Why do patients decline to take part in a research project involving pulmonary rehabilitation?

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Summary
Background: It is important that those taking part in research trials are as representative as possible of those with the disease being studied. In a study of those with chronic obstructive pulmonary disease involving pulmonary rehabilitation, 120 of 297 suitable patients responded that they did not wish to take part in the trial. We were keen to know why these patients declined to take part in the study.

Methods: A total of 120 patients who had responded that they did not wish to take part in the main trial were approached to ask if they would be willing to undertake a semi-structured face-to-face interview in their own home or by telephone. Those who were willing (n = 39) underwent tape-recorded interviews and data analysis was performed using the framework method.

Results: This was a qualitative study which revealed that several themes influenced patients’ willingness or otherwise to take part in a research project involving pulmonary rehabilitation. Travelling to the hospital and location of the rehabilitation, along with competing commitments, and a variable perception of the benefits to the patient were clearly major factors and some had previous negative experiences of either the hospital, healthcare or research. While there was an element of negativity or impaired understanding regarding the research itself, the other factors appeared to be of greater importance.

Conclusion: Recruitment to pulmonary rehabilitation courses or recruitment to research involving pulmonary rehabilitation may be more successful if the location of the rehabilitation can be made as near to the patient’s home as possible, and if the patient is given as much information as possible about what is involved.

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Introduction

In any study, it is clearly important that the patients studied are as representative as possible of the general population of those with that condition. In pharmacological trials, group mean data analysis can obscure individual variations in responses and in such trials genomic profiling is likely to become of increased importance in the future. When assessing other interventions, other behavioural, cultural, socio-economic factors and literacy, may also become important.

In respiratory medicine, pulmonary rehabilitation is increasingly recognised as an important part of management1 and there have been good studies of the characteristics of patients which suggest that they will be benefit from this intervention,2,3 and also studies which attempt to characterise the patients who are most likely to drop out of a pulmonary rehabilitation programme.2

We have recently undertaken a randomised controlled trial of a nurse-led intermediate care package in the management of patients who have been hospitalised with an acute exacerbation of COPD. The intervention involved the patients undertaking a 4-week pulmonary rehabilitation programme, necessitating attendance at a group programme at the hospital for two half days a week, followed by the receipt of detailed personalised self-management advice and follow-up by a nurse specialist for 2 years. Only approximately one-third of patients identified as being suitable for this study agreed to take part in the study, and we were interested to know why the others declined.

Methods

Out of 297 patients suitable to take part in the main study, 122 agreed to participate, 55 did not respond to mailed invitations and 120 responded but declined to take part (Fig. 1). Characteristics of those who were recruited to the study, those who declined and those who agreed to participate in this qualitative study are shown in Table 1. This data did not suggest that severity as judged by lung function, age, number of previous hospital admissions or their length, by themselves were explanations for the non-participation. Twelve months after the start of the main trial we sought the permission of the Riverside Research Ethics Committee to approach these patients to understand better why they declined to take part in this research project, which involved pulmonary rehabilitation. Following receipt of Ethics Committee approval a letter was sent to the patients who had responded but negatively to our request for them to participate up to 18 months previously and they were asked if they would agree to be interviewed. The patients were offered the possibility of having the interview face-to-face in their own home or by telephone, and they were asked to consent to the interviews being tape-recorded. Ten major areas for questioning were constructed to explore reasons why the patients did not participate and these are listed in Table 2. Tape interviews were transcribed and data analysis performed using the framework method.4

Results

Thirty-nine out of 120 patients who previously declined to participate in a research project agreed to participate in this follow-up qualitative study to determine reasons for their original non-participation. Demographic data for the three groups are shown in Table 1. There were no significant differences between the recruited patients and those who declined apart from significantly more smokers declining to take part. Telephone interviews were undertaken with 19 of those agreeing to take part in this study. The other 20 interviews were conducted face-to-face. Interviews lasted between 45 and 90 min. Analysis of the transcribed interviews by the first researcher (RT) showed that six framework themes were identifiable from ten transcripts and these

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**Table 1**

<table>
<thead>
<tr>
<th>Category</th>
<th>Data</th>
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</thead>
<tbody>
<tr>
<td>No. of Admissions 1Jan 2000–31Aug 2004</td>
<td>2305</td>
</tr>
<tr>
<td>No. of patients admitted / 4 years:</td>
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</tr>
<tr>
<td>Alive: 740</td>
<td></td>
</tr>
<tr>
<td>Dead: 507</td>
<td></td>
</tr>
<tr>
<td>Assessment by standard proforma: 574</td>
<td></td>
</tr>
<tr>
<td>Not proforma’d: 166*</td>
<td></td>
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<td>Suitable: 297</td>
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<tr>
<td>Unsuitable: 277</td>
<td></td>
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<tr>
<td>Suitable &amp; Recruited:</td>
<td></td>
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<td>Treatment: 61</td>
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<tr>
<td>Control: 61</td>
<td></td>
</tr>
<tr>
<td>Suitable Declined: 120</td>
<td></td>
</tr>
<tr>
<td>Suitable no Response: 55</td>
<td></td>
</tr>
<tr>
<td>These patients were approached for this study</td>
<td></td>
</tr>
</tbody>
</table>

**Figure 1** A consort diagram to display the group from which patients were recruited for the study. *Lives in other postal districts and attending for pulmonary rehabilitation would be difficult.
were then analysed by a second member of the team (MRP) and there was 86% congruence between the two clinicians/researchers. Subsequent analysis of all of the transcripts showed that the six initial themes from the framework remained, and these are summarised in Table 3. These are discussed in more detail below and the percentages relate to the number of transcripts containing these themes.

### Travel to and location of pulmonary rehabilitation class \( n = 19/39 \) (48.7%)

The first theme involved travel to, and the location of the pulmonary rehabilitation class. Many were unable to travel independently, were housebound or had restricted mobility. Patients were restricted by oxygen and nebuliser regimes. Patients reported difficulties with public transport and parking at the hospital or the location of the class was too far away. One patient commented that “Charing Cross don’t lay on transport (route) … the ambulance picks up the wife and myself because my wife carries me portable oxygen with her … But I, I definitely wouldn’t be able to walk the stairs down to the train and I definitely wouldn’t be able to walk from Hammersmith bus stop all the way round to where you pick up the bus to go to Charing Cross.”

### Perception of Benefit \( n = 19/39 \) (48.7%)

Patients perceived little benefit or advantage to participating in the programme. The following quote gives one example of patients’ views about the lack of benefits to participating in the study:

I mean the thing is if someone goes to see you on this study thing, yeah? And you sit down there for half an hour and you talk and you tell and … there must be something you can say "Well, here we are. Try that. That may help you.”

Patients believed they were on the maximum available treatment and were only interested in research studies.
where new drug treatments were given. Some saw their condition as too severe and no improvement was possible, and there was no guarantee of any benefits. Patients also felt they were better able to manage their disease and that healthcare staff were only there to help with diagnosis, not associated with improving health.

**Competing commitments or demands \{n = 15/39\} (38.5\%)**

Many patients mentioned that they had competing family commitments such as a caring for infirm relatives. They perceived the programme would be a disruption to their usual home routine and home services and many had seasonal commitments such as summer holidays, which would be disruptive as the programme ran during the summer months. Some patients were in full-time employment and the timing of the programme during the day would be difficult. This is illustrated by the following patient quote: “But let me say that my main reason for turning down the study … Was the timing. It was summer and I’d got various things fixed. So it meant sort of messing the family about …. .”

**Poor or negative understanding of research study \{n = 12/39\} (30.8\%)**

There were several sub-themes under the theme of poor or negative understanding of the research study. The first was a lack of understanding of the study content. Patients did not feel they had sufficient information, and in the information, which they did receive, they had difficulty understanding the medical terminology. The second sub-theme was a generally poor understanding of the research process. They perceived they were guinea pigs in the project and they were going to be part of an experimental study to test a cure for COPD. Patients did not understand the concept of randomisation and believed that they would be placed in different groups depending on how ill they were, or they thought they would just have a “try out” or test. There was a suspicion of what the research in general involves as illustrated by the following quote: “I just thought it was a … oh, what can I say … one of these test programmes, do you know what I mean? Like a guinea pig programme.” With regards to the pulmonary rehabilitation there was a perception that the content of the PR would be vigorous, floor based and strenuous.

**Past negative experience(s) \{n = 11\}(28.2\%)**

Patients had negative experience of exercise and other clinical tests and feared that this study may involve clinical tests or had not enjoyed past research experiences. Patients had also been influenced by friends and relatives’ negative experiences and beliefs affecting their willingness to participate. Patients had a poor self-image or self confidence related to exercise. Patients were not keen on a hospital-based programme due to previous MRSA colonisation, negative press and past traumatic illness experiences. Patients also stated that they had past negative experience with healthcare staff resulting in poor perception of competency of healthcare professionals: “See, I’ve got a friend that’s got this … He’s got very bad breathing. And I said to him the other day. And he said “Ah, it’s a waste of time. I was down there,” he said. “Waste of time,” he said “Then we’re sitting there for half the day talking rubbish.” So that didn’t help me. I thought. “Yeah,” he said, “That’s all they done.” “No,” he said, “I ain’t going back there no more.”

**Perception of health status \{n = 10/39\}(25.6\%)**

Under this theme the patients suggested that there was a fear that PR may be detrimental to health and may increase symptoms of breathlessness. There was concern that they would be unable to do PR exercises due to breathlessness, or they may be unwell at the time of study and be too ill to take part in research: “I wasn’t concerned, I just didn’t like the idea of doing meself in. That is hard, but when your breathing is bad it’s a disaster! . just, uh, didn’t like the idea.”

Patients suggested that the unpredictability of their health status restricted their ability to commit to the PR. There were also some concerns that seasonal weather would affect their health status and exercise capacity. In contrast some stated that their ill health was not poor or serious enough to warrant further healthcare intervention.

**Discussion**

Pulmonary rehabilitation comprises a variety of interventions, which may be loosely grouped into the three main categories of exercise training, education and psychological support. Many with chronic obstructive pulmonary disease have breathlessness as a major symptom. Breathlessness, being an unpleasant symptom frequently induced by exercise, leads to a vicious cycle of further inactivity, reduction in fitness and increased symptoms on subsequent exercise. Patients with COPD may be stigmatised and feel guilty because for many they know it was self-induced by smoking, and exercise may not have been undertaken for many years. A perception that pulmonary rehabilitation is associated with gyms and sport may appear particularly threatening. We were initially unclear as to whether it was these factors, which led to these patients declining to take part in our study, or whether it was the experimental aspects of being involved in a research project. Understanding the relative contributions of these aspects would appear to be important in our approach to patients for future studies in this area and is especially important if we are to recruit in a representative fashion. There is little previous published work on recruitment of patients to pulmonary rehabilitation programmes, in spite of studies reporting a high dropout or low recruitment rate.\(^\text{5-7}\) There is some work on what predicts success or failure of a PR programme and the characteristics of those who drop out after initial attendance.\(^\text{4-5}\) Certainly in the studies which have been published, location and ease of access of the pulmonary rehabilitation classes have been a factor and that was clearly so in our study also. Patients also often had negative perceptions as to what they might gain from such a programme or about its applicability to them, whilst others had family or other commitments, which made it difficult for them to undertake something which involved a regular,
twice weekly attendance over several weeks. Whilst a poor or negative understanding of the research component in our invitation did figure in some responses, it was not a dominant theme. One limitation of our study relates to the time between the patient declining to take part in the main study and their recruitment to this study to explore reasons for non-participation. This delay was occasioned by us not deciding to explore these reasons until 12 months had passed and there was a subsequent delay whilst the ethics committee carefully evaluated the study that involved approaching patients who had already declined to take part in research. Whilst delay may have affected the patients’ ability to recall some reasons for non-participation it is unlikely to negate the clear reasons stated.

So how can we improve recruitment to a research project which involves pulmonary rehabilitation, or indeed how can we recruit to pulmonary rehabilitation alone? Three key areas probably need to be addressed and those concern information, location and timing. Information clearly has to be as explicit as possible and whilst there are probably some advantages in this being given by a doctor or nurse known to the patient and trusted by them, we think that study is merited of whether recruitment is enhanced by a previous participant explaining the virtues of the programme to new recruits. The exercise component of a pulmonary rehabilitation programme is also potentially off-putting and perceptions of gymnasia, leotards and performing in public may all influence recruitment. In addition to verbal information, a display of pictures or a video recording of a previous programme may be helpful. The location of a pulmonary rehabilitation programme also merits consideration. There are a number of studies which have looked at hospital versus community exercise programmes for patients with chronic obstructive pulmonary disease.

Patients’ perceptions that they will not benefit may also be addressed by the above methods and video recordings could clearly include vignettes of patients of a variety of types and severities, such that a patient may identify with those. A few positive anecdotes from previous participants along the lines of “I never thought I’d be able to do the gardening again” may have much greater impact than a doctor’s invitation!

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