CLINICAL PRACTICE ARTICLE

Twice versus three-times weekly pulmonary rehabilitation in a real-life clinical setting [v1; ref status: approved with reservations 1, http://f1000r.es/34f]

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Abstract

Aim: Our aim was to compare a less intensive but longer pulmonary rehabilitation programme (PRP) against a more intensive but shorter PRP.
Methods: We carried out an observational, cohort study in a real-life clinical setting in patients primarily with chronic obstructive pulmonary disease (COPD). We compared standard outcomes in patients who were receiving 18 sessions of PRP delivered twice weekly over 9 weeks (Group 1) against similar patients receiving an identical PRP delivered three times weekly over 6 weeks (Group 2). Outcome measures were the St. George's Respiratory Questionnaire (SGRQ), the Incremental Shuttle Walk Test (ISWT) and the number of hospital bed-days pre- and post-PRP.
Results: Both groups showed statistically significant and clinically important improvements post-PRP. The largest effects were seen immediately post-PRP and waned over the following 12 months. Group 1 showed a larger improvement in ISWT immediately post-PRP (Group 1, +92 m *versus* Group 2 +64 m (p=0.001), but there were no differences between groups at 6 (p=0.67) or 12 months (p=0.96). There were no differences in SGRQ between groups immediately post-PRP (p=0.09) or at 12 months (p=0.78). There were no differences between groups in the number of hospital days 12 months prior to PRP versus 12 months post-PRP (p=0.18).
Conclusion: Twice weekly outpatient, multidisciplinary PRP over 9 weeks is as effective as three times weekly PRP over 6 weeks.

Open Peer Review

Referee Status: ?

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Introduction

Randomised trials have demonstrated that Pulmonary Rehabilitation Programs (PRPs) for patients with chronic obstructive pulmonary disease (COPD) can improve dyspnoea, exercise tolerance, health-related quality of life (QoL), and reduce the number of hospital days and the utilization of healthcare resources. Research has demonstrated that PRPs are cost-effective and as such they are now recommended to all patients, who remain breathless despite optimal bronchodilators, irrespective of severity and age[1–4]. In addition, evidence is mounting for the efficacy of PRPs in patients with non-COPD causes of pulmonary impairment[5].

As evidence accumulates, there are now specific recommendations for PRPs regarding patient selection, timing (in relation to exacerbations *etc.*), intensity and type of exercises, educational, psychological and behavioural components, oxygen supplementation, what outcomes to measure and total duration[3–7]. However, there still remain unanswered questions including what are the best sites for delivery of a PRP, whether nutritional supplementation should be offered during PRP, what are optimal target populations and what post-rehabilitation maintenance strategies reduce the declines seen in nearly all settings[7–9]. Other important concerns relate to variable attendance and high drop-out rates in PRPs[10,11]. We have shown that certain factors at enrolment can predict later poor attendance at PRP[10], but interventions to improve the completion rates of these more vulnerable groups are still being researched.

Despite a general improvement in the provision of PRPs since 2003, there remains poor access to PRPs in some parts of the United Kingdom (UK). Those hospitals/community services that provide PRPs describe variable content and staffing and many report long waiting times[12]. However, there is less evidence for other chronic care programs for COPD such as Home Exercise or Hospital at Home[13]. In the current financial climate, reduced resources are available for developing novel strategies for COPD care so optimisation and evolution of those existing services with a good evidence base should be explored.

Comparable efficacy from a longer but less intensive PRPs may allow more flexible working for staff (*e.g.* part-time) to deliver an effective PRP or allow existing full-time staff to offer more than one PRP simultaneously, for example on different weekdays in different sites to improve local access, increase throughput and reduce waiting times.

We present immediate and one year outcomes from a real-life clinical setting comparing the delivery of identical 18-session PRPs, delivered by the same staff, simultaneously across two similar nearby hospitals. This PRP occurred three times per week over 6 weeks or twice per week over 9 weeks within the same Health Board (group of hospitals).

Methods

We sought advice regarding whether ethical approval was required for the study. As this was a retrospective review of prospectively collected routine clinical data (service evaluation) ethics approval was not deemed necessary.

Patients were referred from primary or secondary care onto the PRP. A respiratory physician first checked and optimised treatment and excluded those with dementia, unstable cardiac disease or unwillingness to commit to a program. We include data on all those who attended for pre-PRP assessment (consisting of a brief interview and description of the service) by our physiotherapist and occupational therapist.

Our PRP was closely developed from our mentor's model that has a strong evidence base[14,15]. It consists of 18 sessions of outpatient multidisciplinary input from occupational therapists, physiotherapists (including a teacher of the Chronic Respiratory Disease Exercise instructor course, endorsed by Loughborough College and British Lung Foundation), dietetics staff, pharmacist, physicians, specialist respiratory nurses and a smoking cessation counsellor.

Each session lasted for approximately 2.5 hours starting with supervised, individual exercise prescription of lower extremity training (treadmill, step-ups) and upper extremity training (resistance bands and loose weights). This was followed by group educational activities addressing the causes and types of lung disease and psychological aspects of chronic disability. Individual goal setting, dietary interventions, physiotherapy and occupational therapy were also included with voluntary sessions of relaxation classes and breathing retraining exercises where attention was paid to emotional and social as well as physical aspects of health. Very occasional provision was made for additional sessions following non-attendance or further deterioration *e.g.* two people were awaiting lung transplant.

Completers (defined as attending 12 or more from 18 sessions) were referred to a follow-up component of self-exercise free classes in gyms in local leisure centres. All participants were given a pack at enrolment emphasising regular exercise with personalised goals and information on COPD.

In our health board, we split our daily PRP over 5 days per week between two similar medium-sized hospitals (25 miles apart). One hospital, which serves an urban (ex-industrial) and semi-rural area, offered 18 sessions of PRP, three times weekly over 6 weeks (Monday, Wednesday and Friday afternoons). The other hospital is based in market town serving a rural area; because of greater distances involved in travelling, it offered the identical PRP of 18 sessions but twice weekly over 9 weeks (Tuesday and Thursday afternoons). Both groups were encouraged to exercise at home and the patients receiving PRP twice weekly were asked to try an independent home exercise session on a third day each week, replicating the hospital exercises where possible. The content, staff members and time of day of the PRPs were identical. This was thus a naturalised nested, cohort study allowing a unique opportunity to compare two intensities of identical PRPs.

Subjects completed the SGRQ and Medical Research Council (MRC) dyspnoea scores (under supervision) before completing a baseline ISWT[16] 1 week prior to PRP. They completed the same QoL survey and the ISWT immediately post-PRP and then 6 and 12 months later.

Information regarding admissions was extracted from our hospital database and all data for publication has all been anonymised and approved by our Hospital Caldicott Guardian for export.

We used the statistical package for social sciences (SPSS), version 21.0 (Chicago, Illinois). Data are expressed by means and standard deviations. Analysis of the results was by intention to treat (ITT). Between-group comparisons were carried out at each time point using unpaired samples t-tests, Mann-Whitney and Chi square. Within-group changes were assessed using paired samples t-tests and Wilcoxon rank tests. A *p* value of less than 0.05 was deemed statistically significant.

Results

a) The overall PRP results are described below:

244 patients entered PRP between March 2006 and September 2008.

74% had purely COPD and 26% were disabled by lung disease primarily from other conditions including idiopathic pulmonary fibrosis (5%), bronchiectasis (11%), chronic asthma (7%), kyphoscoliosis (1%) or other respiratory conditions (2%).

48% were male; overall the subjects had a mean age of 66.0±9.5 years, and the mean forced expiratory volume in 1 second (FEV_1) recorded from clinics prior to PRP, was 46±19% predicted.

The median (inter-quartile range) attendance was 13 (7, 16) from a maximum 18 sessions with 56% of patients completing 12 or more sessions.

Complete data on ISWT and QoL scores were available for 223 people at baseline, 161 people post-PRP, 89 people at 6 months and 53 people at 12 months.

The mean ISWT improved from 155±123 metres immediately pre-PRP to 241±152 metres immediately post-PRP ($p<0.001$). This had fallen back slightly to 199±146 metres at 6 months ($p<0.01$ from baseline) and 168±170 metres at 12 months ($p<0.05$ from baseline).

The total SGRQ at baseline was 63.1±15.6, immediately post-PRP was 53.6±15.5 ($p<0.001$), at 6 months was 56.7±15.6 ($p<0.001$ from baseline) at 12 months was 56.6±16.8 ($p=0.07$ from baseline).

The mean number of admissions 6 months prior to PRP was 0.69±1.20 and in the 6 months following PRP was 0.39±0.94 ($p<0.001$).

The mean number of days spent in hospital 6 months prior to PRP was 5.54±15.20 and in the 6 months following PRP was 2.70±8.11 ($p<0.001$).

The mean number of admissions 12 months prior to PRP was 1.05±1.60 and in the 12 months following PRP was 1.11±1.55 ($p=0.66$).

The mean number of days spent in hospital 12 months prior to PRP was 7.35±16.77 and in the 12 months following PRP was 8.63±19.23 ($p=0.55$).

b) Comparison between twice weekly versus three times weekly PRPs:

Table 1 describes the patients enrolled in the two separate PRPs at baseline. Apart from the ISWT, the two groups were similar in baseline characteristics.

Table 2 compares the changes from baseline to 6 and 12 months in both groups. There was a significant difference in the ISWT post-PRP between the two groups but this was no longer apparent 6 or 12

Table 1. Baseline characteristics of the patients attending each of the PRP sessions.

	Hospital 1 (2 sessions per week) n=95	Hospital 2 (3 sessions per week) n=149
Male	48%	48%
COPD	80%	71%
Age (years)	65.9±8.6	66.1±10.1
FEV_1% pred	43±19	47±19
PRP sessions completed	11.2±6.4	11.6±5.8
Shuttle walk (m)*	186±133	135±112
Total SGRQ*	59.0±15.8	65.6±15.0
MRC dyspnoea scale	3.5±1.0	3.6±0.8
Days in hospital previous 6 months	3.4±6.9	6.9±18.6
Days in hospital previous 12 months	4.2±6.9	9.4±20.6

* $p<0.05$

Table 2. Comparison between outcomes in patients of the two PRP groups.

	Hospital 1 (2 sessions per week) n=95	Hospital 2 (3 sessions per week) n=149	*p*-value
ISWT (m) post-PRP	+92±74	+64±61	0.003
ISWT 6 months post-PRP	+49±62	+45±87	0.67
ISWT 12 months post-PRP	+8±27	+35±90	0.86
SGRQ post-PRP	-5.6±11.8	-9.7±12.6	0.09
SGRQ 6 months post-PRP	+0.1±13.2	-5.6±11.4	0.02
SGRQ 12 months post-PRP	-3.7±13.3	-5.4±13.8	0.78
Days in hospital 6 months pre- versus 6 months post-PRP	-1.8±8.7	-5.7±23.9	0.67
Days in hospital 12 months pre- versus 12 months post-PRP	+3.7±14.5	-3.9±23.1	0.18

months post-PRP. This may be due to the significantly lower mean ISWT at baseline. There was a significant difference in the SGRQ scores post-PRP, but again this was not apparent at the later time points. There were no differences in the number of hospital days pre- and post-PRP between the two PRP groups.

Data sets for UK Pulmonary Rehabilitation Programmes in real-life clinical settings

1 Data File

http://dx.doi.org/10.6084/m9.figshare.987086[25]

Discussion

This is the first study to report immediate and medium term outcomes from two PRPs that were identical apart from the intensity of sessions. We found statistically significant and clinically important improvements in ISWT and QoL immediately following both PRPs. These effects were waning but still apparent at 6 months. At 12 months there was an overall mean change of +13 metres in ISWT which, although statistically significant, is unlikely to be clinically important. The mean improvement in total SGRQ of around 7 units from baseline to 12 months, however, is still likely to be clinically important but did not reach statistical significance (p=0.07) and could have occurred through chance and survivor selection bias. There were reductions in the number of hospital admissions and number of days spent in hospital within both PRP groups and as a population overall, comparing the 6-month periods immediately before and after PRP, but no differences in the number of admissions and days in hospital at 12 months. In Griffiths' landmark randomized controlled trial of a PRP with identical staffing and content to ours, occurring three times weekly, there were similar improvements in SGRQ, ISWT and days in hospital (but not number of admissions) in those receiving PRP in addition to usual care[14]. These differences remained statistically different from a control group of people with similar COPD, at 12 months could be at least partly due to deterioration due to progressive COPD in the usual care group. We had no such 'usual care' group like Griffith's group in his randomised controlled trial as not offering PRP's would now be considered unethical. We compared our 12-month outcomes within the same patients one year before, when they were younger and so their disease (and co-morbidity) was probably less advanced. Showing equivalent ISWT and health care utilisation over 1 year, at least shows a halting or stabilising of what has been traditionally labelled a 'chronic progressive irreversible lung disease' (goldcopd.org).

Our patient outcomes are similar to others (that came mainly from more established academic units)[6,8,14,15,18] and this helps to validate our PRP by confirming benefits within an everyday clinical setting. This indicates that PRPs should be offered in a non-teaching group of hospitals. Our outcomes are also comparable or superior to other 'before-and-after' studies in real-life service evaluations. For example, O'Neill *et al.* reported improvements in mean ISWT of around 23 metres immediately after completing a supervised, outpatient PRP over 6 weeks, but their PRP was only once weekly and only reported on 74 patients. Like us, their effects were still apparent but waning at 6 months but not reported at 12 months[16].

The comparison between twice *versus* three times weekly PRPs revealed subtle changes. Interestingly, the less intensive, twice weekly group showed greater improvement in ISWT immediately post-PRP but the groups were not completely matched and this could be confounded by their greater exercise tolerance (higher ISWT) and better disease specific quality of life (lower SGRQ) at baseline. It is easy to suggest that the patients could exercise more at home between supervised hospital sessions so could achieve bigger overall gains in exercise performance, during their hospital attendances.

We had a mixture of people with lung disease and some with very severe airflow obstruction. Garrod *et al.* reported less favourable outcomes in ISWT for those with more severe disease (higher MRC dyspnoea scores), possibly because they attended PRP less frequently[17]. Our actual percentage change in ISWT from baseline

was similar in the twice *versus* three times weekly PRP (6% *versus* 7% improvement); moreover any early differences in ISWT between the twice *versus* three times weekly PRP groups were no longer apparent at 6 and 12 months.

Both groups had statistically significant and clinically important improvements in SGRQ immediately following PRP. Those receiving three times weekly PRP showed a larger change and this difference could be clinically important as a difference of 4 units in the SGRQ is traditionally deemed a clinically important outcome (Meguro 2006). There was a -9.7 change in three times weekly *vs* -5.6 change in twice weekly so difference of 4.1 units between groups in their changes), although this clinically important change could still have occurred through chance (p=0.09). This greater early improvement in QoL may be explained by the more intensive program but is confounded by the poorer QoL at baseline and is easily explained by statistical chance. The difference between groups in SGRQ at 6 months (+0.1 from baseline in twice weekly *versus* -5.6 in the three times weekly) did suggest ongoing benefit only for the latter group *versus* an earlier return to baseline in the less intensive group. However, there were no differences between the two groups in any outcome at 12 months, and the difference in SGRQ at 6 months could be due to a statistical aberration (multiple comparisons) as this single reading went against all the other outcome trends.

Few others have compared more *versus* less frequent sessions in PRPs. Green *et al.* suggested initially that a 7 week course provided greater early benefits in health status than a similarly intensive but shorter 4 week course[18]. The same group then later reported that a 4 week supervised PRP with similar educational content is equivalent to a 7 week supervised PRP in clinical outcomes both at 7 weeks and 6 months[19].

We have previously reported that a longer PRP was associated with lower attendance[10]. Possible reasons could be that participants notice less incremental change and that there is more time for intercurrent illness/exacerbations or other activities to interfere with attendance. This was based on an internal study comparing three sessions over 6 weeks *versus* one session over 18 weeks and was entered along with other attendance predictors in a multi-regression model. The original randomised controlled trial was never completed due to the death of the lead investigator. Marciniuk *et al*. suggested the opposite, *i.e*. that longer PRPs (beyond 6 to 8 weeks) better maintain health gains[7] and Rossi *et al*. reported that a ten session PRP provides only limited clinically significant improvements when compared with a longer 20-session course in outpatients with mild-to-moderate severity COPD[20].

Our study has some weaknesses; this is not a randomised controlled trial and real world observational studies may be confounded by non-randomisation of participants. Our two PRP cohorts were not exactly matched; those enrolled in the three times weekly PRP had a statistically significant higher SGRQ and lower ISWT at baseline suggesting more respiratory impairment, despite similar age, FEV_1 gender and disease mix. Those in the three times weekly PRP tended to have a higher number of admissions and days in hospital before PRP although this could have occurred through chance (p>0.05). The hospital offering the three times weekly PRP serves a larger urban population with higher levels of smoking, more ex-industrial workers and deprivation and so higher COPD prevalence and likely more co-morbidities. Despite a faster turnover and a higher throughput of patients, it has longer waiting times for PRP suggesting a greater local need. Although the absolute improvement in ISWT (metres) was bigger in the hospital offering PRP twice per week, this could be influenced by their greater exercise capacity to begin with and the relative (percentage) improvement from baseline (as opposed to actual metres); immediately post-PRP was similar in both groups (p=0.39).

The study could be open to selection/reporting bias as there was incomplete data especially at 12 months with only around 20% of patients returning to hospital for completion of SGRQs and ISWTs. The lower numbers with available data at 12 months also contributed to a large data spread, especially for ISWT. These re-attenders could be those who obtained the biggest gains and wanted to support the service - or alternatively they could consist predominantly those asking for more help because of limited improvements. However, our attrition rate over 12 months is typical of others, and as a group, these long-term attenders have similar characteristics to others[14]. There were no differences in baseline factors between those who completed data collection and those who did not.

Our study has many strengths. It provides a unique opportunity to describe a real-life service but taking advantage of a real-time 'natural experiment' where two PRPs are identical in staffing and process apart from the intensity. Both services are well-described and follow evidence-based guidelines. The size of our study compares well with others and our patient selection, content, delivery and staffing is typical of many UK hospitals outside of specialist centres. Our immediate and short-term outcomes of PRP are compatible with others and offer some insights into more longitudinal (12 month) data, albeit with some caveats. Real-life observational studies can sometimes yield valuable insights. Atypical staff or patient behaviour does not limit them to the same extent as a randomised controlled trial, nor are they restricted by strict age and severity inclusion criteria, or the exclusion of patients with co-morbid illnesses[21]. Real-life clinical studies are more generisable than randomised trials from specialist centres or those designed/funded by institutions with a financial interest in outcomes.

Our data suggest that offering a longer twice weekly PRP instead of a more intensive three times-weekly PRP leads to similar attendance and has not compromised outcomes. Longer PRPs may provide more opportunities for continuing exercise. Certainly continuing exercise after PRP is now acknowledged to be a vital component on its own[22]. A twice weekly PRP would allow participants to have more time during the week to start exercising independently (*e.g.* attend leisure centres) and to identify early problems/build confidence during their hospital PRP, well before they are discharged from the scheme. This could help address some of the remaining issues with continuing exercise and slowing deterioration after PRP. Importantly, slightly less intensive PRPs allow flexibility in service

provision, for example, re-allocating staff from the third PRP day-of-the-week (*e.g.* Wednesdays) to instead promote sustainable exercise schemes for previous completers or working in the community for those unable to attend the hospital/day care unit[7,17,23]. Alternatively, twice weekly PRP would allow existing staff working a typical 5 day week, to run two PRPs simultaneously per week with one day per week allocated for reviews/baseline assessments. With the increasing pressure on clinical resources, a twice weekly PRP allows less than 50% whole time equivalent staff to run a single PRP over 2 days per week without compromising standards. We now run both PRPs 2 days a week allowing part-time working and the same staff to contribute to other respiratory services within the existing team, whilst monitoring our waiting lists.

Data availability

figshare: Data sets for UK Rehabilitation Programmes in real-life clinical settings, http://dx.doi.org/10.6084/m9.figshare.987086[25]

All data have been anonymised and approved for publication.

Author contributions

KEL conceived the study idea and formulated the design of the study. LT, CD, PH, CL-J were involved in recruitment of patients and data collection. KEL and HAH carried out data analysis. KEL led on the writing of the manuscript. All authors provided input to and reviewed all drafts of the manuscript.

Competing interests

No competing interests were disclosed.

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Data Source

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The subject (impact of the frequency of supervised training) is clinical relevant and not sufficiently evaluated. They have used a real-life study comparing two hospitals with identical rehabilitation except for the number of supervised trainings – twice or three times a week. They have discussed the limitations and strength of this design. They have included enough patients to test for relevant differences between these two programmes. The patients have been adequately characterised at baseline, and the authors have used relevant outcomes.

They write that median attendance was 13 (maximum 18 sessions), but I cannot find data on difference between the two programmes. Information on home training is also welcomed.

They have used proper statistical analyses. It is well written, and data are discussed sensibly in context with other studies.

I have read this submission. I believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Competing Interests: No competing interests were disclosed.