation). The second time period was the 12 months following the completion of the pulmonary rehabilitation program. 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 it was recorded if the subjects used the diary and if so, how many days they ticked as having exercised. 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 6MWD of 48 metres [3] between the IG and CG at twelve months and using a baseline standard deviation (SD) of 59 metres [9]. Forty-eight metres 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. Forty-eight metres 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 (1997) and greater than the 35 metres reported by Puhan et al (2008) [34, 35]. Forty-eight subjects (24 per group) were sufficient to provide 80% power to detect a 48metre 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). 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 program 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), 3, 6 and 12 months. The subject flow reflected the recommendations from the Consolidated Standards of Reporting Trials [26] (CONSORT) statement (Figure 1). 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:

[6MWD: IG = 60m (39 to 82), $p < 0.001$; CG = 65m (45 to 85), $p < 0.001$ and SGRQ: IG = -9 points (-15 to -4), $p = 0.002$; CG = -5 (-90 to -0.2, $p < 0.05$].

Twenty-four subjects in the IG and 24 subjects in the CG completed the 12 months study (Figure 1). The total number who withdrew from the study was 11 out of 59 subjects (18.6%), seven in the IG and four in the CG. There was no significant difference between the subjects who completed the study and those who withdrew for age ($p=0.65$), BMI ($p=0.4$), FEV₁/FVC ($p=0.9$), FEV₁% predicted ($p=0.25$) and 6MWD ($p=0.8$) (Table 1).

Primary Outcomes

Six-minute walk test 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 number of exacerbations (SD) 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: -2 to 0.4)].

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 number of ticks (SD) 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. Twenty-two of the subjects in the IG attended more than 80% of the supervised exercise sessions for the period of the study and two subjects attended less than 50% of sessions.

Adverse events

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

DISCUSSION

In this study the Intervention Group of supervised, weekly, outpatient-based exercise plus unsupervised home exercise successfully maintained exercise capacity and health related quality of life for 12 months following pulmonary rehabilitation. Similar outcomes were observed in the Control Group that was asked to adhere to unsupervised home exercise. These findings are important because they show that it is possible for subjects with moderate COPD to maintain the benefits gained from an eight-week pulmonary rehabilitation program 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 (GOLD Stage II) [1] following an 8-week pulmonary rehabilitation program. 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 program of 6 months duration [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 Control Group that consisted of advice to exercise unsupervised at home five days per week maintained exercise capacity and quality of life at twelve months. This result was similar to the Intervention Group that had the additional support of supervised exercise one-day per week, shown to be important in a previous study [32]. 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 program in these studies was of 6 to 8 weeks duration, however, in both studies subjects had severe COPD (FEV₁% predicted of 46% and 32%) that 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 program of 6 months followed by advice to continue home exercise [27]. The length of the initial program may have allowed subjects time to adopt new behaviours of independent home exercise,

therefore impacting on the long-term outcomes. Interestingly, our initial pulmonary rehabilitation program of 8 weeks followed by advice to exercise 5 days each week at home (Control Group) 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 Control Group in our study. Firstly, it may be related to the regular follow-up testing. Despite no supervised training in the Control Group, the regular re-testing may have encouraged and motivated subjects to continue the home exercise program [31, 32, 33]. In a previous study, COPD subjects reported that follow-up and monitoring was an important factor that helped adherence to an exercise program [31]. 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 program.

Further possible reasons for the maintenance of exercise capacity in the Control Group may be related to the amount of improvement in exercise capacity achieved in the initial pulmonary rehabilitation program 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 program prior to recruitment to the study and those randomised to the Control Group had significantly improved in exercise capacity (6MWD: 65 metres 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 metres and 80 metres from the initial pulmonary rehabilitation program [9, 10, 27]. 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 metres [8] and 23 metres [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 program was largely a walking program that could be easily integrated into daily life [11]. In addition, adherence can be affected by belief about one's disease [28], satisfaction with outcomes [29, 31], psychological state [30, 31], disease exacerbations [32] and supervision [32]. The subjects in the Control Group may have gained positive attitudes towards exercise training following their substantial improvements in 6MWD from the initial pulmonary rehabilitation program [31]. 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 Control Group.

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 reported by Griffiths et al (2000) [5] that 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 weeks), unsupervised, home exercise [33] 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 program 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.

References

1. Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for the diagnosis, management and prevention of chronic obstructive pulmonary disease. 2006. Available at: <http://www.goldcopd.com>. Accessed May 2009.
2. McKenzie D, Abramson M, Crockett A, Glasgow N, Jenkins S, McDonald S, Wood-Baker R, Frith P. The COPD-X Plan: Australian and New Zealand Guidelines for the management of Chronic Obstructive Pulmonary Disease 2008. Available at: <http://www.copdx.org.au/guidelines/index.asp>. Accessed February 2009.
3. Lacasse Y, Goldstein R, Lasserson TJ, Martin S. Pulmonary rehabilitation for chronic obstructive pulmonary disease. Cochrane Database of Systematic Reviews 2006; Issue 4: Art. No: CD003793. DOI: 10.1002/14651858.CD003793.pub2.
4. Cambach W, Wagenaar RC, Koelman PT, Ton van Keimpema AJR, Kemper HCG. The long-term effects of pulmonary rehabilitation in patients with asthma and chronic obstructive pulmonary disease: a research synthesis. *Arch Phys Med Rehabil* 1999; 80:103-111.
5. Griffiths TL, Burr ML, Campbell IA, Lewis-Jenkins V, Mullins J, Shiels K, Turner-Lawlor PJ, Payne N, Newcombe RG, Lonescu AA, Thomas J, Tunbridge J. Results at 1 year of outpatient multidisciplinary pulmonary rehabilitation: a randomised controlled trial. *Lancet* 2000; 355:362-368.

6. Singh SJ, Smith DL, Hyland ME, Morgan MDL. A Short outpatient pulmonary rehabilitation programme: immediate and longer-term effect on exercise performance and quality of life. *Respiratory Medicine* 1998; 92:1146-1154.
7. Ries AL, Kaplan RM, Myers R, Prewitt LM. Maintenance after pulmonary rehabilitation in chronic lung disease. *Am J Respir Crit Care* 2003; 167:880-888.
8. Brooks D, Krip B, Mangovski-Alzamora S, Goldstein RS. The effect of post rehabilitation programs among individuals with chronic obstructive pulmonary disease. *Euro Respir J* 2002; 20:20-29.
9. Guell R, Casan P, Belda J, Sengenis M, Morante F, Guyatt G, Sanchis J. Long-term effects of outpatient rehabilitation on COPD. *Chest* 2000; 117:976-983.
10. Berry M.J, Rejeski, J, Adair, N.E, Ettinger, W.H, Zaccaro, D.J., Sevick, M.A. A randomized, controlled trial comparing long-term and short-term exercise in patients with chronic obstructive pulmonary disease. *Journal of Cardiopulmonary Rehabilitation* 2003; 23:60-68.
11. Steele BG, Belza B, Cain KC, Coppersmith J, Lakshminarayan S, Howard J, Haselkorn JK. A randomized clinical trial of an activity and exercise adherence intervention in chronic pulmonary disease. *Arch Phys Med Rehabil* 2008; 89:404-412.
12. Liu WT, Wang CH, Lin HC, Lin SM, Lee KY, Lo YL, Hung SH, Chang YM,

Chung KF, Kuo HP. Efficacy of a cell phone-based exercise programme for COPD. *Eur Respir J* 2008; 32(3):651-9.

13. Moullec G, Ninot G, Varray A, Desplan J, Hayot M, Prefaut C. An innovative maintenance follow-up program after a first inpatient pulmonary rehabilitation. *Respir Med* 2008; 102(4):556-66.

14. Nici L, Donner C, Wouters E, Zuwallack R, Ambrosino N, Bourbeau J, Carone M, Celli , Engelen M, Fahy B, Garvey C, Goldstein R, Gosselink R, Lareau S, MacIntyre N, Maltais F, Morgan M, O'Donnell D, Prefault C, Reardon J, Rochester C, Schols A, Singh S, Troosters T; ATS/ERS Pulmonary Rehabilitation Writing Committee. American Thoracic Society/European Respiratory Society Statement: Pulmonary Rehabilitation. *Am J Resp Crit Care Med* 2006; 173:1390-1413.

15. Spencer LM, Alison JA, McKeough ZJ. Do supervised-weekly exercise programs maintain functional exercise capacity & quality of life, twelve months after pulmonary rehabilitation in COPD? *BMC Pulmonary Medicine* 2007; 7:7. (<http://www.biomedcentral.com/1471-2466/7/7>).

16. American Thoracic Society / European Respiratory Society Statement: Guidelines for the six-minute walk test. *Am J Respir Crit Care Med* 2002; 166:111–117.

17. Jones PW, Quirk FH, Baveystock CM. The St George's Respiratory Questionnaire (SGRQ). *Respir Med* 1991; 85:25-31.

18. American Thoracic Society & European Respiratory Society Statement: Standardisation of lung function testing: Standardisation of Spirometry. *Eur Resp J* 2005, 26:319-338.
19. Crapo RO, Morris AH, Gardner RM. Reference spirometric values using techniques and equipment that meet ATS recommendations. *Am Rev of Respir Dis* 1981; 123:659-664.
20. American Thoracic Society / European Thoracic Respiratory Society Statement: Standardization of the measurement of Lung Volume. *Eur Respir J* 2005; 26:511–522.
21. Goldman HI, Becklake MR. Respiratory function tests: normal values at median altitudes and the prediction of normal results. *Am Rev Tuberc* 1959; 79:457-467.
22. Singh SJ, Morgan MD, Scott S, Walters D, Hardman AE. Development of a shuttle walking test of disability in patients with chronic airways obstruction. *Thorax* 1992; 47:1019-1024.
23. Revill SM, Morgan MD, Singh SJ, Williams J, Hardman AE. The Endurance Shuttle Walk Test: a new test for the assessment of endurance capacity in COPD. *Thorax* 1999; 54:213-22.
24. Borg GAV. Psychophysical bases of perceived exertion. *Med Sci Sports Exerc* 1982; 14:377-381.

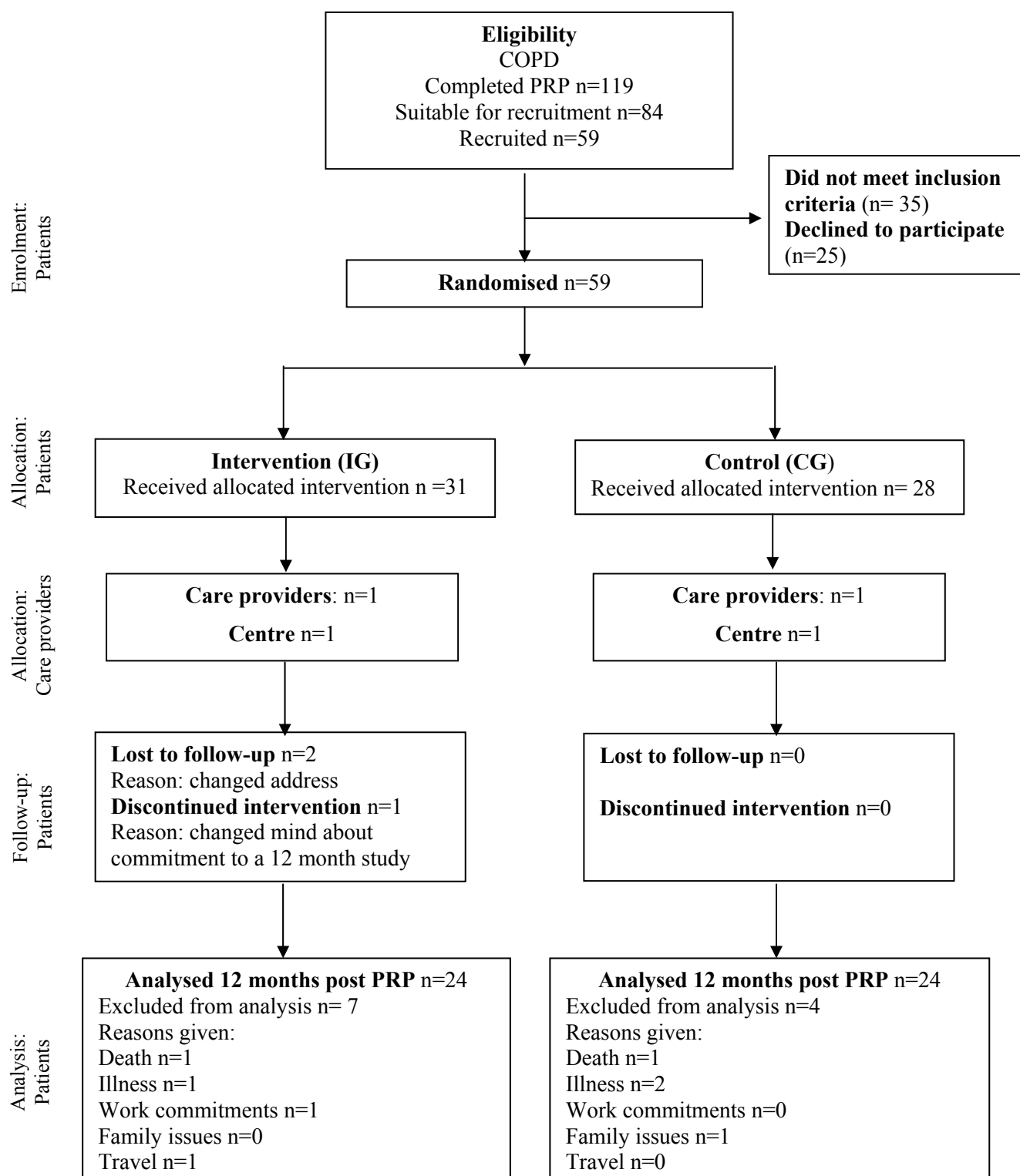
25. Zigmond AS, Snaith RP. The hospital and anxiety scale. *Acta Psychiatr Scand* 1983; 67:361-70.
26. Boutron I, Moher D, Altman D, Schulz KF, Altman DG, Ravaud P for the Consort Group. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. *Ann Intern Med* 2008; 148:295-309.
27. Troosters T, Gosselink R, Decramer M. Short and long-term effects of outpatient rehabilitation in patients with chronic obstructive pulmonary disease: a randomized trial. *Am J Med* 2000; 109(3):207-12.
28. Bateman ED. Improving inhaler technique use on COPD and the role of patient preference. *Eur Respir Rev* 2005; 14:96, 83-84.
29. Anderson KL. The effect of chronic obstructive pulmonary disease on quality of life. *Resp Nurs Health* 1995; 18:547-556.
30. Wepner JB, Wijkstra PJ. The influence of rehabilitation on behaviour modification in COPD. *Patient Education and Counselling* 2004; 52:237-241.
31. O'Shea S, Taylor N, Paratz J. Qualitative outcomes of progressive resistance exercise for people with COPD. *Chron Respir Dis* 2007; 4(3):135-42.

32. O'Shea SD, Taylor N, Paratz J. But watch out for the weather: factors affecting adherence to progressive resistance exercise for persons with COPD. *J Cardiopulm Rehab & Prev* 2007; 27:166-174.
33. Moseley GL. Do training diaries affect and reflect adherence to home programs? *Arthritis & Rheumatism* 2006; 55:662-664.
34. Puhan MA, Mador MJ, Held U, Goldstein R, Guyatt GH, Schünemann HJ. Interpretation of treatment changes in 6-minute walk distance in patients with COPD. *Eur Respir J*. 2008; 32(3):637-43.
35. Redelmeier DA, Bayoumi AM, Goldstein RS, Guyatt GH. Interpreting small differences in functional status: the Six Minute Walk test in chronic lung disease patients. *Am J Respir Crit Care Med*. 1997 Apr;155(4):1278-82.

Acknowledgments

The authors would like to thank Dr Mark Elkins for his assistance with randomization and the Physiotherapy Department at Royal Prince Alfred Hospital for allowing the study to be conducted in the Pulmonary Rehabilitation Gymnasium.

Figure 1: Consort flow diagram



Key: COPD: chronic obstructive pulmonary disease; PRP:pulmonary rehabilitation program; n: numbers

Table 1: Subject characteristics at baseline.

	IG mean (SD)	CG mean (SD)	Excluded mean (SD)
Subjects, n	24	24	11
Male / Female	10/14	12/12	5/6
Age, yrs	65 (8)	67 (7)	68 (10)
BMI, kg/m²	25 (5)	27 (7)	24 (5)
Current smokers, n	6	5	4
FEV₁/FVC %	51 (11)	54 (11)	52 (14)
FEV₁% predicted	57 (21)	60 (16)	50 (23)
6MWD, m	523 (107)	530 (86)	514 (97)

Key: Data are presented as mean ± SD; IG: intervention group; CG: control group; Excluded: excluded from analysis as per Figure 1; n: number; yrs: years; BMI: body mass index; kg/m²: kilogram per metre squared; %: percent; FEV₁/FVC: ratio of forced expiratory volume in one second to forced vital capacity; l: litres; FEV₁% pred: forced expiratory volume in one second percent predicted; 6MWD: six-minute walk distance; m: metres.

Table 2: Exercise capacity and quality of life

	Pre PRP (SD)		Baseline (SD)		3 months (SD)		6 months (SD)		12 months (SD)		Mean difference (b'line to 12 mths) (95% CI)		Mean difference between groups (95%CI) IG – CG
	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 to 10)	-6 (-34 to 11)	5 (-22 to 31)
SGRQT (%)	43 (16)	44 (19)	34* (13)	39* (15)	32 (14)	36 (16)	35 (13)	38 (15)	37 (15)	36 (18)	3 (-0.8 to 7)	-3 (-7 to 3)	5 (-11 to 2)
SGRQ S	52 (24)	57 (21)	38* (19)	48* (19)	40 (19)	40 (22)	41 (23)	46 (24)	46# (22)	43 (24)	8 (0.3 to 15)	-5 (-14 to 4)	12+ (-23 to -0.33)
SGRQ A	58 (19)	57 (23)	53 (19)	54 (21)	51 (20)	54 (20)	50 (20)	55 (18)	53 (19)	52 (24)	0 (-5 to 4)	-2 (-9 to 5)	2 (-10 to 8)
SGRQ I	31 (16)	32 (19)	21* (11)	27 (16)	21 (12)	25 (17)	24 (11)	26 (17)	25 (14)	25 (19)	4 (-0.2 to 9)	-2 (-7 to 4)	4 (-11 to 2)

Key: Data: expressed as a mean value ± standard deviation; 95%CI: 95 percent confidence interval; SD: standard deviation; b'line: baseline;

IG: intervention group; CG: control group; 6MWT: six-minute walk test; m: metres; QOL: quality of life; SGRQ T: Total St George's Respiratory

Questionnaire score; SGRQ S: symptom score; SGRQ A: activity score; SGRQ I: impact score; *: significantly different to pre PRP, p<0.05;

#: significantly different to baseline (post PR) p<0.05; +: significant difference between groups, p<0.05.

Table 3: Exercise capacity, Anxiety and Depression, Hospital Admissions and Length of Stay.

	Baseline (SD)		3 months (SD)		6 months (SD)		12 months (SD)		Mean difference (b'line to 12 mths) (95% CI)		Mean difference between groups (95% CI) IG – CG
	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 to 280)	-1 (-278 to 226)	20 (-48 to 9)
ESWT (sec)	526 (404)	774 (414)	648 (474)	756 (437)	640 (479)	807 (452)	583 (470)	758 (438)	57 (-154 to 271)	-16 (-209 to 177)	68 (-284 to 147)
ESWT (m)	732 (550)	1062 (639)	948 ⁺ (664)	1020 (629)	925 (664)	1080 (641)	837 (668)	1036 (620)	105 (-422 to 431)	-26 (-6 to 278)	122 (-424 to 180)
Anxiety	6 (3)	6 (3)	6 (4)	7 (4)	5 (3)	6 (3)	5 (3)	5 (4)	-1 (-2 to 0.8)	-1 (-3 to 0.4)	0.5 (-2 to 1)
Depression	4 (2)	5 (3)	4 (3)	6 (5)	4 (3)	5 (4)	4 (3)	5 (3)	0 (-1.4 to 0.6)	0 (-2 to 1)	0.13 (-2 to 2)
Hosp Admiss (n)	0.3 (0.8)	0.6 (0.1)	n/a	n/a	n/a	n/a	0.3 (1)	0.5 (1)	0 (-0.5 to 0.6)	-0.1 (-0.4 to 0.2)	0.2 (-0.4 to 0.7)
Hosp LOS (d)	5 (20)	4 (10)	n/a	n/a	n/a	n/a	1.4 (5)	3 (7)	3.6 (-11 to 5)	1 (-5 to 2)	1.6 (-2 to 5)

Key: Data: expressed as mean ± standard deviation; 95%CI: 95 percent confidence interval; SD: standard deviation; b'line: baseline;

IG: intervention group; CG: control group; n= number of subjects; ISWT: incremental shuttle walk test; ESWT: endurance shuttle walk test;

m: metres; sec: seconds; Hosp Admiss: hospital admissions; Hosp LOS: hospital length of stay; d: days; n: number;

n/a: not applicable to this time point; ⁺: significantly different to baseline, p<0.05.

Figure Legends

Figure 2:

Data are reported in mean values; error bars represent standard error; 6MWD: six-minute walk distance; m: metres; Pre: before pulmonary rehabilitation; B'line: baseline (following the completion of pulmonary rehabilitation); mths: months; * significant improvement from before rehabilitation in both groups $p < 0.05$; %: percent; ----◇----: control group; —■— : intervention group.

Figure 2: Results for six-minute walk distance

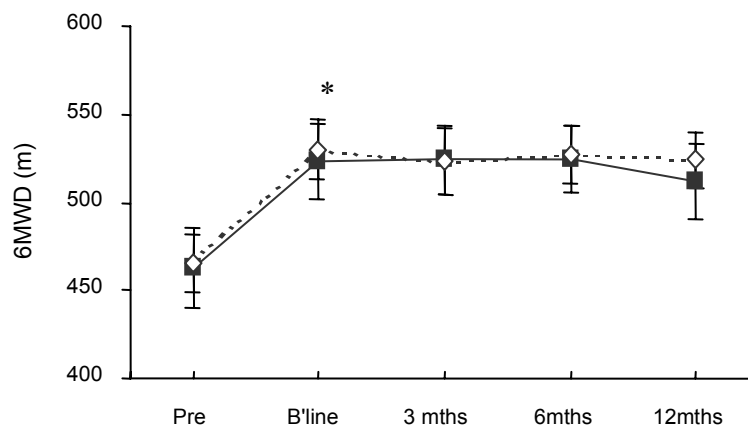


Figure 3:

Data are reported in mean values; error bars represent standard error; SGRQ: St George's Respiratory Questionnaire; m: metres; Pre: before pulmonary rehabilitation; B'line: baseline (following the completion of pulmonary rehabilitation); mths: months; * significant improvement from before rehabilitation in both groups $p < 0.05$; %: percent; ----◇----: control group; —■— : intervention group.

Figure 3: Results for the St George's Respiratory Questionnaire (total score)

