

Supplementary information

Comprehensive care programme for patients with chronic obstructive pulmonary disease (COPD) --- A randomized controlled trial (RCT)

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More details about the interventions:

Respiratory nurse intervention: There were 2 1-hour sessions of one to one (individual education, not in a group) education educations. The nurses used a set of printed illustrations to educate the patients about COPD. The contents of education included the anatomy and physiology of the respiratory system, the pathophysiology of COPD, smoking cessation, technique of using the medications, dyspnoea management, nutrition, self-management (what to do when there is increasing symptoms including breathing technique, use of medications, when to call for help, telephone number of nurses also provided if any question arise), and exacerbation reduction skills, coping with psychological distress and relaxation technique, social and community support, and if appropriate, knowledge on long-term oxygen therapy. Inhaler technique was covered in the first session. The nurses also checked the inhaler technique of the patients in the second session and mistakes were corrected. Patients were given opportunities to ask any question related to their medical problems.

Physiotherapist intervention: The physiotherapist provided every patient an individualized physical training programme to perform at home or a short course out-patient pulmonary rehabilitation. The physiotherapist would assessed the patients in the first session and

recommended physical training to the patient depending on their maximum predicted heart, any comorbidities like ischaemic heart disease, tolerance of the patient and mobility limitation. The physiotherapists also taught the patients proper breathing techniques and how to cope with daily activities. The subjects were offered supervised exercise at the rehabilitation unit of our physiotherapy department thrice per week for 8 weeks and spent 2 h in each session. For patients who were unwilling to come back frequently or would like to come back for fewer sessions, home physiotherapy would be recommended. Supervised exercise training in form of out-patient visits including the use of treadmill, arm cycling, and arm and leg weight training, was provided with intensity adjusted by the physiotherapist, based on the tolerability and physiological variables (oxygen saturation and heart rate) of the patient. The target training intensity was 60–70% of their maximum predicted heart rate. For home exercises, subjects were recommended to perform home exercises for at least 20 min a day and that included walking, running and stretching exercises.

More details about the usual care group:

There is no intervention applied to the usual care group. The attending physician determined the patient's medication and follow up as per normal practice (e.g. continued follow up by the patient's original doctor/clinic appointment). They were not provided with the nursing education, physiotherapist training, optimization of medications by respiratory physicians and nurse telephone hotline.

Randomization: A random number generator was used to assign the patient to the intervention or control group. A computer programme (allocation by minimisation) was used to assist the randomization of subjects in equal opportunity in either group but taking into account 5 factors:

age (<70 or ≥ 70 years), sex, length of hospital admission (<7 or ≥ 7 days), 6 minute walk test (<100 or ≥ 100 metres), and predicted FEV1 (<30 or $\geq 30\%$). This minimization method is adopted in a previous study by Man et al ¹

Sample size calculation: In our previous study that assessed the infectious etiologies of patients admitted to hospital for AECOPD over a year, among the 313 subjects with lung function with over 600 episodes of admission, we found that 56.3% of the patients were readmitted to the hospital for another episode of AECOPD within the next 12 months.² In a multi-center randomized clinical trial conducted in 7 hospitals in Canada with the intervention consisting of comprehensive patient education program administered through weekly visits by trained health professionals over a 2-month period with monthly telephone follow-up, hospital admissions for exacerbation of COPD were reduced by 39.8% in the intervention group compared with the usual care group.³ Using these studies^{2, 3} as the background data, we estimated the sample size using the Power Analysis and Sample Size for Windows software (PASS 2008, NCSS, Kaysville, Utah). By assuming the intervention arm will decrease the readmissions from the baseline 56.3% by 39.8%, there would be a 22.5% difference in proportions between the intervention and control arm. A sample size of 73 in each group can achieve 80% power to detect a difference between the group proportions of 0.225, using a two-sided alpha 0.05 and a power of 0.8. Assuming a drop out rate of 30%, each arm would need 95 subjects.

References

1. Man WD, Polkey MI, Donaldson N, Gray BJ, Moxham J. Community pulmonary rehabilitation after hospitalisation for acute exacerbations of chronic obstructive pulmonary disease: randomised controlled study. *Bmj* 2004;329:1209.

2. Ko FW, Ip M, Chan PK, Fok JP, Chan MC, Ngai JC, Chan DP, Hui DS. A 1-Year Prospective Study of the Infectious Etiology in Patients Hospitalized With Acute Exacerbations of COPD. *Chest* 2007;131:44-52.
3. Bourbeau J, Julien M, Maltais F, Rouleau M, Beaupre A, Begin R, Renzi P, Nault D, Borycki E, Schwartzman K, Singh R, Collet JP. Reduction of hospital utilization in patients with chronic obstructive pulmonary disease: a disease-specific self-management intervention. *Arch Intern Med* 2003;163:585-91.