The effect of a respiratory home nurse intervention in patients with chronic obstructive pulmonary disease (COPD)

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Abstract

Background: Chronic obstructive pulmomary disease (COPD) is associated with substantial mortality, morbidity, and costs to the health care system. With the increasing interest in outreach care programmes it is important to evaluate their impact upon patients and health services, for conditions such as COPD.

Aim: To determine the effectiveness of an outreach respiratory nurse in a shared care approach, with collaboration between general practitioners and hospital services, in the management of patients with severe COPD.

Methods: Patients with severe COPD attending The Queen Elizabeth Hospital, Adelaide participated in a randomised controlled trial of a home based nursing intervention (HBNI) over 12 months with outcome measures including mortality rate, hospital service utilisation, FEV_1 and health related quality of life (HRQL) using a modified Dartmouth Primary Care Co-operative Quality of Life questionnaire.

Results: There were 48 subjects in each study arm, with no differences in mortality rate (eight deaths in the HBNI group and seven in the control group), hospital admissions, length of stay, number of outpatient and Emergency Service visits. The study had inadequate follow-up of FEV_1 and HRQL within the control group. Within the HBNI group, a small improvement in HRQL (in three of ten indices measured) was demonstrated, despite a deterioration in FEV_1 (11% reduction, $p=0.04$) compared to baseline. Quality of life of HBNI subjects' carers did not change.

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Conclusion: An increased level of care given by an outreach respiratory nurse in a shared care approach for patients with severe COPD produced small improvements in HRQL but did not result in the prevention of deaths or reduced health care utilisation. (Aust NZ J Med 1999; 29: 718-725.)

Key words: Chronic obstructive pulmonary disease (COPD), outreach, respiratory health care worker, nurse.

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) refers to a spectrum of lung disorders characterised by progressive irreversible airflow obstruction. COPD is a major global disease and is associated with significant mortality and morbidity.[1] In Australia, COPD is the fourth leading cause of death and accounted for 4831 deaths in 1995 (3.8% of all deaths).[2]

In the 1995 National Health Survey, chronic bronchitis or emphysema were self-reported in 10.6% of the 65-74 year age group.[3] COPD is a major cause of hospitalisation and ranked fourth highest in terms of health care utilisation in Adelaide public hospitals in 1996/1997. The readmission rate in this patient group is high and the length of stay (LOS) in 1996/97 in Adelaide public hospitals was 7.8 days. The cost of COPD admissions in South Australia to the State and Federal Governments during this period has been estimated at over $5.5 million.[4]

The Queen Elizabeth Hospital (TQEH), a 383 bed teaching hospital, is located in Adelaide's Western suburbs, a region of high respiratory disease burden and has approximately 1500 admissions per year, with the principal diagnosis of COPD accounting for 16% of medical admissions, 12,445 occupied beds days with an average LOS of 8.3 days.[5] Measures to reduce this load through alternative care strategies could substantially cut hospital costs in this region. Outreach health care delivery in the community, given by a respiratory health worker with encouragement of self-management behaviours, is one measure which may lead to reduced admissions and LOS. Self-management through education may optimise patient health and permit early detection of deteriorations such that exacerbations are managed earlier. Better management of patients' domiciliary needs provided by such an intervention may also facilitate hospital discharge and increase the interval between outpatient department (OPD) visits. However, reducing admissions may displace the care burden to ambulatory settings, including general practice and carers. Also, current evidence from the United Kingdom indicates that COPD admissions and LOS actually increase as a result of an outreach respiratory care intervention.[6] Although there is increasing interest in outreach care in Australia, the impact of such care for COPD is unknown. In addition, a home based nursing intervention (HBNI) may influence the lung function of patients with COPD by reducing the rate of decline in FEV_1 by maintaining the patient's optimal respiratory state with judicious use of antibiotics, and inhaler therapy where a reversible airways disease component is present. However, studies have not been able to demonstrate improvement in FEV_1 to date compared to control group subjects.[7,8] Studies of outreach nursing programmes for chronic lung disease in the United Kingdom and North America[6-8] have inconsistently indicated reduced mortality with some improvement in some health related quality of life (HRQL) indices. Overall there have been limited measureable benefits. Also, carer HRQL may be adversely affected by reducing institutional and hospital care of a chronically ill patient, leading to reduced carer respite.

This is the first such study to be reported in the Australian setting, with an emphasis upon shared care with more active involvement of patient, local medical officer, and hospital practitioner and co-ordinated by an outreach respiratory nurse. Such a shared care approach may provide several benfits including: (1) improved care to the patient with more readily available access to local or hospital practitioners and improved communication about therapy and goals between the patient, local and hospital practitioner; (2) the hospital practitioner receives greater insight into the patient's emotional/social situation in their home setting and is assisted in managing intercurrent illnesses by the outreach nurse and local medical officer; (3) the local medical officer has more direct access to consultant advice and optimal use of ancillary services via the outreach nurse and hospital. This approach is recommended by the National Health Strategy.[9]

Our hypotheses were that an outreach nurse/ shared care approach to COPD management would result in reduction of the following:

1 hospital admissions and LOS

2 emergency department and hospital outpatient department attendances

3 mortality;
and improvment in:
4 FEV_1 and HRQL of patients
5 HRQL for patient carers.

METHODS

Sampling Frame

Patients with a principal diagnosis of COPD attending TQEH as in-patients or outpatients were invited to participate in the study. Patients were also referred from general practitioners (GPs). To be eligible for inclusion patients had to be aged greater than 40 years, have a FEV_1/FVC ratio of less than 60%, no other active major illnesses at time of entry into study, be in a stable state, have a carer involved in their management, be able to speak and read English and give written consent. This study was performed with institutional ethics committee approval.

Patients were randomised as they were enrolled, following discharge from hospital, and from OPD and regional GPs over a period of ten months into the HBNI or control groups from two lists of randomly computer generated numbers for the intervention group and the control group.

Study Factors

- The age and gender of participants, smoking status, carer status, psychological co-morbidities and their requirement for home oxygen were recorded on entry into the study. The presence of cardiac co-morbidity and the total number of admissions prior to entry into the study was determined by examination of case notes.
- *Health Care Utilisation*

The number of respiratory hospital admissions and LOS, and the number of Outpatient Department and Emergency Service visits was determined by examination of case notes over the 12 month study period. Baseline characteristics (all prior respiratory hospital admissions) were measured retrospectively from patient case notes.

- HRQL was assessed using the Dartmouth Primary Care Co-operative Quality of Life questionnaire (COOP).[10] This questionnaire was modified in two ways: (i) a supplementary item specifically related to dyspnoea was added. (When do you become short of breath? With – extreme effort: walking up a steep hill/jog at slow pace; moderate effort: walking up stairs/easy digging in garden; little effort: walking on a level surface at regular pace; very little effort: walk at slow pace/washing dishes; at rest: sitting or lying down); (ii) the item regarding Physical Condition (What is the most strenuous level of activity you can do for two minutes?) was altered by deleting the 'Heavy' category: jog at fast pace, and was replaced with an 'Extremely Light' category: eating, getting out of bed, in order to relate more appropriately to the level of activity of patients with severe COPD. The remaining eight items refer to the subject's emotional and overall condition and how these impact upon the subject's ability to perform daily and social activities, and the subject's perceptions of pain and change in condition. The COOP questionnaire features a simple graphic layout, with documented reliability and validity in a range of settings including respiratory disease,[11,12] and was selected in view of the level of morbidity of the subjects to be enrolled. High COOP scores indicated worsening of the subject's condition. The carer also completed a COOP questionnaire, with minor modification to indicate their identity as the carer rather than the patient. An *a priori* intention was to administer COOP questionnaires to control subjects at baseline and at 12 months. Attempts to perform questionnaires in the control subjects were unsuccessful due to a combination of (i) these subjects perceived no immediate benefit of the trial; and (ii) the burden of participating in a study, including questionnaires, was greater than expected for those patients who had advanced airways disease.
- COOP scores and FEV_1 measurements were also utilised during the interim months to assist the outreach worker in identification of exacerbations.
- FEV_1 of in-patients and patients in the domestic setting was measured using a Microlab 3300 spirometer. An *a priori* intention was to perform spirometry on the control subjects at baseline and at 12 months. For the reasons outlined above this outcome was not measured in control subjects at 12 months.
- Mortality (including deaths due to respiratory disease and to other co-morbidities).

Intervention

Subjects randomised into the intervention group were recruited from the Thoracic Medicine ward and OPD, and local general practices. In-patients were visited by the HBNI respiratory nurse, and when it was considered potentially beneficial case conferences occurred prior to discharge with a social worker, +/- hospital medical officer, +/- GP (in person or by tele-conference), +/- HBNI in attendance specifically according to each case's needs. Goals for discharge were inserted into patients' notes and discharge requirements

documented. Upon discharge the HBNI nurse arranged an early review (usually within seven days) in the patient's home. HBNI staff evaluated patients recruited by GPs and through Thoracic Medicine OPD in the home setting and discussed with the GP their unmet needs and facilitated involvement of domiciliary services, Meals on Wheels, oxygen therapy assessment at home, provision of appliances such as dosettes, shower chairs, bed and toilet aids and towelling dressing gowns to facilitate drying off. The intervention group received HBNI in addition to their usual care from outpatient clinics and GP services. HBNI consisted of visits at two to four week intervals over 12 months with spirometry and oximetry performed at each visit and the results communicated to the GP. Ongoing education, including the technique of inhaler medication use, and encouragement of medication compliance and to improve fitness was given. The fitness advice (given when requested or on an as needs basis) included information on upper and lower limb training, intimacy advice and coping strategies for shortness of breath. The nurse also aimed to make early identification of exacerbations, as suggested by purulent sputum and ankle oedema. Educational material was provided in liaison with GPs for those subjects continuing to smoke. Subjects were counselled to reduce or stop smoking and on request were given smoking cessation information, ongoing encouragement and referred to their GP for nicotine replacement therapy. COOP HRQL questionnaires were administered bi-monthly during the study. The control group received usual care and education from outpatient clinics and GP services. This study was unblinded.

Statistical Analysis

The primary outcomes in this study were health service utilisation, mortality and HRQL. FEV_1 and carer HRQL were secondary outcomes. The group receiving HBNI was compared with the group receiving normal outpatient care at baselines and after 12 months by intention to treat. The significance of the differences between the two groups was tested by unpaired *t* tests for parametric data, the Fisher's Exact Test for non-parametric data and Chi squared tests for nominal data. Changes in COOP HRQL scores in the HBNI group were analysed for significance using paired *t* tests.

A principal research question was to reduce our hospital admission rate from approximately 36% (a figure based upon available data at our hospital) to 12%. A sample size calculation indicated that 47 subjects were required for each group, at 80% power with 95% confidence.[13]

TABLE 1
Baseline Characteristics of a Home Based Nursing Intervention and Control Groups. Mean (SE)

	HBNI group *n*=48	Control group *n*=48
Age (years)	70.0 (1.2)*	69.8 (1.2)
males (*n*)	27†	31
females (*n*)	21†	17
Smoking history (%)‡		
ex-smokers	81†	91
current	17†	9
never	2	0
Carer status (%)‡		
carer	92†	86
no carer	8†	14
Cognitive assessment (%)‡		
normal	98†	100
abnormal	2†	0
FEV_1 (L)	0.84 (0.06)*	0.90 (0.07)
Total number of admissions/patient prior to study**	7.6 (1.0)*	6.0 (0.8)
Home oxygen use (*n*)	17†	19
LTOT	9	11
LTOT+portable	5	4
portable only	1	2
emergency use only	1	1
LTOT/CPAP	1	1
Cardiac disease (*n*)	15†	13

*Not significantly different *t* test
†Not significantly different by Chi square statistic.
‡Full smoking history, carer status and cognitive assessment was obtained from a randomly selected subset of 22 of 48 control group subjects.
**Number of respiratory admissions over total length of time for which a patient's case notes exist at The Queen Elizabeth Hospital.
LTOT=long term oxygen therapy; CPAP=continuous positive airways pressure.

RESULTS

Of 105 patients approached to participate, 96 accepted. There were 48 subjects in each of the intervention and control groups. In the HBNI group, 22 subjects were recruited through the OPD, 14 were in-patients and 12 were referred by GPs.

Spirometry results and the prevalence of home oxygen usage indicate the high level of severity of the disease in this patient group. The overall mean FEV_1 at baseline was 0.87 L, and in the HBNI group the mean per cent predicted FEV_1 was 33%. The mean baseline COOP score obtained in the HBNI group was comparable to the mean score of a group of elderly subjects in residential care.[11] During the 12 month study, eight subjects died in the HBNI group (respiratory related deaths =seven, aortic aneurysm=one) and seven subjects died in the control group (respiratory related deaths=four, cardiac

arrest=two, sepsis=one). Five subjects refused to continue in the control group, expressing a desire to be transferred to the intervention group. Four subjects in the intervention group also dropped out of the study, two going to nursing homes and two who refused further involvement. Data from all subjects were analysed by intention to treat.

Baseline measures were not significantly different with respect to characteristics presented in Table 1, consistent with successful randomisation.

Lung Function and QOL

Using an unpaired t test on available HBNI subjects, the mean FEV_1 at 12 months (mean =0.74 L, 29.5% predicted, SE=0.05, n=36) was not significantly different compared to baseline (mean=0.84 L, 33.3% predicted, SE=0.06, n=47). Using a *post hoc* paired t test for subjects who did not die or drop out, there was a significant deterioration in lung function. At 12 months, the mean FEV_1 from 35 HBNI subjects fell to 0.74 L from 0.82 L at baseline (p=0.04).

Baseline and 12 month COOP scores were available on 30 and 29 HBNI subjects respectively. Twelve month COOP scores were only available on six control subjects. Due to this lack of data, a *post hoc* pre-post analysis was performed on HBNI COOP scores. Total COOP scores significantly decreased from 33.2 (SE=1.1) at baseline to 30.2 (SE=1.2) at 12 months in the HBNI group indicating an improvement in total HRQL at 12 months (p=0.013).

When individual items from the COOP questionnaire were compared between baseline and 12 months, three scores regarding emotional condition, difficulty doing daily tasks because of physical and emotional health and general HRQL, were significantly lower (p=0.01, p=0.03, p=0.03 respectively). At completion of the study, two participants could not perform daily tasks because of physical health and emotional problems compared to ten subjects at baseline. Twelve subjects had improved at least one category of this COOP Chart item and five had deteriorated by the end of the study. The number of subjects experiencing severe to extreme emotional problems such as anxiety and depression fell from 14 at baseline to six at the end of the study. Sixteen subjects improved at least one category of this COOP Chart item and five had deteriorated by the end of the study. In regard to general HRQL of the patients, i.e. the item 'How had things been going?', after 12 months HBNI, 11 subjects had improved at least one category of the COOP Chart and five had deteriorated, and there were at least three subjects less in four of the five categories at 12 months compared to baseline, although subjects shifted in both directions.

Of the other seven items regarding physical condition, dyspnoea, requirement of social support, social activities, pain, overall condition and perception of change in condition, there were no significant differences between the baseline and 12 month scores. Of 29 HBNI group COOP scores obtained at 12 months, 22 subjects showed improvement in HRQL compared to baseline and seven deteriorated. COOP scores of the patient's carer were not significantly different at 12 months

TABLE 2
Hospital Admissions and Length of Stay in Home Based Nursing Intervention (HBNI) and Control Group, Frequency (% of Total) at 12 Months

Hospital admissions	HBNI group frequency (%)	Control group frequency (%)
0	14 (29.8)	20 (44.4)
1	16 (34.0)	11 (24.4)
2	8 (17.0)	6 (13.3)
≥3	9 (19.1)	8 (17.8)
Total number of subjects	47 (100)	45 (100)
Pearson Chi square (df=3), =2.29, p=0.52.		
Length of stay (days)		
0	14 (29.8)	20 (44.4)
1-10	13 (27.7)	9 (20.0)
11-20	8 (17.0)	10 (22.2)
21-90	12 (25.5)	6 (13.3)
Total number of subjects	47 (100)	45 (100)
Pearson chi square (df=3), =3.97, p=0.26.		

TABLE 3
Outpatient Department and Emergency Service Visits to Home Based Nursing Intervention (HBNI) and Control Group, Frequency (% of Total) at 12 Months

Outpatient visits	HBNI group frequency (%)	Control group frequency (%)
0	10 (21.2)	10 (21.7)
1-2	20 (42.5)	17 (40.0)
3-4	12 (25.5)	13 (28.2)
≥5	5 (10.6)	6 (13.0)
Total number of subjects	47 (100)	45 (100)
Pearson Chi square (df=3), =0.36, p=0.95.		
Emergency Service visits		
0	33 (70.2)	40 (87.0)
1	9 (19.2)	5 (10.9)
≥2	5 (10.6)	1 (2.1)
Total number of subjects	47 (100)	45 (100)
Fisher's Exact Test p=0.10.		

(25.0 [SE=1.5]) compared to baseline (24.3 [SE=1.0]). COOP questionnaires were not administered to the control group for reasons previously described.

Hospital Services Utilisation

No reduction was observed in the number of hospital admissions, LOS, OPD visits, or Emergency Service visits during the 12 month study period in either the HBNI or control groups (Tables 2, 3). There was, however, an observed trend to increased emergency service utilisation.

The costs associated with the HBNI were not prospectively tracked, but the average length of visit was one hour for the first visit and 30 minutes for subsequent visits.

Predictors of Mortality

Home oxygen had been prescribed to 37% of our study participants. Significantly more patients requiring home oxygen died than those who did not ($p<0.001$). Baseline use of home oxygen was a predictor of mortality (OR=8.91, 95% CI: 2.4, 40.2). The number of admissions in the previous year, baseline FEV_1 and age of the participants did not predict mortality ($p=0.06$, $p=0.28$, $p=0.96$ respectively).

DISCUSSION

We conducted a randomised control trial (RCT) of the efficacy of an outreach respiratory nurse in the shared care management of patients with severe COPD. In relation to our hypotheses, there was no reduction in hospital admissions, hospital bed days, outpatient visits, or emergency service visits.

Using the modified COOP questionnaire, we demonstrated an improvement in the total score in subjects remaining in the intervention group at 12 months, with improvements in three individual items: general HQOL, emotional state and ability to perform daily tasks. There was a decline in lung function at 12 months compared to baseline in the intervention group, and mortality was equally high in both groups.

Limitations of this study included the absence of 12 month comparative HRQL and lung function information for control subjects. Feedback from the outreach workers indicated that the HBNI group required considerable attention to both psychosocial and medical problems. The questionnaire burden in our subjects was noted by the HBNI staff to be high, particularly for control subjects who perceived very little benefit from the study and this consequently precluded 12 month control group evaluation as planned *a priori*. There was no pre-terminal COOP score in the 15 subjects who died during the study and the sensitivity to change of COOP scores has not been described in this patient group. The 12 month follow up COOP scores in the surviving intervention subjects should therefore be interpreted with caution. The graphic COOP HRQL scores are not disease specific for COPD, but have the advantage of brevity and previously reported subject acceptance[15] in addition to previously demonstrated validity and reliability.[11,12] These features were considered to be priorities in this chronically ill, elderly patient group. A supplementary dyspnoea question was added to the COOP Chart, and there was no change in the intervention group at 12 months compared to baseline for this item. This supplementary item has not been validated as part of a COOP questionnaire, but is unlikely to affect adversely the validity of the questionnaire. For outcome measures of health care utilisation, all utilisations up to the time of death were included in analysis, which was based upon an intention to treat approach. Given the near equal mortality in each study group, it is unlikely that death has confounded the relationship between HBNI and health service utilisation.

The subjects' visits to their GP or extra nurse calls were not recorded as an outcome as the focus of this study was based upon hospital related service utilisation. Therefore, the burden-shift, cost-shifting, or cost savings to general practice resources, which is an important issue, could not be assessed in our study. Furthermore, an outreach care programme which educates patients and maintains their best respiratory state might yield additional cost-savings through optimal use of airways disease medication. However, medication use was not assessed in this study.

Our failure to demonstrate a reduction in health service utilisations was consistent with previous studies in other settings. Cockcroft *et al.*,[6] reported increased admission rates and longer duration of stay in the intervention group in the United Kingdom, and Bergner *et al.*,[7] reported a failure of the intervention to reduce health care system utilisations in the United States. In the only report to evaluate health care system costs comprehensively, Bergner *et al.*,[7] also demonstrated that outreach care incurred higher overall medical care costs than standard care.

One of the roles of the respiratory nurse was to provide education to the patients, and therefore encourage greater self-surveillance of symptoms.

The observed trend to increased emergency service utilisation in our study may reflect this. It is unlikely that the HBNI group were more ill than the control group, as indicated by mortality rates, hospital admission rates, and baseline indicators of effective randomisation. The findings of our study are consistent with previous reported findings,[6-8] that outreach nursing care does not result in prevention of exacerbations and reduced hospital expenditure.

Notwithstanding the limitations of the COOP questionnaire, the improvements demonstrated at 12 months in the intervention group appear remarkable given the ongoing decline in lung function and mortality rate in the subjects overall. The improvement may therefore indicate a psychological benefit to the patients, provided in the home setting by visiting outreach workers, as is suggested by improved emotional condition, but not level of dyspnoea. The improvements may also be due to a Hawthorne effect, which is difficult to quantify as follow up COOP questionnaires were not performed in the control group. Littlejohns *et al.*,[8] also evaluated HRQL, and demonstrated that outreach nursing care was associated with some improvement in the physical component of the Sickness Impact Profile at 12 months, but not other indices.

The absence of significant change in the carers' HRQL during the intervention in our study suggests no HBNI benefit to carers. Conversely, had hospitalisations been reduced in the HBNI group, there may have been a risk of a care burden shift away from hospitals to the carers in the home setting, but our results do not indicate this outcome.

We found no improvement in mortality, which is consistent with the reports of Bergner *et al.*,[7] and Cockcroft *et al.*[6] In the study by Littlejohns *et al.*,[8] a significant reduction in mortality was reported. Of 96 subjects enrolled in our study, 15 (16%) died during the 12 month study, compared to 6% in the Littlejohns study. It is likely that our subjects had more severe COPD than the Littlejohns study, as indicated by lower % predicted FEV_1 in the HBNI group at baseline and at 12 months, and that our intervention was unable to prevent death. Also, 37% of subjects required home oxygen in our study, and this was a significant predictor of mortality. Oxygen use was not stated in the Littlejohns report.

Using intention to treat analysis, FEV_1 was not significantly different after 12 months HBNI compared to baseline. However, this unpaired analysis did not have the 12 month FEV_1 of 12 subjects who later died or dropped out. Therefore, a sensitivity analysis paired *t* test on subjects with both baseline and 12 month FEV_1 data was performed, which did demonstrate a significant decline in lung function over 12 months in survivors. This decrease in FEV_1 in the HBNI group and the overall mortality reflects the chronic and progressive nature of this illness in our subjects. Other studies[6-8] of the effect of such intervention have also failed to demonstrate an increase in FEV_1 and peak expiratory flow rate compared to standard COPD care, indicating the limited potential for reversal of advanced airways obstruction.

HBNI in severely limited COPD patients proved human resource intensive, in keeping with the conclusions of Bergner *et al.*,[7] with little measureable benefit. RCTs have now been reported across different countries with dissimilar health care systems, and have failed to demonstrate improvements in most of the outcomes measured. However, this may indicate the need for longer follow-up, and perhaps the need to use outcome measures which are more sensitive to change. Also, the societal value of emotional well-being and HRQL in chronically and severely ill patients requires consideration in evaluating such programmes.

In exploring new forms of health care delivery for COPD away from hospitals, the inclusion of home rehabilitation in HBNI may provide greater benefits than have been demonstrated with HBNI to date. Home based rehabilitation programmes for COPD have demonstrated improvements in dyspnoea and HRQL scores (emotion and mastery components), and exercise tolerance, in the absence of an increase in FEV_1.[16,17] A meta-analysis of COPD rehabilitation programmes in a variety of settings also demonstrates benefits, although these were restricted to the acute effects.[16] None of the subjects in our study participated in pulmonary rehabilitation programmes. The integration of a home based rehabilitation programme, with ongoing long-term encouragement through HBNI, needs to be evaluated. None of the patients participating in this study who were current smokers (eight in the HBNI group) stopped smoking and none underwent lung volume reduction – or lung transplant surgery. Patient support groups may also provide assistance to individuals with COPD, with relatively little direct financial impact. There is, however, little evidence of the effectiveness of patient support groups for COPD to date. A pre-post study of eight COPD patients given support

and education over five weeks and using a validated instrument to measure mood state showed no improvement in mood or a reduction in exacerbations of dyspnoea.[19] In the absence of improvements in these outcomes, however, subjects expressed an increased ability to cope with their disease.

Future studies require attention to several issues including (i) a larger sample size studied over longer duration to provide increased power to detect smaller changes in outcomes measured; and (ii) the questionnaire burden, particularly to the control group who suffer advanced chronic lung disease, as indicated by the high mortality of subjects who agreed to participate in this study. Ethically appropriate use of incentives to maintain patient participation requires consideration. However, questionnaire burden must be balanced against the value of measurement of an even more comprehensive range of outcomes including medication use and costs, smoking cessation and health service utilisation including GP visits, locum service use and also service utilisation at other hospitals. Furthermore, consideration of feasibility and incentive issues for GPs will be necessary in order to address the unavailability of GPs for participation in case conferences. ■

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