

A randomised 2 × 2 trial of community versus hospital pulmonary rehabilitation for chronic obstructive pulmonary disease followed by telephone or conventional follow-up

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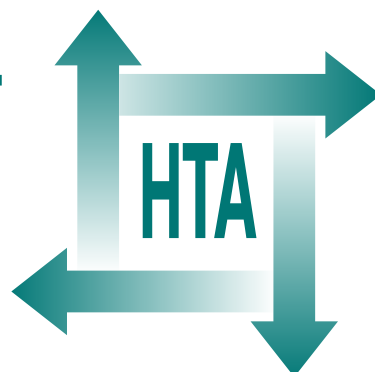
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Executive summary

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Executive summary

Background

Pulmonary rehabilitation is a well-established treatment modality for chronic obstructive pulmonary disease (COPD), recommended in national and international guidelines. The rationale for its use is the observation that breathless people limit their exercise and become cardiovascularly deconditioned, leading to further exercise limitation and a spiral of decline. Exercise training breaks this cycle leading to an improvement in exercise capacity and health-related quality of life, and decreasing breathlessness. Although well supported by research, this has usually been carried out in a hospital environment, and it is clear that the benefit is progressively lost once the course terminates. A programme producing a change in lifestyle is likely to produce more sustained benefits. We hypothesised that a community programme would be seen as more relevant to patients' own lifestyles than a treatment administered in a hospital. However, the converse may be true. People may see community treatment as more trivial than treatment administered in an important hospital. Indeed, one Australian trial, the only other large comparative trial to address this, suggested that community rehabilitation might be less effective.

This trial set out to test this in the context of routine NHS treatment. In addition to effects on exercise capacity and health-related quality of life, we also assessed the health economic impact.

Following a rehabilitation programme, it is unclear whether continued interventions may enhance persistence of effect. We hypothesised that regular telephone encouragement would be cost-effective in encouraging continued exercise and consequent prolongation of benefit.

Objectives

This study sought to establish:

1. Is pulmonary rehabilitation carried out in a community setting more effective than that carried out in a standard hospital setting,

immediately or after 18 months of follow-up, as assessed by exercise capacity and indices of health-related quality of life?

2. Is telephone follow-up useful in prolonging the beneficial effects of a pulmonary rehabilitation programme?
3. What is the most cost-effective choice for the setting of pulmonary rehabilitation, and is telephone follow-up a cost-effective option?

Methods

Patients with COPD diagnosed by respiratory physicians according to Global Initiative for Chronic Obstructive Lung Disease guidelines were randomised to receive rehabilitation in a hospital or community setting. Treatment was in a group setting, twice per week for 6 weeks, according to a standardised protocol. Hospital and community groups were supervised by the same team. Research participants were also randomised in 2×2 factorial fashion to hospital or community rehabilitation and telephone or standard follow-up with review. Exercise capacity, generic and disease-specific quality of life, and health economic data were collected pre and post rehabilitation, and at 6, 12 and 18 months following rehabilitation.

Results

A total of 240 participants had evaluable data. Of these, 129 were randomised to hospital rehabilitation (64 with telephone follow-up and 65 with no telephone follow-up) and 111 to community rehabilitation (55 with telephone follow-up and 56 with no telephone follow-up). For the primary outcome measure, there were 162 patients with data for analysis: hospital rehabilitation with no telephone follow-up ($n = 38$); hospital rehabilitation with telephone follow-up ($n = 48$); community rehabilitation with no telephone follow-up ($n = 43$); and community rehabilitation with telephone follow-up ($n = 33$). For the acute phase post-rehabilitation outcomes, before patients had the opportunity for telephone follow-up, we compared outcomes between the 76 patients in the community rehabilitation group and the 86 patients in the hospital rehabilitation group.

The primary efficacy response variable was the percentage change relative to baseline, i.e. $[(\text{end of rehabilitation} - \text{baseline}) / \text{baseline}] \times 100$, in distance walked during the endurance shuttle walking test (ESWT), as specified in the protocol. Patients in the hospital rehabilitation group increased the distance they could walk at the post-rehabilitation follow-up by 283 m [standard deviation (SD) 360 m], an increase relative to baseline of 109% (SD 137%). Patients in the community rehabilitation group increased the distance they could walk at the post-rehabilitation follow-up by 216 m (SD 340 m), an increase relative to baseline of 91% (SD 133%). There was no significant difference in improvement between the groups, mean difference in the change in distance walked was 17.8% (95% CI -24.3 to 59.9, $p = 0.405$, $n = 161$) in favour of hospital rehabilitation.

For longer term outcomes at 6, 12 and 18 months post rehabilitation there was no evidence of a rehabilitation group effect. After allowing for the initial post-rehabilitation baseline distance walked, time (follow-up visit) and the factorial design (telephone follow-up group), the average difference in the post-rehabilitation follow-up distance walked on the ESWT between the hospital and community rehabilitation groups was 1.5 m (95% CI -82.1 to 97.2, $p = 0.971$). There was also no evidence of a telephone follow-up group effect. After allowing for the initial post-rehabilitation baseline distance walked, time (follow-up visit) and the factorial design (rehabilitation group), the average difference in the post-rehabilitation follow-up distance walked on the ESWT between the telephone and no-telephone groups was 56.9 m (95% CI -25.2 to 139, $p = 0.174$). The high attrition rate during follow-up gives rise to some uncertainty in these results, although data imputation does not suggest that important differences were concealed by differential dropout.

The pulmonary rehabilitation programme used was shown to produce clinically important benefits in exercise capacity and health-related quality of life acutely. This declined as expected during follow-up. There was no difference between hospital or community groups in terms of acute effect or persistence of effect. Telephone follow-up did not significantly alter maintenance of exercise capacity or generic quality of life indices. Although disease-specific quality of life assessed by the Chronic Respiratory Questionnaire was statistically significantly better maintained after telephone follow-up than after standard care, the mean effect was small and below the accepted minimum

important difference. Health economic analysis favoured neither hospital nor community settings, and nor did it clearly favour telephone follow-up or routine care.

Exploratory post hoc analysis suggested that the team delivering the care could have a large effect on magnitude of improvement. A significant proportion of those apparently suitable for rehabilitation and agreeing to it dropped out before commencing the programme.

Conclusions

Implications for health care

- Pulmonary rehabilitation delivered in a community setting has similar efficacy to that produced in a more traditional hospital-based setting, both settings producing significant improvements in terms of exercise capacity and quality of life acutely and after long-term follow-up.
- Telephone follow-up versus standard care showed no difference in exercise capacity or generic measures of health-related quality of life. There was however a small improvement in disease-specific quality of life in the telephone follow-up group. Although statistically significant, the mean effect was below the minimum important difference.
- Health economic analysis showed that neither hospital nor community programmes were greatly favoured. The choice to adopt either model will depend on local factors of convenience, existing availability of resources and incremental costs.
- Planning of service delivery needs to acknowledge that uptake of pulmonary rehabilitation by those who might potentially benefit will be incomplete. Measures to enhance this (e.g. transport provision and convenience) have the potential to have major public health impact.
- Our data suggest that staff characteristics may be important in gaining optimal outcome. Care should be taken in staff recruitment and training.

Implications for research

- There is a clear need for further research to identify ways of enhancing uptake of pulmonary rehabilitation programmes by those with potential to benefit from them. This needs to include detailed qualitative

research to identify patient-centred strengths and weaknesses in such standard models of pulmonary rehabilitation.

- Further research is required into the efficacy and safety of community rehabilitation programmes in important patient groups not covered by this study, in particular those receiving long-term oxygen therapy and those with cardiac failure.
- Initial maximal exercise testing was carried out in a hospital setting. Further research is required into the safety of such maximal testing in community settings.
- Our exploratory analyses suggest that the magnitude of benefit of a pulmonary rehabilitation programme may be significantly affected by the team supervising this intervention, and admits the possibility that such an effect could be large. This merits further specific research.

- Telephone follow-up using a very simple model produced some improvement in long-term disease-specific indices of health-related quality of life. Research is required to test whether more complex telephone follow-up models could produce further benefit, and to test the cost benefit of any such approach.

Trial registration

This trial is registered as ISRCTN86821773.

Publication

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Third, through its Technology Assessment Report (TAR) call-off contract, the HTA programme commissions bespoke reports, principally for NICE, but also for other policy-makers. TARs bring together evidence on the value of specific technologies.

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Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

The research reported in this issue of the journal was commissioned by the HTA programme as project number 01/15/10. The contractual start date was in November 2002. The draft report began editorial review in May 2008 and was accepted for publication in June 2009. As the funder, by devising a commissioning brief, the HTA programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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