Community-based recruitment of patients with COPD into clinical research

Abstract Identifying subjects for clinical trials is difficult and the evidence base for recruitment strategies is limited, particularly in the field of COPD. We compared the efficiency and patient characteristics of different community-based recruitment strategies during a non-commercial COPD trial in the UK. Recruiting from general practice COPD registers was less efficient and identified patients with significantly milder disease than recruiting through pulmonary rehabilitation and patient groups. We report our experience and propose that pulmonary rehabilitation and patient groups may represent an enriched pool of COPD patients to recruit into clinical trials.
Trial registration number: EudraCT 2011-001063-43

INTRODUCTION

Recruitment of patients into clinical trials is challenging and many publicly funded trials in the UK miss their targets.[1] Many studies investigating COPD may wish to recruit from patient groups or primary care; however, in contrast to the low rates reported by recent large interventional trials (eg, 7%[2]), evidence suggests that patients on UK general practice (GP) databases do not fulfil diagnostic criteria for COPD when retested.[3] Optimal strategies for recruiting these patients have not been adequately explored.

METHODS

Recruitment pathways

Three approaches were used during recruitment of subjects to a recent non-commercial trial of oral antibiotics in stable COPD.

1. Local GP surgeries wrote to patients on their COPD register, and interested patients replied directly to the study team using preaddressed reply slips.
2. Similarly, local pulmonary rehabilitation (PR) groups wrote to COPD patients on their database.
3. Study team members gave educational talks to local PR and patient support groups, and at the end described current research plans. Interested patients approached the study team directly.

Centres were reimbursed for sending letters according to standard research tariffs.

Screening

Interested patients were contacted and a screening visit arranged which included a full medical history and postbronchodilator spirometry. Patients were considered eligible if COPD was confirmed with FEV_1 <80% predicted and FEV_1 to FVC ratio <0.7.

Analysis

The efficiency of identifying eligible patients was assessed by comparing the reply and screening failure rates. External time and financial costs were estimated per eligible patient identified, excluding researcher salaries. Patient characteristics were compared by recruitment source.

RESULTS

Between January 2012 and May 2013, 37 GP surgeries and four PR groups sent letters to 2300 and 469 patients, respectively. Reply rates were similar from both sources (21% and 22%) and 156 (7%) and 37 (8%) of these patients attended screening. The educational talks identified 53 patients, of whom 23 (43%) were screened. Approaches 1 and 2 had screen failure rates of 35% and 19%, while approach 3 had the lowest (13%). Figure 1 summarises these pathways and gives information on the estimated time and financial commitments per eligible patient identified.

Eligible patients recruited from GP surgeries had significantly milder disease than those from PR and patient groups (mean (SD) FEV_1 63% predicted (20) vs 53% (18, p=0.003), FEV_1 to FVC ratio 0.55 (0.11) vs 0.50 (0.11, p=0.007), exacerbations in the previous year 1.7 (2.0) vs 2.7 (3.4, p=0.029)), as well as lesser smoking history and fewer medication

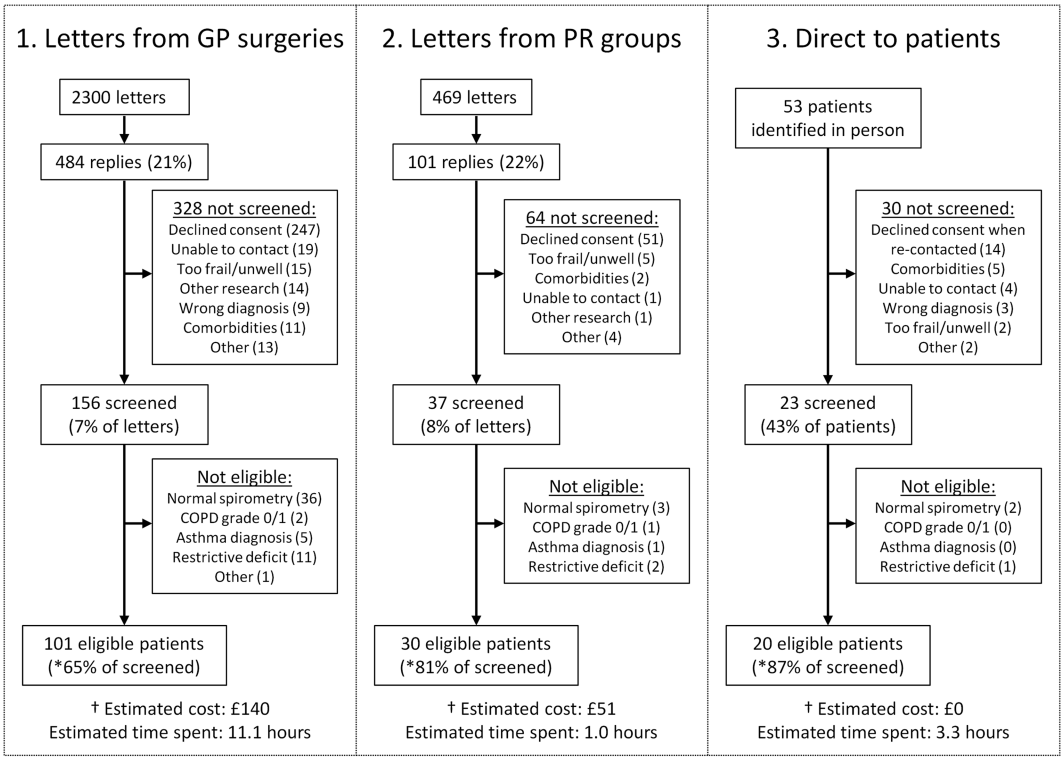

Figure 1 Flow diagram detailing the three different recruitment pathways.

prescriptions. Further information is detailed in the online supplement.

DISCUSSION

We found that recruiting patients from GP COPD databases was less efficient, more costly, and identified patients with milder disease than through PR and patient groups. However, the pool of patients accessible via GPs was larger and more representative of the wider population. Recruitment via PR and patient groups may therefore target an enriched population useful for smaller studies, and researchers planning future studies of COPD should prioritise resources accordingly.

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Contributors SEB, EE-E, GCD, IN and JAW planned the study and recruitment strategies and wrote the protocols and materials. SEB, EE-E and JPA contacted the individual patient identification centres to organise recruitment. SEB and JPA gave the talks to the patient groups, contacted and screened the patients and collected the data. SEB wrote the first draft and performed the main data analysis. All authors contributed to the data interpretation and to the writing of the paper. All authors approved the final draft. JAW will act as guarantor.

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