How long should Outpatient Pulmonary Rehabilitation be? 
A randomised controlled trial of four-weeks versus seven-weeks.

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ABSTRACT

Background: The evidence of benefit for pulmonary rehabilitation (PR) programmes is established. However the optimal duration of a PR programme is not known. We completed a randomised controlled trial with patients with COPD to assess whether a four-week PR programme was equivalent to our conventional seven-week PR programme at equivalent time points of seven-weeks and six months.

Methods: 100 patients (56 men) with stable COPD of mean (SD) age 70 (8) years, forced expiratory volume in one second (FEV₁) 1.13 (0.50) litres were randomised to either a seven-week (n=50) or four-week (n=50) supervised PR programme. Patients were assessed at baseline, completion of the supervised PR programme and six months later. Patients randomised to the four-week group were also assessed at the seven-week time point. Outcome measures were: Incremental Shuttle Walking Test, Endurance Shuttle Walk Test (ESWT) Chronic Respiratory Questionnaire – Self Reported and the Breathing Problems Questionnaire.

Results: 41 patients in each group completed the PR programme. Patients made significant within group improvements after supervised rehabilitation. There were no statistically significant differences between group for any other measure at the seven-week or six month time points., except the patients in the four-week group attained higher ESWT times (mean difference (95% CI) 124 seconds (17.00 to 232.16), p=0.024) at the seven-week time point.

Conclusions: A shortened four-week supervised pulmonary rehabilitation programme is equivalent to a seven-week supervised pulmonary rehabilitation programme at the comparable time points of seven-weeks and six months.
INTRODUCTION

The progress of chronic obstructive pulmonary disease (COPD) is associated with increasing breathlessness, disability and frequent hospitalisations. Pulmonary rehabilitation (PR) has been shown to reduce disability in Chronic Obstructive Pulmonary Disease. The evidence of benefit for pulmonary rehabilitation is now established and lies in studies that have demonstrated improvements in exercise performance and health status. Recent guidelines for the treatment of COPD have emphasised the importance of PR programmes as part of an integrated multi-disciplinary approach ¹. However, the optimum length of a supervised PR programme is still debated. In the UK, many PR programmes are substantially over subscribed. It is therefore of particular interest that the minimum effective length of a pulmonary rehabilitation programme be established.

A previous randomised controlled trial completed by Green and colleagues ² compared a four-week out patient PR programme with the conventional seven-week out patient PR programme. Outcomes were reported for each group at the end of the supervised rehabilitation periods. These end points were therefore different for each of the two groups. Green et al² concluded that the seven-week programme resulted in greater benefits for health status than those found in the shortened four-week group. There was also a trend for greater improvements in exercise performance for the seven-week group. However it was not clear whether results for the four-week group would have been comparable to those in the seven-week group when assessed at identical the time point of seven-weeks. This would have taken into account any “lag effect” of any improvements in health status over a period of time. Green and colleagues ² also argued that it would be interesting to lengthen the follow up period of this original study to six months in order that the effect of differing durations be identified in the longer term. We therefore designed a further randomised controlled trial, which would explore whether this was the case. This study aimed to establish whether a four-week supervised PR programme was equivalent to a seven-week supervised PR programme at comparable time points of seven-weeks. A secondary aim of this study was too examine the effects of a four and seven-week supervised PR programme after six months.

METHODS

Patients
This was a prospective randomised controlled trial. 100 patients with COPD were randomised to either the conventional seven-week supervised PR programme or to the four-week supervised PR programme. Patients with significant musculo-skeletal, cardiac or cognitive problems were excluded from the study, as they would be unable to participate in the PR programme. Full ethical approval was obtained from the Leicestershire Ethics Committee and informed written consent was obtained from all subjects.

Study Protocol
The study protocol is detailed in figure 1. Patients were recruited from our pulmonary rehabilitation waiting list from secondary care referrals. An initial assessment was completed and patients were then randomised (using previously prepared and consecutively numbered sealed envelopes) to either the conventional seven-week supervised PR programme or to the four-week supervised PR programme. Patients
were recruited consecutively on a convenience basis at the time of the initial assessment (1 patient refused). All patients completed all primary and secondary outcome measures at the time of the initial assessment, before commencing the PR programme. All outcome measures were repeated upon completion of the supervised PR programme (either four or seven-weeks). Upon completion of the supervised PR programme all patients were instructed to continue with their home training programme. Those patients randomised to the four-week programme were then given an appointment for a further assessment equivalent to seven-weeks after the commencement of PR (i.e. three weeks later). Patients in the four-week group were asked to contact the PR department if they developed an exacerbation of their COPD within this three week home training period. No other contact with the patient was undertaken during this period. Assessments at 4, 7 weeks or 6 months were completed by a blinded assessor not involved in the delivery of the rehabilitation programme.

**Outcome Measures**

The Incremental Shuttle Walking Test (ISWT) and the Endurance Shuttle Walk Test (ESWT) were primary outcome measures for this study. The ISWT was used to measure maximal exercise performance. All patients completed one practice walk. The ESWT measured sub-maximal exercise performance. This test is completed following the ISWT. Patients walked at a constant speed equating to 85% of predicted VO2 peak of the performance on the ISWT.

Secondary outcome measures were the Chronic Respiratory Questionnaire – Self Reported (CRQ-SR) and the short form Breathing Problems Questionnaire (BPQ). The CRQ-SR is a reliable and valid measure of health status in patients with COPD. It is comprised of four domains: dyspnoea, fatigue, emotion and mastery. As the questions in the CRQ-SR are identical to the operator led version an assumption was made that the previously reported MCID of 0.5 per domain is valid for the CRQ-SR. Higher scores indicate better health status. This measure has been shown to be sensitive to change following pulmonary rehabilitation. The BPQ is a 10 item self-administered questionnaire, which examines the functional and emotional impact of respiratory disease. A total score is produced ranging from 0 to 30 with lower scores indicating better health status. This measure has been previously shown to be sensitive to change following a short course of pulmonary rehabilitation.

**Pulmonary Rehabilitation Programme**

The PR programme took place at Glenfield Hospital, University Hospitals of Leicester NHS Trust. The aim of the programme is to improve both physical performance and health status. Patients attended twice weekly with each session lasting for two hours, our institute offers a rolling programme. The session was divided into one hour of supervised exercise and one hour of education. All patients also completed a home training programme.

The education programme consisted of a rotation of 14 sessions of seminars and discussions covering the following topics: relaxation, disease education, dietary advice, benefits advice, energy conservation, medication advice, chest clearance and breathing control techniques. Those patients randomised to the four-week PR programme would miss a proportion of these talks. Therefore, all patients in the four-
week group were given a manual of comprehensive written information covering all the education topics.

During each week, patients received one hour of supervised aerobic training and one hour of supervised strength training exercises. Supervised aerobic training sessions consisted of walking and cycling. Progression was achieved through weekly increases in duration. Patients were instructed to walk at a speed equal to 85% of predicted peak VO₂ as calculated from the ISWT. Total continuous walking times were recorded and patients also completed daily training walks at home. These were recorded on a home training diary. These home sessions were unsupervised; patients were advised to increase the duration of their walk rather than the intensity. This was monitored weekly in the supervised sessions. During the supervised strength training sessions patients completed four separate exercises (bicep curls, sit to standing, pull-ups and step ups). Patients were completed these exercises using hand weights and were instructed to complete 3 sets of 10 repetitions of each exercise. Perceived exertion scores were recorded and hand weights increased when these scores were equal to or below 13. Patients were instructed to complete these exercises three times a week, including the once weekly-supervised session.

Analysis of Data
A power calculation for an equivalence trial was completed and it was calculated 40 patients would be required in each group, based upon a difference of 20 metres mean improvement on the Incremental Shuttle Walking Test between the two groups. Recruitment of 100 patients would then allow for a study drop out rate of 20%. Statistical analysis was completed using Statistical Package for Social Science (SPSS) software (version 13). Baseline characteristics and exercise data are presented as mean +/- standard deviation. Mean and range is identified for quality of life scores. The within group differences have been compared using repeat measures analysis of variance, post hoc analysis identifying were significant differences occurred. Between group comparisons have been compared with analysis of variance technique for repeat measures with weeks on rehabilitation being the dependent factor. Analysis between groups was performed at equivalent time points i.e. baseline, 7 weeks and 6 months. Further analysis was completed between groups at comparable time points, comparing the difference at the end of the supervised component of training. To take into account possible baseline differences in exercise performance univariant analysis of variance was performed with baseline exercise performance as a covariant. Where analysis of variance identified a significant difference post hoc tests were completed with correction for multiple measures. Mean difference and 95% confidence intervals (CI) are presented for comparisons within and between groups. Significance was set at p<0.05.

RESULTS
100 patients were recruited to the study. 50 patients were randomised to the four-week PR programme and 50 patients to the seven-week PR programme. Baseline characteristics of these patients are presented in table 1. In total, 18 patients withdrew from the study (9 from each group) before they completed the seven-week time point of the study and the reasons are detailed in figure 1. This level of dropouts is similar...
to that experienced in our routine clinical service. No baseline differences in age, gender distribution or pulmonary function were found between the two groups. There were also no differences for either group when study dropouts were compared to those who completed the study, in terms of age; gender distribution, pulmonary function and baseline ISWT score.

Table 1 Baseline demographic data, exercise assessments and health status

<table>
<thead>
<tr>
<th></th>
<th>Four week group</th>
<th>Seven week group</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>Male: Female</td>
<td>29:21</td>
<td>27:23</td>
</tr>
<tr>
<td>Age (years)</td>
<td>68.2 (7.7)</td>
<td>71.96 (8.3)</td>
</tr>
<tr>
<td>Current smokers (n)</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>FEV₁ (litres)</td>
<td>1.16 (0.52)</td>
<td>1.11 (0.47)</td>
</tr>
<tr>
<td>FVC (litres)</td>
<td>2.45 (0.97)</td>
<td>2.17 (0.57)</td>
</tr>
<tr>
<td>FEV₁/FVC</td>
<td>0.50 (0.17)</td>
<td>0.51 (0.14)</td>
</tr>
<tr>
<td>MRC score</td>
<td>3.6 (2-5)</td>
<td>3.8 (2-5)</td>
</tr>
<tr>
<td>ISWT (metres)</td>
<td>196.0 (117.1)</td>
<td>166.3 (96.5)</td>
</tr>
<tr>
<td>End Borg breathlessness score</td>
<td>4.6 (2-9)</td>
<td>4.5 (1-9)</td>
</tr>
<tr>
<td>End perceived exertion score</td>
<td>14.4 (11-17)</td>
<td>13.8 (9-17)</td>
</tr>
<tr>
<td>ESWT (seconds)</td>
<td>183.8 (108.6)</td>
<td>165.5 (104.1)</td>
</tr>
<tr>
<td>CRQ-SR dyspnoea</td>
<td>2.6 (1.5)</td>
<td>2.8 (1.1)</td>
</tr>
<tr>
<td>CRQ-SR fatigue</td>
<td>3.5 (1.1)</td>
<td>3.5 (1.2)</td>
</tr>
<tr>
<td>CRQ-SR emotion</td>
<td>4.4 (1.1)</td>
<td>4.2 (1.2)</td>
</tr>
<tr>
<td>CRQ-SR mastery</td>
<td>4.4 (1.3)</td>
<td>4.3 (1.4)</td>
</tr>
<tr>
<td>BPQ</td>
<td>13.3 (4.9)</td>
<td>13.9 (4.6)</td>
</tr>
</tbody>
</table>
Values are mean (SD) or mean (range)
FEV₁ = forced expiratory volume in one second, ISWT = Incremental Shuttle Walking Test, ESWT = Endurance Shuttle Walking Test, CRQ-SR = Chronic Respiratory Questionnaire – Self Reported, BPQ = Breathing Problems Questionnaire

Of those patients who completed rehabilitation a total of 71 patients were reassessed at the six months after completing the rehabilitation programme, 36 from the four-week PR programme and 35 from the seven-week PR programme. The reasons for non-attendance at the six month follow up assessment were: exacerbation of COPD (n=5), died (n=2) had moved away from area (n=1), patient did not attend but no reason given (n=6).
Within group comparison –

4 week group
Within group analysis identified that there was a significant difference in ISWT performance between the four time points. Post hoc analysis revealed that the difference did not reach significance between the 4 and 7 week measurement (mean difference 95% CI 6.7m (22.8 to –9.5m). All other comparisons were statistically significant. The improvement in the ISWT from baseline to 4 weeks was 56.9m (95% CI 41.2 to 72.2m). At 6 months the improvement from baseline was 34.2m (15.8 to 52.7m) (figure 2a)

The pattern of response was similar for the ESWT. Analysis revealed that there was a significant difference in performance over the 4 time points. Post hoc analysis identified that there was difference between all time points except between 4 weeks and 6 months. Mean improvement between baseline and 4 weeks was 222.9 secs (95% CI 152.4 to 293.5 secs). Unlike the ISWT performance continued to improve after the 4 weeks of rehabilitation, mean increase from 4 to 7 weeks was 115.0 secs (95% CI 36.8 to 193.1 secs). The mean increase from baseline to 7 weeks was 337.8 secs (95% CI 245.9 to 429.8 secs) (figure 2b)

The CRQ-SR for the dyspnoea domain identified significant differences. Post hoc analysis identified improvements between baseline and 4 weeks (p<0.05), further modest improvement were achieved at 7 weeks for these 3 domains but they were not statistically significant. At 6 months there was no significant difference from baseline. This pattern was repeated from the domains of emotion and fatigue. All 4 domains achieved clinically important changes at the 4 week time point. Interestingly statistical significance was delayed until the 7 week assessment time point for mastery. The mean values for the difference in mastery at 7 weeks (mean 1.1, 95% CI –0.01 to 1.0) was double the mean value at 4 weeks (mean 0.5 95% CI 0.7 to 1.5), (figure 3) Analysis of the BPQ results again identified significant differences across the time points, there were significant improvements between baseline and week 4 and 7, no important changes were observed between weeks 4 and 7. The score declined over the subsequent 6 months, and was not significantly higher than baseline.

7 week group
There was a significant difference in performance on the ISWT over the 3 assessment times (baseline, 7 weeks and 6 months). The mean increase between baseline and 7 weeks was 52.4m (95% CI 41.9 to 62.9m). The difference at 6 months remained statistically significant 28.8m (95% CI 13.4 to 44.2m) (figure 2 a). Analysis of endurance performance yielded a similar pattern. Post hoc analysis identified a significant improvement from baseline to 7 weeks; mean improvement 216.6secs (95% CI 132.0 to 301.2 secs), which remained significantly higher at 6 months, mean, difference 121 secs (64.5 to 177.7 secs) (figure 2b). We secured clinical and statistically important changes in the CRQ-SR (all domains p<0.001) (figure 3) and the BPQ from baseline to 7 weeks

Between group
Comparisons were made between the 4 and 7 week rehabilitation group at equivalent time points, i.e. at baseline, 7 weeks and 6 months. Overall the ISWT and ESWT data showed that there was no significant difference overall between the groups. At seven weeks the mean difference in performance on the ISWT was 15.5m (95% CI –6.9 to 37.9m) in favour of the four week group. Differences in the ESWT again in favour of
Comparison at the end of supervised rehabilitation.

Univariate analysis of variance was employed to identify the changes observed at the end of a period of exercise supervision. Results were further analysed by including baseline performance as a covariant. Improvement of performance on the ISWT and the ESWT were compared between baseline and 4 weeks for the 4 week group, and baseline and 7 weeks for the 7 week group. The mean improvement in the ISWT in the 4 week group at 4 weeks was 57.5m (95% CI 44.2 to 70.8m) and 50.0m (95% CI 38.9 to 62.1m) for the 7-week group at 7 weeks. There was no statistically significant difference between these improvements. The results were not influenced by baseline performance of the ISWT. There was a statistically significant difference in performance on the ESWT in favour of the 4 week group. The mean difference was 116.9 secs (11.7 to 222.3 secs), this difference has taken into account any differences at baseline. The CRQ-SR data did not reveal any statistically significant differences between the two groups at this equivalent time point. There was a trend for the mastery and fatigue score to be lower but this did not reach statistical significance. The BRQ results were similar.

DISCUSSION

These results indicate that a four-week supervised PR programme is equivalent to a seven-week supervised PR programme at comparable time points of seven-weeks and six months following completion of the programme. Importantly, the overall response to PR is similar to that documented in other trials. Interestingly the four-week group attained higher improvements in endurance walking times when compared to the seven-week group at the seven-week time point. There was also a trend for the four-week group to attain greater improvements in all other outcome measures, although this did not reach statistical significance. A combination of hospital and home training appears to be as effective as supervised hospital based training. However, it is accepted that further study is needed to support this view.

At the four-week time point, the four-week group largely matched the seven-week group with regard to improvements in both measures of exercise performance and health status. Patients in this trial could clearly not be blinded to the length of their supervised rehabilitation programme, however the assessor was blinded to the intervention. It could be that the patients in the four-week group knew that they only had four-weeks in which to gain from the supervised element of the PR programme. Importantly because only the four-week group were reassessed after four-weeks of supervised training we do not know if this response to PR occurred in the seven-week group at the four-week time point. We believe that this may be that this is the general response in rehabilitation and not simply a phenomenon seen in patients who know they only have four-weeks of supervised PR available to them.

Changes in health status were similar to the results we reported previously. This earlier study failed to attain clinically important improvements in CRQ scores at four-weeks. In this current study the data acquired at the end of the supervised programme revealed statistically and clinically significant changes in all domains except mastery, by the 7 week time point dyspnoea improved again (p<0.05). Mastery improved by the 7 week assessment to a comparable level to the 7 week supervised group making
large improvements in the three weeks of unsupervised home activity. The mastery domain reflects the level of control and confidence that patients feel they have with regard to managing their respiratory disease. It may be that patients gained confidence from realising that their level of exercise performance increased during the home training phase of the study, away from any hospital support or intervention.

It is also important to note that at six months, patients in both groups were able to maintain some of the improvements in exercise performance noted at the seven-week time point. However, improvements in exercise performance and health status are not wholly maintained six months after completion of PR. It is accepted that there is no control group within this study but this pattern of deterioration has been noted in other trials. It has previously been accepted that the progression of the underlying respiratory disease and co-morbidity are very important factors. These patients have a progressive disease and exacerbations may hinder compliance to the home training advice that patients receive upon discharge from the rehabilitation programme.

Compared to other studies the immediate outcome to rehabilitation is favourable, despite the relatively short intervention in both groups. Ries et al secured a modest improvement in six minute walking test distance, less than the acknowledged minimal clinically important difference, again over a 6 week period. A recent review document catalogued the immediate improvement in rehabilitation over varying lengths of programmes, most programmes identified in this review failed to achieve the MCID for the six minute walking test. The randomised controlled reported by Griffiths included a year follow up after rehabilitation and a control period. Data showed that patients were significantly better at 12 months compared to a control group, which would inevitably decline with time. The ISWT data revealed patients had declined to baseline in performance to baseline values at 12 months. Our data reveals that patients have retained about half of the performance benefit at 6 months, suggesting our population have declined in capacity in a similar way to the Griffiths population.

One of the methodological problems with this study was that all of the patients in the four-week group knew that they were going to be reassessed at the seven-week time point. It could be argued that this knowledge of this impending reassessment may have artificially influenced compliance to their home training programme. It is also accepted that because of the drop out rate, this study was underpowered at the six month time point. Larger studies may be needed to confirm the equivalence of a four-week programme in the longer term.

It is also accepted that there were some non-responders to rehabilitation in both treatment groups. This is clearly important to recognise but was not the primary focus of this study. Further large prospective trials are needed to investigate the length of rehabilitation programmes and could be competency driven in contrast to completing previously predefined PR programme lengths.

In summary, this study has shown that a shortened four-week supervised pulmonary rehabilitation programme is capable of achieving similar results to a seven-week supervised pulmonary rehabilitation programme at the comparable time point of seven-weeks and the absolute end of supervised rehabilitation. It is recognised that the provision of pulmonary rehabilitation services in the United Kingdom and other developed countries is poor and is currently only provided to a small minority of people with disabling lung disease. A shorter supervised programme may facilitate a
more effective use of resources and result in pulmonary rehabilitation being offered to a greater number of patients.

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Legends
Figure 1 Study design
Figure 2a and 2b. Mean (SE) performance on the ISWT (a) and ESWT (b) for the 4 and 7 week supervised rehabilitation group at baseline, 4 weeks (for the 4 week group), 7 weeks and 6 months

Figure 3 CRQ SR results – The mean score of the 4 domains of the CRQ-SR measured at 4 and 7 weeks for the 4 week group and at 7 weeks for the 7 week group. The horizontal line represents the MCID of 0.5

Reference List


Initial assessment n=100

4 week programme n = 50

4 weeks of supervised rehabilitation – reassessment

3 weeks of unsupervised rehabilitation – reassessment

41 patients completed study
9 patients failed to complete:
Reasons:
Exacerbation of COPD (n=2)
Transport problems (n=1)
Other illness (n=1)
Patient dropped out (n=2)
Unable to attend 7 week assessment due to ill health (n=2)

6 month follow up assessment (n=36)

7 week programme n = 50

7 weeks of supervised rehabilitation – reassessment

41 patients completed study
9 patients failed to complete:
Reasons:
Exacerbation of COPD (n=2)
Other illness (n=1)
Patient dropped out (n=2)

6 month follow up assessment (n=35)
How long should outpatient pulmonary rehabilitation be? A randomised controlled trial of four-weeks versus seven-weeks
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