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**EVALUATION OF A TRANSITIONAL CARE PROGRAMME FOR
PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY
DISEASE IN GUANGZHOU CHINA:
A RANDOMIZED CONTROLLED TRIAL**

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THE HONG KONG POLYTECHNIC UNIVERSITY
SCHOOL OF NURSING

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FOR PATIENTS WITH CHRONIC OBSTRUCTIVE
PULMONARY DISEASE IN GUANGZHOU CHINA:
A RANDOMIZED CONTROLLED TRIAL

WANG SHAO LING

A thesis submitted in partial fulfilment of the requirements
for the degree of Doctor of Philosophy

April 2013

CERTIFICATE OF ORIGINALITY

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Abstract of thesis entitled

Evaluation of a transitional care programme for patients with chronic obstructive pulmonary disease in Guangzhou China: A randomized controlled trial

Submitted by Wang Shao Ling

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At the Hong Kong Polytechnic University in April 2013

Abstract

Background: Chronic obstructive pulmonary disease (COPD) exerts an enormous burden on patients, the healthcare services and society as a whole. The impacts of COPD can be minimised if effective management strategies are implemented, particularly when patients are transferred from hospital to home after suffering an acute exacerbation. However, postdischarge support is still an unmet need for many patients, and an issue that has not received enough attention from healthcare providers and the healthcare system in mainland China. It is necessary to build up research evidence to guide clinical practice, research and policy-making in the development of transitional care in China.

Aim: To evaluate the effectiveness of a COPD transitional care programme (COPD-TCP) for Chinese patients with COPD, as measured by clinical, psychosocial, functional, fiscal and satisfaction outcomes.

Method: The study constituted a randomised controlled trial (RCT). Sixty subjects admitted with COPD to a respiratory disease institute in Guangzhou, China from November 2008 to December 2009 were recruited and randomly assigned to an

intervention group (n = 30) and a control group (n = 30). Both groups received the usual discharge care offered in the site hospital. The intervention group underwent a COPD-TCP delivered by four trained nurse case managers (NCMs) with support from a clinical team comprising physician, nutrition specialist, programme coordinator and nursing manager. The COPD-TCP commenced within 72 hours before discharge and lasted until the sixth week of the transition to home postdischarge, involving one inpatient visit, two home visits, four telephone follow-ups and a 24-hour NCM hotline.

The main outcome measures were the 6-minute walk distance (6MWD) test, Seattle Obstructive Disease Scale (SOLQ) scores, COPD Self-Efficacy Scale (CSES) scores, COPD-related readmission and direct cost of readmission, and COPD Transitional Care Patient Satisfaction Questionnaire (CTCPSQ) scores. Data collection was conducted at baseline (T0), immediately post-intervention (T1) and three months follow-up (T2). Both Intention-to-treat (ITT) and Per-Protocol (PP) analyses were performed. Group comparisons were computed by repeated measures analysis of variance (ANOVA), repeated measures analysis of covariance (ANCOVA), and the Pearson chi-square test or Mann-Whitney U-test.

Results: The ITT analyses revealed a significant between-group difference in the 6MWD test ($F_{(1, 57)} = 4.90, p = 0.031$), with a minimal important difference of 36.36 metres. A significant interaction between group and time was found in the two subscale scores of the SOLQ (physical function: $F_{(1.568, 90.949)} = 4.47, p = 0.021$; emotional function: $F_{(1.531, 88.807)} = 3.53, p = 0.045$), as well as in the total score of the CSES ($F_{(1.568, 90.927)} = 13.87, p < 0.001$). Significant differences were also found

between the control and intervention groups in the COPD-related readmission rate at 12 weeks postdischarge (12/30[40.0%] vs. 5/30[16.7%], $\chi^2 = 4.02$, $p = 0.045$) and in the cost of COPD-related readmissions at 6 weeks postdischarge (interquartile range: 7638.9 vs. 5718.0, $U = 3.00$, $p = 0.014$). Moreover, the intervention group was more satisfied than the control group (service satisfaction score: Med. = 95.83 vs. Med. = 75.00, $U = 123.00$, $p < 0.001$; education satisfaction score: Med. = 93.75 vs. Med. = 56.23, $U = 65.50$, $p < 0.001$).

Conclusion: The COPD-TCP was found effective in improving exercise capacity, self-efficacy and quality of life, reducing the COPD-related readmission rate and direct cost of readmission, and enhancing patient satisfaction. The results of this study suggest that transitional care contributes to enhancing the health of COPD patients during the recovery stage following hospitalisation for an exacerbation episode. This study provides evidence in support of the healthcare reforms in mainland China, informing healthcare providers that transitional care support benefits patients in terms of both health outcomes and healthcare costs.

List of presentations and publications

Conference presentations:

1. Wang, S. L. (2009a, June). *Nursing research and high quality care*. Paper presented at the Cross-strait Four Places—Hong Kong, Macau, Taiwan and Mainland China Hospital Nursing Management Forum, Xiamen, China.
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2. Wang, S. L., Fu, S. Y., Chow, K.Y., & Wong, K. Y. (2011). Transitional care for a patient with chronic obstructive pulmonary disease. *Chinese Journal of Nursing*, 46(8), 758–760. doi: 10.3761/j.issn.0254-1769.2011.08.007
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7. Wong, J. Y., Wang, S. L., & Zhou, J. Y. (2010). Use of Omaha System in community nursing and transitional care. *Chinese Journal of Nursing*, 45(4), 320–322. doi:10.3761/j.issn.0254-1769,2010.04.012
8. Wong K. Y., Wang, S. L., & Martin, K. (2012). Individualized advanced nursing practice. In K. Y. Wong (Ed.), *Introduction to advanced nursing practice* (2nd ed., pp. 96–139). Beijing: People's Medical Publishing House.

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Glossary of commonly used abbreviations and symbols

AACVPR	American Association of Cardiovascular and Pulmonary Rehabilitation
ACCP	American College of Chest Physicians
AECOPD	Acute exacerbation of chronic obstructive pulmonary disease
APN	Advanced Practice Nurse
ANCOVA	Analysis of covariance
ANOVA	Analysis of variance
ATS	American Thoracic Society
BMI	Body mass index
BTS	British Thoracic Society
cm	Centimetre/s
CM	Case Management
CNS	Clinical Nurse Specialist
COPD	Chronic obstructive pulmonary disease
C-CSES	Cantonese version of the COPD Self-efficacy Scale
CI	Confidence interval
CRQ	Chronic Respiratory Questionnaire
CSES	COPD Self-efficacy Scale
C-SOLQ	Chinese version of the Seattle Obstructive Lung Disease Questionnaire
CTCPSQ	COPD Transitional Care Patient Satisfaction Questionnaire
ERS	European Respiratory Society
FEV ₁	Forced expiratory volume in the first second
FVC	Forced vital capacity
GOLD	Global Initiative for Chronic Obstructive Lung Disease
HbA1c	Glycated hemoglobin
HR	Hazard ratio
HRQOL	Health-related quality of life
CU	Intensive care unit
IS	Intervention Scheme
ITT	Intention-to-treat
kg	Kilogram/s

l	Litre/s
m	Metre/s
m ²	Square metre/s
MRC	Medical Research Council
MID	Minimal important difference
mg	Milligram/s
NCM	Nurse Case Manager
NCCCC	National Collaborating Centre for Chronic Conditions
NHLBI	National Heart Lung and Blood Institute
PCS	Problem Classification Scheme
PP	Per-Protocol
P-CSES	Putonghua version of the COPD Self-efficacy Scale
PRSO	Problem Rating Scheme for Outcomes
SpO ₂	Pulse oximeter oxygen saturation
SOLQ	Seattle Obstructive Lung Disease Questionnaire
RCT	Randomised controlled trial
TCG	Teaching, Guidance, and Counselling
6MWD	6-minute walk distance
6MWT	6-minute walking test
S	Surveillance
SGRQ	St. George's Respiratory Questionnaire
TCP	Transitional care programme
TP	Treatments and Procedures
WHO	World Health Organization

CHAPTER ONE

INTRODUCTION

1.1 Introduction

This chapter begins with the background to the study, followed by its aim, objectives and significance. The organisation of the entire thesis is presented at the end of the chapter.

1.2 Background of the study

Chronic obstructive pulmonary disease (COPD) is a major public health problem worldwide. The updated Global Initiative for Chronic Obstructive Lung Disease (GOLD, 2011) defined COPD as

a common preventable and treatable disease ... characterized by persistent airflow limitation that is usually progressive and associated with an enhanced chronic inflammatory response in the airways and the lung to noxious particles or gases. Exacerbations and comorbidities of COPD contribute to the overall severity in individual patients. (p. 2)

The most common symptoms of COPD are dyspnoea (or breathlessness), chronic cough and excessive sputum production, with dyspnoea the hallmark symptom (Rabe et al., 2007). Patients may encounter difficulty in doing daily activities such as dressing or walking up a short flight of stairs as their condition gradually worsens. Systemic manifestations include weight loss, nutritional abnormalities and skeletal muscle wasting, and the common comorbidities of COPD are cardiovascular disease, osteoporosis, diabetes, metabolic syndrome, depression, infections and lung cancer

(Agusti et al., 2003; Barnes & Celli, 2009; GOLD, 2011; Medical Administrative Department of the Ministry of Health, 2012). Acute exacerbations, another hallmark of COPD, can cause a quick decline in lung function, resulting in a poor quality of life, repeated hospitalisations and increased risk of death (Anzueto, 2010; Hunter & King, 2001; Rabe et al., 2007; Spencer, Calverley, Burge, & Jones, 2004).

COPD not only substantially impairs patients' functioning and quality of life, but also imposes an enormous burden on the healthcare system and society (Fletcher et al., 2011; Sharafkhaneh et al., 2010). This disease is one of the most challenging health issues the world faces, and China is no exception (Fang, Wang, & Bai, 2011; GOLD, 2011; Medical Administrative Department of the Ministry of Health, 2012).

1.2.1 Global concern for COPD

A study assessing the global burden of disease predicted that COPD would rank fifth in terms of the burden of disease by 2020 (Murray & Lopez, 1997), and the World Health Organization (WHO, 2008) predicted that it would be the world's third leading cause of death by 2030. A recent study on the global economic burden of non-communicable diseases reported that the global cost of COPD-related illness would rise from US\$2.1 trillion in 2010 to US\$4.8 trillion in 2030 (Bloom et al., 2011).

Although COPD is not curable (WHO, 2012), it is preventable and treatable (GOLD, 2011; Rabe et al., 2007). With the aim of increasing global awareness of COPD and decreasing the morbidity and mortality of the disease, the National Heart, Lung, and Blood Institute (NHLBI), in collaboration with the WHO, founded GOLD in 1998

and published the first GOLD report, *Global Strategy for Diagnosis, Management and Prevention of COPD*, in 2001 (Pauwels et al., 2001). Numerous studies have been conducted on COPD throughout the world in the past decade. International clinical guidelines and Cochrane reviews have revealed that an effective management strategy, such as smoking cessation, appropriate pharmacologic therapy and pulmonary rehabilitation, can reduce COPD symptoms and the frequency of exacerbations, as well as improve health-related quality of life (HRQOL) (GOLD, 2011; Lacasse, Goldstein, Lasserson, & Martin, 2006; Rabe et al., 2007). The modern management of COPD involves both pharmacologic and non-pharmacologic therapies (Gelberg & McIvor, 2010; GOLD, 2011; Hurst & Wedzicha, 2009; Rabe et al., 2007), and integrated strategies are recommended (Roberts, Maslin, & Bakerly, 2010).

1.2.2 COPD in mainland China

1.2.2.1 Burden of COPD

The aforementioned global burden of disease study noted that COPD killed 1.4 million people in the East Asia and Pacific regions in 2001, accounting for 50% of the disease's global mortality in that year, and China made the major contribution to that toll (Mathers, Lopez, & Murray, 2006). According to Chinese reports on respiratory diseases, COPD is one of the most common types, accounting for 1 million deaths and over 5 million disabilities every year. It is ranked as the third leading cause of death in rural areas and the fourth in urban areas (Zhong et al., 2007). A large-population, spirometry-based cross-sectional survey conducted by Zhong et al. (2007) revealed that the overall prevalence of COPD in China is 8.2% in people aged 40 and above, and is higher among men than women (12.4% vs. 5.1%).

A significantly higher prevalence of COPD is found in rural residents, the elderly and smokers, those with less education and a lower body mass index (BMI), those with pulmonary problems during childhood or a family history of pulmonary diseases, and those exposed to occupational dust, biomass fuels and poor ventilation in the kitchen (Zhong et al., 2007). The true prevalence of COPD is likely to be even higher than that reported, as a result of the many undiagnosed cases owing to the inability to access or afford care (Yao et al., 2005; Yin, Zhang, Li, Jiang, & Zhao, 2011). The overall morbidity rate of COPD in China was 6.9‰ (urban: 6.6 ‰; rural: 7.1‰) in 2008, ranking it seventh among the country's 10 main chronic diseases in that year (Ministry of Health of the People's Republic of China, 2010).

COPD treatments are extremely costly and impose an enormous economic burden on individuals, families and society. A study based on Chinese health statistics estimated that the direct cost of hospitalisation for COPD was RMB890 million in 2007 (RMB-US\$ exchange rate: 1RMB = 0.16290 US\$; only the RMB figures are given hereafter). In the same year, the per capita net income of rural and urban residents was RMB4,140 and RMB13,786, respectively. The per-hospitalisation cost of COPD treatment amounts to roughly 110% and 34%, respectively, of rural and urban residents' average total annual income (Qi, 2009). Another health-care expense survey carried out among 723 COPD outpatients in six large cities in China conducted by He et al. (2009a) found the annual per capita direct medical cost (including the cost of hospitalisation, outpatient visits and over-the-counter drug purchases) to be RMB11,744. The indirect medical cost (including transport, nutrition and end-of-life care expenses) is RMB1,570. Thirty-six per cent of patients with a job report an average of 17 working days lost every 12 months because of COPD, and 17% of their

family members report an average of 14 working days lost owing to the need to take care of the patients (He et al., 2009a). In addition to the significant social and economic individual burden caused by COPD, the condition also imposes a significant burden on the healthcare system.

The increasing burden that COPD places on the healthcare system of China is evidenced by the more than two-fold increase in the hospital admission rate between 1993 and 2008, rising from 0.7‰ to 1.6‰ (Ministry of Health of the People's Republic of China, 2010). A study carried out in Guangzhou reported that 2,768 patients with COPD were admitted to a general hospital from January 2006 to December 2007, of which 32.8% of those aged 60-74 were readmitted twice and 26.8% were readmitted three times, indicating that readmission frequency increases with age (Guang, Chen, Zhao, & Shun, 2008).

1.2.2.2 Unmet health care needs for COPD

The burden associated with COPD underscores the importance of developing strategies to prevent and manage the disease in mainland China. In 1997, the first edition of COPD guidelines was published, detailing the definition, diagnosis, assessment, prevention and treatment of COPD (Chinese Medical Association Respiratory Disease Branch COPD Group, 1997). To keep up with the GOLD documents and to achieve better understanding and management of COPD in China, the Respiratory Branch revised these initial guidelines in 2002 (Chinese Medical Association Respiratory Disease Branch COPD Group, 2002) and updated them again in 2007 (Chinese Medical Association Respiratory Disease Branch COPD Group, 2007). In addition to these efforts made at the societal level, the Ministry of

Health of the People's Republic of China also recently issued a newly revised version, *Guidelines for Diagnosis and Management of COPD (2011 edition)* (Medical Administrative Department of the Ministry of Health, 2012). Since the issuance of the first guidelines, COPD has become a major area of interest for respiratory physicians and researchers. A large body of research has been conducted to emphasise the need for COPD prevention, early diagnosis and standardised management (Sun, 2010).

Although awareness of COPD is increasing in mainland China, its management still focuses on the acute stage during hospitalisation and relies primarily on pharmacologic treatment (Sun, 2010; Zhou et al., 2010). Non-pharmacologic treatments such as education and pulmonary rehabilitation have been neglected, and disease control and prevention lag behind. Patients are not knowledgeable about how to manage the condition themselves (Fang et al., 2011), and current intervention measures such as smoking cessation, pulmonary rehabilitation, nutrition support, drug treatments and psychosocial aids are implemented primarily on a case-by-case basis to hospital patients who have already developed moderate or severe symptoms (Fang et al., 2011; Zhou et al., 2010).

Many people with COPD do not manage to receive an early diagnosis or appropriate treatment at the appropriate time (Li, Liu, & Xu, 2010). Patients with the illness are still suffering from unmet healthcare needs, especially when they are transferred from hospital to home after suffering from an acute exacerbation. A recent cohort study in mainland China revealed that the recrudescence rate of COPD is 7.35% in one month, 25% in three months, 55.62% in six months and 88.23% in 12 months

(Wang et al., 2012). Optimal management strategies should be adopted and strengthened to promote the effective chronic disease management of COPD.

1.2.3 Transitional care support for Chinese people with COPD

Transitional care generally refers to care and services that promote the safe and timely transfer of patients from acute care to subacute care or from hospital to home (Naylor, 2000). The transitional care model was developed under the guidance of the three-variable framework of quality of care, which includes outcomes, patient satisfaction and cost, and is called the Quality-Cost Model of Advance Practice Nurse (APN) Transitional Care (Brooten et al., 2002). Development of this model can be traced to a 1980s study on the use of transitional nursing care delivered by APNs to promote the early discharge of vulnerable groups from hospital. Carried out by a research team at the University of Pennsylvania, the study focused on providing the most effective healthcare service at the lowest cost in response to the changes then occurring in healthcare in the United States (Brooten et al., 2002).

More than two decades of research on the transitional care model and its effects have demonstrated that transitional care programmes (TCPs) can improve patient outcomes and reduce healthcare costs for various chronic disease groups, such as those suffering from chronic heart disease (Naylor et al., 1994, 2004), diabetes (Wong, Mok, Chan, & Tsang, 2005), stroke (Chalermwannapong, Panuthai, Srisuphan, Panya, & Ostwald, 2010; Yeung, 2012) and kidney disease (Chow & Wong, 2010; Wong, Chow, & Chan, 2010), as well as COPD (Neff, Madigan, & Narsavage, 2003; Shu et al., 2011). Neff, Madigan and Narsavage (2003) conducted a pilot study at a large multidisciplinary agency in Ohio to evaluate the effectiveness

of transitional home care for patients with COPD. Eighty subjects were recruited and assigned to an intervention group (cared for by an APN-directed and -supervised pulmonary disease management team with transitional home care) or control group (cared for by nurses as part of routine home care). The nursing care for the intervention group patients included home visits and telephone contact with a nurse specialist who was available by phone 24 hours a day. The findings revealed that, compared with their counterparts in the control group, the patients in the intervention group had less anxiety and depression, better activities of daily living scores, a shorter length of hospital stays, and fewer rehospitalisations and acute care visits.

With the provision of comprehensive seamless care, a TCP is able to benefit patients with COPD when they are discharged from hospital to home after an acute episode. Such programmes can also meet the increasingly recognised need for an integrated approach to the effective management of COPD.

1.3 Aim and objectives of the study

The overarching aim of this study was to evaluate the effectiveness of a COPD transitional care programme (COPD-TCP) for patients with COPD in Guangzhou, China, as measured by clinical, psychosocial, functional, fiscal outcomes and satisfaction. More specifically, the study set out to develop and implement a TCP suited to the needs of Chinese people with COPD. The study's primary and secondary objectives were as follows.

Primary objectives

- To compare the effects of the COPD-TCP on the exercise capacity between the intervention group receiving COPD-TCP and the control group receiving usual care;
- to compare the COPD-TCP's effects on the self-efficacy between the intervention and control groups;
- to compare the effects of the COPD-TCP on HRQOL between the intervention and control groups;
- to compare the effects of the COPD-TCP on the readmission between the intervention and control groups;
- to compare the effects of the COPD-TCP on the direct cost of readmission between the intervention and control groups; and
- to compare the programme's effects on patient satisfaction between the intervention and control groups.

Secondary objective

- To explore the experience of the intervention group of patients who underwent COPD-TCP.

1.4 Significance of the study

Transitional care was first introduced to China among a group of patients with coronary heart disease when a randomised controlled trial (RCT) was launched in Tianjin, China in 2002-2003 (Zhao, 2004; Zhao & Wong, 2009). An innovation in the provision of seamless care for patients, transitional care soon after became a hot topic in nursing research, a new intervention for clinical practice and a new service in the healthcare system of mainland China (Xu, 2012; Zhang, Ye, & Liu, 2012). In the

past few years, researchers have tried to deliver TCPs to various patient groups, such as patients with puerperium in the primipara (Mao, Xing, & Wang, 2007), severe craniocerebral injury (Yang, Zhai, Li, & He, 2010), stroke (Qian, Zhu, & Chen, 2011; Zhou, Ho, & Zhao, 2009), colorectal cancer with colostomy (Zhang, Zheng, & Huang, 2011) and COPD (Wang, Fu, Chow, & Wong, 2011), as well as those needing peritoneal dialysis (Li, Zhou, Li, Wang, & Yu, 2012).

However, the concept of transitional care has not been widely introduced or investigated empirically until recently (Dong, Shang, Yao, & Hou, 2012; Xu, 2012; Zhang et al., 2012). There is thus a lack of research evidence from well-designed studies, particularly RCTs (Dong et al., 2012; Xu, 2012). Opportunity exists for the development of transitional care, as healthcare providers, researchers and decision-makers all face the challenge of providing more accessible and affordable care to the population. However, the challenges of introducing a well-designed transitional care model to support patients with chronic diseases such as COPD should not be underestimated, and there are considerable organisational, cultural, social, economic and regulatory barriers in mainland China, not to mention problems with the competence levels of existing nursing staff (Dong et al., 2012; Xu, 2012; Zhang et al., 2012). This research endeavours to build a transitional care model that will gain the support of physicians and hospital managers and equip nurses with the necessary competence to run the programme before subjecting it to empirical testing.

The aim of this study was not only to implement a transitional programme, but at the same time to develop a group of nurses who are competent in providing transitional care to patients. A structured postdischarge programme has been successfully

introduced in a Guangzhou hospital to interface with inpatient discharge care. Accordingly, this study has significant value not only for clinical practice, but also in encouraging management initiatives supported by scientific evidence.

1.5 Organisation of the thesis

This thesis consists of 9 chapters. Following this introductory chapter is Chapter 2, which presents a complete literature review. This review focuses on two major aspects: COPD management and transitional care. Chapter 3 describes the research methodology adopted in this study, which involved the main RCT, validation study and focus group interview. Chapters 4 to 6 detail the process of implementing the study, organised in the sequence of programme development, including transitional care model and evidence-based intervention protocols (Chapter 4), instrument validation (Chapter 5) and RCT implementation (Chapter 6). Chapter 7 reports the quantitative and qualitative findings, and is divided into two parts: Part 1 reports the findings of the main study, and Part 2 summarises the findings of the focus group interview. Chapter 8 discusses the study findings. Finally, Chapter 9 explores the limitations and implications of the study, suggests areas for future study and draws conclusions.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

As briefly described in Chapter 1, COPD is characterised by a persistent decline in lung function and frequent exacerbations of symptoms, representing an urgent need for the efficient management of COPD to reduce the disease burdens on individuals, society and the healthcare system. The overarching aim of this study was to develop and evaluate a COPD-TCP for Chinese patients with COPD. The literature review in this chapter focuses on previous research on the management of COPD and transitional care. The search strategies undertaken for the review of the literature in English included an electronic database search of the Cumulative Index of Nursing and Allied Health Literature (CINAHL), Index Medicus (MEDLINE), PsycINFO and the Cochrane Central Register of Controlled Trials (CENTRAL, *The Cochrane Library*). A search of the literature in Chinese was carried out via the CAJ full-text database. The search terms included COPD, obstructive lung disease, chronic disease, treatment, disease management, self-management, pulmonary rehabilitation, home-based intervention, transitional care, discharge planning, home follow-up, quality of life, self-efficacy, readmission and similar terms. An extensive literature review was conducted, including a search of abstracts, full research papers, reports of RCTs, systematic reviews and meta-analyses, evidence-based practice guidelines and unpublished dissertations.

The chapter begins with a review of COPD exacerbations and their impacts, followed by a review of the current management practices for COPD to explore efficient

strategies to meet the needs of patients after hospitalisation with an exacerbation of COPD. It next reports a critical review of home TCPs for patients with chronic illness, before finally turning to a discussion of the care deficits in existing health services in mainland China.

2.2 COPD exacerbations and impacts

COPD is a disease characterised by the incomplete reversibility of airflow limitations, and is progressive in nature. Exacerbations of COPD are important events in the course of the disease that indicate its progression. A COPD exacerbation is defined as an acute event characterised by a worsening of the patient's respiratory symptoms from his or her stable state that is beyond normal day-to-day variations and that leads to a change in regular medication in a patient with underlying COPD (GOLD, 2011; Rodriguez-Roisin, 2000). Such worsening generally includes an acute increase in one or more of the following cardinal symptoms: cough increasing in frequency and severity, sputum production increasing in volume and/or changing in character, and increasing dyspnoea (Wedzicha & Seemungal, 2007). Most exacerbations are caused by respiratory tract infection (GOLD, 2011). Viruses can induce airway inflammation and exacerbations (Seemungal et al., 2001), and exacerbations may be caused by bacterial species (Patel et al., 2002). Pollutants are a trigger for exacerbation episodes as well (Anderson et al., 1997).

Exacerbations of COPD result in demonstrable changes in airway and systemic inflammation and further impairment in lung function (Hurst & Wedzicha, 2007). Recovery is incomplete in a significant proportion of patients presenting with them. Seemungal, Donaldson, Bhowmik, Jeffries, and Wedzicha (2000) found that,

following exacerbation onset, the median time to symptom recovery was 7 days (interquartile range [IQR]: 4 to 14) days, and the median time to lung function recovery (assessed by peak expiratory flow rate [PEFR]) was 6 (IQR: 1 to 14) days. They reported that some exacerbations had a prolonged recovery or might indeed never result in full recovery (around 25% and 7% of exacerbations had not returned to baseline PEFR at 35 and 91 days, respectively) (Seemungal et al., 2000). Hurst and Wedzicha (2007) noted that exacerbations generally become both more frequent and more severe as the severity of the underlying COPD increases. It has also been reported that patients who have more symptoms during exacerbations have an increased chance of sputum purulence and longer recovery times (Donaldson et al., 2003).

Exacerbations of COPD contribute to long-term decline in lung function, and are associated with reduced health status and increased morbidity, mortality and socioeconomic costs (Donaldson, Seemungal, Bhowmik, & Wedzicha, 2002; GOLD, 2011; Groenewegen, Schols, & Wouters, 2003; Seemungal et al., 1998; Spencer et al., 2004; Yohannes, Baldwin, & Connolly, 2005; Wedzicha & Seemungal, 2007). Studies have also revealed that exacerbation negatively affects a patient's quality of life and that such an effect is related to COPD exacerbation frequency (Miravittles et al., 2004; Seemungal et al., 1998; Spencer et al., 2004). In the UK, Spencer et al. (2004) investigated the impact of preventing exacerbations on deterioration of health status in COPD by observing the rates of deterioration, as measured by the St George's Respiratory Questionnaire (SGRQ) total score among 613 patients with moderate to severe COPD for a maximum of 3 years. Patients were stratified into three exacerbation groups: 91 patients with no exacerbations, 285 with infrequent

exacerbations (< 1.65 exacerbations in year 1) and 235 with frequent exacerbations (> 1.65 exacerbations in year 1). They reported frequent exacerbations to be independently associated with a worse baseline SGRQ score ($p < 0.0001$) and a more rapid rate of deterioration in health status ($p = 0.0003$). Exacerbation frequency and rate of decline in forced expiratory volume in the first second (FVE₁) were independently related to the rate of deterioration in SGRQ scores.

COPD exacerbations are also significantly associated with mortality, and there is a significant risk of mortality in the period after discharge (GOLD, 2011; Groenewegen et al., 2003; Yohannes et al., 2005). In the Netherlands, 171 patients were included in a study in which the mortality rate during the hospital stay was 8% (Groenewegen et al., 2003). Yohannes et al. (2005) recorded a 1-year mortality rate of 36% in a group of patients discharged from hospital following acute exacerbations of COPD in the UK. All-cause mortality in the three years after hospitalisation is as high as 49% in the GOLD report (GOLD, 2011). Moreover, exacerbations lead to high costs. In China, Chen et al. (2008) investigated the costs of hospitalisation in patients with acute exacerbations of COPD (AECOPD) and the associated factors. A total of 439 patients were enrolled in the study. The mean hospital stay was 20.70 days, and the median cost was RMB11,597.60. The use of non-invasive or invasive ventilation, intensive care unit (ICU) stay, and the use of antibiotics and systemic steroids were found to be the major determinants of hospitalisation costs. The authors concluded that AECOPD has a great impact on healthcare resource utilisation and that long-term regular treatment to reduce the frequency of acute exacerbations will help to reduce the social and economic burden of COPD (Chen et al., 2008).

2.3 Management of COPD

The impact of exacerbations is significant, and efficient management is thus of great importance. The GOLD guidelines assert that the prevention, early detection and prompt treatment of exacerbations can influence the clinical progression of COPD by ameliorating its effects on quality of life and minimising the risk of hospitalisation (GOLD, 2001, 2006, 2008, 2011).

Management of COPD involves pharmacologic and non-pharmacologic treatments (Gelberg & McIvor, 2010; Wise & Tashkin, 2007). In management of the disease, it is important to perform systemic care directed at preventing disease progression, relieving symptoms, improving exercise tolerance, improving health status, preventing and treating complications, and reducing mortality (GOLD, 2006). According to the GOLD guidelines, an effective COPD management programme includes four components: disease assessment and surveillance, reduction of risk factors, management of stable COPD and exacerbation management (GOLD, 2006, 2011).

2.3.1 Disease assessment and surveillance

COPD management is based on an individualised assessment of the patient's disease severity, response to various therapies, and educational level and willingness to apply the recommended management strategy. In addition, as COPD is a progressive disease, the patient's lung function can be expected to worsen over time. As a result, the assessment and monitoring of COPD includes an assessment of symptoms and the monitoring of disease progression, the development of complications, and pharmacotherapy and other medical treatment (GOLD, 2006).

2.3.2 Reducing risk factors

It has been proposed that COPD is to some extent preventable, for example, through avoidance of exposure to tobacco smoke, occupational dust and chemicals, and indoor and outdoor air pollution (GOLD, 2006, 2011). GOLD (2006, 2011) suggests that smoking cessation is the single most effective and cost-effective intervention for reducing the risk of COPD development and halting its progression. The National Collaborating Centre for Chronic Conditions (NCCCC, 2004) recommends that all patients who are still smoking, regardless of their age, be encouraged to stop. A five-step programme for intervention to help patients to stop smoking has also been proposed (Clinical Practice Guideline Treating Tobacco Use and Dependence 2008 Update Panel, Liaisons, and Staff, 2008; Fiore, 2000). The five steps are: (1) Ask: to systematically identify all tobacco users at every visit; (2) Advise: to strongly urge all tobacco users to quit; (3) Assess: to determine the willingness to make a quit attempt by asking whether the patient is willing to make such an attempt at this time; (4) Assist: to aid the patient in quitting with a cessation plan, practical counselling, intratreatment social support, and the use of approved pharmacotherapy and supplementary materials if appropriate; and (5) Arrange: to schedule follow-up contact either in person or via the telephone (Rabe et al., 2007).

2.3.3 Managing stable COPD

In the past decade, in addition to the efforts made to relieve the symptoms of the acute onset of the disease, considerable attention has also been drawn to the importance of actively managing stable COPD so as to control the further deterioration of the disease.

2.3.3.1 Health education and disease self-management

Health education is strongly recommended by many evidence-based guidelines as an essential integrated component of pulmonary rehabilitation, smoking cessation and a COPD management programme. These guidelines include the *Global Initiative for Chronic Obstructive Lung Disease, Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease* (Global Initiative for Chronic Obstructive Lung Disease [GOLD], 2001, 2006, 2011), *Chronic Obstructive Pulmonary Disease: National Clinical Guideline on Management of Chronic Obstructive Pulmonary Disease in Adults in Primary and Secondary Care* (National Collaborating Centre for Chronic Conditions [NCCCC], 2004), *American Thoracic Society/European Respiratory Society Statement on Pulmonary Rehabilitation* (Nici et al., 2006), *International Primary Care Group (IPCG) guidelines: Management of Chronic Obstructive Pulmonary Disease (COPD)* (Bellamy, 2006), *Intermediate Care—Hospital-at-Home in Chronic Obstructive Pulmonary Disease: British Thoracic Society Guideline* (British Thoracic Society Guideline Development Group [BTSGDG], 2007) and *Pulmonary Rehabilitation: Joint ACCP/AACVPR Evidence-Based Clinical Practice Guidelines* (Ries et al., 2007).

It is believed that education can play a vital role in improving skills, the ability to cope with illness and health status, although some studies have indicated that health education alone does not improve exercise performance or lung function (GOLD, 2006). It is also widely accepted that knowledge of the disease does not necessarily effect behavioural change (Effing et al, 2007). In recent years, studies have inclined toward emphasising self-management skills, and there has been a shift from the traditional teaching style to self-management education (Effing et al, 2007; Nici et al.,

2006; Trappenburg et al., 2011). Bourbeau et al. (2003) conducted a multi-centre RCT and provided evidence that a multicomponent, skill-oriented self-management programme integrated with an exacerbation action plan and home exercise can reduce hospitalisations, emergency visits, and unscheduled physician visits and improve HRQL. An updated Cochrane review of 15 group comparisons drawn from 14 trials proved that self-management education is associated with a reduction in hospital admissions (Effing et al., 2007).

GOLD (2006) stated that the goals of education are to enable patients to understand the nature of their disease, the risk factors for progression and their role in disease management, and the role of healthcare providers in achieving optimal management and health outcomes. Directed at improving patients' quality of life, education should be tailored to the needs and environment of the individual patient, interactive, simple to follow, practical, and suited to the intellectual and social skills of the patient and his or her caregivers (GOLD, 2006). The British Thoracic Society Guideline Development Group (BTSGDG, 2007) proposes the inclusion of an education programme in home care or chronic disease management interventions for stable COPD patients.

2.3.3.2 Pulmonary rehabilitation

Pulmonary rehabilitation programmes are now well established as a comprehensive approach in COPD rehabilitation (GOLD, 2006). Three evidence-based pulmonary guidelines, as well as GOLD, were reviewed for this study. Table 2.1 summarises the recommendations or practice guideline statements in: (1) *Global Initiative for Chronic Obstructive Lung Disease, Global Strategy for the Diagnosis, Management,*

and Prevention of Chronic Obstructive Pulmonary Disease (updated 2006) (GOLD, 2006); (2) *British Thoracic Society Statement: Pulmonary Rehabilitation* (BTS statement hereafter) (British Thoracic Society Standards of Care Subcommittee on Pulmonary Rehabilitation, 2001); (3) *American Thoracic Society/European Respiratory Society Statement on Pulmonary Rehabilitation* (ATS/ERS statement hereafter) (Nici et al., 2006); and (4) *Pulmonary Rehabilitation: Joint ACCP/AACVPR Evidence-Based Clinical Practice Guidelines* (ACCP/AACVPR guidelines hereafter) (Ries et al., 2007). GOLD states that the goals of pulmonary rehabilitation are to reduce symptoms, improve quality of life, and increase physical and emotional participation in daily activities. The guideline developers agreed that the expected outcomes of pulmonary rehabilitation are patient-centred outcomes such as symptoms and severity, performance in daily activities, exercise capacity and HRQOL. Its benefits in relieving dyspnoea or breathlessness, along with improved exercise capacity and better HRQOL, are confirmed with the rich evidence contained in the GOLD and BTS statements. GOLD has also reported that pulmonary rehabilitation not only reduces the number of hospital days and length of hospital stays, but also the anxiety and depression associated with COPD.

It has been suggested that COPD patients at all stages of the disease may benefit from exercise training programmes (GOLD, 2006), and pulmonary rehabilitation can be carried out in the hospital, community or home (British Thoracic Society Standards of Care Subcommittee on Pulmonary Rehabilitation, 2001). Although there is no agreement on the components of such a programme, it is strongly recommended that it should be comprehensive (GOLD, 2006). A comprehensive programme would generally include endurance and exercise training, patient

education, psychosocial support and nutritional counselling. The ATS/ERS statement and ACCP/AACVPR guidelines provide a more detailed practice guide on an intervention design that addresses the type, mode, intensity and duration of exercise training. The latter highlight three important features of a successful rehabilitation programme (see Table 2.1 below), which are multidisciplinary, individual and attention to physical and social function (Ries et al., 2007).

Table 2.1 Recommendations of clinical guidelines on pulmonary rehabilitation

Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (GOLD, 2006)
The principal goals of pulmonary rehabilitation are to reduce symptoms, improve quality of life, and increase physical and emotional participation in everyday activities. (p. 56) <u>Patient selection and programme design:</u> (p. 56) - Although more information is needed on criteria for patient selection for pulmonary rehabilitation programmes, COPD patients at all stages of the disease appear to benefit from exercise training programmes, improving with respect to both exercise tolerance and symptoms of dyspnoea and fatigue (Evidence A). <u>Benefits of pulmonary rehabilitation:</u> (pp. 56–57) - Improves exercise capacity (Evidence A). - Reduces the perceived intensity of breathlessness (Evidence A). - Improves HRQOL (Evidence A). - Reduces the number of hospitalisations and days in the hospital (Evidence A). - Reduces anxiety and depression associated with COPD (Evidence A). - Strength and endurance training of the upper limbs improves arm function (Evidence B). - Benefits extend well beyond the immediate period of training (Evidence B). - Improves survival (Evidence B). - Benefits have been seen in patients with a wide range of disability, although those who are chair-bound appear unlikely to respond even to home visiting programmes (Evidence A). - Benefits do wane after a rehabilitation programme ends, but if exercise training is maintained at home, the patient's health status remains above pre-rehabilitation levels (Evidence B). - Those with Medical Research Council (MRC) grade 5 dyspnoea may not benefit (Evidence B). - Some data indicate that continuing smokers are less likely to complete pulmonary rehabilitation programmes than non-smokers (Evidence B). <u>Components of pulmonary rehabilitation programmes:</u> (p. 57) The components of pulmonary rehabilitation vary widely from programme to programme, but a comprehensive pulmonary rehabilitation programme includes exercise training, nutrition counselling and education. - The minimum length of an effective rehabilitation programme is 6 weeks; the longer the programme continues, the more effective the results (Evidence B). - A reduction in BMI is an independent risk factor for mortality in COPD patients (Evidence A). <u>Economic cost of rehabilitation programmes:</u> (p. 58) A Canadian study showing statistically significant improvements in dyspnoea, fatigue, emotional health and mastery found that the incremental cost of pulmonary rehabilitation was \$11,597 (CDN) per person. A study from the United Kingdom provided evidence that an intensive (6-week, 18-visit) multidisciplinary rehabilitation programme was effective in decreasing use of the health services (Evidence B). <i>Notes: Evidence A: evidence from RCTs with rich body of data; Evidence B: evidence from RCTs with limited body of data.</i>

Table 2.1 Recommendations of clinical guidelines on pulmonary rehabilitation (Con't)

BTS Statement: Pulmonary rehabilitation (British Thoracic Society Standards of Care Subcommittee on Pulmonary Rehabilitation, 2001) <u>Settings:</u> (p. 828) Pulmonary rehabilitation is effective in all settings, including hospital inpatient, hospital outpatient, the community and the home. [A] <u>Programme content:</u> (P. 828) Physical aerobic training, particularly of the lower extremities (brisk walking or cycling), is mandatory. [A] <u>Benefits of pulmonary rehabilitation:</u> (p. 829) Evidence exists that a multi-professional individually tailored programme of rehabilitation, including prescribed endurance exercise training, should: • Improve functional exercise capacity [Ia] • Improve health status [Ia] • Reduce dyspnoea [Ia] • Have some health-related economic advantages [Ib] <i>Notes: (Ia) = evidence based on meta-analysis of RCT evidence; (Ib) = evidence from at least one RCT; [A] = grade of evidence (levels Ia, Ib) requiring at least one RCT.</i>
American Thoracic Society/European Respiratory Society Statement on Pulmonary Rehabilitation (Nici et al., 2006) <u>Exercise performance:</u> (p. 1394) • A minimum of 20 sessions should be delivered at least three times per week to achieve physiologic benefits; twice weekly supervised sessions plus one unsupervised home session may also be acceptable. • High-intensity exercise produces greater physiologic benefits and should be encouraged; however, low-intensity training is also effective for those patients who cannot achieve this level of intensity. • Interval training may be useful in promoting higher levels of exercise training in more symptomatic patients. • Both upper and lower extremity training should be utilised. • The combination of endurance and strength training generally has multiple beneficial effects and is well tolerated; strength training would be particularly indicated for patients with significant muscle atrophy. <u>Additional strategies to improve exercise performance:</u> (p: 1395) • Oxygen supplementation during pulmonary rehabilitation, regardless of whether oxygen desaturation during exercise occurs, often allows for higher training intensity and/or reduced symptoms in the research setting. However, at the present time, it is still unclear whether this translates into improved clinical outcomes.

Table 2.1 Recommendations of clinical guidelines on pulmonary rehabilitation (Con't)

- In selected patients with severe chronic respiratory disease and suboptimal response to exercise, Non-invasive positive-pressure ventilation (NPPV) may be considered as adjunctive therapy, as it may allow for greater training intensity by unloading the respiratory muscles.
- Because NPPV is a very difficult and labour-intensive intervention, it should be used only in those with demonstrated benefit from this therapy. Further studies are needed to further define its role in pulmonary rehabilitation.
- Although the data are inconclusive, inspiratory muscle training could be considered as adjunctive therapy in pulmonary rehabilitation, although primarily in patients with suspected or proven respiratory muscle weakness.
- Neuroelectrical muscle stimulation (NMES) may be an adjunctive therapy for patients with severe chronic respiratory disease who are bedbound or suffering from extreme skeletal muscle weakness.

Body composition: (p. 1397)

- Pulmonary rehabilitation programmes should address body composition abnormalities, which are frequently present and under-recognised in chronic lung disease. Intervention may be in the form of caloric, physiologic, pharmacologic or combination therapy.

Self-management education: (p. 1399)

- The educational component of pulmonary rehabilitation should emphasise self-management skills.
- Self-management should include an action plan for early recognition and treatment of exacerbations and discussions regarding end-of-life decision-making.
- In selected patients, instruction in breathing strategies and bronchial hygiene techniques should be considered.
- The transference of educational training and exercise adherence to the home setting should be emphasised.

Psychological and social considerations: (p. 1399)

- Screening for anxiety and depression should be part of the initial assessment.
- Although mild or moderate levels of anxiety or depression related to the disease process may improve with pulmonary rehabilitation, patients with significant psychiatric disease should be referred for appropriate professional care.
- Promotion of an adequate patient support system is encouraged.

Outcome assessment: (p. 1402)

- Assessment of patient-centred outcomes, such as symptoms, performance in daily activities, exercise capacity and HRQL, should be an integral component of pulmonary rehabilitation.

Program Organisation: Practice guidelines: Not available

Healthcare Utilisation: Practice guidelines: Not available

Table 2.1 Recommendations of clinical guidelines on pulmonary rehabilitation (Con't)

Pulmonary Rehabilitation: Joint ACCP/AACVPR Evidence-Based Clinical Practice Guidelines (Ries et al., 2007)
<u>Important features of successful rehabilitation:</u> (p. 6S) • <i>Multidisciplinary:</i> Pulmonary rehabilitation programmes utilise expertise from various healthcare disciplines, which is then integrated into a comprehensive, cohesive programme tailored to the needs of each patient. • <i>Individual:</i> Patients with disabling lung disease require an individual assessment of needs, individual attention and a programme designed to meet realistic individual goals. • <i>Attention to physical and social function:</i> To be successful, pulmonary rehabilitation must pay attention to psychological, emotional and social problems, as well as physical disability, and help to optimise medical therapy to improve lung function and exercise tolerance. <u>Outcomes of comprehensive pulmonary rehabilitation programmes:</u> Lower extremity exercise training, dyspnoea; HRQOL, health-care utilisation and economic analysis; survival, psychosocial outcomes and long-term benefits of pulmonary rehabilitation. <u>Grade 1A recommendations on duration, intensity, components and post-rehabilitation maintenance strategies of pulmonary rehabilitation:</u> • A programme of exercise training of the muscles of ambulation is recommended as a mandatory component of pulmonary rehabilitation for patients with COPD. (p. 9S) • Pulmonary rehabilitation improves the symptoms of dyspnoea in patients with COPD (p. 9S) • Pulmonary rehabilitation improves HRQOL in patients with COPD. (p. 11S) • Six to twelve weeks of pulmonary rehabilitation produces benefits in several outcomes that decline gradually over 12 to 18 months. (p. 13S) • Both low- and high-intensity exercise training produce clinical benefits for patients with COPD. (p. 18S) • The addition of a strength-training component to a programme of pulmonary rehabilitation increases muscle strength and muscle mass. (p. 20S) • Unsupported endurance training of the upper extremities is beneficial in patients with COPD and should be included in pulmonary rehabilitation programmes. (p. 24S) <i>Notes: Grade 1A = strong recommendation that comes from well-designed RCTs yielding consistent and directly applicable results.</i>

2.3.3.3 Pharmacological therapy

Although none of the existing medications for COPD is able to modify the long-term decline in lung function associated with the disease, effective pharmacological therapy can relieve patients' symptoms, increase their ability to accomplish everyday activities, reduce the frequency of exacerbations and improve their quality of life (Bellamy et al., 2006; Chinese Medical Association Respiratory Disease Branch COPD Group, 2007; GOLD, 2006). For the symptomatic management of COPD, bronchodilator medications are given on an as-needed basis or on a regular basis to prevent or reduce symptoms and exacerbations. According to international and national guidelines, the principal bronchodilator treatments are β_2 -agonists, anticholinergics and methylxanthines, which are used singly or in combination (Chinese Medical Association Respiratory Disease Branch COPD Group, 2007; GOLD, 2006). In addition, inhaled glucocorticosteroids are recommended in patients with stage III (severe) and stage IV (very severe) COPD and/or repeated exacerbations, and oral corticosteroids or antibiotics are required for repeated or infectious exacerbations of COPD. Long-term oxygen is added if there is chronic respiratory failure. The administration of oxygen (> 15 hours/day) to patients with chronic respiratory failure has been shown to increase survival rates (GOLD, 2006).

2.3.4 Management of exacerbations

The goals of COPD exacerbation treatment are to minimise the impact of a current exacerbation and prevent the development of subsequent exacerbations (GOLD, 2011; Martinez, Han, Flaherty & Curtis, 2006). Wilkinson, Donaldson, Hurst, Seemungal and Wedzicha (2004) pointed out that early recognition of exacerbations

and prompt treatment improve exacerbation recovery, enhance HRQOL and reduce the risk of hospital admission.

2.3.4.1 Assessment of an exacerbation

According to clinical guidelines, assessment of an exacerbation is based on the patient's medical history and clinical signs of severity and the results of such laboratory tests as pulse oximetry, chest radiography and electrocardiography, if available (GOLD, 2011). Increased breathlessness is the main symptom of an exacerbation, and is often accompanied by wheezing and chest tightness, increased cough and sputum, change in the colour and/or tenacity of sputum, and fever. Patients may also have some nonspecific complaints, such as tachycardia and tachypnoea, malaise, insomnia, sleepiness, fatigue, depression and confusion (GOLD, 2006). Signs of severity include: use of accessory respiratory muscles, paradoxical chest wall movements, worsening or new onset of central cyanosis, development of peripheral oedema, haemodynamic instability, signs of right heart failure and reduced alertness. A change in the patient's mental status is the most important sign of a severe exacerbation, and signals the need for an immediate evaluation in hospital (GOLD, 2006).

2.3.4.2 Hospital management of COPD exacerbation

Patients are considered for hospitalisation if any of the following characteristics exists (GOLD, 2006, 2011).

- Marked increase in intensity of symptoms, such as sudden development of resting dyspnoea
- Severe underlying COPD

- Onset of new physical signs (e.g. cyanosis, peripheral oedema)
- Failure of exacerbation to respond to initial medical management
- Significant comorbidities (revised in 2011 GOLD: Presence of serious comorbidities [e.g. heart failure or newly occurring arrhythmias])
- Frequent exacerbations
- Newly occurring arrhythmias (deleted in 2011 GOLD)
- Diagnostic uncertainty (deleted in 2011 GOLD)
- Older age
- Insufficient home support

Bronchodilators, corticosteroids and antibiotics are the three classes of medications most commonly used for an exacerbation, and oxygen therapy is a key component of hospital treatment (GOLD, 2006, 2011). Some patients need admission to an ICU and ventilator support.

In China, the clinical pathway for COPD management proposed by the Ministry of Health (2009) is as follows.

- Standard inpatient treatment includes: (1) smoking cessation; (2) general treatment regimen such as oxygen therapy and rest; (3) symptom-based medication, i.e. drugs for relieving cough, sputum and asthma; (4) antibiotics; and (5) management of comorbidities.
- The standard length of stay is 10 to 21 days.
- The discharge criteria are: (1) symptoms significantly reduced and (2) patient has been clinically stable for 12-24 hours.

2.3.4.3 Follow-up and ongoing care

After an exacerbation, the patient's symptoms and lung function may take several weeks to recover (Seemungal et al., 2000), and he or she should be reviewed periodically until his or her health status returns to its pre-exacerbation level (Bellamy et al., 2006; GOLD, 2006, 2011). The GOLD guidelines suggest following up patients for 4-6 weeks with regard to their: (1) ability to cope in usual environments; (2) measurement of FEV₁; (3) inhaler technique; (4) understanding of the recommended treatment regimen; and (5) need for long-term oxygen therapy and/or home nebuliser (GOLD, 2006). From the medical perspective, a post-exacerbation follow-up constitutes a good opportunity to review a patient's pharmacologic therapy and to consider stepping up treatment or adding rehabilitation and oxygen therapy (Bellamy et al., 2006). Strategies should also be adopted to prevent further exacerbations by re-emphasising the need for smoking cessation, considering the addition of inhaled glucocorticosteroids to the patient's medication regimen and emphasising the importance of regular influenza vaccination and the like (Hurst & Wedzicha, 2009).

Ongoing monitoring is suggested to assess the patient's quality of life and whether treatment goals are being met, to assess his or her ability to cope with the disease, to encourage adherence to the treatment plan, to review the side effects of the drugs he or she is taking, and to adapt treatment to new advances in therapy (Bellamy et al., 2006). An action plan as a tool for disease self-management has been found useful in helping patients to seek timely help (Bourbeau et al., 2003, 2006; Kalpan, 2009; Walters, Turnock, Walter, & Wood-Baker, 2010). Meta-analyses also show that pulmonary rehabilitation after an acute exacerbation of COPD can reduce the risk of

hospital admissions and mortality and lead to large improvements in HRQOL and exercise capacity (Puhan et al., 2011; Puhan, Scharplatz, Troosters, & Steurer, 2005).

2.4 Home TCPs for chronic illness

Patients with COPD are generally discharged home before their symptoms have been fully alleviated following hospitalisation for an exacerbation. As in other chronic diseases, a lack of intervention to ensure the continuity of care increases the risk of rehospitalisation during COPD patients' transition from hospital to home. This gap in continuity management of the disease needs to be bridged with efficient intervention strategies.

Boult et al. (2009) proposed 15 successful care models for older Americans with chronic conditions, one of which is the transitional care model. As discussed in the previous chapter, a transitional care model is specially designed to promote the safe and timely transfer of patients from acute care to subacute care or from hospital to home (Naylor, 2000). Since the initial study testing the Quality-Cost Model of APN Transitional Care with very low birth weight infants was carried out in 1986 (Brooten et al., 2002), transitional care has developed further. A considerable number of studies carried out overseas and in Hong Kong have accumulated an extensive body of evidence in this area. To design the intervention in the current study based on the best available evidence, a search was conducted for all RCTs published during the 1990-2011 period. Of the 188 articles found (158 in English and 30 in Chinese), those meeting all three of the following inclusion criteria were included in this review: (1) the RCT assessed the effects of a discharge-planning

plus home follow-up programme intervention; (2) the study population was individuals with chronic diseases or chronic conditions; and (3) the study targeted one of the five following categories of outcomes suggested by Urden (2001) for evaluating nursing interventions.

- *Clinical outcomes*: a) physiological response, b) symptom control, c) mortality or survival, and d) other
- *Psychosocial outcomes*: a) coping or stress management, b) anxiety or depression, c) adherence, d) knowledge (cognitive or psychomotor) and e) others
- *Functional outcomes*: a) quality of life, b) functional status (self-care, mobility or ADL) and c) other
- *Fiscal outcomes*: a) readmission (rate or frequency of readmission to hospital, home care or other services, or time to first readmission), b) length of stay, c) utilisation of healthcare services (emergency room visit or outpatient visit), d) costs of healthcare services (direct and indirect cost) and e) other
- *Satisfaction*: a) consumer (patient or caregiver) and b) other

Studies were excluded from the review if they: (1) included a comprehensive discharge-planning intervention but no post post-discharge component; (2) had post-discharge follow-up components but no discharge-planning intervention; and/or (3) had discharge-planning or post-discharge follow-up provided by professionals other than nurses.

The two following tables summarise the pertinent details of 22 RCTs (see next section for a list) investigating hospital-to-home transitional care for chronic illness.

Table 2.2 provides a summary of the citations, study population, care features (delivery mode, provider and coordination), duration of follow-up, outcome measures and main findings of each RCT. Table 2.3 continues the summary with the study interventions, including intervention duration, time of follow-up initiation, intervention strategies and care quality assurance strategies.

Table 2.2 Summary of study population, care features and outcomes of RCTs of home transitional care for chronic illness

Number	Study	Study population	Care features			Outcome measures & main findings (I vs. C)							
	Researcher(s), year, Country	Patient groups, sample size	Delivery mode 1=in-hospital visit 2=home visit; 3=telephone follow-up; 4=patient initiated call	Provider and coordination mode 1=APN/CNS/CNC/NP; 2=RN; 3=CN/PN/HCN; 4=physician; 5=allied health professionals; 6=social worker; 7=caregiver; 8=others; (^=coordinator)	C coordination: 1=healthcare service 2=social service 3=healthcare referral or consultation (=Indirect)	Duration of follow-up (weeks)			Psychosocial outcome: a=anxiety/depression; b=coping; c=adherence; d=knowledge; e=others	Clinical outcome: a=physical respond; b=symptom control; c=mortality; d=others	Functional outcome: a=quality of life; b=functional status; e=others	Fiscal outcome: a=readmission; b=length of stay; c=utilization of healthcare service; d=cost; e=others	Satisfaction: a=consumer; b=others
1.	Naylor et al., 1994 United States	Cardiac diagnoses I=72, C=70	1; 3; 4	1 ^A ; 3; 4; 7 (joint intervention)	1; 2; 3	12					NS ^b	+ ^a , + ^b , NS ^c , + ^d	NS ^a
2.	Rich et al., 1995; Rich et al., 1993* United Sates	Congestive heart failure I=142, C=140	1; 2; 3; 4*	2 ^A ; 4; 5; 6; 7* (multidisciplinary team intervention)	2; 3	12	NS ^c				+ ^a	+ ^a , + ^d	
3.	Naylor et al., 1999 United States	Mixed diagnoses I=177, C=186	1; 2; 3; 4	1 ^A ; 4; 7 (joint intervention)	1; 2; 3	24		NS ^a			NS ^b	+ ^a , + ^b , NS ^c , + ^d	NS ^a
4.	Egan et al., 2002 Australia	COPD I=33, C=33	1; 3	1; 2 ^A ; 4; 7 (joint intervention)	1; 2; 3	12	NS ^b	NS ^a			+ ^c (affectionate support)	NS ^a	+ ^a , + ^b (staff) (qualitative results)
5.	Harrison et al., 2002 Canada	Heart failure I=92, C=100	1; 2; 3	2 ^A ; 3; 8 (home care coordinator) (joint intervention)	1	12					+ ^a	+ ^a , + ^c	
6.	Laramee et al., 2003 United States	Heart failure I=141, C=146	1; 3; 4	1 ^A ; 4; 5; 6; 7 (joint intervention)	1; 2; 3	12		+ ^b				NS ^a , NS ^b , NS ^d	+ ^a

I = Intervention group; C = Control group; APN = Advanced Practice Nurse; CNP = Clinical Nurse Specialist; CNC = Clinical Nurse Consultant; NP = Nurse Practitioner; RN = Registered Nurse; CN = Community Nurse; PN = Primary Nurse; HCN = Home Care Nurse;

*Information from additional publication of same study; NS = Not significant; + = positive effect; - = negative effect.

Table 2.2 Summary of study population, care features and outcomes of RCTs of home transitional care for chronic illness

Number	Study	Study population	Care features		Duration of follow-up (weeks)	Outcome measures & main findings (I vs. C)				
	Researcher(s), year, Country	Patient groups, sample size	Delivery mode 1=in-hospital visit 2=home visit; 3=telephone follow-up; 4=patient initiated call	Provider and coordination mode 1=APN/ CNS/CNC/NP; 2=RN; 3=CN/PN/HCN; 4=physician; 5=allied health professionals; 6=social worker; 7=caregiver; 8=others; (=coordinator)	Coordination: 1=healthcare service; 2=social service; 3=healthcare referral or consultation (=Indirect)	a=physical respond; b=symptom control; c=mortality; d=others	Clinical outcome: a=anxiety/depression; b=coping; c=adherence; d=knowledge; e=others	Psychosocial outcome: a=quality of life; b=functional status; c=others	Functional outcome: a=readmission; b=length of stay; c=utilization of healthcare service; d=cost; e=others	Satisfaction: a=consumer; b=others
7.	Kwok et al., 2004 Hong Kong	Chronic lung disease I=77, C=80	1; 2; 4	3 ^A ; 4 (joint intervention)	1; 2; 3	24	NS ^d (6 MWD)	+ ^e (social handicap)	NS ^b	NS ^a , NS ^b , NS ^c
8.	Naylor et al., 2004 United States	Heart failure I=118, C=121	1; 2; 4	1 ^A ; 4 (joint intervention)	1; 2; 3	52		+ ^a , NS ^b	+ ^a , + ^b , + ^d	+ ^a
9.	Daly et al., 2005 United states	Mixed diagnoses** I=231, C=103	1; 2; 3	1 ^A ; 4; 5; 7; 8 (joint intervention)	1; 2; 3	8	NS ^c	+ ^a	NS ^a , + ^b , + ^d	
10.	Wong, Mok, et al., 2005 Hong Kong	Diabetes I=52, C=49	1; 3	1 ^A ; 4; 5 (joint intervention)	1; 3	24	NS ^a	+ ^c	NS ^a , + ^b , NS ^c , + ^d	NS ^a
11.	Coleman et al., 2006 United States	Mixed diagnoses** I=379, C=371	1; 2; 3	1 ^A ; 7 (joint intervention)	1 ^A ; 2 ^A	24			+ ^a , + ^d	
12.	Balaban et al., 2008 United States	Mixed diagnoses** I=47, C=49	1; 3	2 ^A ; 3; 4 (joint intervention)	1	4			NS ^a , NS ^c , + ^d (outpatient follow-up)	

I = Intervention group; C = Control group; APN = Advanced Practice Nurse; CNP = Clinical Nurse Specialist; CNC = Clinical Nurse Consultant; NP = Nurse Practitioner; RN = Register Nurse; CN = Community Nurse; PN = Primary Nurse; HCN = Home Care Nurse; 6 MWD = six minute walk distance;

*information from additional publication of the same study; **COPD diagnosis included; NS = Not significant; + = positive effect; - = negative effect

Table 2.2 Summary of study population, care features and outcomes on RCTs of home transitional care for chronic illness

Number	Study	Study population	Care features			Outcome measures & main findings (I vs. C)					
	Researcher(s), year, Country	Patient groups, sample size	Delivery mode	Provider and coordination mode		Duration of follow-up (weeks)	a=physical respond; b=symptom control; c=mortality; d=others				
			1=in-hospital visit 2=home visit; 3=telephone follow-up; 4=patient initiated call	Coordination: 1=healthcare service; 2=social service; 3=healthcare referral or consultation (=Indirect) 1=APN/ CNS/CNC/NP; 2=RN; 3=CN/PN/HCN; 4=physician; 5=allied health professionals; 6=social worker; 7=caregiver; 8=others; (=coordinator)			Clinical outcome: a=physical respond; b=symptom control; c=mortality; d=others	Psychosocial outcome: a=anxiety/depression; b=coping; c=adherence; d=knowledge; e=others	Functional outcome: a=quality of life; b=functional status; c=others	Fiscal outcome: a=readmission; b=length of stay; c=utilization of healthcare service; d=cost; e=others	Satisfaction: a=consumer; b=others
13.	Kwok et al., 2008 Hong Kong	Heart failure I=49, C=56	1; 2; 4	3 ^A , 4	1; 2; 3	24	NS ^d (6 MWD)		+ ^b	NS ^a , NS ^d	
14.	Wong et al., 2008 Hong Kong	Mixed diagnoses** I=166, C=166	1; 2	3 ^A (multidisciplinary supported)	3	4			NS ^b	NS ^a , NS ^d	+ ^a
15.	Allen et al., 2009 United States	Ischemic stroke I=190, C=190	1; 2; 3	1 ^A ; 2; 4; 5; 6 (joint intervention)	1; 2	24	NS ^c	+ ^d ; NS ^c (risk management)	NS ^a ; NS ^b	NS ^b	
16.	Parry et al., 2009 United States	Mixed diagnoses** I=49, C=49	1; 2; 3	2 ^A ; 7 (joint intervention)	1 ^A	12	NS			+ ^a	
17.	Zhao & Wong, 2009; China	Heart failure I=100, C=100	1; 2; 3	2; 3 ^A (joint intervention)	1 ^A , 3	12		+ ^c ; + ^d		NS ^a , - ^c	+ ^a
18.	Chalermwannapong et al., 2010 Thailand	Stroke I=33, C=34	1; 2; 3	2 ^A ; 3; 4; 5; 7 (joint intervention)	1; 2 ^A , 3	12			+ ^a , + ^b		

I = Intervention group; C = Control group; APN = Advanced Practice Nurse; CNP = Clinical Nurse Specialist; CNC = Clinical Nurse Consultant; NP = Nurse Practitioner; RN = Registered Nurse; CN = Community Nurse; PN = Primary Nurse; HCN = Home Care Nurse; 6-MWD = 6-minute walk distance;

*Information from additional publication of same study; **COPD diagnosis included; NS = Not significant; + = positive effect; - = negative effect.

Table 2.2 Summary of study population, care features and outcomes of RCTs of home transitional care for chronic illness

Number	Study	Study population	Care features			Outcome measures & main findings (I vs. C)					
	Researcher(s), year, Country	Patient groups, sample size	Delivery mode 1=in-hospital visit 2=home visit; 3=telephone follow-up; 4=patient initiated call	Provider and coordination mode 1=APN/ CNS/CNC/NP; 2=RN; 3=CN/PN/HCN; 4=physician; 5=allied health professionals; 6=social worker; 7=caregiver; 8=others; (^=coordinator)		Duration of follow-up (weeks)	Clinical outcome: a=physical respond; b=symptom control; c=mortality; d=others	Psychosocial outcome: a=anxiety/depression; b=coping; c=adherence; d=knowledge; i=others	Functional outcome: a=quality of life; b=functional status; c=others	Fiscal outcome: a=readmission; b=length of stay; c=utilization of healthcare service; d=cost; q=others	Satisfaction: a=consumer; b=others
19.	Chow & Wong, 2010 Hong Kong	Renal failure I=43, C=42	1; 3; 4	1 ^A ; 4; 7 (joined intervention)	3	12	+ ^b		+ ^a		+ ^a
20.	Wong, Chow, et al., 2010 Hong Kong	Kidney disease I=49, C=49	1; 3	1 ^A ; 2 (joined intervention)	3	13	NS ^a ; NS ^b	+ ^c	+ ^a	NS ^a ; NS ^c	+ ^a
21.	Qian et al., 2011 China	Stroke I=23, C=19	1; 2; 3; 4	2 ^A ; 7	3	12			NS ^a ; + ^b		+ ^a
22.	Wong et al., 2011 Hong Kong	Mixed diagnoses# I=272, C=283	1; 2; 3	1 ^A ; 4; 6; 8(volunteers) (joined intervention)	1 ^A ; 2; 3	12		+ ^b	+ ^a	+ ^a ; + ^b	+ ^a

I = Intervention group; C = Control group; APN = Advanced Practice Nurse; CNP = Clinical Nurse Specialist; CNC = Clinical Nurse Consultant; NP = Nurse Practitioner; RN = Registered Nurse; CN = Community Nurse; PN = Primary Nurse; HCN = Home Care Nurse;

*Information from additional publication of same study; # COPD diagnosis included; NS = Not significant; + = positive effect; - = negative effect.

Table 2.3 Summary of interventions in RCTs of home transitional care for chronic illness

Number	Study	Intervention duration	Care strategies								Time of initiate home visit or telephone follow-up (hour)	Care quality assurance strategies						
			Care planning, (Δ=individualised) Assessment, (Δ=comprehensive)	Goal setting	Education or counselling, (Δ=with reinforcement)	Psychosocial support	Medication reconciliation	Lifestyle intervention	Risk or symptom self-management	Ongoing monitoring of health problem, (Δ=adherence focused)		Protocol guided intervention	Evidence-based practice	Use of structured document	Use of the Omaha System	Use of education tool	Case or team conference or meeting	Training for healthcare provider or volunteer
1	Naylor et al., 1994	2	Y ^Δ	Y ^Δ	Y ^Δ					Y	<48	Y		Y				Y
2	Rich et al., 1993*, 1995	N	Y ^{Δ‡}	Y ^{Δ‡}	Y ^Δ	Y	Y [†]	Y	Y*	Y ^{Δ‡}	<48	Y*		Y*		Y		
3	Naylor et al., 1999; Naylor, 2000*	4	Y ^Δ	Y ^Δ	Y	Y ^Δ	Y	Y	Y	Y ^Δ	<48	Y	Y	Y	Y*	Y		Y
4	Egan et al., 2002	6	Y ^Δ	Y	Y ^Δ	Y			Y	Y ^Δ	<168	Y					Y	Y
5	Harrison et al., 2002	2	Y	Y	Y			Y		Y	<24	Y	Y	Y		Y	Y	
6	Laramée et al., 2003	12	Y	Y ^Δ	Y ^Δ	Y		Y	Y	Y ^Δ	<72	Y	Y	Y		Y	Y	Y
7	Kwok et al., 2004	24	Y ^Δ		Y ^Δ	Y	Y	Y	Y	Y ^Δ	<168	Y						Y
8	Naylor et al., 2004	12	Y ^Δ	Y ^Δ	Y	Y ^Δ		Y	Y	Y	<24	Y	Y	Y				Y
9	Daly et al., 2005	8	Y	Y ^Δ	Y	Y ^Δ	Y	Y		Y	<48	Y		Y			Y	Y
10	Wong, Mok, et al., 2005	fixable	Y ^Δ	Y	Y	Y ^Δ		Y	Y	Y	<168	Y		Y				
11	Coleman et al., 2006	4	Y	Y ^Δ	Y	Y ^Δ	Y		Y	Y	<72	Y	Y	Y				Y
12	Balabon et al., 2008	1	Y	Y	Y						<72	Y		Y		Y		
13	Kwok et al., 2008	24	Y ^Δ		Y ^Δ		Y	Y	Y	Y	<168	Y						

*Information from additional publication of same study; †provided by other provider; ‡provided by both nurse and other provider; Y = yes; NS = not specified.

Table 2.3 Summary of interventions in RCTs of home transitional care for chronic illness (Con't)

Number	Study	Intervention duration	Care strategies								Time of initiate home visit or telephone follow-up (hour)	Care quality assurance strategies							
			Assessment, (=comprehensive)	Care planning, (=individualised)	Goal setting	Education or counseling, (=with reinforcement)	Psychosocial support	Medication reconciliation	Lifestyle intervention	Risk or symptom self-management		Ongoing monitoring of health problem, (=adherence focused)	Protocol guided intervention	Evidence-based practice	Use of structured document	Use of the Omaha System	Use of education tool	Case or team conference or meeting	Training for healthcare provider or volunteer
14	Wong et al., 2008	4	Y [^]	Y [^]		Y [^]				Y	<168	Y	Y	Y			Y		
15	Allen et al., 2009	24	Y	Y [^]		Y			Y	Y	Y [^]	<168	Y	Y	Y				
16	Parry et al., 2009	4		Y [^]	Y	Y [^]	Y		Y	Y	Y [^]	<72	Y	Y	Y			Y	
17	Zhao & Wong, 2009	4	Y [^]	Y [^]	Y	Y [^]	Y	Y [†]	Y		Y [^]	<48	Y	Y	Y	Y		Y	
18	Chalermwannapong et al., 2010	4	Y	Y		Y [^]	Y		Y		Y [^]	<48	Y	Y	Y		Y	Y	
19	Chow & Wong, 2010; Zhou, 2006*	6	Y [^]	Y [^]	Y	Y [^]	Y		Y		Y [^]	<72	Y	Y	Y	Y	Y*	Y	
20	Wong , Chow, et al., 2010	6	Y [^]	Y [^]	Y	Y [^]	Y		Y		Y [^]	<72	Y	Y	Y	Y		Y	
21	Qian et al., 2011	4	Y [^]	Y [^]		Y [^]	Y		Y		Y [^]	<168	Y	Y	Y	Y	Y	Y	
22	Wong et al., 2011	4	Y [^]	Y [^]	Y	Y [^]	Y	Y [†]	Y		Y [^]	<168	Y	Y	Y	Y		Y	
Number of studies/Average (hour) [§]		7.95 [§]	21 14 [^]	20 15 [^]	10	22 19 [^]	14	10	17	12	21 17 [^]	96.00 [§]	22	13	19	7	8	7	
Mode		4										<168							

* Information from additional publication of same study; †provided by other provider; ‡provided by both nurse and other provider; Y = yes; N = not specified.

2.4.1 Findings of the review on home transitional care RCTs

Studies and study locations

Twenty-two RCTs were included in the present review (Allen et al., 2009; Balaban, Weissman, Samuel, & Woolhandler, 2008; Chalermwannapong et al., 2010; Chow & Wong, 2010; Coleman, Parry, Chalmers, & Min, 2006; Daly, Douglas, Kelley, O'Toole, & Montenegro, 2005; Egan, Clavarino, Burrridge, Teuwen, & White, 2002; Harrison et al., 2002; Kowk et al., 2004; Kwok, Lee, Woo, Lee, & Griffith, 2008; Laramée, Levinsky, Sargent, Ross, & Callas, 2003; Naylor et al., 1994, 1999, 2004; Parry, Min, Chugh, Chalmers, & Coleman, 2009; Qian et al., 2011; Rich et al., 1995; Wong et al., 2008; Wong, Chow, et al., 2010; Wong, Ho, Yeung, Tam, & Chow, 2011; Wong, Mok, et al., 2005; Zhao & Wong, 2009). These 22 RCTs were conducted in Australia, Canada, mainland China, Hong Kong, Thailand and the United States. Ten of the studies cited were carried out in the United States, the origin of transitional care.

Study populations

The study populations of the 22 trials included a range of chronic disease groups, including cardiac disease or heart failure, chronic lung disease or COPD, kidney disease or renal failure, and diabetes and stroke. Seven of the 22 studies tested a transitional care intervention with mixed medical diagnoses, and the other 15 were disease-specific. Eight of the studies involved a COPD population (Balaban et al., 2008; Coleman et al., 2006; Daly et al., 2005; Egan et al., 2002; Kwok et al., 2004; Parry et al., 2006; Wong et al., 2008, 2011).

Care features

Care delivery mode, care provider and care coordination were the care features examined.

Care delivery mode

All 22 of the RCTs met the inclusion criteria and included an in-hospital pre-discharge visit plus follow-up. A follow-up mode involving a home visit, telephone follow-up or patient-initiated call was applied in 15, 16 and 9 studies respectively. Seventeen studies included two or three follow-up modes.

Care provider

The providers of transitional care included nurses, physicians, allied health professionals (e.g. physiotherapists, occupational therapists and dieticians), social workers, caregivers and volunteers. About 70% (n = 15) of the studies involved a multidisciplinary intervention or multidisciplinary support. Caregivers (family members or caretakers) took part in the care process in about 45% (n = 10) of the studies.

Care coordination

Care was coordinated by an APN (clinical nurse specialist [CNS], nurse practitioner [NP] or nurse consultant [NC]) in half of the studies (n = 11); seven studies were led by registered nurses (RNs) and four by community nurses or home visit nurses. In 18 of the studies, nurses helped in the coordination of the healthcare service either directly (e.g. by arranging the healthcare service for the patients) or indirectly (e.g. by encouraging or instructing the patients to use the service). In 13 of the studies,

nurses also helped to arrange or coordinate social services for patients, and in 12 nurses referred the patients to physicians or allied health professionals, to a healthcare service such as the emergency room or recommended hospitalisation.

Duration, intensity and initial time of intervention and follow-up

The average duration of the interventions was calculated on the basis of the information provided in the 22 studies. The average duration was about 8 weeks, although the durations ranged widely (less than 1 week: n = 1; 2 weeks: n = 2; 4 weeks: n = 8; 6 weeks: n = 3; 8 weeks: n = 1; 12 weeks: n = 2; 24 weeks: n = 3). All of the studies began the intervention with an in-hospital visit during hospitalisation. Some began the intervention within 48 hours of admission to the ward and continued it throughout hospitalisation (Studies 1-6, 8, 10-11 and 19). All of them initiated the home visit or telephone follow-up within 7 days of discharge, and more than 60% (n = 14) initiated the post-discharge follow-up within 3 days. The follow-up duration ranged from 4 to 52 weeks, with an average of 16 weeks and mode of 12 weeks (n = 10).

Intervention: Care strategies and quality assurance

The most common care strategies applied in the 22 studies were assessment, care planning, education or counselling, and ongoing monitoring of health problems. The next most common strategy was lifestyle intervention (n = 17), followed by psychological support (n = 14), risk or symptom self-management (n = 12), goal setting (n = 10) and medication reconditioning (n = 10).

Programme implementation was guided by protocols in all 22 studies. The majority of the studies (n = 13) adopted evidence-based practice. Structured documents were used in 19 studies, and seven applied the Omaha System. Primary implementation of specific interventions for identified groups of patients with a secondary focus on family caregivers was found in 50% of the studies (n = 11). Educational tools to guide patients' interventions were specially designed in eight studies, and to qualify the healthcare providers or caregivers involved, including nurses, social workers and volunteers, seven studies provided intervention training.

Outcome measures and main findings on transitional care

A variety of primary and secondary outcomes in five categories were reported: clinical outcomes (n = 10), psychosocial outcomes (n = 9), functional outcomes (n = 16), fiscal outcomes (n = 19), and satisfaction outcomes (n = 12, included one study reported qualitative findings). Of the 22 studies, the five most frequently targeted outcomes were readmissions (n = 18), patient satisfaction (n = 12, included one study reported qualitative findings), quality of life (n = 10), costs (n = 10) and length of stay (n = 9). All of the studies reported positive findings in at least one category. The five most frequently reported outcomes exhibiting a statistically significant positive effect were quality of life (n = 8), readmission (n = 8), patient satisfaction (n = 8, quantitative findings not included), costs (n = 7) and length of stay (n = 6).

2.4.2 Insights from the review

2.4.2.1 People involved in transitional care

Transitional care is widely used in various groups of clients requiring extended care.

The main target groups for transitional care in the 22 RCTs reviewed here fell into one of two types, disease-specific or mixed disease diagnoses. All of the programmes were case management-driven, with nurses acting as case manager, coach, advocator or simply coordinator of the care or service. APNs played a vital role in transitional care in these studies. Fully half involved APNs delivering care to patients with positive outcomes (Allen et al., 2009; Chow & Wong, 2010; Coleman et al., 2006; Daly et al., 2005; Laramée et al., 2003; Naylor et al., 1994, 1999, 2004; Wong et al., 2011; Wong, Chow, et al., 2010; Wong, Mok, et al., 2005). Transitional care was provided through the joint efforts of or with support from a multidisciplinary or interdisciplinary team. A multidisciplinary team generally included professionals from the areas of medicine, physical and occupational therapy, pharmacy, nutrition, social work and community or home nursing. Patients and their family members or caregivers also participated in the care process in most studies.

As transitional care is aimed at cost-effective outcomes, the use of highly qualified nurses is emphasised in the literature. APNs usually assume responsibility for transitional care delivery, as they are regarded as well prepared for the role. Specially trained RNs and community nurses are also able to fulfil such responsibilities. In Egan et al. (2002), for example, an RN who had been appointed as the case manager of the respiratory unit contributed to the successful implementation of a case management programme. The authors strongly recommended the case manager role and suggested that a good case manager should have (1) advanced knowledge in the clinical specialty area; (2) well-developed communication and negotiation skills; (3) the ability to work as part of a multidisciplinary team; (4) the ability to advocate on behalf of clients; (5) education expertise for both clients and staff; and (6) knowledge

of outcome management. In addition to the training provided to healthcare providers, some of the studies provided special training or preparation to other caregivers such as volunteers (Wong et al., 2011) and patients' family members or caregivers (Allen et al., 2009; Chow & Wong, 2010; Naylor et al., 1994).

2.4.2.2 Transitional care interventions

The intervention elements (i.e. mode of delivery, dose, components and activities) varied from study to study. All of the reviewed hospital-to-home TCPs consisted of two phases of care: a discharge-planning phase and a postdischarge follow-up phase. However, the intensity of the interventions differed. Some of the studies initiated the in-hospital visit within 48 hours of admission followed by intensive visits, such as the three studies by Naylor and her team (Naylor et al., 1994, 1999, 2004), whereas others offered only one visit before discharge, such as those carried out in Hong Kong by Wong and her team (Wong et al., 2008, 2011; Wong, Chow, et al., 2010). Patient-centred discharge plans focus on the needs, preferences and goals of patients and their family caregivers, emphasising communication among patients, family caregivers and healthcare providers. In the studies considered here, postdischarge follow-ups were commonly delivered through both home visits and by telephone. Patient-initiated calls to obtain timely help were available in some studies. The first home visit took place, on average, 96 hours after discharge rather than within 48 hours, as recommended in the APN-led transitional care model proposed by Naylor et al. (1994, 1999). Most of the studies included a number of follow-ups, which allowed the provision of ongoing surveillance of changes in disease condition, treatment regimen, and health-related behaviour, reinforcement of knowledge and

skills for self care or disease self-management, psychosocial support for patients and caregivers and referrals when medical assistance was required.

The transitional care studies targeted at specific disease groups emphasised disease-specific evidence-based interventions (Allen et al., 2009; Chalermwannapong et al., 2010; Chow & Wong, 2010; Harrison et al., 2002; Laramée et al., 2003; Naylor et al., 2004; Qian et al., 2011; Zhao & Wong, 2009), and efficient programmes were characterised by the implementation of evidence-based protocols. Care quality was ensured by using information systems to facilitate smooth communication between healthcare providers and the healthcare system and to strengthen the relationship between healthcare providers and patients. A structured documentation system such as the Omaha System was generally applied to standardise nursing care.

2.4.2.3 Beneficial effects of transitional care

The desired outcomes of the TCPs involved all five areas of outcomes for clinical practice proposed by Urden (2001): clinical outcomes, psychosocial outcomes, functional outcomes, fiscal outcomes and satisfaction. Fiscal outcomes in terms of healthcare utilisation (i.e. readmission rate, frequency of readmission, time to first readmission, length of stay, emergency room visit, outpatient visit and use of other healthcare services) and costs were the main concerns of the transitional care studies. At least one positive outcome was associated with the transitional care interventions.

More positive outcomes were achieved in the programmes that adopted advanced access to knowledgeable healthcare providers, self-management education, an

individualised care plan, a guideline-based intervention, and multidisciplinary support or involvement. In addition, the more successful programmes for COPD tended to use APNs to carry out interventions; the programmes provided by respiratory ward RNs or community nurses were the least efficient (Balaban et al., 2008; Egan et al., 2002; Kwok et al., 2004; Parry et al., 2009; Wong et al., 2008).

2.4.2.4 Features of transitional care

On the whole, the studies under review demonstrated that transitional care meets patients' care needs during their transition from hospital to home through the provision of comprehensive, continuous, coordinated and collaborative care, dubbed the 4 Cs model by Wong, Mok, et al. (2005). Most or all of the features of the 4 Cs model are shared by many of the transitional care models discussed above, but Wong and her team proved the model to be effective in the Chinese population with chronic illnesses.

2.5 Summary of literature review

Suboptimal posthospital management is expected to lead to more frequent exacerbations and hospital readmissions, and is associated with increased mortality, impaired lung function and poor quality of life. Global strategies for the effective management of COPD emphasises treating the disease across its stages with both preventive and therapeutic measures. However, in mainland China, attention is often allocated to acute disease treatment rather than to the possibly more efficacious and cost-effective means of exacerbation prevention. Postdischarge continuity care is an urgent need among Chinese patients with COPD. Transitional care support is very

important if patients living with COPD are to be made less reliant on hospital care and stabilised in the community.

It is imperative that the implementation of transitional care be based on research-supported interventions. For COPD management, clinical guidelines offer recommendations for effective interventions. However, ways to apply these globally accepted recommendations in posthospital COPD exacerbation care and improve their performance have received little attention. In addition, although the positive outcomes reported in several studies contained samples of mixed disease diagnoses, including COPD, the results are not conclusive for COPD patients. Of the 22 home transitional care RCTs reviewed, only two were targeted at COPD as a single-disease group, and their findings showed TCPs to be less effective than those that investigated other chronic disease groups. Moreover, little is known about whether transitional care, integrated with pulmonary rehabilitation, health education and self-disease management, can help healthcare providers and patients in mainland China to manage COPD effectively.

This chapter reviews the impacts of COPD exacerbations, thereby demonstrating the urgent need for postdischarge care. This review of current strategies for management of the disease and efficient COPD management models suggested salient features for inclusion in the transitional model applied to the COPD patients in this study. It also shed light on the key outcomes that needed to be included to enhance the model's effectiveness.

CHAPTER THREE

METHODOLOGY

3.1 Introduction

This chapter focuses on the methodological issues involved in the study. The first section states the study hypotheses. The second section discusses the study's design, and the final section its ethical considerations.

3.2 Study hypotheses

The aim of the study reported in this thesis was to test the six following research hypotheses.

1. There will be no difference in exercise capacity between participants receiving transitional care and participants receiving usual care.
2. There will be no difference in HRQOL between participants receiving transitional care and participants receiving usual care.
3. There will be no difference in self-efficacy between participants receiving transitional care and participants receiving usual care.
4. There will be no difference in participant satisfaction between participants receiving transitional care and participants receiving usual care.
5. There will be no difference in the COPD-related readmissions between participants receiving transitional care and participants receiving usual care.
6. There will be no difference in the direct cost of COPD-related readmissions between participants receiving transitional care and participants receiving usual care.

3.3 Study design

A randomised controlled trial (RCT) was carried out to examine and explain the outcomes of the COPD-TCP. A series of validation studies were conducted to develop the validity and reliability of the questionnaires and study protocols used in the RCT. Focus group interview was used to collect secondary data from patients who underwent the COPD-TCP, complementing with the quantitative study in explaining the findings (Hennink, 2007). The study consisted of two stages (see Figure 3.1). Stage I was the preparation stage, and involved programme development and validation studies. Stage II was the main study, implementing the RCT and began with the training of nurse case managers (NCMs).

3.3.1 Randomised controlled trial

An RCT, the gold standard in scientific inquiry for evaluating the effect of an intervention (Polit & Beck, 2004; Schulz, Altman, Moher, & CONSORT Group, 2010), was adopted as the main methodology of this study to address the research objective, that is, to evaluate the effectiveness of a transitional care programme for Chinese patients with COPD by detecting the differences between an intervention and control group in clinical, psychosocial, functional, satisfaction and fiscal outcomes. The study's outcome measures were examined at baseline, immediately following the intervention period (6-week assessment) and at study exit (12-week assessment). Participants were randomly allocated to one of two groups, the control group or intervention group, to reduce selection bias. The study was single-blinded, that is, the data collector was blinded to the group allocation, but the intervention nurses were not. In addition, the participants were most likely aware of the group to

which they had been allocated by nature of the care they received at discharge and postdischarge.

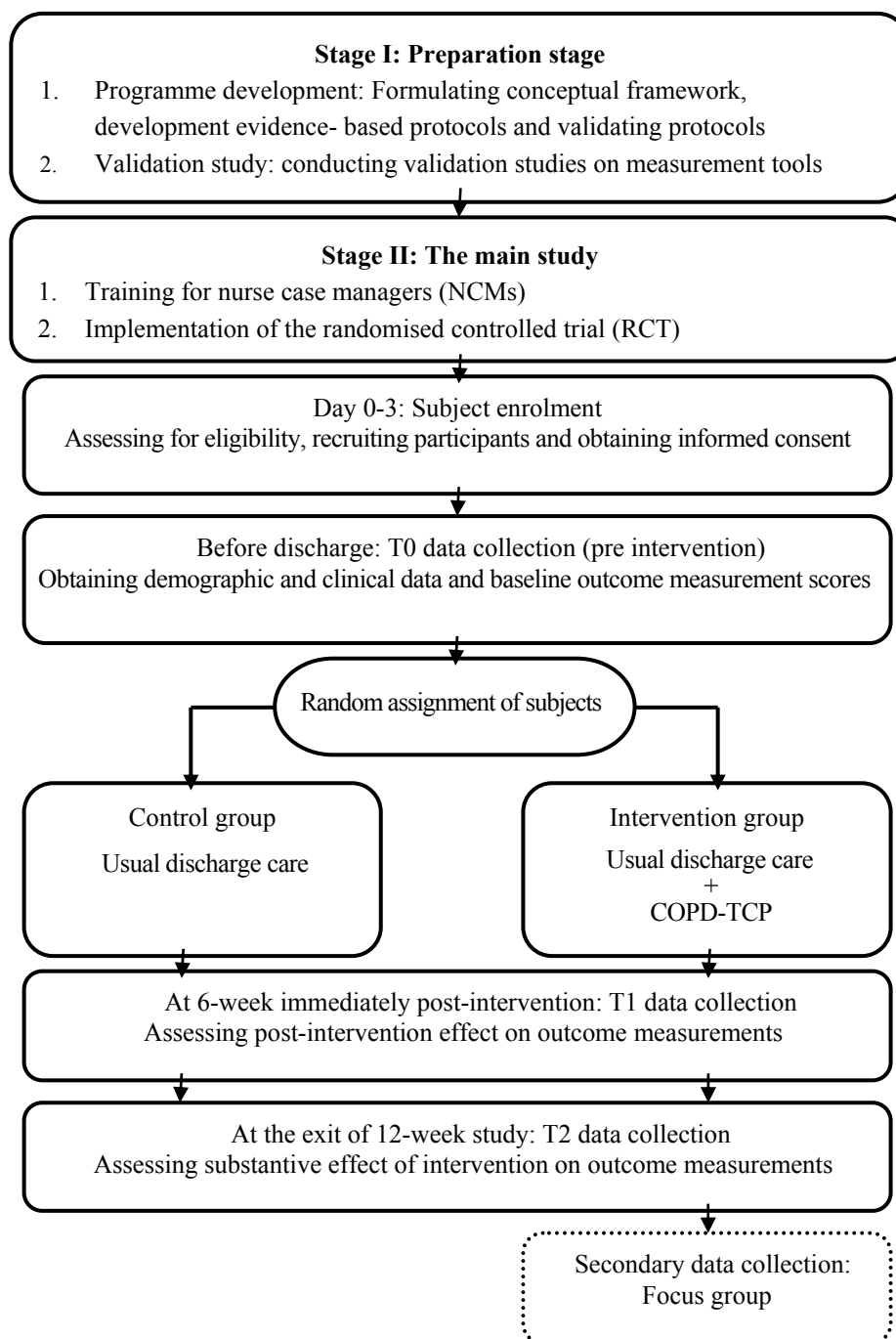


Figure 3.1 Flowchart of study stages

Additional strategies were taken to prevent the introduction of bias at each stage of the study. For example, participant enrolment and allocation were performed by a project coordinator who was not involved in the intervention or assessment. In addition, the NCMs who delivered the intervention to the intervention group took care of only those patients assigned to them, and were unaware of whether the remaining patients belonged to the control or intervention group. All data collected were indicated by code only to avoid identification. Moreover, strategies were adopted to eliminate between-group contamination. For example, if participants in both groups were admitted to the same hospital room, one of them was reassigned to another room to reduce the opportunity for intervention participants to meet control participants, and vice versa. Also, the discharge planning intervention was conducted in a separate area – the treatment room or health education room in the wards.

3.3.2 Validation study

Ensuring the quality of measurements is important in minimising measure-related error during the data collection process. In this study's preparation stage, validation studies were conducted on three of the questionnaires used in the main RCT (see Chapter 5 Method: Instrument validation). The intervention protocols that were specially designed to guide the study implementation also underwent validation procedures, including expert validation and pilot testing (see Chapter 4, section 4.5 validation of programme protocols).

3.3.3 Focus group

A focus group is a group of interviewees taking part in a focus group interview, in which the interviewer makes use of the communication between interviewees to

collect data (Kitzinger, 1995). Kitzinger (1995) considered this data collection method to be particularly useful for exploring people's attitudes and experiences, and regarded a group size of 4 to 8 participants as ideal. In this study, two focus group interviews were held. Group discussion was guided by a series of open-ended questions related to the COPD-TCP, and participants were encouraged to explore issues of importance to them. The group discussions were videotaped using a digital recorder.

In order to ensure optimal representation, patients who did not attend the focus group were asked to give their written responses on the exact questions asked in the focus group interviews. Data collected from focus groups were transcribed verbatim by nurse who was not involved in the study and experienced in doing transcripts. The transcripts were checked against the original audio by the doctoral student investigator. The patient written responses together with the interview transcripts were analysed .

Thematic analysis, a method for identifying, analysing and reporting patterns (themes) within data was employed in this study. Data analysis process was structured around the six phase process for conducting a rigorous thematic analysis proposed by Braun and Clarke's (2006). They were: (1) familiarising oneself with the data, (2) generating initial codes, (3) searching for themes, (4) reviewing themes, (5) defining and naming themes, and (6) producing the report. Braun and Clarke (2006) outlined the criteria for conducting good thematic analysis as listed below and they have guided the research team in the process of data analysis.

- The transcripts have been checked for accuracy.

- Equal attention has been given to each data item in coding.
- Themes have not been generated from a few vivid examples.
- All relevant extracts for each theme have been collected.
- Themes have been checked against each other and back to the original data set.
- Themes are coherent, consistent and distinctive.
- Data have been analysed rather than just described.
- The extracts illustrate the analytic claims.
- Analysis tells a convincing and well-organised story.
- There is a good balance between analytic narrative and extracts.
- Enough time has been given to complete all phases of the analysis.
- The assumptions about, and specific approach to, thematic analysis are clearly explicated.
- There is a good fit between what the researcher claims to do, and what is shown to have been done.
- The language and concepts are consistent with the epistemological position of the analysis.
- The researcher is positioned as active in the research process.

Two data analysers (the doctoral student investigator and another PhD student) independently analyzed the qualitative data. Then, they compared their results with each other and discussed to deal with the discrepancy. The discussions focused on (1) checking the equivalence of the translation on the extracts; and (2) examining if the themes could cover the data well and include relevant data, and the similarities and differences between the themes. During this process, another investigator, the chief

supervisor of the student did a member check after the data had been collected, translated and fully analyzed.

3.4 Ethical considerations

Prior to the initiation of this study, a study proposal was submitted for review. Ethical approval was obtained from The Hong Kong Polytechnic University Research Committee (Project ID: HSEARS20061221005), and administrative approval was granted by the hospitals that served as the sites for the main RCT and the validation and pilot studies. These were the First Affiliated Hospital of Guangzhou Medical University (which was involved in the main RCT and the validation studies), Guangdong General Hospital (involved in the questionnaire validation study) and First Affiliated Hospital, Sun Yat-sen University (involved in the protocol validation and pilot study). All of those who joined the RCT or validation studies received written information (Appendix 3.1a, 3.2a) on the nature and purpose of the study, a participant's right to privacy, confidentiality and anonymity, and assurance of the voluntary nature of participation and right to withdraw from the study at any time without adverse consequences. Formal written consent (Appendix 3.1b, 3.2b) was obtained from all participants prior to participation.

To ensure confidentiality, the research assistants, study nurses and doctoral student investigator responsible for data collection, documentation or statistical analysis kept all data and documents safe. Hard copies of the data and the digital recorder were stored in a locked filing cabinet, and electronic data were stored on a computer with password-protected access. The doctoral student investigator alone had access to all

of the raw data. Efforts were also made to ensure participants' anonymity. All questionnaires were assigned a study identification number and contained no personal identifying information. However, strict anonymity was not practicable for the nursing records or participants' action handbooks, because these bore the participants' names for intervention purposes. The alternative strategy of removing all names from the records once participants had exited the study was adopted instead.

The main study was designed to meet the postdischarge needs of patients with COPD. An RCT was carried out to test the effectiveness of an experimental intervention before its widespread implementation. Participants had an equal chance of being assigned to the intervention or usual care (control) group. They also had the right to withdraw at any time, even after they had agreed to participate, and healthcare services were not withheld from any participant. The intervention group received the experimental intervention in addition to the usual discharge care. The control group received usual discharge care, and were provided with a comprehensive assessment, tailored health education and a health educational booklet at study completion.

An assurance of safe practice was considered one of the most important issues in designing the intervention. Intervention protocols were developed in accordance with the best available evidence on beneficial support for patients with COPD. In the event of respiratory distress occurring during the assessment tests (spirometry and the 6MWT) or exercise training, an emergency protocol was in place to ensure participant safety throughout the study.

3.5 Summary

This chapter provides an overview of the study's research methodology. The next three chapters further describe the methods applied in each research stage, including programme development, instrument validation and RCT implementation.

CHAPTER FOUR

DEVELOPMENT OF THE COPD TRANSITIONAL CARE PROGRAMME

4.1 Introduction

The main goal of this study was to develop and implement a TCP suited to the needs of Chinese people with COPD and subject it to empirical testing. Programme development as a fundamental and initial stage of this goal underwent two main processes: formulation of a conceptual framework and development of programme protocols. This chapter details the COPD transitional care programme (COPD-TCP) and its development process. The first section describes the conceptual framework formulation and depicts a transitional care model. The second section summarises the approach and the methods used to develop programme protocols. The third section presents the intervention protocols, and the last section concludes with the programme's pilot testing.

4.2 Formulating the COPD-TCP conceptual framework

The conceptual framework was first developed to serve as a foundation of programme design. It was derived from the foregoing literature review, and based on the 4C's transitional care model (Wong, Mok, et al., 2005), Omaha System (Martin, 2005) and GOLD guidelines (GOLD, 2006).

4.2.1 The 4C's transitional care model

The 4C's transitional care model was developed by Wong, Mok et al. (2005) in a transitional care study of patients with diabetes in Hong Kong between 2001 and 2003 (Wong, Mok, et al., 2005). In this study, 101 participants were randomised into

a intervention group and a control group. The intervention group was discharged home with the support of a postdischarge follow-up programme that included a weekly or biweekly telephone call from a nurse to enhance patients' knowledge and skills for self-care. The results showed the intervention group to have had a greater decrease in Glycated hemoglobin (HbA1c), a higher blood monitoring adherence score, a higher exercise adherence score, a shorter hospital stay and a lower cost of care relative to the usual care group. Wong, Mok et al. (2005) concluded that it was feasible to integrate treatment into the real-life environments of patients with diabetes and that nurse-led transitional care was a practical and cost-effective model. The authors summarised the features of their transitional care model into four 'C's', namely, comprehensiveness, continuity, coordination and collaboration, and further elaborated upon them as follows.

- Comprehensiveness means that the case manager conducts a systematic assessment of the client's condition, is responsible for anticipating his or her needs and facilitates the transition to post acute care.
- Continuity refers to care that is ensured through regular, active and sustained follow-up.
- Coordination means that the case manager operates across the spectrum of care to collaborate with the healthcare team in responding to patients' needs.
- Collaboration not only occurs among healthcare professionals but also between provider and patient.

Since the initial 4C's transitional care model was developed, it has been tested in various patient groups (coronary heart disease, peritoneal dialysis, chronic kidney disease, elderly with chronic disease, colostomy and stroke) in both Hong Kong and

mainland China (Chow, 2006; Wong, Chow, & Chan, 2010; Wong et al., 2008, 2011; Yeung, 2012; Zhao & Wong, 2009; Zhang et al., 2011). It has been proved to be practicable and effective in Chinese settings and suitable for clients with chronic illnesses (Wong et al., 2011; Wong, Mok, et al., 2005; Zhao & Wong, 2009). The 4C's model provides a conceptualised structure for developing transitional care services in the Chinese healthcare system.

4.2.2 The Omaha System

The Omaha System (Martin, 2005) is a comprehensive and standardised classification system that originated at the Visiting Nurse Association of Omaha in the US state of Nebraska. It is a model that reflects the health situation of the individual, family and community based on the practitioner-client relationship; the value of the problem-solving process; and the concepts of critical thinking, clinical decision-making and quality improvement (Garvin, Martin, Stassen, & Bowles, 2008; Martin, 2005). The Omaha System includes three components (the Problem Classification Scheme [PCS], Intervention Scheme [IS] and Problem Rating Scheme for Outcomes [PRSO]) that offer a relational, reliable, and valid structure and set of terms to describe health and healthcare phenomena (Garvin et al., 2008; Martin, 2005).

The PCS is a taxonomy with four distinct hierarchical levels ranging from broad to specific: domain, problem, modifier, signs or symptoms (Martin, 2005). Problems are the fundamental concept used to describe health issues in the Omaha System, which includes 42 health problems grouped into four domains (environment, psychosocial, physical and health-related behaviour). Each problem is identified by

its associated signs and symptoms, focus (individual, family or community) and nature (health promotion, potential or actual). The PCS enables nurses to complete a client-centred comprehensive assessment, assists them in focusing on and quantifying clients' health-related concerns, and offers them cues and clues to guide nursing practice (Martin, 2005).

The IS is an organised framework of nursing actions or activities that are designed to address specific problems and to improve, maintain or restore health and/or prevent illness (Martin, 2005). It includes four categories of intervention (Martin, 2005): Teaching, Guidance, and Counselling (TGC); Treatments and Procedures (TP); Case Management (CM); and Surveillance (S). These four broad categories of intervention are accompanied by targets or objects of nursing action. The IS helps practitioners to organise their care plans, implement interventions specific to clients' problems and document the services they deliver (Garvin et al., 2008; Martin 2005).

The PRSO comprises three 5-point Likert-type scales that offer an evaluation framework for measuring a client's specific problems with regard to knowledge, behaviour and status (Martin, 2005). With ongoing assessment, the ratings serve two meaningful purposes: to guide the care plan and to indicate the client's progress throughout the care process (Martin 2005).

The Omaha System is designed to enhance practice, documentation and information management, and it supports evidence-based practice, quality improvement, critical thinking and communication (Martin, 2005; Martin, Monsen, & Bowles, 2011). It has been applied in a variety of clinical settings (i.e. hospital, home care, clinic and

community) and in many countries (e.g. Andorra, Canada, China, Japan, Korea, New Zealand, Sweden, the United Kingdom and the United States), and by a multidisciplinary team of practitioners, educators and researchers (Martin, 2005; Martin et al., 2011). A substantial body of research (transitional care studies included) has used it as a tool to organise and document intervention, analyse data, and evaluate outcomes for care quality monitoring and enhancement (Chow, 2006; Chow et al., 2008; Martin, 2005; Martin et al., 2011; Monsen, Westra, Yu, Ramadoss, & Kerr, 2009; Naylor, 2004; Wong, Wang, & Zhou, 2010; Zhao & Wong, 2009).

4.2.3 The GOLD guidelines

The GOLD guidelines are a set of evidence-based guidelines specifically designed, following concerted worldwide effort, to provide global strategies for the diagnosis, management and prevention of COPD. Since the first GOLD guidelines were published by the NHLBI and WHO in 2001, they have been periodically updated and made available on the GOLD website (<http://www.goldcopd.com/>). The GOLD guidelines are the most referenced COPD practice guidelines worldwide, and the 2006 updated version (GOLD, 2006) was adopted as the basic national guideline for the diagnosis and treatment of COPD in mainland China (Chinese Medical Association Respiratory Disease Branch COPD Group, 2007).

According to the GOLD guidelines (GOLD, 2006), an effective COPD management plan includes four components: assess and monitor the disease, reduce risk factors, manage stable COPD and manage exacerbations. The goals of effective COPD management are to: (1) prevent disease progression; (2) relieve symptoms; (3) improve exercise tolerance; (4) improve health status; (5) prevent and treat

complications; (6) prevent and treat exacerbations; and (7) reduce mortality. The benefits and risks to the individual concerned and the costs to the community are also to be considered when selecting a management plan (GOLD, 2006). The GOLD guidelines not only indicate the direction and outcomes of COPD management, but also provide scientific evidence to guide the design of the specific interventions required.

4.2.4 The 4C's COPD transitional care model

This study built upon the foregoing conceptualised framework, with the intervention constructed as an integrated model. This model, the 4C's COPD transitional care model (COPD-TCM hereafter), is able to respond to the current healthcare system reform in mainland China, which emphasises the provision of more accessible and affordable healthcare. The 4C's in the name refer to the aforementioned 4C's transitional care model developed by Wong, Mok et al. (2005), the Omaha System (Martin, 2005) provides the model with a framework for the assessment, intervention and outcome management process, and the GOLD guidelines (GOLD, 2006) guide the evidence-based disease-specific management. The COPD-TCM also incorporates the concepts of holistic care, evidence-based practice, disease self-management and outcome management, and client, client-nurse and client-nurse-system interface. Figure 4.1 provides an overview of the model.

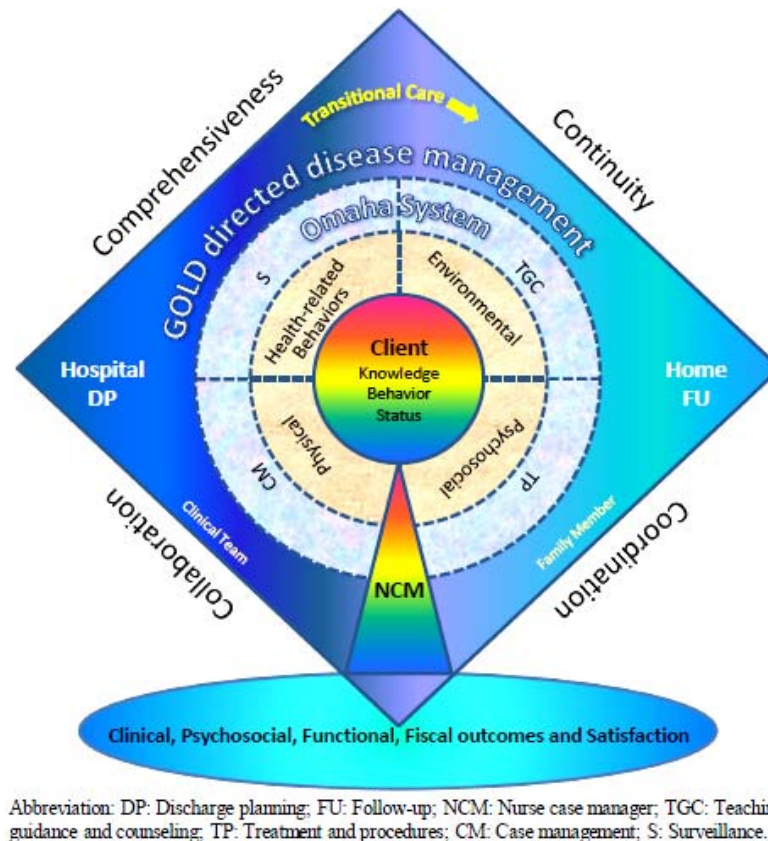


Figure 4.1 The 4C's COPD-TCM

COPD is a chronic disease that not only impairs the individual sufferer's functioning and quality of life, but imposes a heavy burden on his or her family, society and the healthcare system. The key goal of the COPD-TCM is to help clients to live with COPD and to enjoy an optimal quality of life. The model provides comprehensive discharge planning and home follow-up care for clients hospitalised for COPD. The care is led by specially trained respiratory nurses, who act as NCMs and operate across the spectrum of care. With managerial support from the hospital, the NCMs coordinate care in response to the individual client's needs, and collaborate with a clinical team, as well as with clients and their family members, to continue the care from hospital to home. The Omaha System, which provides a holistic approach, addresses clients' unmet needs with regard to knowledge, behaviour and status related to their health problems, which fall into one of the four domains of

environmental, psychosocial, physical and health-related behaviour. The NCMs provide GOLD-directed evidence-based care through teaching, guidance and counselling, treatment and procedures, case management, and surveillance to help solve clients' health problems. The clients to whom the model is delivered are expected to make continual efforts at COPD self-management to facilitate changes in knowledge, behaviour and status, which it is hoped will, in turn, improve clinical, psychosocial, functional, fiscal outcomes and satisfaction.

4.3 Developing evidence-based protocols

Evidence-based protocols constitute a series of evidence-based written care plans specifying the procedures to be followed in providing transitional care to patients with COPD. They are formulated to ensure that consistent quality of care is received across patients, thereby also ensuring the quality of the research reported herein. To provide quality care, nurses must implement interventions based on the best research evidence available (Brown, 2009; Polit & Beck, 2008). Making informed decisions about appropriate interventions for patients is an important starting point for quality care and the key to successful implementation of the COPD-TCP. Making such decisions requires knowledge integrated from the best available research evidence, clinical expertise and patient preferences, a well-established approach known as evidence-based practice (Marshall, 2006; Sackett, Straus, Richardson, Rosenberg, & Haynes, 2000) and one that was adopted in the current study to develop the intervention protocols for the COPD-TCP.

4.3.1 Generating best research evidence

As COPD is a global healthcare problem that has attracted the interest of researchers and healthcare professionals around the world, practical resources to support evidence-based intervention are rapidly evolving. Collins, Voth, DiCenso, and Guyatt (2005) proposed that, to answer a focused foreground question, the most efficient approach is to begin with a pre-processed resource. Pre-processed resources are products that are reviewed and have been chosen from the methodologically strongest and clinically most important studies. The ascending hierarchy of pre-processed information is: single original studies, synopses of single studies, syntheses (systematic reviews), synopses of syntheses (evidence-based journal abstracts) and systems (practice guidelines, clinical pathways or evidence-based textbook summaries) (Collins et al., 2005).

The literature search conducted for protocol development began with the highest level of resources suggested by Collins et al. (2005) and focused on the highest level of recommendations drawn from the GOLD guidelines (GOLD, 2006, 2008) and related international clinical guidelines for COPD management. These recommendations are to base interventions on evidence from well-designed RCTs that provide a consistent pattern of findings in the population (GOLD, 2006, 2008). Nine international guidelines, 15 systematic reviews or meta-analyses and 64 RCTs were consulted for the best research evidence adopted in this study. In addition to evidence from the literature, local current practice standards, procedures, protocols and policies were also reviewed (Marshall, 2006), as the aim of the study was to develop and implement a transitional programme that was tailor-made to suit the needs of Chinese people with COPD.

4.3.2 Interfacing evidence and expert clinical practice

Clinical expertise refers to informed opinion from multidisciplinary experts in the given specialism, the individual and collective experience of expert nurses in specialist practice, and outcomes associated with traditional practice (Marshall, 2006). Development of the 4C's COPD-TCP was based primarily on the experience of Hong Kong and overseas countries. The programme took into account factors related to the clients, healthcare providers and healthcare system, and its feasibility, practicality, cultural adaptability and appropriateness were all assessed. To gain valuable clinical experience, the research team carried out clinical observations and site visits and conducted an expert interview.

The clinical observations and site visits took place in the early stage of the research design. The principal investigator (who was also the chief supervisor of this thesis's student author) and student investigator, or the student investigator on her own, went to three hospitals and three community centres in Hong Kong to observe their inpatient, outpatient and home-based pulmonary rehabilitation programmes or extended health services for patients with COPD. The investigators also paid site visits to two potential research hospitals and six community centres in Guangzhou to learn about local clinical practice and policies, as well as the structure and operation of the mainland healthcare system.

During the protocol development process, the student investigator paid visits to 20 experts in Hong Kong and Guangzhou. These experts included an APN (rehabilitation), APN (respiratory), APN (community nursing), nursing manager (community and extended care services), nursing manager (community nursing),

nursing professors, the Nursing Director of the Health Bureau, consultants in-charge and professors of respiratory medicine, nutrition specialists, occupational therapists, physiotherapists, an academic professional in rehabilitation, and a lung function test technician. They provided their opinions on the planning of the research and on the practical considerations involved in implementing transitional care in a mainland Chinese setting. These experts also provided valuable suggestions on the components of the programme, including medication regimen, nutrition, disease self-management, and home-based rehabilitation multidisciplinary collaboration, as well as the conducting of the lung function test and introduction of the physiotherapy and occupational therapy techniques.

4.3.3 Considering patient preferences

Patient preferences refer to the expectations, concerns and requirements that patients bring to the clinical experience, and involve ethnic, religious, gender, age, psychosocial and ethical influences (Malloch & Porter-O'Grady, 2006; Marshall, 2006). Surveys, interviews and home visits were conducted in Guangzhou to learn about patients' preferences.

The care needs of the patients were first surveyed during questionnaire validation studies. A total of 150 COPD outpatients and 53 AECOPD inpatients gave responses to three questions. To the first question, "Do you need to be taken care of by others during sickness?", more than half the respondents ($n = 108$, 52.7%) answered yes, with the inpatient group expressing a much greater need (outpatients: $n = 64$, 42.7%; inpatients: $n = 44$, 83.0%). To the second question, "Who takes care of you during sickness?", most ($n = 197$, 96.1%) reported being taken care of by a family member

or helper (outpatients: $n = 145$, 96.7%; inpatients: $n = 52$, 98.1%). To the last question, “What is the time availability of the care you receive?”, a majority of respondents ($n = 178$, 86.8%) said they could receive care from a family member or helper anytime (outpatients: $n = 138$, 92.0%; inpatients: $n = 40$, 75.5%). The remaining 18.0% ($n = 27$) said they could access such care some of the time (outpatients: $n = 12$, 8.0%; inpatients: $n = 13$, 24.5%). These findings suggested that patients with COPD need continuous support, particularly those who have been hospitalised and then discharged with AECOPD.

Face-to-face interviews were then conducted to further explore patients’ acceptance of and expectations for transitional care. Four male and two female patients admitted with AECOPD (mean age: 72.67 ± 4.8 years, mean COPD history: 12.50 ± 6.9 years) participated in these interviews. They all said that the first time for them to hear about such a service was when the investigator introduced the transitional care concept to them. When asked whether they would accept follow-up care from nurses to assist their recovery, five answered in the affirmative, and one said that he did not have any need for such care. In discussing their history and experience of the disease, their chief complaint was shortness of breath, which limited their daily activities. They were especially concerned about their course of recovery, the frequent onset of their disease and the burden of the medical costs involved. They expected that a transitional care service would help to alleviate their suffering, help them to recover speedily and decrease their medical costs.

Finally, home visits were paid to eight community COPD patients (six men and two women, with a mean age of 70.63 ± 11.2 years and a mean COPD history of $12.25 \pm$

9.0 years) to investigate the actual needs of this patient population. The common health problems identified included respiratory problems, non-adherence to medication regimen, poor inhalation technique, lack of self-care knowledge and skills, lack of regular exercise and indoor air pollution caused by cooking fumes or burning incense.

4.4 Evidence-based protocols of the COPD-TCP

The information collected through best research evidence, clinical expertise and patient preferences provided the basis for the structural design of the COPD-TCP, as well as the components and procedures of the protocols for that design.

4.4.1 Overview of the COPD-TCP

Patients with COPD are at risk of recurrent exacerbations and hospital readmissions, as most are discharged when their symptoms are under control but not necessarily completely resolved (GOLD, 2006; Mushlin, Black, Connolly, Buonaccorso, & Eberly, 1991; Sharma, Kuo, Freeman, Zhang, & Goodwin, 2010). Follow-up assessment is recommended for 4 to 6 weeks after hospital discharge for patients recovering from an episode of AECOPD (GOLD, 2006), and pulmonary rehabilitation programmes of 6-12 weeks are also recommended (British Thoracic Society Pulmonary Rehabilitation Guideline Development Group, 2012; GOLD, 2006). The minimum length of an effective programme is 6 weeks (GOLD, 2008). Researchers have also reported that a 6-week TCP can have positive effects (Chow, 2006; Egan et al., 2002). Apart from the above research evidence, calculation on the previous year's COPD admission data provided by the study hospital showed that among those readmitted cases, 50% readmissions were within 42 days (6 weeks)

postdischarge. Resource input such as available manpower and time, one of the major concerns of hospital managers was also taken into consideration. As an innovative and original programme, the research team would like to see if a TCP designed with suggested minimum duration could benefit Chinese patients with COPD. Guided by the 4C's COPD-TCM, a 6-week nurse-led COPD-TCP was designed specifically for Chinese COPD patients discharged from hospital to home.

The COPD-TCP consisted of two phases: predischage planning and home follow-up. The predischage planning phase was designed to prepare patients and caregivers for home care, and had the following specific purposes.

- To identify patients' COPD self-management needs and readiness in the domains of environmental, psychosocial, physical and health-related behaviour.
- To empower patients with the knowledge and skills necessary to engage in COPD self-management and home-based rehabilitation.
- To cultivate in patients a positive attitude towards COPD and health behaviour modification.
- To further family members' understanding of the importance of family support in improving patients' health status.
- To initiate a plan for home care with patients' active participation.

The programme intervention protocols were initiated at least 72 hours before discharge.

The intent of the home follow-up was to provide seamless home-to-hospital care to patients through the ongoing implementation of the programme intervention

protocols. The follow-up intervention lasted 6 weeks, and involved two home visits (within 72 hours of discharge and at 4 weeks postdischarge), four telephone follow-up calls (at weeks 2, 3, 5 and 6 postdischarge) and a 24-hour NCM hotline. The overall aims of the home follow-up were to provide continual professional support to patients and their families, as well as to facilitate active implementation of home-based rehabilitation and self-management of the disease. The following specific objectives were set for each of its components.

- Home visits: (1) to assess the patients' living environment so as to identify environmental risk factors and provide appropriate advice; (2) to identify and discuss problems encountered by patients in adapting to normal life after discharge; (3) to adjust the goal of the care plan according to the real living condition; and (4) to reinforce the health education provided to the patient and family members in the predischARGE planning phase.
- Telephone follow-ups: (1) to check whether the patient was following the care plan; (2) to provide encouragement and reinforcement to patients regarding their progress; (3) to discuss patients' problems and concerns with them; (4) to provide psychosocial support to patients; and (6) to readjust the goal and care plan if needed.
- Hotline: to enable patients to seek timely help and to discuss their condition or concerns with their NCMs, as needed.

The care programme was delivered by NCMs for each patient with support from a hospital clinical team. The clinical team comprised both frontline professionals, i.e. a physician and nutrition specialist who worked closely with the NCMs when required, and managers (i.e. department directors in respiratory nursing or medicine, head

nurses and a project coordinator) who provided managerial support and facilitated coordination of the programme's implementation.

Implementation of the COPD-TCP was guided by four evidence-based intervention protocols: the surveillance protocol; teaching, guidance and counselling protocol; treatment and procedure protocol; and case management protocol. The protocols are described in detail in the following paragraphs, along with the rationales for each.

4.4.2 Surveillance protocol

Because COPD is a progressive disease, a patient's lung function can be expected to worsen over time. According to the GOLD guidelines, it is important to assess symptoms, to monitor disease progression and the development of complications, and to monitor pharmacotherapy and other medication treatment (GOLD, 2006, 2008).

The nursing intervention began with an assessment to identify the client's problems. This assessment was designed both to identify new problems and to determine which problems required ongoing monitoring and evaluation. Thus, the surveillance protocol had two interrelated parts: assessment and surveillance.

Part one: Assessment

Assessment was based on the PCS of the Omaha System, and covered 33 of the 42 COPD-related problems in the PCS. Signs and symptoms were noted from an observation, physical examination, physical and functional measures, laboratory

results and assessment results. The components and procedures of assessment were as follows.

- Comprehensive assessment of environmental, psychosocial, physical and health-related behaviour using the Assessment and Evaluation Form (Appendix 4.1) was carried out during an inpatient visit (72 hours before discharge) and in follow-up home visits (within 72 hours of discharge and at week 4 postdischarge).
- Brief Omaha problem assessment of previously identified environmental, psychosocial, physical and health-related behaviour problems through weekly telephone call (at weeks 2, 3, 5 and 6 postdischarge) using the Telephone Follow-up Record (Appendix 4.2).
- Physical examination of chest, vital signs, SpO₂, height and weight (before discharge).
- Review of spirometry, 6MWT, blood glucose and other test results when needed (before discharge).
- Measurement of disability using the MRC dyspnoea scale (Bestall et al., 1999) (at each visit).
- Observation of colour, amount, consistency, and odour of sputum and of skin colour (at each visit).
- Nutrition assessment based on percentage of ideal body weight, BMI, and albumin (before discharge) and 24-hour diet recall (during the first home visit).
- Assessment of baseline inhalation technique if inhaler was prescribed (before discharge) using the Inhalation Technique Checklists.

- Assessment of baseline knowledge and skills, as required, using the Health Education Records (before and after teaching during each visit).
- Assessment of exercise performance using the Exercise Intensity Assessment Form and based on patients' before- and after-exercise Borg dyspnoea and fatigue scores and SpO₂ (before and after walking and arm exercise).

Part two: Surveillance

Surveillance focused on patients' current status and the progression of or changes in signs and symptoms or knowledge and behaviour related to the problems identified in the previous encounter. The targeted components for surveillance included the following.

- Environment: indoor air pollution (dust, odours, cooking practices and incense burning).
- Exercise: adherence to 6-week home-based exercise training (at least 3 days per week and 30 days in 6 weeks) and progression and adverse effects, if any.
- Signs and symptoms-physical: evidence of disease or infection (lung sounds, vital signs, blood pressure, skin colour) and changes in symptoms (cough, sputum colour, amount and characteristics, shortness of breath).
- Signs and symptoms-mental/emotional: evidence of anxiety and/or depression.
- Relaxation and breathing techniques: use of breathing technique (pursed-lip breathing) and energy conservation technique when needed.
- Medication action and side effects: possible side effects of medication taken (e.g. yeast infection).

- Medication administration: adherence to medication regimen, inhalation technique and adherence to oxygen therapy if applicable.
- Medication setup: medication organisation and storage.
- Medical care: receipt of care as scheduled and adherence to COPD action plan.
- Dietary management: weight monitoring and adherence to dietary recommendations or diet prescribed.
- Behaviour modification: smoking cessation if applicable.
- Durable medical equipment: correct use of oxygen and oxygen delivery devices if applicable.

The three sets of nursing records and evaluation forms used in the assessment served as a guide for the NCMs in conducting ongoing patient assessment and evaluation.

4.4.3 Teaching, guidance and counselling protocol

The GOLD guidelines recommend health education as an essential component of any COPD management programme (GOLD, 2006, 2008). An effective health education programme should address the knowledge and skills necessary for patients to adhere to medical regimens and disease-specific nursing procedures that guide changes in health behaviour and provides patients with the emotional support needed to control their disease and live optimal-quality lives (Effing et al., 2007).

Teaching, guidance and counselling were provided throughout the programme, starting with a 30-minute face-to-face teaching session during the pre-discharge planning phase and continuing on to the home follow-up phase (NCM home visits and weekly phone calls). Patients' family members or caregivers were invited to join

this process wherever possible. The health education and telephone follow-up records were used to facilitate the process and allow the NCMs to intervene on the basis of individual need. A package of educational materials was provided to each patient prior to discharge, including a booklet entitled *Rehabilitation Trip: Action Plan Guide*; handbook called *Rehabilitation Trip: Action Plan Handbook*, which was accompanied by an action plan; healthcare service information; and a self-monitoring measure, such as the two modified Borg Scales, i.e. the Borg Rating of Perceived Exertion Scale and Borg Rating of Perceived Dyspnoea Scale (Borg, 1982; Kendrick, Baxi, & Smith, 2000).

The contents of the following teaching, guidance and counselling target interventions were compiled in accordance with several guidelines (see Table 4.1), and teaching, guidance and counselling were provided in the following areas.

- a. Disease anatomy and physiology: respiratory system and COPD disease process and risk factors.
- b. Physical signs and symptoms: typical symptoms of COPD, prevention of exacerbation, importance of self-monitoring and symptom management (action plan).
- c. Respiratory care: importance of disease self-management; preventive measures to minimise the risk of flare-up, including avoidance of allergens, second-hand smoke, indoor and outdoor air pollution, and temperature extremes; and personal hygiene and coughing technique.
- d. Exercise: importance of daily exercise, and the recommended 6-week home-based exercise training programme.

- e. Medication action and side effects: prescribed oral and inhalation medication, e.g. bronchodilators, glucocorticosteroids, antibiotics, mucolytic agents and any other drugs.
- f. Medication administration: importance of adherence to medication regimens; correct dose, frequency, schedule and number of drugs as prescribed; and correct inhalation technique and inhaler care.
- g. Medical care: outpatient follow-up as scheduled.
- h. Relaxation and breathing techniques: pursed-lip breathing, relaxation exercise if needed.
- i. Mobility and transfers: balanced rest and activity.
- j. Dietary management: nutrition and COPD, nutrition assessment (24-hour diet recall record), eating a healthy, balanced diet for well-nourished patients, dietary advice for the under- and over-nourished, and referral to nutrition specialist for prescribed diet in special cases.
- k. Durable medical equipment, safety and physical signs and symptoms of home oxygen (if home oxygen therapy prescribed): rational administration of oxygen (> 15 hours per day) to increase survival (GOLD, 2008), care of oxygen and oxygen delivery devices, oxygen safety precautions, reporting signs and symptoms, and recording daily oxygen administration.
- l. Substance use cessation: importance of smoking cessation for current smokers.
- m. Others: use of the teaching booklet, daily log, healthcare service information card and Borg scales.

Table 4.1 Topics for COPD education programme, as suggested by clinical guidelines

Topics	Guidelines*			
	NCCCC, 2004	ATS/ERS, 2006	IPCRG, 2006	GOLD, 2008
COPD knowledge: nature, risk factors	✓	✓	✓	✓
Exacerbation management/Action plan	✓	✓	✓	✓
Medication/Inhalation techniques	✓	✓	✓	✓
Breathing strategies/Dyspnoea management	✓	✓	✓	✓
Smoking cessation/Irritant avoidance	✓	✓	✓	✓
End-of-life issues/Advance directives/Coping	✓	✓	✓	✓
Benefits of physical exercise	✓	✓	✓	
Oxygen therapy	✓	✓		✓
Nutrition/Diet	✓	✓	✓	
Anxiety/Depression/Emotion management	✓	✓	✓	
Self-management skills	✓	✓		✓
Seeking help/Use of adaptive aids	✓	✓		✓
Energy conservation/Work simplification techniques	✓	✓		
Secretion clearance techniques	✓	✓		
Relaxation/Stress management	✓	✓		
Leisure, travel	✓	✓		
Loving relationships/Sexuality	✓	✓		
Health-related behaviours	✓			
General therapy				✓
Home-care support	✓			
Complications				✓
Co-morbidities			✓	
Vaccination	✓			
Goal setting and rewards	✓			
Making a change plan	✓			
Benefits system	✓			
Support group	✓			
Managing surgery (non-thoracic)	✓			

Guidelines*: NCCCC, 2004: Chronic obstructive pulmonary disease. National clinical guideline on management of chronic obstructive pulmonary disease in adults in primary and secondary care (NCCCC, 2004); ATS/ERS. 2006: American Thoracic Society/European Respiratory Society statement on pulmonary rehabilitation (Nici et al., 2006); IPCRG, 2006: International Primary Care Group (IPCG) guidelines: Management of chronic obstructive pulmonary disease (COPD) (Bellamy, 2006); GOLD, 2008, Global initiative for chronic obstructive lung disease: Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease, Updated 2008 (GOLD, 2008).

4.4.4 Treatment and procedures protocol

The treatment and procedures protocol involved the treatment regime prescribed by the patient's physician and nursing procedures specifically designed for the COPD-TCP. It had two targets: nursing care and exercise.

Nursing care

Nursing care consisted of the following procedures.

- a. Understanding the patient's expectations of the COPD-TCP
- b. Setting mutual goals with the patient at each visit and telephone follow-up
- c. Creating an individualised care plan before discharge (Appendix 4.3) and duplicating it in the patient's daily log
- d. Reviewing the care plan during home follow-up
- e. Monitoring the patient's adherence to prescribed medication regimen

Exercise

The GOLD guidelines posit that all COPD patients benefit from following an exercise training programme (GOLD, 2006, 2008). The results reported in these guidelines and in meta-analyses and Cochrane reviews have demonstrated that pulmonary rehabilitation increases exercise tolerance, reduces perceived dyspnoea, fatigue, anxiety, depression, hospital readmissions and mortality, and improves patients' sense of control over their condition and their quality of life (GOLD, 2008; Lacasses, Martin, Lasserson, & Goldstein, 2007; Puhan et al., 2011; Salman, Mosier, Beasley, & Calkins, 2003).

In addition to the GOLD guidelines, three other pulmonary rehabilitation guidelines were used to substantiate the exercise training plan: (1) BTS statement (British Thoracic Society Standards of Care Subcommittee on Pulmonary Rehabilitation, 2001); (2) ATS/ERS statement (Nici et al., 2006); and (3) ACCP/AACVPR guidelines (Ries et al., 2007).

According to these guidelines, pulmonary rehabilitation is effective at any stage of the disease (GOLD, 2008) and in all settings, including the patient's home (British Thoracic Society Standards of Care Subcommittee on Pulmonary Rehabilitation, 2001; Nici et al., 2006). Training of the muscles of ambulation (walking or cycling exercise) is a mandatory component of any rehabilitation programme, and upper extremity training should also be included. A combination of endurance and strength training has multiple beneficial effects in increasing muscle strength, muscle mass and overall endurance (Nici et al., 2006; Ries et al., 2007). The minimum length of an effective rehabilitation programme is 6 weeks (GOLD, 2008), and the benefits of a 6- to 12-week programme wane over 12 to 18 months (Ries et al., 2007). A programme with a minimum of 20 sessions should be provided, and patients should perform exercises at least three times per week to achieve physiologic benefits (Nici et al., 2006). Both low- and high-intensity exercise training produce clinical benefits (Ries, 2007), and both interval and continuous training can be applied safely and effectively (British Thoracic Society Standards of Care Subcommittee on Pulmonary Rehabilitation, 2001). A 6-week home-based exercise training plan involving both lower and upper extremity training was specially designed for the patients joining the COPD-TCP. The detailed plan is as follows.

Exercise training components

- Walking exercise training: daily walking at high-level intensity ($> 60\%$ maximal work rate or symptom limited), 30 minutes per day for 6 weeks; interval training (repeated periods of near-maximal exercise alternating with short intervals of rest) for patients who are more disabled because of COPD (Nici et al., 2006).
- Upper extremity training: daily unsupported arm exercise, once per day for 6 weeks, without weights (Level 1 to Level 3) in the first 3 weeks and with weights (Level 4 to Level 6) in the second 3 weeks, adding one level of exercise each week (if a given level had been completed for a consecutive week). Table 4.2 presents the prescription for the upper-arm exercise and its recommended intensity (levels). The arm exercises were modified from Bauldoff, Hoffman, Sciurba, and Zullo (1996), and are detailed in Chapter 6.

Table 4.2 Prescription for the upper-arm exercise*

Description	
Type of exercise	Unsupported arm exercises with or without weights
Number of sets	3
Number of repetitions	6
Intensity	Light weights (0-1.2 kg)/high repetitions (3 sets x 6 repetitions) Level 1-3 without weight for the first 3 weeks if appropriate Level 4-6 with weight for the next 3 weeks if appropriate • Level 1 (L1): 1 set x 6 repetitions without weight • Level 2 (L2): 2 set x 6 repetitions without weight • Level 3 (L3): 3 set x 6 repetitions without weight • Level 4 (L4): 3 set x 6 repetitions with 0.2 kg weight in each hand • Level 5 (L5): 3 set x 6 repetitions with 0.4 kg weight in each hand • Level 6 (L6): 3 set x 6 repetitions with 0.6 kg weight in each hand
Programme duration	6 weeks
Training frequency	Daily

*This upper-arm exercise is modified from Bauldoff et al. (1996).

The use of supplemental oxygen during exercise is recommended when SpO₂ is below a value of 90% (British Thoracic Society Standards of Care Subcommittee on Pulmonary Rehabilitation, 2001).

Intervention procedures

- Before discharge: exercise plan initiated by assessing the patient's physical and psychosocial readiness and health-related exercise behaviour, discussing the importance of exercise, teaching 3 sets of upper-arm exercises and encouraging postdischarge practice (see also 4.4.2 Surveillance protocol: Part One (j) and 4.4.3 Teaching, guidance and counselling protocol: d).
- First home visit: actual exercise performance in the home environment assessed, with one supervised walking session, continuing supervision of upper-arm exercise, supervision of exercise self-monitoring using the Borg Scale and dyspnoea management strategies, i.e. pursed-lip breathing and positioning, completion of initial individualised exercise plan (Appendix 4.3), recording of exercise recommendations in patient's daily log and reminder to the patient to keep records.
- Second home visit: patient's progress examined, upper-arm exercise with weight supervised and exercise plan adjusted according to the assessment result.
- Weekly telephone call: checking exercise adherence and detecting problems in the patient's report, reinforcing exercise behaviour and adjusting exercise plan as appropriate (Appendix 4.2).

4.4.5 Case management protocol

The various guidelines emphasise the concepts of integrative care and multidisciplinary team work in the management of COPD (GOLD, 2008; NCCC, 2004). These concepts are also characteristics of transitional care, in which nurses play an important role in care coordination.

In the COPD-TCP, nurses acted as case managers, offering timely care by referring patients to a physician or to other healthcare services whenever needed. Case management included the following targeted activities.

- a. Medical care: communication with physician for medication adjustment; physician referral or coordination for outpatient follow-up appointment, emergency department visit or readmission, if needed; and additional visit or telephone call following emergency department visit or readmission (see also Appendices 4.2 and 4.4).
- b. Nutritionist care: nutrition specialist referral if risk of severe malnutrition was indicated (percentage ideal body weight less than 60%, BMI less than 16 kg/m² (NCCC, 2004) and serum albumin less than 25g/L) and follow-up of referral.
- c. Nursing care: 24-hour telephone hotline to receive immediate help from an NCM (the participating NCMs took turns manning the hotline).

The foregoing intervention protocols were presented in the form of a nursing record book, nursing guideline, patient action guide and handbook that were purpose-designed for use in the study implementation: (1) *COPD Transitional Care Programme Implementation Record*, which constitutes the nursing documentation

using the Omaha System; (2) *COPD Transitional Care Programme Nursing Guideline* (Appendix 4.5), which contains flow charts and supporting information to guide the implementation of transitional care; (3) *Rehabilitation Trip: Action Plan Guide*, a practical guide for disease management; and (4) *Rehabilitation Trip: Action Plan Handbook*, which serves as a quick guide and log book for patient actions.

4.5 Validation of the programme protocols

The final procedure in programme development was protocol validation. Panel reviews and pilot testing constituted the methodology adopted to examine the relevance, validity, reliability and practicability of the COPD-TCP protocols.

4.5.1 Panel reviews

Panel reviews were conducted to assess the relevance and validity of the intervention protocols and to ensure intervention fidelity. They involved three independent panels comprising clinical, administration and academic experts (Lynn, 1986; Mowbray, Holter, Teague, & Bybee, 2003; Sidani & Braden, 2011). The first validation was performed by a panel in Hong Kong that consisted of one professor and one assistant professor from the study university and two nursing managers with extensive clinical and managerial experience in COPD rehabilitation and extended service or community nursing. These experts were responsible for reviewing all of the documents prepared for the next validation in Guangzhou.

The second panel review was conducted by a multidisciplinary panel in Guangzhou. This panel was responsible for validating the nursing guideline and nursing records, patient action plan guide and patient handbook and ensuring their applicability in the

mainland Chinese setting. Ten experts were invited to the panel review meeting: one physiotherapist, one dietician, one professor and one physician in respiratory medicine, two nursing directors, one health education nurse, one community nurse, and two head nurses in respiratory nursing.

The final panel review was carried out by a panel in the study hospital. Eleven experts representing clinical practice at different levels or areas of administration joined this validation exercise: the vice dean of the hospital (in charge of nursing, research and respiratory medicine), the nursing director and vice nursing director of the hospital, the director of the hospital's research department, a professor in charge of clinical respiratory medicine, a professor in charge of research in the respiratory institute, the director of the nutrition department, the head nurse of the respiratory institute, a senior nurse in respiratory nursing, a physician in respiratory medicine, and a nurse in charge of nursing research in the hospital. A letter of invitation, the Research Protocol Review Feedback Form (Appendix 4.6) and the validation documents were sent to each expert two weeks before the validation meeting. During the meeting, the student investigator gave a presentation on the programme design, and the experts then held a discussion on the nursing record book, nursing guideline, patient action guide and handbook. The student investigator took notes on the experts' comments during the discussion. After the meeting, each expert was asked to complete an evaluation form independently, and these were collected by the student investigator. Table 4.3 below summarizes the findings and the panel review input to the intervention protocols:

Table 4.3 Findings of the opinion of the panel and panel review input to the intervention protocols

Opinions of panel	Panel review input to the protocols
Panel 1:	
- Agreement on all the documents for 2nd round panel review. - Comments: - To use a flowchart to show the referral arrangement instead of description - To add a remark column to all the assessment forms so that nurses could easily review the problems indentified previously and make the follow-up more efficient - The words in the patient action plan too small for elderly patient to read	- A chart of referral arrangement is added in the nursing guideline - A remark column has been added to each of the inhalation assessment form, the knowledge assessment form and the skills assessment form - An A3 size poster of the action plan summary chart is prepared in addition to the one in the patient handbook
Panel 2:	
- Agreement on the applicability of the documents designed for the programme, including the nursing guideline, nursing records, patient action plan guide and handbook - Comments: For Nursing records: - Too much contents in the Nursing Plan Form - To consider using the existing referral sheet of the hospital For the nursing instruction: - To use the Chinese standard in nutrition assessment For patient action plan guide: - Several typos found For patient hand book: - To print the name of the hospital on the book instead of filling in by person - To use one page for a week's record	- Changes to the Nursing records: - The Nursing Plan Form is redesigned to streamline the contents - The existing hospital referral sheet is adopted - Two formulas for calculation of percentage of ideal body weight and BMI added to the Assessment and Evaluation Form under nutrition problem is used according to the Chinese standard - A separate Nursing Referral Sheet designed for the study and two blank record sheets added for nurse to make record on referral and others - The nutrition assessment criteria is revised - Typos corrected - The handbook revised and the name and address of the study hospital printed on the hand book

Table 4.3 Findings of the opinion of the panel and panel review input to the intervention protocols (con't)

Opinion of panel	Panel review input to the protocols
Panel 3: • Agreement on the application of all the intervention protocols in the study hospital • Agreement on assigning a clinical team to support the study • Comments: 1) Concerning about the intervention consistency as the NCMs have varied work experience and only received short period of training 2) Hoping to identify problems through pilot study to reduce error 3) Patients' acceptance of home visit and emphasizing on the good relationship between nurses and patients and their family in order to gain their trust may be a concern 4) Suggestion for the pilot study: Two nurses to go home visit in pair so that they can learn and share with each other 5) Concerning about the safety of home visit	Notes: Comments of the panel were mainly on study implementation issues, the following strategies were taken in response to the comments: 1) A structured program is provided to all NCMs and all practiced on an exercise case to ensure consistency 2) Uniforms and home care nursing bags provided to NCMs for home visits 3) Mobile contact to ensure safety and seek help 4) Four demonstration visits were conducted before the study began 5) The student investigator accompanied with NCMs to home visit in the pilot study 6) Strategies for quality maintenance were taken as planned 7) Strengthen project coordinator's communication skills in inviting participants during the pilot testing 8) After the pilot testing, three documents were added to the protocols, including a letter to the physicians to explain the purpose of the study and ask for collaboration in informing the date of patient discharge, a checklist for sample screening and a information card with a specialist outpatient timetable and the hotline contact number for intervention participants

4.5.2 Pilot testing

The protocols were also pilot-tested in the field to assess the practicability (both for COPD and the mainland Chinese setting), acceptability (appropriateness,

effectiveness, convenience and safety of implementation) and feasibility (ease of delivery and facilitation and hindrance of implementation) of the interventions and the reliability of the assessment tools (Sidani, Epstein, Bootzin, Moritz, & Miranda 2009). The pilot testing underwent two phases. The first phase testing was conducted to assess an initial COPD-TCP which involved the joined effort of hospital nurses and community nurses (Wang, Huang, & Zhou, 2009). During this phase, the four intervention protocols were tested on COPD inpatients ($n = 8$, for discharge planning intervention), community patients ($n = 6$, for postdischarge follow-up intervention) and post-discharge patients ($n = 2$, for the implementation of an 8-weeks COPD-TCP) from the potential research sites (involving 2 hospitals and 6 community centres). Thirteen nurses participated in this phase, including NCMs ($n = 4$), head nurses ($n = 2$) and the project coordinator ($n = 1$) from other two hospitals and NCMs ($n = 6$) from the six community centres. The results of the first phase testing guided the refinement of the intervention protocol. The COPD-TCP with the four protocols aforementioned in this chapter was further tested in the second phase pilot testing at the study hospital. The four refined protocols were confirmed after a series of tests to be ready for use in the main RCT.

The interrater reliability of Omaha System documentation and exercise and inhalation technique assessment checklists were also established during the pilot testing. For the Omaha assessment and evaluation, the four NCMs assessed a standardized patient using the Assessment and Evaluation Form independently. Internal consistency of their ratings on the PCS and PRSO as calculated by intra-class correlation coefficient (ICC) were 0.93 and 0.89 respectively. To test the interrater reliability of the Telephone Follow-up Record, the four NCMs took turns to

initiate a telephone call to a stimulated patient. All of them finished the Telephone Follow-up Record independently on a selected audio-taped telephone call. Agreement of their records was assessed and the coefficient of agreement was 0.88. Interrater reliability of the assessment checklists was examined while the four NCMs rated the performance demonstrated by a patient at the same time. The ICCs of their ratings on the Upper-arm exercise checklist, PMD inhaler checklist, Accuhaler checklist HandiHaler checklist and Turbuhaler checklist ranged from 0.95-0.98.

4.6 Summary

This chapter presents the entire process of programme development, including formulation of the 4C's COPD-TCM and development of the evidence-based protocols. The nursing model functioned as a theoretical guide, and the intervention protocols provided practical guidance for the COPD transitional care intervention. Both facilitated achievement of the current study's intended outcomes. The next chapter continues the discussion with the study's preparation phase, which focused on instrument validation.

CHAPTER FIVE

INSTRUMENT VALIDATION

5.1 Introduction

This chapter reports validation studies on the three questionnaires that were used as instruments to collect data for measuring the study outcomes, including HRQOL, self efficacy and patient satisfaction. The background section states the importance and overall aims of these validation studies. Following this section, an overall view of the study design is described before giving the detailed description of the specific background and objectives, validation procedures and results of each of these three validation studies. A discussion section is used to address the overall findings of these instrument testing studies and application of the three questionnaires. At the end is the conclusion section.

5.2 Background of instrument validation

For the study purposes, three questionnaires were used for evaluating study outcomes including HRQOL, self efficacy and patient satisfaction. These three instruments respectively were the Seattle Obstructive Lung Disease Questionnaire (SOLQ), the COPD Self-Efficacy Scale (CSES) and the COPD Transition Care Patient Satisfaction Questionnaire (CTCPSQ). The SOLQ was translated from the source questionnaire, the CSES was revised from a Cantonese version and the CTCOSQ was a new questionnaire developed specifically for the current study.

Valid and reliable measurements are critical to intervention studies where the differences between baseline and post-intervention assessment data are used to

evaluate intervention outcomes (Portney & Watkins, 2009). The translated instrument should also be validated before its application so as to address the cultural relevance and the needs of the population (Maneesriwongual & Dixon 2004). A newly developed questionnaire should be tested for its psychometric properties (Rattray & Jones, 2007). Obviously, ensuring the validity and reliability of measurements is a critical early step in conducting clinical trials with scientific value. As a result, three validation studies were conducted before the commencement of this RCT: Study 1, validation of the Putonghua version of the CSES; Study 2, validation of the Chinese version of the SOLQ; and Study 3, validation of a newly developed CTCPSQ. The overall aims of these instrument testing studies are to develop the Chinese version of the SOLQ and the Putonghua version of the CSES and the CTCPSQ, as well as to establish their psychometric evidence before their actual use in the main study.

5.3 Design of the validation studies

All the three validation studies underwent two stages: Stage 1, development of questionnaire (a language modification, translation or item generation process); and Stage 2, psychometric testing for validity and reliability. Table 5.1 shows an overall view of the design of the three studies.

Table 5.1 Summary of the design of the three validation studies

	Study and Procedures	Participants	Statistics
<i>Study 1:</i>	<i>Validation study of the Putonghua version of the CSES</i>		
Stage 1:	Development of questionnaire (language modification)		
	• Approval from author • Item rewording • Author review	2 authors	Agreement
	• language equivalence • Confirmation of the first version • Content validation	3 experts	Agreement CVI
	• language equivalence • content relevance		
Stage 2:	Psychometric testing		
	• Internal consistency • Test-retest reliability	95 patients 25 patients	Cronbach's alpha ICC _{3,1}
<i>Study 2:</i>	<i>Validation study of the Chinese version of the SOLQ</i>		
Stage 1:	Development of questionnaire (translation)		
	• Approval from author • Forward translation • Backward translation	1 translator 1 translator	
	• Confirmation of the first version • Content validation (1st round)	12 experts	Agreement
	• language equivalence • cultural relevance • Content validation (2nd round)		CVI
	• content relevance • representativeness		
Stage 2:	Psychometric testing		
	• Construct validity:		
	• Item-level and scale-level construct validity	190 patients	Correlation
	• Convergent validity (with FS-36)	75 patients	Correlation
	• Convergent validity (with CSES)	95 patients	Correlation
	• Reliability: Internal consistency	190 patients	Cronbach's alpha
	• Reliability: Test-retest reliability	60 patients	ICC _{3,1}
<i>Study 3:</i>	<i>Validation study of the CTCPSQ</i>		
Stage 1:	Development of questionnaire		
	2 Construct identification		
	3 Item generation		
	4 Content validity	7 experts	CVI
Stage 2:	Psychometric testing		
	• Content validity (floor/ceiling effects)	106 patients	Percentage
	• Item-level construct validity	106 patients	CITC
	• Validity: factor analysis	106 patients	
	• Reliability		
	• Internal consistency	106 patient	Cronbach's alpha
	• Test-retest reliability	30 patients	ICC _{3,1}

Abbreviation: CVI = content validity index; CITC = corrected item-total correlation; ICC_{3,1} = intraclass correlation coefficients model 3, single measure (Shrout & Fleiss, 1979).

It is well acknowledged that validation studies should address two major concerns of any instrument, namely validity and reliability (Portney & Watkins, 2009; Rebar, Gersch, MacNee & McCabe, 2011; Tappen, 2011). Validity is defined as the degree to which an instrument measures what it proposes to measure (Portney & Watkins, 2009). Validity of the three questionnaires was estimated by way of content validity, construct validity or convergent validity. Reliability refers to an instrument's ability to measure a construct consistently. Internal consistency and test-retest reliability were two approaches used to ensure reliability (Rebar et al., 2011).

The three validation studies were conducted from 2007 to 2008. The Guangzhou Institute of Respiratory Disease collaborated with the research team on the validation studies. Three expert panels comprising experts from both Hong Kong and mainland China participated in the content evaluation process of the three validation studies (each panel for one validation study). Subjects for field studies were mainly recruited from the First Affiliated Hospital of the Guangzhou Medical University, and some of the subjects who joined the validation study of the CTCPSQ were recruited from the Guangdong General Hospital. A convenient sample was considered from the outpatient departments of the study sites. The inclusion criteria were: Patients who were (1) diagnosed COPD and confirmed in stable condition by a physician; (2) aged 40 or older than 40 years; (3) able to read Chinese or able to communicate in either Putonghua or Cantonese; and (4) a volunteer for the study. Patients who required treatment in hospital or emergency department for COPD exacerbation or change in medication regimen were excluded. Additional inclusion criteria were set for subjects participating in the test-retest reliability testing (no change in treatment regimen during two weeks, and disease condition remaining

stable); and Study 3 (having completed a pulmonary rehabilitation programme or a health education programme). The following sections give detailed descriptions of the specific background, objectives, validation procedures and results of each of these three validation studies.

5.4 Validation study of the Putonghua version of the COPD Self-Efficacy Scale (P-CSES)

5.4.1 Background and objectives

The original CSES was developed by Wigal, Creer and Kotnses in 1991. This scale was designed to evaluate the perceptions and beliefs of patients with COPD regarding their ability to manage or avoid breathing difficulty while engaging in physical activity or while experiencing psychosocial stressors. A total of 34 items loaded on 5 factors: negative effect, intense emotional arousal, physical exertion, weather/environment, and behavioural risk factors (Wigal et al., 1991).

The original CSES was translated into Chinese (in Cantonese dialect, hereafter called the Cantonese version of the Self-Efficacy Scale, C-CSES) and its psychometric properties were evaluated with Chinese patients with COPD in Hong Kong (Wong, Wong & Chan, 2005). This C-CSES was a modified version with 31 items loading in the same factors as the original scale. It was reported as having good validity and reliability: content validity index (CVI) ranging from 0.64 to 0.85, and test-retest reliability $r = 0.88$ (Wong, Wong, et al., 2005). However, this C-CSES was written in dialect and expressed with Hong Kong Chinese style that was somehow different from the official language used in mainland China. Thus, there was a need to develop a new Chinese version that could be used by the Chinese population in mainland

China, while the research team tested the convergent validity of the Chinese version of the SOLQ in the next validation study at the same time. This validation study was conducted to assess the content validity, internal consistency and test-retest reliability of the new Chinese version, the Putonghua version of the COPD Self-Efficacy Scale (P-CSES) in a sample of patients with COPD in mainland China.

5.4.2 Development of questionnaire — language modification

The process of questionnaire modification underwent the following five steps: *Step 1*: A letter was sent to the first author of the C-CSES for approval to use the questionnaire in the current study. *Step 2*: The student investigator, who had a background of years of living and working in both mainland China and Hong Kong, reworded the name, the instruction, and revised 14 out of 31 items of the C-CSES to make up the initial draft of the P-CSES (Table 5.2). *Step 3*: Two authors of the C-CSES were invited to review the language equivalence of this first draft. They received a questionnaire to guide the review process (Appendix 5.1a) and returned it to the research team with their ratings and comments. *Step 4*: The research team reviewed the authors' ratings and comments. Discrepancies were found for items 11, 20 and 21. Further revision of these items was made to form the second draft of the P-CSES. *Step 5*: The second draft was sent to an expert panel for content validation. The panel comprised three professional experts from Guangzhou, China who had extensive clinical experience in respiratory medicine or nursing (one medical professor and two head nurses). Similarly, each panel member received an evaluation questionnaire to guide the validation process (Appendix 5.1b). The results are shown in Table 5.2.

Table 5.2 Language modification for the P-CSES and content validity

Item	Statements of the Cantonese version and original English version	Rewording
1.	當我感到太疲勞時。When I become too tired.	
2.	當四周的空氣都濕氣時。When there is humidity in the air.	Yes
3.	當我從溫暖的天氣/環境，進入寒冷的天氣/環境時。When I go into cold weather from a warm place.	Yes
4.	當我經歷情緒的壓力和苦惱時。When I experience emotional stress or become upset.	Yes
5.	當我上樓梯上得太快時。When I go up stairs too fast.	
6.	當我否認我有呼吸困難時。When I try to deny that I have respiratory difficulties.	
7.	當我周圍都有香煙的煙霧時。When I am around cigarette smoke.	
8.	當我生氣時。When I become angry.	
9.	當我運動或付出很大的體力時。When I exercise or physically exert myself.	
10.	當我感到我的生活難過時。When I feel distressed about my life.	Yes
11.	我性交不足或不舉時。When I feel sexually inadequate or impotent.	Yes
12.	當我感到無奈時。When I am frustrated.	
13.	當我舉起重物的物件時。When I lift heavy objects.	
14.	當我呼喊或呼叫。When I yell or scream.	Yes
15.	當我躺床上休息時。When I am lying in bed.	
16.	在非常熱或寒冷的天氣。During very hot or very cold weather.	Yes
17.	當我笑得很多時。When I laugh a lot.	
18.	當我沒跟隨合當的日常飲食。When I do not follow a proper diet.	Yes
19.	當我感到無助時。When I feel helpless.	
20.	當我受到感染(喉嚨、鼻竇、傷風感冒等)。When I get an infection (throat, sinus, colds, the flu, etc).	Yes
21.	當我感到孤立而不想理會所有人或所有事時。When I feel detached from everyone and everything.	Yes
22.	當我經歷到憂慮時。When I experience anxiety.	Yes
23.	當我在污染的環境中。When I am around pollution.	
24.	當我吃得過多時。When I overeat.	
25.	當我感到沮喪或意氣消沉時。When I feel down or depressed.	Yes
26.	當我在空氣不流通的房間運動時。When exercise in room that is poorly ventilated.	Yes
27.	當我害怕時。When I am afraid.	
28.	當我經歷到失去重要的物件或愛人時。When I experience the loss of a valued object or a loved one.	
29.	當我家中有問題時。When there are problems in the home.	Yes
30.	當我感到不能勝任時。When I feel incompetent.	
31.	當我匆忙時。When I hurry or rush around.	
		No. of items
Total number of items adjusted for language (1 st draft)		14/31
Total number of items adjusted for language (final version)		12/31
Authors in agreement on language adjustment (1 st draft, n=2)		28/31
Experts in agreement on language equivalence (2 nd draft, n=3)		31/31
Experts in agreement on content relevance (2 nd draft, n= 3)		CVI
(I-CVI)		31*
(S-CVI/Ave)		31/31
		Percentage
Total number of items adjusted for language (1 st draft)		45.16
Total number of items adjusted for language (final version)		38.70
Authors in agreement on language adjustment (1 st draft, n=2)		90.32
Experts in agreement on language equivalence (2 nd draft, n=3)		100.00
Experts in agreement on content relevance (2 nd draft, n= 3)		CVI
(I-CVI)		1.00
(S-CVI/Ave)		1.00

I-CVI = item level content validity index; S-CVI/Ave = scale level content validity index/average;

* I-CVIs of all 31 items are 1.00.

Both of the average item CVI and average scale CVI of the P-CSES were 1.00, indicating excellent content validity. For language equivalence of the second draft of the P-CSES, all of the items were accepted by the experts, but they provided suggestions for minor amendments of several items. After further discussion among the team, the wordings of items 21 and 30 of the C-CSES were retained as they could be understood by the local population. Finally, language adjustment was made for 38.7% of the items (12 of 31 items) in addition to the name and instruction part of the C-CSES, and the final P-CSES was compiled for further psychometric testing in the next stage.

5.4.3 Psychometric testing

A convenient sample of 95 COPD outpatients participated in this study. There were 85 (89.5%) male and 10 (10.5%) female subjects, with a mean age of 67.67 ± 11.3 years and a mean COPD history for 11.71 ± 9.3 years. Among this sample, 25 patients completed the instrument in two weeks interval.

Table 5.3 presents the reliability testing results. The ICC for the CSES total score was 0.85, while the five subscale ICCs ranged from 0.74 to 0.82 (ICC: 0.82 for intense emotional arousal, 0.80 for weather/environment, 0.81 for physical exertion, 0.77 for negative affect, and 0.74 for behavioural risk factors, respectively). Internal consistency assessed by Cronbach's Alpha for all subscales was over 0.70 (intense emotional arousal 0.91, weather/environment, 0.91, physical exertions 0.76, negative affect 0.89, and behavioural risk factors: 0.83).

Table 5.3 Internal consistency and test-retest reliability of the P-CSES

Scale	items	Internal consistency (n = 95)	Test-retest reliability (n = 25)	
		Cronbach's Alpha	ICC	95% CI
Intense emotional arousal	11	0.91	0.82**	0.63 - 0.92
Weather/environment	7	0.91	0.80**	0.61 - 0.91
Physical exertion	5	0.76	0.81**	0.62 - 0.91
Negative affect	6	0.89	0.77**	0.54 - 0.89
Behavioural risk factors	2	0.83	0.74**	0.50 - 0.88
CSES Total for all items	31	0.96	0.85**	0.69 - 0.93

ICC = intraclass correlation coefficient, CI = confidence interval;

* * Correlation is at the 0.01 level (2-tailed)

5.4.4 Summary of findings

The P-CSES was confirmed after language adjustment involving 38.7% of the items of the C-CSES. Experts on the content validation panel accepted all items (both I-CVI and S-CVI/Ave were 1.00), indicating that the P-CSES addressed the original dimensions. This revised P-CSES had statistical evidence to support good reliability in terms of internal consistency and test-retest reliability. The P-CSES was ready to be used in the following study.

5.5 Validation study of the Chinese version of the Seattle Obstructive Lung Disease Questionnaire (C-SOLQ)

5.5.1 Background and objectives

Improvement in HRQOL is an important goal of disease management in COPD patients (GOLD, 2006). The most commonly used instruments for detecting change of HRQOL in response to therapy or non-pharmacologic interventions for COPD populations include generic instruments such as the Medical Outcomes Study Short Form-36 (SF-36) and the Sickness Impact Profile, and disease-specific instruments such as the Chronic Respiratory Questionnaire (CRQ), the St. George's Respiratory

Questionnaire (SGRQ) and the SOLQ (Santo Tomas & Varkey, 2004). Engström, Persson, Larsson and Sullivan (2001) asserted that both disease-specific and generic instruments should be used when assessing QOL. Other researchers argued that disease-specific instruments were superior to generic instruments as they consider the major or key components that influence COPD to be more sensitive, and have greater potential to demonstrate a significant and meaningful change (Mahler, 2000; Pickard, Yang & Lee, 2011; Santo et al., 2004). As a result, a disease-specific questionnaire is adopted to measure participants' HRQOL in this main study.

When doing the literature review in the planning stage of the current study, we found that no adequately validated Chinese version of the above mentioned three disease-specific questionnaires were available for use in our study in mainland China. The research team determined to translate and apply the SOLQ in the study for its following advantages: (1) brief – it is composed of 29 items, less than CRQ (50 items) and SGRQ (76 items); (2) easy to use – it is self-administered; and (3) unique – items were generated from generic and disease-specific HRQOL questionnaires, the SF-36 and the CRQ, with evidence of excellent convergent validity (Tu, McDonell, Spertus, Steele, & Fihn, 1997). Moreover, the result of the validation study of the source questionnaire revealed that the coping skills scale was highly correlated with the CSES (Tu et al., 1997), which is another main outcome measure in the current study. It was necessary to investigate if the same result could be yielded by using both of the Chinese versions of these questionnaires in the Chinese population. The specific objectives of the testing of the instrument were therefore set as follows:

- To translate the original SOLQ into a Chinese version of the SOLQ (C-SOLQ) for measuring HRQOL of Chinese people with COPD;

- to examine content validity of the C-SOLQ;
- to evaluate the internal consistency of the C-SOLQ;
- to investigate the convergent validity between the C-SOLQ and SF-36;
- to investigate the convergent validity between the C-SOLQ and the P-CSES;
- and
- to test the test-retest reliability of the C-SOLQ.

5.5.2 The original English version SOLQ

The SOLQ was developed in the United States by Tu and the team in 1997. It consists of 29 items covering four major domains of quality of life, namely physical function, emotional function, coping skills and treatment satisfaction. The physical function scale (PFS) assesses the degree of dyspnea and the extent of physical limitation. The emotional function scale (EFS) measures the impact of the disease on patients' psychological well-being. The coping skills scale (CSS) measures self-efficacy. The treatment satisfaction scale (TSS), measures how satisfied patients are with the care they have received specifically for their pulmonary disease.

The individual items of the SOLQ are rated on a Likert-type scale, some from 1 to 5, and some from 1 to 7. Responses to the questions of a scale are summed into a raw score, and then transformed to a normalized score ranging from 0 to 100. This normalized score is calculated by subtracting the lowest possible score from the raw score, then dividing this by the range of possible scores and multiplying by 100. An individual score is calculated for each of the four scales, where 0 is the worst case and 100 represents the highest possible function. SOLQ scales were demonstrated by Tu et al.'s study to be reliable (Cronbach's α 0.79 to 0.93 and intra-class correlation

coefficients 0.64 to 0.87) and valid (change in SOLQ scores correlated highly with corresponding CRQ in dyspnea, emotional burden and mastery scales; coping skills subscale correlated with CSES). A change of 5 points in SOLQ score is considered clinically significant (Santo et al., 2004; Tu et al., 1997). The SOLQ has been used to detect the change in HRQOL and the outcomes of intervention, e.g. pulmonary rehabilitation and health education, and to predict hospitalization and mortality in patients with COPD (Belza et al., 2005; Fan et al., 2002; Petty et al., 2006; Tu et al., 1997).

5.5.3 Development of questionnaire—translation process

The validation procedures of the C-SOLQ began with the translation process. This process mainly followed the steps of instrument translation recommended by Maneesriwongual and Dixon (2004). It involved the following steps:

Step 1: Getting approval for translation and utilization of the SOLQ

An email with brief introduction of the study was sent to the developer of SOLQ, Dr Sin-Ping Tu, to seek approval for conducting a translation and validation study of the SOLQ from English into Chinese. The translation process began after formal approval was received.

Step 2: Forward translation

A professor of respiratory medicine from Guangzhou, China, who has 5 years' working and study experience abroad and 17 years' experience in academic translation, was invited to translate the original SOLQ into Chinese. The student investigator met with the translator to explain the purposes and the utilization of the

SOLQ. The translator was asked to translate the SOLQ into Chinese. The forward translated questionnaire was then ready for backward translation.

Step 3: Backward translation

Another bilingual translator from Hong Kong, a nursing professional with 5 years' working experience in the field of COPD and 10 years' translation experience, was invited to translate the C-SOLQ into English. A copy of the forward translated SOLQ was sent to the translator for backward translation. The translator was reminded not to review the original SOLQ and to submit the back translated version of the SOLQ.

Step 4: Confirming the first Chinese version of the SOLQ

After the backward translation, the student investigator compared the backward translated English SOLQ with the original version to assess the compatibility between the two versions. Separate phone calls were made afterwards to the two translators by the student investigator to discuss the discrepancies identified. After discussion, the student investigator revised the forward translated SOLQ according to the translators' comments. This revised draft was reviewed and confirmed by the project team. The project team reviewed the revised draft and previously identified discrepancies were further discussed by comparing the forward and backward translation version with the original version. The second draft of the questionnaire was then produced and ready for expert panel's review.

Step 5: Panel view on the cultural relevance and language equivalence

Panel members were recruited according to the following criteria: (1) bilingual in Chinese and English; (2) an expert from clinical nursing, community nursing, nursing education, nursing management, respiratory medicine, rehabilitation or health science research; (3) with clinical or research experience in the COPD field; and (4) willing to participate in this validation study. Experts from both Hong Kong and Guangzhou were invited with the mainland Chinese experts being familiar with the Chinese culture and specialized in COPD medicine, clinical nursing, or physiotherapy while the experts from Hong Kong had extensive experience in community nursing or occupational therapy, or rich experience in conducting research including instrument development. This gave the research team an opportunity to pool wisdom to ensure the quality of the translated questionnaire. Altogether, 12 professional experts (6 from Hong Kong and 6 from Guangzhou, China) with 10.67 ± 5.0 years required experience in the field were invited to evaluate the cultural relevance and language equivalence of the translated and original versions. An email was sent to each member of the panel with a package composed of invitation letter, the original English version SOLQ, and a panel review questionnaire (Appendix 5.2a). Panel members conducted the evaluation of the fluency, semantic equivalence and cultural relevance of the C-SOLQ independently.

Data collected from the panel review questionnaire were analyzed (Table 5.4). The average percentage of experts in agreement on the translation fluency and accuracy for all items was 86.2% (ranging from 50% to 100% for each item), and the average percentage of experts in agreement on culture relevance for all items was 93.7% (ranging from 33.3% to 100% for each item). Panel experts expressed reservations

on the culture relevance of six items: (1) item 2a: Vigorous activities, such as running, participating in strenuous sports (e.g., swimming, jogging, tennis); (2) item 2c: Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf; (3) item 2e: Lifting or carrying groceries; (4) item 2h: Walking more than a mile; (5) item 2i: Walking several blocks, and (6) item 2j: Walking one block. Experts argued that some activities listed in items 2a and 2c, such as tennis, bowling, golf, pushing a vacuum cleaner, were unpopular among the Chinese. For items 2a, 2c and 2j, Chinese people used “metre” instead of “mile” to measure distance and did not use “block” to describe distance. Based on the experts’ recommendations, these culturally specific items were amended adapting to Chinese culture. Two experts who had overseas living experience disagreed on the direct translation of “groceries” for “日雜用品” in item 2e, as in the US, “groceries” usually includes food items and there are articles for daily use at grocery stores too. Further explanation was therefore added to this item “提舉或攜帶雜貨用品（如賣菜、購物等）” after consulting the author of the original SOLQ.

Step 6: Panel view on the content relevance and representativeness

After the exercise in affirming the cultural relevance and language equivalence, the latest version of the C-SOLQ (Appendix 5.2b) was sent to each member of the same panel for assessing the content validity in terms of content relevance and representativeness. As with the first review of cultural relevance, panel members gave their responses by rating on a four-point Likert-type scale, and further comments or recommendations were invited. All panel members finished and returned their questionnaires to the research team. The data collected were calculated and comments and recommendations were reviewed.

Table 5.4 Content validity of the C-SOLQ

Scales/items	Language equivalence		Cultural relevance		Content relevance	
	Experts in agreement	%	Experts in agreement	%	Experts in agreement	I-CVI
<i>Physical Function (18 items)</i>						
1a. Low in energy or tired	9	75.0	12	100.0	12	1.00
2a. Vigorous activities, such as running, participating in strenuous sports (e.g. swimming, jogging, tennis)	8	66.7	10	83.3	12	1.00
2b. Lifting or moving heavy objects (e.g. furniture, children)	11	91.6	12	100.0	12	1.00
2c. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	11	91.6	7	58.3	12	1.00
2d. Climbing several flights of stairs	11	91.6	12	100.0	12	1.00
2e. Lifting or carrying groceries	8	66.7	10	83.3	12	1.00
2f. Climbing a hill or one flight of stairs	12	100.0	12	100.0	12	1.00
2g. Bending, kneeling or stooping	10	83.3	12	100.0	12	1.00
2h. Walking more than a mile	11	91.6	4	33.3	12	1.00
2i. Walking several blocks	10	83.3	9	75.0	12	1.00
2j. Walking one block	10	83.3	10	83.3	12	1.00
2k. Bathing or dressing yourself	12	100.0	12	100.0	12	1.00
2l. Getting in or out of bed	12	100.0	12	100.0	12	1.00
3a. Normal daily activities	12	100.0	12	100.0	12	1.00
3b. Most strenuous activities	9	75.0	12	100.0	12	1.00
4a. Normal daily activities	12	100.0	12	100.0	12	1.00
4b. Most strenuous activities	9	75.0	12	100.0	12	1.00
5a. Short of breath	12	100.0	12	100.0	9	0.75
Average S-CVI		87.5		89.8		0.99
<i>Emotional Function (5 items)</i>						
1c. Embarrassed by your coughing or heavy breathing	11	91.6	12	100.0	12	1.00
1d. You could not enjoy life	11	91.6	12	100.0	12	1.00
5b. Afraid to exercise	10	83.3	12	100.0	12	1.00
5c. Afraid getting angry would worsen your breathing	12	100.0	12	100.0	12	1.00
5f. You were a burden on your family and friends	11	91.6	12	100.0	12	1.00
Average S-CVI		91.6		100.0		1.00
<i>Coping Skills (4 items)</i>						
1b. Frightened when you had difficulty breathing	10	83.3	12	100.0	10	0.83
5d. Worried you wouldn't be able to breathe at all	9	75.0	12	100.0	11	0.92
5e. Your breathing problems were out of control	9	75.0	12	100.0	11	0.92
7. During the <u>past 4 weeks</u> , how often did you feel confident dealing with your breathing problems?	6	50.0	12	100.0	10	0.83
Average S-CVI		70.8		100.0		0.87
<i>Treatment Satisfaction (2 items)</i>						
6a. The explanation given by your doctor or health care provider about your breathing problems	12	100.0	12	100.0	12	1.00
6b. The current treatment for your breathing problems	10	83.3	12	100.0	12	1.00
Average S-CVI		91.7		100.0		1.00
<i>SOLQ (29 items)</i>						
Average S-CVI		86.2		93.7		0.97

Abbreviation: I-CVI = item-level content validity index; S-CVI/UA = scale-level content validity index, universal method;

Note. Experts: n = 12; the number of experts in agreement was counted if expert rated either 4 or 3 on the content relevance rating scale (4 = very relevant/strongly agree, 3 = relevant/agree, 2 = irrelevant/disagree, 1 = very irrelevant/strongly disagree).

The results of content validity of the C-SOLQ are presented in Table 5.4. The S-CVI/Ave of the four subscales was: 0.99 (PFS), 1.00 (EFS), 0.87 (CSS) and 1.00 (TSS), respectively. The PFS, EFS and TSS demonstrated excellent content validity while the CSS met the minimum requirement (Polit, Beck & Owen, 2007). When examining the content validity at item level, only one item in the PFS (item 5a) had an I-CVI lower than 0.78 (I-CVI = 0.75). However, several experts criticized the relevance of putting item 5a: “Short of breath” in the physical function domain; and queried if item 1b: “Frightened when you had difficulty breathing” should be placed in the emotional function domain, and the appropriateness of including item 7: “During the past 4 weeks, how often did you feel confident dealing with your breathing problems?” in the CSS in assessing coping skills.

For the results of the representativeness evaluation, 11 experts rated the scale. All of them agreed that the overall scale adequately represented the assessment of HRQOL for Chinese people with COPD (5 experts rated it with a score of “3” and 6 experts rated it “4”). The panel regarded all the subscales as adequately representing the assessment of their loading domains except for the coping skills subscale (9 out of 11 experts rated 3 or 4, with an average percentage of agreement of 81.8%). Experts pointed out that those items in the CSS referred to emotional function rather than coping skills and wondered about the adequacy of items in representing the construct of coping skills.

Apart from the evaluation of content relevance and representativeness, further recommendations were provided by several experts on the accuracy of transferring the distance of blocks into metres. Based on all recommendations proposed by

experts, improvements to the second draft were made to produce the third draft. One more round validation was carried out by three experts selected from the previous expert panel. They further confirmed the language equivalence, cultural relevance and content relevance of the C-SOLQ. The final draft of the C- SOLQ was then ready to be used for field study.

5.5.4 Psychometric testing

A convenience sample of 190 COPD outpatients participated in this round of testing. The mean age of the participants was 68.48 ± 9.9 years. The majority of them ($n=173$, 91.1%) were male. Illiterate participants accounted for 12.6% ($n=24$). More than 57% of them ($n=109$) were retired. They had a history of COPD for 10.99 ± 9.1 years. Participants who agreed on the second administration ($n=60$) completed the same C-SOLQ at an interval of two weeks.

5.5.4.1 Testing of Validity

Construct validity

Construct validity was first examined for structure validity using corrected item-total correlation. The results of the entire C-SOLQ and each subscale are presented in Table 5.5. As shown in the table, item-total correlation of the 29 items ranged from 0.24 to 0.72. Low correlation was found in items 6a and 6b, which had a correlation below the acceptable criterion of 0.30 (Nunnally & Bernstein, 1994). However, the domain statistical results revealed that all correlations in each subscale were greater than 0.30 with a range of 0.33 to 0.76 for PFS, 0.33 to 0.58 for EFS, 0.51 to 0.88 for CSS and 0.66 to 0.66 for TSS.

Table 5.5 Item mean, standard deviation and corrected item-total correlation of the C-SOLQ items (n=190)

Scales/Items	Subscale C-SOLQ			
	Mean±SD	CITC	CITC	
<i>Internal consistency of physical function scale</i>				
1a Low in energy or tired	4.73±1.7	0.49	0.56	
2a Vigorous activities, such as running, participating in strenuous sports ...	1.61±1.2	0.53	0.48	
2b Lifting or moving heavy objects...	1.90±1.3	0.60	0.53	
2c Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	3.35±1.4	0.75	0.70	
2d Climbing several flights of stairs	2.76±1.4	0.70	0.61	
2e Lifting or carrying groceries	3.94±1.3	0.74	0.72	
2f Climbing a hill or one flight of stairs	4.11±1.2	0.68	0.67	
2g Bending, kneeling or stooping	4.43±1.0	0.46	0.48	
2h Walking more than a mile	3.49±1.6	0.72	0.68	
2i Walking several blocks	4.01±1.4	0.76	0.70	
2j Walking one block	4.44±1.1	0.67	0.60	
2k Bathing or dressing yourself	4.52±1.0	0.57	0.57	
2l Getting in or out of bed	4.81±0.6	0.33	0.37	
3a Normal daily activities	3.40±1.2	0.70	0.69	
3b Most strenuous activities	1.89±1.4	0.45	0.40	
4a Normal daily activities	3.66±1.0	0.64	0.62	
4b Most strenuous activities	2.11±1.3	0.54	0.50	
5a Short of breath	4.46±1.3	0.68	0.72	
<i>Internal consistency of emotional function scale</i>				
1c Embarrassed by your coughing or heavy breathing	5.95±1.3	0.33	0.30	
1d You could not enjoy life	4.74±1.7	0.55	0.53	
5b Afraid to exercise	4.04±2.1	0.44	0.59	
5c Afraid getting angry would worsen your breathing	5.57±1.6	0.53	0.58	
5f You were a burden on your family and friends	5.76±1.6	0.58	0.52	
<i>Internal consistency of coping skills</i>				
1b Frightened when you had difficulty breathing	6.06±1.3	0.51	0.38	
5d Worried you wouldn't be able to breathe at all	6.12±1.5	0.72	0.52	
5e Your breathing problems were out of control	5.51±1.6	0.72	0.68	
7 During the past 4 weeks, how often did you feel confident dealing with your breathing problems?	5.86±1.2	0.88	0.69	
<i>Internal consistency of treatment satisfaction scale</i>				
6a The explanation given by your doctor or health care provider about your breathing problems	3.98±0.7	0.66	0.24	
6b The current treatment for your breathing problems overall	3.77±0.8	0.66	0.29	

CITC = corrected item-total correlation.

Spearman's rho was computed to further examine where each subscale reflected deferent construct. The results in Table 5.6 show that PFS, EFS and CSS were

moderately correlated, with a correlation coefficient ranging from 0.48 to 0.60. TSS had a weak correlation with PFS ($r=0.26$) and minimal correlation with the other two subscales (EFS and CSS).

Table 5.6 Correlation between the C-SOLQ subscales (n = 190)

Scale	Physical function	Emotional function	Coping skills	Treatment satisfaction
Physical function	1.00	0.59**	0.48**	0.26**
Emotional function	0.60**	1.00	0.59**	0.09
Coping skills	0.48**	0.59**	1.00	0.10
Treatment satisfaction	0.26**	0.09	0.10	1.00

** . Correlation is significant at the 0.01 level (2-tailed).

Convergent validity of the C-SOLQ and the Chinese version SF-36

The Chinese version of the Short Form 36 Health Survey Questionnaire (SF-36) was applied in this test after getting approval for its use in the current study from authors. This Chinese version SF-36 (Appendix 5.3) was developed by Fang and Hao (2005). As with the original English version, the Chinese Version FS-36 consists of 36 items grouped under 10 questions. The scores of the 36 items are summated into eight domains: physical functioning (10 items), role-physical (4 items), bodily pain (2 items), general health (5 items), vitality (4 items), social functioning (2 items), role-emotional (3 items), mental health (5 items), and self-perceived health (1 item) (Fang & hao, 2005). All items are scored on a 3-6 point Likert scale except for seven items in role physical and role emotional subscales, that are answered in a yes/no format. Raw scores are then transformed to a normalized score ranging from 0 to 100. Higher scores represent better health status.

Altogether 75 participants from the cohort completed the C-SOLQ and the Chinese version SF-36 at the same time. Pearson correlation was performed to explore the relation between the C-SOLQ and SF-36, and the results are presented in Table 5.7. From the table, it can be seen that the three health-related subscale scores (PF, EF and CS) of the C-SOLQ were significantly correlated to all to SF-36 subscale scores except for the body pain subscale score. The PF subscale score of the C-SOLQ was highly correlated with the physical function subscale score of the SF-36 ($r = 0.82$), and moderately correlated with the social function subscale score of the SF-36 ($r = 0.64$). Moderate correlations were also found between C-SOLQ EF and physical function of the SF-36 ($r = 0.54$) and C-SOLQ EF and general health of the SF-36 ($r = 0.50$).

Table 5.7 Correlation coefficient between the C-SOLQ and the SF-36

SF-36	C-SOLQ			
	PF	EF	CS	TS
Physical function	0.82**	0.54**	0.39**	0.21
Role-physical	0.40**	0.30**	0.26*	0.27*
Body pain	0.13	0.11	0.14	-0.01
General health	0.42**	0.50**	0.36**	0.31**
Vitality	0.37**	0.38**	0.34**	0.26*
Social functioning	0.64**	0.48**	0.45**	0.18
Role-emotional	0.38**	0.30**	0.29*	0.32**
Mental health	0.40**	0.40**	0.35**	0.18

Pearson Correlation, ** Correlation is significant at the 0.01 level (2-tailed),

*Correlation is significant at the 0.05 level (2-tailed).

Convergent validity of the C-SOLQ and the P-CSES

The P-CSES was developed in our first validation study. This questionnaire has 31 items assessing self-efficacy in patients with COPD, and consists of five dimensions: negative affect; intense emotional arousal; physical exertion; weather/environment;

and behavioural risk factors. To estimate the convergent validity between the C-SOLQ and the P-CSES, another 95 participants from the cohort finished the C-SOLQ and the P-CSES at the same time period.

Table 5.8 reveals statistical analysis results of the correlation coefficient between the C-SOLQ and the P-CSES. All the C-SOLQ subscale scores were significantly correlated with the total score of the P-CSES and the majority of the P-CSES subscale scores. However, the correlations were low (r : ranged from 0.22, $p<0.05$ to 0.40, $p<0.01$), especially for the coping skills scale score of the C-SOLQ with the corresponding subscale and the total scores of the P-CSES (intense emotional arousal: $r = 0.32$, $p<0.01$; weather/environment: $r = 0.28$, $p<0.01$; negative affect: $r = 0.23$, $p<0.05$; behavioural risk factors: $r = 0.32$ a $p<0.01$; physical exertion $r = 0.15$, $p = 0.176$; and CSES total: $r = 0.29$, $p<0.01$; respectively).

Table 5.8 Correlation Coefficient between the C-SOLQ and the P-CSES (n = 95)

P-CSES	C-SOLQ			
	PF	EF	CS	TS
Intense emotional arousal	0.28**	0.37**	0.32**	0.17
Weather/environment	0.16	0.37**	0.28**	0.25*
Physical exertion	0.40**	0.30**	0.15	0.06
Negative affect	0.24*	0.40**	0.23*	0.26**
Behavioural risk factors	0.22*	0.36**	0.32**	0.26*
CSES total	0.32**	0.40**	0.29**	0.25*

Spearman's rho correlation, ** Correlation is significant at the 0.01 level (2-tailed),
*Correlation is significant at the 0.05 level (2-tailed).

5.5.4.2 Testing of reliability

Internal consistency of the four C-SOLQ subscales was first assessed using the data from all participants (n=190). Table 5.9 shows that the Cronbach's alpha of all the four subscales were above 0.70 (PFS: 0.92, EFS: 0.75, CSS: 0.73 and ST: 0.79 respectively). Data from 60 subjects who administrated the same instrument at an interval of two weeks were then computed to test the external reliability (also see Table 5.9). The findings indicated a very strong correlation in three of the subscales (PF: ICC=0.82, EF: ICC=0.84, and CS: ICC=0.82), while the TS (ICC=0.56) showed a moderate correlation between 0.50 and 0.75 (Portney & Watkins, 2009).

Table 5.9 Internal consistency and test-retest reliability of the C-SOLQ

Scale	Internal consistency (n=190)			Test-retest reliability (n=60)		
	Items (n)	Mean±SD*	Cronbach's alphas	1 st Test Mean±SD	2 nd Test Mean±SD	ICC
Physical function	18	63.59±15.0	0.92	68.16±17.3	63.93±19.3	0.82**
Emotional function	5	26.06±5.8	0.75	69.50±21.6	69.11±21.9	0.84**
Coping skills	4	23.44±4.6	0.73	78.54±20.0	77.99±20.0	0.82**
Treatment satisfaction	2	7.75±1.4	0.79	71.88±18.6	66.46±20.8	0.56**

ICC = intraclass correlation coefficient;

* Mean±SD was calculated based on the item row scores of a scale.

5.5.5 Summary of findings

The PFS, ESS and TSS demonstrated excellent content validity (S-CVI/Ave > 0.90) while the CSS met the minimum requirement (S-CVI/Ave of 0.80); and only one item in the PFS (item 5a) had an I-CVI slightly lower than 0.78 (Polit et al., 2007). Item-total scale correlations were satisfactory (>0.30) for all the four scales. Correlations among the four scales were less than 0.70 which supported the multidimensionality of the questionnaire (Carey & Seibert 1993). In addition, the correlation between the SOLQ physical function scale and the SF-36 physical

function scale was substantial ($r = 0.82$). Significant correlations were also found between another two health-related scales (EF and CS) and all the SF-36 subscales except for body pain scale. This indicated that the three SOLQ health-related scales measure similar constructs of the SF-36, especially for the physical function domain. However, the correlation between the SOLQ coping skills scale score and the P-CSES total score and all the subscale scores were lower than expected: intense emotional arousal (0.35), weather/environment (0.39), negative affect (0.33), behavioural risk factors (0.43), physical exertion (0.14), and CSES total (0.34), respectively. For reliability, the C-SOLQ demonstrated good internal consistency (with a Cronbach's alpha > 0.7 for EF and TS, >0.8 for CS and >0.9 for PF), and external consistency (test-retest with an ICC >0.75 for the three health-related scales, including PF, EF and CF).

5.6 Validation study of the COPD Transitional Care Patient Satisfaction Questionnaire (CTCPSQ)

5.6.1 Background and objectives

Evidence from the previous literature review proved that patient satisfaction would be one of the important outcome measures for nursing interventions in a transitional care programme or a COPD management programme (Brooten, Youngblut, Kutcher, & Bobo, 2004; Hermiz et al., 2002; Naylor, Aiken, Kurtzman, Olds & Hirschman, 2011; Vrijhoef, Van Den Bergh, Diederiks, Weemhoff & Spreeuwenberg, 2007). To effectively measure patient satisfaction with nursing care, a valid and reliable instrument that is sensitive to patients' expectations and to nurses' efforts should be used (Forbes & Brown, 1995). The aims of this study were to develop a COPD Transitional Care Patient Satisfaction Questionnaire (CTCPSQ), an

instrument used to measure the satisfaction of Chinese people with COPD received transitional care or usual post-discharge nursing intervention; and to examine the psychometric properties of this newly developed questionnaire. The specific objectives included:

- To develop a patient satisfaction questionnaire that could be used to evaluate the effect of transitional care or post-discharge nursing intervention for COPD patients;
- to examine the content validity of the CTCPSQ;
- to investigate the factor structure of the CTCPSQ;
- to evaluate the internal consistency of the CTCPSQ; and
- to test the test-retest reliability of the CTCPSQ.

5.6.2 Development of the questionnaire

The questionnaire development stage underwent two major steps: to identify the domain of content and to generate the instrument items (Wynd, Schmidt, & Schaefer, 2003). Various sources and methods were applied at this stage, including getting evidence from previous research about the concept, interview findings related to the concept, experts' knowledge regarding the concept, and individual's experiences with the concept (Rattray & Jones, 2007; Rebar et al., 2011).

Step 1: Identification of content domain

What factors contributed to patient satisfaction? Research showed that satisfaction with nursing care was the crucial factor in patients' overall satisfaction or dissatisfaction with their experiences (Abramowitz, Côté & Berry, 1987). What made patients satisfied with nursing care? It was suggested that patient satisfaction was

related to patients' expectations of how their general healthcare needs and condition-specific needs were met in healthcare institutions (Asadi-Lari, Tamburini & Gray, 2004). During the clinical observation period, six in-patients interviewed by the student investigator expressed their care needs and expectations for nursing care. The findings revealed that what they were most concerned about was their speedy recovery, the frequent onset of their disease, and medical fees. The interview gave us insights into patients' expectations of nursing care and service that indicated patients needed continuous, convenient, timely and cost-effective care. The transitional care for patients with COPD should be targeted to meet with patient's care needs.

Health education was shown to be associated with patient satisfaction in the COPD population (Gallefoss & Bakke, 2000; Hermiz et al., 2002). Health education had been designed as one of the key components in the current transitional care programme to address patients' needs. Patients' satisfaction with health education should be another main construct of interest, including the essential content of education and the basic knowledge and skills for COPD management. During the education as well as the nursing care process, elements of nurse-patient interaction such as nurses' communication skills and service attitude were also key attributes of patient's satisfaction with nursing care (Wagner & Bear, 2009). On the whole, the two important aspects to be assessed are patient's satisfaction with the care or service they received, and the components specific to disease management in terms of education.

Step 2: Item generation

Resulting from the first step, the initial item-pool generation included 14 items and

was divided into three sections consisting of two domains and a global item. The first domain was intended to measure a client's satisfaction with nursing service. It comprised five items asking respondents to rate their degree of satisfaction with: (1) timeliness of the care provided by nurse(s); (2) care provided by nurse(s) on solving breathing problems; (3) convenience of the care provided by nurse(s); (4) communication between nurse(s) and oneself; and (5) service attitude of the nurse(s). The second domain was targeted to measure patients' satisfaction with health education. It comprised eight items asking respondents to rate their degree of satisfaction with the health education or guidance provided by nurses: (1) COPD self-management knowledge (e.g. infection prevention, elimination of disease risk factors, etc.); (2) rehabilitation training (e.g. aerobic exercise, upper-arm exercise, relaxation exercise); (3) medication regimen (e.g. use of inhalation drugs, oral medication); (4) coughing technique; (5) breathing control technique; (6) coping with worsening symptoms; (7) nutrition(diet) instruction; and (8) home oxygen therapy. The final section was a global item, asking respondents to rate their overall satisfaction with post-discharge care or transitional care. All item statements were written in neutral or positive wordings and each section was supplemented by an open-ended question (i.e. 'Overall, I consider that nursing service is :_____'). The 5-point Likert-type response scale employed was: 1 = very satisfied, 2 = satisfied, 3 = neutral, 4 = dissatisfied, 5 = very dissatisfied.

Step 3 Content validation

This initial 14-item scale along with an evaluation questionnaire (Appendix 5.4) was sent to an expert panel for content validation. The panel comprised two academics with extensive experience in instrument development and one nursing manager with

more than 10 years experience on COPD community nursing and rehabilitation care from Hong Kong, and three professors with extensive experience in clinical nursing, nursing research as well as nursing management and one nurse with 25 years experience in respiratory nursing from Guangzhou, China. The relevance and representativeness of the scale items were rated by the expert panel. Data collected from the returned evaluation questionnaires were computed to yield the I-CVI and S-CVI. The results demonstrated that the 14-item CTCPSQ had excellent content validity. I-CVIs of the 14 items ranged from 0.86 to 1.00, and S-CVI/Ave was 0.98. All experts agreed that items on each domain represented the domain content and domains in entire scale related to the concept of patient satisfaction (proportion agreement: 100%).

5.6.3 Psychometric testing

The psychometric testing of the CTCPSQ was carried out in the two study sites in Guangzhou, China. Data were collected from an outpatient sample of 106 participants (male: 89 and female: 17; aged 72.03 ± 7.55 ; with a COPD history of 9.59 ± 8.02 years). All of these patients had finished a pulmonary rehabilitation programme (n=50) or a health education programme (n=56). Among this sample, 30 participants administered the CTCPSQ on two occasions, two weeks apart.

Item validation

Table 5.10 presents the item statistics of the 14 CTCPSQ items, including item mean, standard deviation, skewness and corrected item-total correlation. It can be seen from the table that corrected item-total correlation of all items ranged from 0.54 to 0.87. The mean scores of all items were notably higher than the mid-point (3.00), ranged

from 3.81 to 4.44, although skewnesses of 12 out of 14 items were within the recommended range (skewnesses between -1 to +1). Item scores were well distributed but did not span the entire scale range. Ceiling effect was noted in all items, ranging from 28.3% to 46.2%, exceeding the suggested maximum criterion of 20%. As testing was conducted using a sample of participants who completed a rehabilitation or education programme, such findings were expected, and all the 14 items were kept for further validation.

Table 5.10 Item analysis of the CTCPSQ items (n=106)

Items	Mean±SD	Skewness	% Floor/ ceiling effect	CITC
1. Timeliness of the care	4.38±0.5	-0.41	0.0/39.6	0.63
2. Convenience of the care	4.32±0.6	-0.80	0.0/36.8	0.61
3. Communication between nurse(s) and me	4.32±0.6	-0.82	0.0/37.7	0.67
4. Care in solving my breathing problem	4.33±0.6	-1.09	0.0/39.6	0.67
5. Service attitude of nurse(s)	4.44±0.6	-0.63	0.0/46.2	0.54
6. COPD self-management knowledge	4.01±1.0	-0.91	0.0/34.0	0.68
7. Rehabilitation training (e .g. ...)	3.92±1.0	-0.75	0.0/34.0	0.87
8. Medication regimen	4.26±0.8	-1.28	0.0/41.5	0.75
9. Coughing technique	3.94±1.1	-0.75	0.0/36.8	0.81
10. Breathing control technique	4.00±1.0	-0.79	0.0/35.8	0.80
11. Coping with worsening symptoms	3.87±1.1	-0.58	0.0/37.7	0.75
12. Nutrition (diet) instruction	3.91±1.0	-0.69	0.0/40.6	0.76
13. Home oxygen therapy	3.81±1.0	-0.07	0.0/28.3	0.49
14. Overall satisfaction with the post-discharge nursing service	4.33±0.6	-0.84	0.0/38.7	0.66

CITC = corrected item–total correlation;

** $p < 0.01$.

5.6.3.1 Testing on construct validity

Factor analysis with principal component analysis (Munro, 2005) was performed to explore the construct validity of the CTCPSQ. Bartlett's test of sphericity (BT) and the Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy were examined

before conducting exploratory factor analysis. The results showed that the data were appropriate for exploratory factor analysis (KMO = 0.90, ≥ 0.8 as required; Bartlett's test value = 1,112.52, $p < 0.01$). The principal components analysis extracted two factors from the 14 items of the CTCPSQ, according to the change of eigenvalue in the scree plot (Figure 5.1), and eigenvalues rule that was greater than 1.0.



Figure 5.1 Scree plot for 14-item CTCPSQ scores ($n = 106$)

Table 5.11 presents the factor loadings, which were the correlations between each of the 14 variables and the two factors resulted from a varimax (orthogonal) rotation technique. It can be seen that in total, the two factors accounted for 67.76% of the variable variance, where the first and the second factor accounted for 36.09% and 31.66% of the variance of the 14 variables. Items 1, 2, 3, 4, 5 and 14 were associated the most with the first factor, and items 6, 7, 8, 9, 10, 11, 12 and 13 were associated the most with the second factor. According to the content of these two sets of items, the two factors were named 'education satisfaction' and 'service satisfaction'. Factor

loadings of education satisfaction domain ranged from 0.66 to 0.85, and service satisfaction domain ranged from 0.62 to 0.85. With a cut-off point of 0.50, none of items were loaded in both factors. These factor analysis results well supported the theoretical construct of the CTCPSQ, and suggested that item 14, which was originally treated as a global item, was included in the service satisfaction domain.

Table 5.11 Factor structure (varimax rotated solution) of CTCPSQ (n = 106)

Items	Description	Factors	
		1	2
Item 7	Rehabilitation training (e.g. aerobic exercise, upper-arm exercise, relaxation exercise) (<i>Education</i>)	0.85	
Item 9	Coughing technique (<i>Education</i>)	0.83	
Item 11	Coping with worsening symptoms and seeking medical help (<i>Education</i>)	0.82	
Item 10	Breathing control technique (<i>Education</i>)	0.80	
Item 12	Nutrition (diet) instruction (<i>Education</i>)	0.76	
Item 8	Medication regimen (e.g. use of inhalation drugs, oral medication) (<i>Education</i>)	0.68	
Item 13	Home oxygen therapy (if applicable) (<i>Education</i>)	0.67	
Item 6	COPD self-management knowledge (e.g. infection prevention, elimination of disease risk factors, etc.) (<i>Education</i>)	0.66	
Item 1	Timeliness of the care provided by nurse (<i>Service</i>)		0.85
Item 3	Convenience of the care provided by nurse (<i>Service</i>)		0.83
Item 4	Communication between nurse and me (<i>Service</i>)		0.81
Item 2	Care provided by nurse on solving my breathing problem (<i>Service</i>)		0.78
Item 14	Overall, are you satisfied with the post-discharge nursing service provided? (<i>Service</i>)		0.75
Item 5	Service attitude of nurse (<i>Service</i>)		0.62
Variance explained (Overall variance explained =67.76 %)		36.03	31.66
Rotated eigenvalues		5.05	4.43

Extraction Method: Principal Componentanalysis; Rotation Method: Varimax with Kaiser Normalization; Rotation converged in 3 iterations;
Factor 1: Education satisfaction, Factor 2: Service satisfaction.

5.6.3.2 Testing of reliability

Reliability of the CTCPSQ (with two subscales) was assessed using data from the entire sample (n=106) for internal consistency, and 30 participants for test-retest reliability (see Table 5.12). The results revealed that Cronbach's alphas were 0.90 for service satisfaction scale, and 0.93 for both of the education satisfaction scale and the overall consistency of 14 items. A high degree of reliability was found between the twice CTCPSQ measurements ($ICC = 0.86$ for the service satisfaction scale, and $ICC = 0.90$ for the education satisfaction scale, and $ICC = 0.91$ for the CTCPSQ total score, respectively).

Table 5.12 Internal consistency and test-retest reliability of the CTCPSQ

Scale	Internal consistency (n=106)			Test-retest reliability (n=30)		
	No. of Items	Mean±SD	Cronbach's alphas	1 st Test Mean±SD	2 nd Test Mean±SD	ICC
Service satisfaction	6	26.12±2.9	0.90	81.25±8.4	80.28±8.1	0.86
Education satisfaction	8	31.71±6.5	0.93	74.90±11.3	76.25±12.7	0.90
CTCPSQ	14	57.84±8.7	0.93	78.07±8.8	78.26±9.3	0.91

CTCPSQ = COPD Transitional Care Patient Satisfaction Questionnaire;
ICC = intraclass correlation coefficient.

5.6.4 Summary of findings

Content validation by experts achieved agreement on the theoretical construct of the initial version of the CTCPSQ. Construct validity of the CTCPSQ was supported by factor analysis, which generated two factors that were congruent with the original theoretical mapping of domains. In addition to the 5 items, the service satisfaction subscale (domain) included the global item that was initially considered, while the education satisfaction subscale (domain) consisted of all the 8 items in the initial version. These two subscale scores demonstrated excellent internally consistent

reliability with a Cronbach's alpha of 0.90 and 0.93. The ICCs (0.86 for service satisfaction scale and 0.90 for education satisfaction scale) were very high as well, indicating "excellent" agreement between the test-retest scores. Nevertheless, ceiling effect was showed on all items with a test sample of participants having finished a rehabilitation or education programme.

5.7 Discussion

To achieve high quality measurement was a vital task as well as a challenge for researchers while using the questionnaire as a method of data collection in a RCT. In order to ensure the quality of the outcome measures, three validation studies were conducted for three questionnaires, the P-CSES, C-SOLQ and CTCPSQ. Validity and reliability, which were widely accepted as being the two primary aspects of the quality of quantitative research measures, were the focus of these three studies (Portney & Watkins, 2009; Rebar et al., 2011; Tappen, 2011). According to the specific objectives of each study, various approaches to assess validity and reliability were applied in the process. Findings obtained provided evidence to support use of the three questionnaires in the current RCT.

5.7.1 Strengths, limitations and implementation of the P-CSES

The P-CSES was directly revised from the C-CSES and retained the same structure of 31 items collapsed into five subscales: negative affect, intense emotional arousal, physical exertion, weather or environment and behavioural risk factors (Wong, Wong, et al., 2005). The current scale demonstrated higher scale CVI for all the five scales than the C-CSES (1.00 to 1.00 vs. 0.64 to 0.85) and comparable high test-retest reliability (ICC=0.85 for the current scale total score vs. $r=0.88$ for the

C-CSES total score). Additional evidence of good internal consistency was obtained with a Cronbach's alpha ranged from 0.76 to 0.91 for the five scales.

However, the psychometric properties of the P-CSES were not fully assessed in this validation study. Yet its construct validity, reliability and responsiveness to change were further proven by the recent studies that adopted the P-CSES (also named Chinese version of the CSES) developed in this study. This Chinese version of the CSES has been used in correlation studies to investigate the correlation of self-efficacy and psychology of patients with COPD (Ma, Zhao, Lu & Tan, 2009) and correlation of QOL and self-efficacy (Yu, Guo, Zhou, Xiao & Hu, 2012); in a predictive study to explore factors associated with self-efficacy in patients with stable COPD (Wang, Zhang & Liu, 2011); and in RCTs to evaluate the effectiveness of a health education programme on self-efficacy in patients with COPD (Ma, Zhao, Liu & Ai, 2009) and self-management programme on the knowledge, beliefs and behavioural outcomes of patients with COPD (Han et al., 2012). Our validation findings as well as the published evidence supported the application of the Chinese version of the CSES to measure self-efficacy in the current study.

5.7.2 Strengths, limitations and implementation of the C-SOLQ

The SOLQ was developed based on the model of the CRQ and its items derived from both CRQ and SF-36, and included three health-related domains and a domain address on treatment satisfaction (Tu et al., 1997). The C-SOLQ retained the structure of the source questionnaire. Validation results provided evidence supporting satisfactory reliability and validity for the C-SOLQ, especially for its three health-related scales. As expected, it was appropriate to measure the HRQOL

in Chinese people with COPD. Our findings proved the uniqueness of the physical function scale of the SOLQ in assessing the same domain of physical function scale of the SF-36 as claimed by authors of the source questionnaire (Tu et al., 1997). Significant correlations were also found between the three health-related scales and majority SF-36 scales.

Nevertheless, this validation study failed to demonstrate a high correlation between the coping skills scale and CSES as reported for the original SOLQ (Tu et al., 1997). The coping skills scale consisted of four items addressing psychological coping aspects, but was inadequate to measure self-efficacy in patients with COPD on multidimensional aspects, as in the CSES. The treatment satisfaction scale had an acceptable internal consistency (Cronbach alpha: 0.79) and test-retest reliability (ICC: 0.56). Portney and Watkins (2009) pointed out that a reliable instrument may not be valid; a valid instrument must be reliable. Further approach such as factor analysis is needed to explore the construct of the C-SOLQ with a larger sample size. Furthermore, the treatment satisfaction scale had only two items to assess patients' satisfaction with treatment of breathing problems. It was inadequate in measuring patients' satisfaction with the TCP in the current study.

Quality of life (QOL) measure usually refers to a patient's functioning, well-being and general health perception in physical, psychological and social domains. Taking the advantage of the feasibility of the SOLQ, the three health-related scales have been used in clinical trials to evaluate the impact of education or rehabilitation on QOL in patients with COPD (Belza et al., 2005; Petty et al., 2006; Steele et al., 2010). Based on our validation findings as well as the published evidence, the C-SOLQ (the

three health-related scales) would be appropriate for use in the current studies to assess patients' HRQOL.

5.7.3 Strengths, limitations and implementation of the CTCPSQ

The CTCPSQ was a self-developed questionnaire specific to measuring patients' satisfaction with the TCP intervention. According to theoretical consideration, the questionnaire comprised the two domains that characterize the two main themes of patient satisfaction with transitional care: service satisfaction and education satisfaction. Factor analysis showed good model fit for the theoretical model which suggested adequate construct validity of this new questionnaire. The high level Cronbach's alpha and ICC estimates indicated that the CTCPSQ had acceptable internal and external consistency reliability.

Although the CTCPSQ satisfied basic psychometric criteria, closer examination highlighted limitations that might restrict its use in the current study. Ceiling effect was noted for all the CTCPSQ items. This might be due to a post-intervention sample being used for the testing. It was remarked by researchers that ceiling effect makes it difficult to grade improvements or detect changes after intervention (Terwee et al., 2007; Wamper, Sierevelt, Poolman, Bhandari, & Haverkamp, 2010). To maximize its strengths, it could be used to detect differences between groups or to make pre- and post-intervention comparisons. Another drawback of this questionnaire was its inadequacy to fully reflect patients' satisfaction in regard to their expectation of and experience with the care they received. This was also a common drawback of using quantitative methods to collecting satisfaction data. Use of a qualitative approach such as focus group interviews in combination with questionnaire to collect data may

help to capture a more meaningful picture of patients' satisfaction (Merkouris, Papathanassoglou & Lemonidou, 2004).

5.8 Conclusion

It is important to achieve the highest quality of measurements possible in our research. This chapter presented the whole process of the three validation studies for the three questionnaires. The study findings provided evidence supporting the use of the SOLQ, CSES and TCTPSQ in the main RCT to evaluate the intervention outcomes on HRQOL, self-efficacy and patient satisfaction.

CHAPTER SIX

IMPLEMENTATION OF THE RANDOMIZED CONTROL TRIAL

6.1 Introduction

This chapter focuses on the methods employed in the main RCT study. It consists of nine sections, including this introduction and concluding summary. The seven remaining sections describe the study setting and participants, sample size estimation, subject randomisation, study intervention, study measures and instruments, data collection and data analysis.

6.2 Study setting and participants

6.2.1. Study setting

The First Affiliated Hospital of Guangzhou Medical University, located in the downtown area of Guangzhou, China, served as the research site for this study. The hospital specialises in respiratory disease and houses a State Key Laboratory for Respiratory Disease, the Guangzhou Institute of Respiratory Disease. It has more than 1,500 beds (including more than 310 beds in the respiratory institute) and provides a comprehensive service to the public.

Both the hospital and the institute were willing to work with our research team to establish evidence for the introduction of transitional care to nursing practice. A designated research and clinical team was formed to carry out the RCT. Team members from the hospital included the nursing directors of both the hospital and institute, the physician in charge of the respiratory units, a project coordinator, a data collector, a respiratory physician and four NCMs. The respiratory physician worked

closely with the project coordinator and NCMs in confirming participants' eligibility, provided timely consultation to the NCMs whenever needed and saw referral cases. Support was also available from the Nutrition Counselling Department, Respiratory Outpatient Department, Emergency Department and respiratory wards when participants were referred for medical help.

The usual discharge care provided to all participants in this study was provided by the hospital and governed by the following standardised procedure. A patient's physician decided on his or her discharge 3 days prior to the discharge date. On the day of discharge, the physician prescribed a week's worth of medication for the patient to take home. A brief discharge summary was written on the patient's outpatient record, and a follow-up appointment was made for about one week after discharge. Nursing care included (1) finalising all of the records and giving the patient a debit note to settle payment; (2) providing medications with brief instructions; (3) giving advice on disease prevention, rest and exercise, nutrition and outpatient follow-up; (4) informing the patient of the availability of free health education pamphlets on COPD; and (5) providing the unit's contact telephone number in case the patient had any questions.

6.2.2 Study participants

All patients admitted to the aforementioned hospital with a diagnosis of COPD that was confirmed by a respiratory physician between November 2008 and December 2009 were screened for study eligibility. The inclusion and exclusion criteria were as follows.

Inclusion criteria

- Diagnosed with COPD according to the criteria set out in national guidelines (Chinese Medical Association Respiratory Disease Branch COPD Group, 2007) and spirometrically confirmed in any of the GOLD stages of COPD severity (GOLD, 2006);
- hospitalised with an acute COPD exacerbation; and
- aged 40 or older.

Exclusion criteria

- Co-existing respiratory condition (e.g. asthma or lung cancer);
- co-morbid condition limiting or likely to limit exercise capacity (e.g. unstable ischemic heart disease, acute congestive heart failure, severe inflammatory joint disease or severe claudication pain);
- existence of a serious psychiatric disorder such as schizophrenia or bipolar disorder;
- residing out of the service area (patient's home could not be reached by public transport or on foot within 60 minutes);
- discharge to another hospital or nursing home;
- inability to speak Cantonese or Putonghua and/or read and write Chinese;
- inability to be contacted by phone/mobile phone; or
- participation in another research programme;
- inability to provide informed consent.

6.3 Sample size estimation

A study's sample size has a strong bearing on its statistical power, and appropriate sample size estimation is therefore very important. The power of a statistical test is defined as the probability that it will yield statistically significant results (Cohen, 1988). Power analysis has been suggested as the most appropriate method of sample size determination (Polit & Beck, 2004). A priori power analysis (also called prospective power analysis) is regarded as an efficient way of controlling statistical power before a study is conducted (Faul, Erdfelder, Lang, & Buchner, 2007; Thomas, 1997). Sample size estimation for this study was based on three key outcome measures that reflected the essence of the COPD-TCP: 6MWD, the PF component of the SOLQ and the overall CSES score.

The sample size necessary to detect an anticipated clinical difference in 6MWD, the SOLQ PF score and the CSES total score with a desired level of power was computed by G*Power 3. The calculations involved three parameters: the desired power level ($1 - \beta$), pre-specified significance level (α) and expected effect size. Power at 80% and an alpha level of 0.05 are widely accepted and commonly used in social science research (Faul et al., 2007; Munro, 2005). The effect size (difference between the null and alternative hypotheses) is usually taken from the literature, and should be based both on what can be regarded as clinically and substantively meaningful and on what previous studies in a related area have found (Browner, Newman, Hearst, & Hulley 2001; Plichta & Garzon 2009). As no previous studies testing a transitional care model in the same way as the current study were available to guide the selection of an appropriate effect size, estimation was based on the most similar studies that could be found.

For 6MWD, the estimated sample size was based on post-intervention group mean $\pm$ SD, intervention group 391.31 ± 68.63 and control group 332.10 ± 59.46 , taken from Oh's (2003) study of a home-based rehabilitation programme. A standard effect size of 0.92, power of 0.8 and two-sided significance level of 0.05 would require 20 participants per group. Allowing for a dropout rate of 20%, the total sample size was set at 48 (24 participants in each group).

Calculation of the sample size for the CSES total score was based on data from a study carried out in mainland China that used the Chinese version of the CSES developed in the preparation phase of the current study to evaluate the effect of a health education programme on self-efficacy in patients with COPD (Ma, Zhao, Liu, et al., 2009). Power of 80%, a significance level of 0.05 and a dropout rate of 20% when a standard effect size of 0.76 was adopted suggested that a target of 68 participants (34 per group) was required for the CSES total score (Ma, Zhao, Liu, et al., 2009).

For the PF score of the SOLQ, sample size estimation was calculated using an indirect method (Berben, Sereika, & Engberg, 2012; Rosenthal, 1991) in which an approximate effect size was determined on the basis of an exact p -value of 0.018 and a sample size of 58. These figures were reported by Belza et al. (2005) in a study carried out to detect HRQOL changes following a pulmonary rehabilitation programme. Calculation included two steps. In the first step, the effect size was calculated in terms of the correlation coefficient (r) using the following formula (Rosenthal, 1991, p 19).

$$r = \frac{z}{\sqrt{n}} = \frac{2.365615}{\sqrt{58}} = \frac{2.365615}{7.6157731} = 0.3106204,$$

where $z = 2.365615$ and $n = 58$. The z -value of 2.365615 was converted from a p -value of 0.009 (the reported two-tailed p -value of 0.018 divided by 2) using the z -score calculator available at <http://sampson.byu.edu/courses/z2p2z-calculator.html>. The second step was to obtain a Cohen's d from the resulting r (Rosenthal, 1991), as follows.

$$d = \frac{2r}{\sqrt{1-r^2}} = \frac{2 \times 0.3106204}{\sqrt{1-0.3106204^2}} = \frac{0.6212408}{0.903515} = 0.6875821.$$

With an effect size of 0.69, G*Power 3 yielded 34 participants per group. Assuming a 20% dropout rate, a total sample size of 82 participants (41 in each group) would be required to detect a clinically significant effect with power of 80% at an α level of 0.05 in the PF subscale score of the SOLQ.

The sample size necessary to test the three key outcomes computed above ranged from 48 to 82 participants. When several sample sizes are indicated, it is recommended that the study opt for the largest size (Browner et al., 2001; Plichta & Garzon, 2009). As a result, the target sample size for the current study was 82.

6.4 Subject randomisation

Randomisation was carried out to assign participants to either the control or intervention group to remove contrived selection bias and help to achieve balance between the study and control groups for factors correlated with outcomes and for events that might affect subjects during the course of the study (Conlon & Anderson, 1990; Portney & Watkins, 2009). Before commencement of the main study, the doctoral student investigator generated a prior randomisation list with 41 sets of numbers (two numbers [1 and 2] in each set; 1-2, 2-1 ... 2-1 in sequence) using the

Research Randomizer (<http://www.randomizer.org/>). These 41 sets of numbers were printed separately on 82 notecards, with one number on each card. All of the notecards were sealed and glued to a piece of cardboard in the original sequence. This piece of cardboard was then used for random assignment in conjunction with a screening checklist developed to check whether a prospective participant met all of the eligibility criteria.

All of the participants were enrolled and allocated by the project coordinator from the hospital, a head nurse who was not involved in the implementation of the intervention or data collection or data analysis procedures. Newly admitted cases were reviewed every Tuesday and Friday (within 72 hours of a patient's admission) for eligibility by means of a medical record review, face-to-face interview and diagnosis confirmation by a physician. If a patient fulfilled the eligibility criteria, he or she was invited to participate in the study. Those who consented to take part and provided signed informed consent were then subjected to the random allocation.

The randomisation process continued with the assignment of participants to groups. Participant allocation proceeded according to the time at which an interested participant returned his or her written consent form. As soon as the project coordinator received this form, she chose one of the sealed notecards from the cardboard and unfolded it. The number written thereon indicated the group to which the participant was to be allocated, with 1 representing the intervention group and 2 the control group. The allocation sequence was concealed until the interventions were assigned. The initial blinded random allocation of participants to the intervention or control group was preserved throughout the trial to minimise bias in the latter's evaluation.

6.5 Study intervention

The study intervention was a COPD transitional care programme (COPD-TCP) comprising two phases: discharge planning and 6-week home follow-up. All participants in the intervention group received the COPD-TCP, as well as the usual discharge care. The control group participants received the usual discharge care alone. The COPD-TCP was delivered by four well-trained NCMs with support from the research and clinical teams. Implementation of the COPD-TCP is described in the following paragraphs.

6.5.1 Discharge planning phase

The COPD-TCP began in its first phase with discharge planning. The project coordinator called one of the four NCMs as soon as she received notification from a physician of a participant's discharge. This NCM then visited the patient who had been assigned to her within the 72 hours prior to discharge to implement discharge planning.

6.5.1.1 Comprehensive health assessment

A comprehensive assessment based on the Omaha System framework was first conducted. The patient's current condition was assessed in the domains of psychosocial, physical and health-related behaviour. Objective evidence supporting the identification of the Omaha problems was obtained through physical examination of the chest, measurement of vital signs, height and weight, investigation of sputum and skin colour, and a laboratory report review (albumin, blood sugar, spirometry and other test results). Corresponding to the purpose of the study intervention, four additional assessments were also conducted to address common problems in patients

with COPD in terms of the Omaha problems: respiration, nutrition, physical activity and medication regimen. The patient's ADL-related dyspnoea level was assessed using the MRC dyspnoea scale (Bestall et al., 1999). Nutrition status was examined to identify the risk of malnutrition by calculating the patient's percentage of ideal body weight and BMI and interpreting the serum value of albumin. An inhalation technique assessment was made if the patient had been prescribed inhalation medication to take home. The patient's inhalation technique was scored on a corresponding assessment checklist (Pressurised metered dose inhaler checklist, Accuhaler checklist, HandiHaler checklist or Turbuhaler checklist). The score obtained indicated the level of behavioural appropriateness as well as the patient's need for teaching (e.g. the lower the score, the less appropriate the behaviour and the more intensive the supervision required). The patient's exercise capacity was assessed by reviewing his or her baseline 6MWT result.

6.5.1.2 Teaching, guidance and counselling

Following the comprehensive assessment, the Omaha intervention scheme was used to guide the NCM in addressing the patient's problems. The NCM delivered an individually tailored education session to equip the patient with the knowledge and skills required for disease self-management. A family member or caregiver was invited to join this session if available. Teaching, guidance and counselling were targeted on the following specific intervention items: disease anatomy and physiology, physical signs and symptoms, respiratory care, exercise, medication action and side effects, medication administration, dietary management (nutrition assessment), substance use cessation and use of programme material and documentation (see Chapter 4, section 4.4.3 for detailed content).

Two important techniques were taught during this education session: the three sets of upper-arm exercises and the inhalation technique specific to the individual patient's current medication device (pressurised metered dose inhaler, Accuhaler, HandiHaler or Turbuhaler). These techniques were taught using the physical demonstration and return demonstration methods to facilitate the learning process. For example, after giving feedback on the patient's previous assessed performance, the NCM used a placebo device to demonstrate the correct technique to the patient. Then, the patient followed the NCM in practising the technique step by step. After practising one to three times, if the patient was able to perform a return-demonstration, the NCM evaluated his or her performance again using a checklist. The NCM pointed out any deficiencies found in this performance, discussed them with the patient and noted them down in the checklist for follow-up during the home visits. A teaching booklet showing each acquired technique with pictures and written descriptions was given to the patient to serve as a guide for self-learning and practice.

6.5.1.3 Treatment and procedures

In the previous two sessions, the NCM gradually established rapport with her patient, and the patient became more knowledgeable about his or her disease. The NCM further developed the core intervention actions on treatment and procedures with specific nursing care and exercise targets. She collaborated with the patient to identify and prioritise care goals and then developed a care plan to achieve those goals. The NCM developed a care contract with the patient, and the patient signed his or her name on the following statement printed in the patient's handbook.

Overcoming chronic obstructive pulmonary disease: I can do it

Chronic obstructive pulmonary disease, abbreviated as COPD, is a chronic and progressive lung disease characterised by airflow limitations. The main symptoms include cough, sputum, and shortness of breath and the symptoms may result in repeated exacerbations. The long-term effects will lead to decline in the function of the heart and the lungs, leading to inadequate physical strength to cope with the activities of daily living. Taking a proactive approach to dealing with this disease will help to control the condition.

I (_____) understand that comprehensive rehabilitation at home after discharge is very important; I am the master in the management of my own disease.

I am confident that, through adhering to rehabilitation training under the guidance of the medical staff and performing good self-management of the disease, my exercise capacity can be increased, symptoms reduced and controlled, and quality of life improved.

For the exercise regime, the patient was recommended to engage in a 6-week home-based exercise programme consisting of daily walking and upper-arm exercises. In the discharge planning phase, the NCM initiated the home-based exercise training programme by supervising the patient as he or she attempted the three following sets of unsupported non-weight-bearing upper-arm exercises (Bauldoff et al., 1996).

- Exercise 1: (1) Start with the arms crossed on the lap, with the elbows straight and the palms facing down; (2) lift the arms up, out and apart until fully extended above the head, approximately 45 degrees from the vertical; (3) rotate the hands to finish with the palms facing posteriorly; and (4) then reverse the movement to return to the starting position.
- Exercise 2: (1) Start with the arms at the sides, elbows straight and palms facing posteriorly; (2) lift the arms out and up until they are vertical above the head; (3) rotate the hands to finish with the palms facing posteriorly; and (4) reverse to return to the starting position.
- Exercise 3: (1) Start with the arms down at the sides, elbows straight and palms facing posteriorly; (2) lift the arms out and up to horizontal while rotating the hands to finish with the palms facing forward; and (3) move the arms forward to meet in the midline, and reverse the motion to return to the starting position.

The patients were given additional instructions for performing the exercises. They were told: (1) to sit in a chair with back support, to keep both feet flat on the floor and the hips and knees at a 90-degree angle, and to place a small pillow behind them to support their lower back; (2) not to lock their elbows during the straight arm lifts and not to perform motions beyond a level that caused them pain or significant discomfort; (3) to perform one repetition per inhalation and to complete one set (six repetitions) on consecutive inhalations if possible; and (4) to begin the number of sets of each exercise as tolerated, and rest up to 1 minute between sets. They were told that an individualised exercise plan would be determined at the first home visit.

6.5.1.4 Case management

The discharge planning phase took approximately 75 minutes, and ended with case management intervention on activities or referrals, as appropriate. Nutritionist care was provided if the patient was identified as at risk of severe malnutrition (percentage of ideal body weight less than 60%, BMI less than 16 kg/m² and serum albumin less than 25g/L). The NCMs communicated about the case with the nutrition specialist responsible for providing support to the research and clinical teams. An appointment was arranged for the patient before discharge, and the patient was advised to meet with his or her NCM after consultation with the nutrition specialist for further instruction on a scheduled date. At the end of this visit, the NCM transferred the patient to home care by providing contact information (her name and the hotline telephone number was written in the patient's handbook) and making an appointment for the first home visit.

6.5.2 Home follow-up phase

The COPD-TCP progressed to its second phase immediately after the patient was discharged, and the nursing intervention extended from hospital to the patient's home for 6 weeks. During this phase, the same NCM who had conducted the discharge planning continued the postdischarge care for her patient with two home visits and four telephone follow-ups, in addition to answering the hotline and making unscheduled visits or telephone calls if needed. The four categories of the Omaha interventions were implemented at each encounter.

6.5.2.1 Home visits

The NCM visited her patient at home within 72 hours of hospital discharge and at week 4 postdischarge. The first home visit lasted approximately 90 minutes, and the second around 60 minutes. The interventions provided during these two home visits included the following.

Comprehensive assessment

Assessments conducted at the patient's home included a comprehensive assessment based on the Omaha System framework. In addition to diagnosing new health problems, if any, the assessment placed emphasis on the environmental domain (particularly any hazards in the home environment) and the follow-up of previously identified problems. Supplemental assessments included a physical examination (observation of pulse, blood pressure, respiratory rate, temperature, oxygen saturation, chest auscultation and sputum appearance), nutrition assessment (a 24-hour diet recall assessment of the patient's dietary pattern) and exercise assessment of the mode and intensity of exercise (which is elaborated upon in the treatment and procedures section below).

Surveillance

Surveillance focused on the current status and possible progression or change in the patient's signs and symptoms, knowledge and/or behaviour, as well as adherence to the treatment regimen and nursing procedures provided, involving all the targeted components stated in the surveillance protocols (see pp.70-71). Respiration, medication regimen, nutrition, environment and circulation were the five most common health problems identified and closely monitored by NCMS in the current

study. To ensure safe unsupervised exercise training, patients were asked to rate their Borg dyspnoea and fatigue scores pre and post exercise and note down any symptoms associated with exercise training such as pain, dizziness. The NCMs checked on their records and condition during each encounter.

Teaching, guidance and counselling

The disease self-management knowledge and techniques acquired in the postdischarge education session were reinforced during both home visits. In addition, during the first home visit, the NCM delivered the content of the education protocols that had not been specifically addressed at discharge, including (1) medical care: outpatient follow-up as scheduled; (2) relaxation and breathing techniques: pursed-lip breathing (with demonstration if required) and relaxation exercise if needed; (3) mobility and transfers: balanced rest and activity; (4) dietary management: nutrition and COPD: eating a healthy balanced diet for well-nourished patients, dietary advice for under- and over-nourished patients and compliance with prescribed diet for patients referred to the dietician; and (5) durable medical equipment, safety and physical signs and symptoms of home oxygen (if needed): care of oxygen and oxygen delivery devices, oxygen safety precautions, reporting signs and symptoms, and home oxygen record.

Treatment and procedures

If the patient was on home oxygen therapy, the NCM also made a durable medical equipment (oxygen) check in addition to the aforementioned teaching and surveillance. The essential nursing treatment and procedures during home visits were

to determine or readjust the individualised exercise plan through the following processes.

Determining mode and intensity of arm exercise: The arm exercise training consisted of three sets of standard arm exercises taught in the discharge planning phase. This training graduated from Level 1 (6 repetitions of each exercise without weights) to Level 6 (3 sets of 6 repetitions of each exercise with 0.6 kg weights in each hand). Determination of the mode (with or without weights) and intensity (Level 1 to Level 6) of training was guided by the patient's oxygen situation during performance and degree of dyspnoea and fatigue upon completion of an exercise. The patient was asked to perform the upper-arm exercise moving from Level 1 to Level 3. Upon completion of each exercise set, his or her SpO₂ was measured using a pulse oximeter, and perceived dyspnoea and fatigue were assessed on a modified 0- to 10-point Borg scale. Determination of the intensity of the arm exercise was therefore based on the level that the patient could tolerate. According to the programme design, the patient was advised to perform without-weight (mode) arm exercises and move from his or her tolerated level up to Level 3 in the first three weeks. Starting from week 4, after reassessment at the second home visit, the patient was advised to progress from Level 4 to Level 6 in the with-weight mode (with 0.2 kg to 0.6 kg weights held in each hand) in the second three weeks. The initial weight (0.2 kg) was determined by whether the patient could complete 6 repetitions of the 3 sets of exercises with it, with measured post-exercise SpO₂ $\geq$ 90%, decreasing $\leq$ 5%, and dyspnoea and fatigue scores $\leq$ 3. An increase in weights was strongly encouraged by the NCMs during a telephone follow-up if the patients could manage 6 repetitions of all three exercises with the initial weight for 7 days.

Determining mode and intensity of walking exercise: The walking exercise was 6-week symptom-limited daily walking, and the duration of each training section was 30 minutes. The patient was allowed to take short rests (2 minutes each) if needed within the targeted exercise time (exclusive of rests). Similar to the arm exercises, the mode and intensity of walking (continuous or intermittent walking) were based on the SpO₂ and Borg score results of a walking test. Patients' walking performance was assessed against the baseline 6MWT results at the first home visit to determine the appropriate mode and intensity for an individualised exercise plan. Before the assessment, the NCM looked for a nearby smooth and safe outdoor walking route on which she and the patient could first perform the walking exercise together. The patient then walked for 30 minutes under the NCM's supervision. While they were walking, the NCM continuously monitored the patient's SpO₂ using a pulse oximeter and instructed him or her to walk at a comfortable pace, i.e. a speed that did not lead to breathlessness, and to continue walking as long as could be tolerated, but to stop and relax for a while if needed. She also instructed the patient to use pursed-lip breathing while walking, especially during the resting time, and to rate his or her symptoms of perceived breathlessness and fatigue at the end of the walk. A single session of 30 minutes of continuous walking per day was recommended if the patient could do so with measured post-exercise SpO₂ $\geq$ 90%, decreasing $\leq$ 5%, and dyspnoea and fatigue scores $\leq$ 3. Patients who needed to rest during the 30-minute walk were encouraged to increase their walking intensity gradually. Proper assessment of physical activity intensity using a Borg scale was made at this performance assessment. The use of supplemental oxygen during exercise was advised by NCMs if the patients had exercise-induced oxygen desaturation (SpO₂ <

88%) or if he or she was already receiving long-term oxygen therapy and his or her SpO₂ had decreased by more than 5% (or was below a value of 90%).

At the end of each follow-up, the health goals set in the previous encounter were reviewed, and new goals established if appropriate. All goals were set in agreement between the patient and the NCM. It was important that patients were able to achieve those goals. The goals setting in this study involved three steps as elaborated below (Table 6.1).

Table 6.1 Steps and elements of mutual goal setting

Steps and elements	An example of mutual goals setting between NCM #B and Patient #37)
Step1: Develop care contract with patient	The NCM explained the importance of goal setting and discussed on the contract content with patient. The patient signed the contract with he expressed full understanding of its content (p.134).
Step 2: Patient stated his/her expected goals	The NCM invited the patient to express his expectation for joining the COPD-TCP. Some of the expected goals of the patient included : (1) to be able to complete in accordance with agreement; and (2) to maintain health so as to live longer
Step 3: Nurse and patient set weekly mutual goals	The NCM and the patient set and reviewed his mutual goals during each encounter, with illustrations as followings: <i>Week 1:</i> (1) To take medications as prescribed; (2) to keep on doing exercise (L3); and (3) to stop smoking. <i>Week 2:</i> (1) To stop smoking; (2) to keep on doing exercise (L3); and (3) to take medications on time. <i>Week 3:</i> (1) To continue with no smoking; (2) to keep on doing exercise (L3); and (3) to monitor blood pressure. <i>Week 4:</i> (1) To keep on doing exercise (L4); (2) to keep on quitting smoking; and (3) to monitor blood pressure. <i>Week 5:</i> (1) To keep on doing exercise (L5); (2) to keep on quitting smoking; (3) to eat balance diet. <i>Week 6:</i> (1) To keep on doing exercise (L6); (2) to go to hospital for respiratory outpatient department follow-up; and (3) to keep on quitting smoking.

Notes: L= level of arm exercise.

Examples were from the nursing record by NCM F and patient log book of Patient #37.

Case management

If the patient required immediate medical consultation during a visit, it was provided. The NCM would call the physician on the clinical team for advice on medication management, treatment alternatives and strategies to address specific patient problems. Other types of medical intervention included physician referral, arrangement of an outpatient or Emergency Department follow-up appointment, or readmission to hospital. The patient's family member or caregiver was encouraged to become actively involved in the patient's disease self-management. At the end of the visit, the case manager reminded the patient of his or her next outpatient follow-up appointment and of the hotline that was available 24 hour a day if they needed further help from an NCM. In addition, the time of the next telephone follow-up was confirmed.

6.5.2.2 Telephone follow-up

The NCM continued the intervention through weekly telephone contact between the two home visits. Hence, the telephone follow-ups took place at weeks 2, 3, 5 and 6 postdischarge. The NCM called her patient at the appointed time. After introducing herself and giving her warm regards to the patient, the NCM initiated a brief Omaha problem assessment and surveillance by asking about the patient's overall health condition, and then asking specific questions designed to: (1) assess the patient's current respiratory condition (signs and symptoms-physical: cough, sputum colour, amount and characteristics, shortness of breath) and the presence of changes that might indicate the possibility of a COPD exacerbation (e.g. change in volume, colour or tenacity of sputum, decreased exercise tolerance, fever, chest tightness, ankle or leg oedema); (2) monitor changes from other specific health concerns that had been

identified in the previous interaction; (3) monitor the progress of, problems with and adherence to the home-based exercise programme; (4) check on any medical care received, such as an outpatient follow-up visit; (5) check with the patient on his or her medication regimen (the NCM asked the patient to bring his or her medications to the telephone for a review, and they then discussed any medication-related problems); (6) monitor compliance with dietary management, particularly for patients receiving nutritionist care; (7) monitor behaviour modification, such as smoking cessation or second-hand smoke avoidance if applicable; and (8) check on home oxygen administration if applicable. While needs were being identified, the NCM also reviewed the patient's progress with regard to the goals established during the previous visit or call, and then set new goals with the patient. The NCM ended the telephone call with words of encouragement and arranged the time for the next follow-up, if applicable. At the end of the last call, that was made before the patient exited the programme, the NCM encouraged him or her to continue with the disease self-management efforts and offered congratulations on the successful completion of the 6-week home-based rehabilitation programme.

All telephone calls were guided by the telephone follow-up implementation record sheet based on the Omaha System framework (Appendix 4.2). The mean length of calls was 10.68 ± 4.37 minutes. During each call, the patient was encouraged to relay his or her concerns and to ask questions, and the NCM provided timely encouragement, information and emotional support in response to individual needs. Any problems that could not be handled over the telephone, such as a problem needing medical attention, prompted an additional visit or referral, as appropriate.

The following two sections give detailed information on the referral care and hotline provided throughout the study period.

6.5.2.3 Referrals

Referrals were provided to meet the various needs of the patients based on the case management protocol. The specific referrals the NCMs provided to the intervention group patients include the following.

- Nutrition Counselling Department referral: two patients who were identified as being at risk of severe malnutrition were referred to the nutrition specialist in the clinical team. Both received a nutrition prescription. After the consultation, they met with their case managers in hospital for further instruction on implementation of the prescription and discussed a care plan for managing their diet. Their progress in and adherence to the prescription were monitored during subsequent home visits and telephone calls.
- Respiratory Outpatient Department referral: five participants were referred to the outpatient department of the hospital or to the team's physician for medication adjustment or treatment of a worsened condition.
- Emergency Department referral: one participant was referred to the Emergency Department in response to a call to the hotline.
- Hospital admission referral: two participants were admitted to the hospital with NCM assistance.

In addition to these multidisciplinary referrals, two participants received an additional telephone follow-up on the day after discharge from a readmission to hospital during the 6-week intervention period.

6.5.2.4 Hotline

The four NCMs served as resource support for the intervention group patients, and took turns manning the telephone hotline, which was available 24 hours a day, 7 days a week. The nurses were provided with a mobile phone to answer the hotline when they were on call. The hotline number and name of the NCM on call at a given time were written in the patients' handbooks, and patients were advised to call the hotline for help whenever they needed it. During the study period, 6 participants called the hotline for their seemingly condition and got immediate help from the on call NCM.

6.5.3 Fidelity of intervention implementation

The study included 30 intervention participants. All of them received the initial phase of intervention before discharge from hospital, and 24 of them (80%) completed the 6-week intervention programme. Thirty (100%) discharge planning visits were conducted while participants were in hospital, and 53 (88.3% of those planned) follow-up visits were made to participants' homes. The four NCMs also placed 154 (85.6% of those planned) telephone follow-up calls to the participants.

The following strategies were adopted to ensure the fidelity of intervention implementation (Sidani & Braden, 2011). The intervention was implemented according to the intervention protocols, and its actual delivery was monitored by the doctoral student investigator. She acted as observer, being physically present at 20% (6/30) of the discharge planning visits and 30.2% (16/53) of the home visits conducted by the four NCMs for the intervention group participants (including those who later dropped out of the study). She gave immediate feedback to the NCMs after each visit and acknowledged the appropriateness of the intervention where applicable.

All of the telephone follow-ups and hotline calls were audio-taped, and the doctoral student investigator regularly reviewed the recordings to check for compliance with the protocols. The NCMs also provided her with their complete nursing intervention records as they completed each case. Research meetings involving the investigator(s), NCMs and other members of the clinical team were held bimonthly to review the intervention process, to discuss issues of concern and to conduct case reviews. Research notes were taken to document both intervention and non-intervention activities for implementation evaluation. In addition, regular reports on progress and problems encountered during the study were sent to the principal investigator, the chief supervisor of the doctoral student investigator, to ensure that timely instruction was available for advice and decision-making. Moreover, the study hospital provided consistent managerial support during intervention implementation, which was facilitated by efficient communication between the research team and the Nursing Department. Finally, participants were encouraged to adhere to the intervention during each encounter with their case manager, that is, during the predischarge and home visits and during the telephone follow-ups. Table 6.2 summarises the extent of participant compliance with the intervention elements.

Table 6.2 Summary of participant compliance with items in the set protocol (n = 21)

Intervention elements	Engagement and adherence
• Disease self-management	Mutual goal setting with nurse: n = 21 Signed self-management contract: n=21 Carried out care plan: n = 21
• Management of worsening symptoms	Following the action plan in seeking help when needed: visited emergency room: n = 3 visited physician: n = 3 called hotline: n = 6 non-adherence (purchase of over-the-counter drug): n = 1
• Medication regimen compliance (dose, frequency, number of drugs, inhalation technique)	Oral medication prescribed: n = 21 Adherence: n = 20; non-adherence (self-medication): n = 1 Inhalation medication prescribed: n = 19 Adherence: n = 19 Remark: adherence was counted if non-adherence behaviour was corrected after intervention
• Long-term oxygen therapy (LTOT)	LTOT prescribed n = 7 Received oxygen therapy: n = 7 (Min: 10 hours, Max: 20 hours; ≥ 15 hours as recommended: Yes, n = 5; No, n = 2) Self-administered oxygen 1-4 hours daily: n = 4
• Rehabilitation exercises: walking and upper-arm exercise	Walking: 30 minutes daily for 6 weeks advised: n = 21 Adherence: n = 21 (100%, Min: 30, Max: 42, Median: 41, Mode: 42, Mean $\pm$ SD: 39.62 ± 3.09 days) Upper-arm exercise: once daily for 6 weeks advised: n = 21 Adherence: n = 21 (100%, Min: 31, Max: 42, Median: 41, Mode: 42, Mean $\pm$ SD: 40.10 ± 2.74 days) Remark: adherence was counted as at least 3 days per week and 30 days in total General reasons given for stopping exercise: raining, feeling dizzy, catching a cold, in pain
• Symptom management	Applied coping techniques (e.g. coughed effectively, used pursed-lip breathing) when needed: n = 21
• Diet management and nutrition	Diet management prescribed: n = 2 Adherence: n = 2 Diet adjustment advised by nurse: n = 11 Adherence: n = 11
• Smoking cessation and avoidance of passive smoking	Current smoker: n = 3 Planning to stop smoking: n = 3; stopped smoking: n = 2; reduced smoking: n = 1
• Scheduled outpatient follow-up	Implemented: n = 21 (including participants who were persuaded by their case managers, n = 3)
• Documentation	Requested: n = 21 Completed: n = 21

Note: Information was summarised from participant and nurse records.

6.6 Outcome measures

The measures that captured the outcome of the COPD transitional care programme covered the five types of essential outcomes in nursing practice proposed by Urden (2001). They were clinical outcome – exercise capacity; psychosocial outcome – self-efficacy; functional outcome – HRQOL; fiscal outcome – readmissions and cost; and satisfaction outcome – patient satisfaction. The first three were the key outcome measures in this study, as they reflected the essence of the COPD-TCP. Three instruments and one test were used to evaluate these outcomes in addition to the existing readmission data from the hospital information system and the Sociodemographic and Clinical Data Sheet (Appendix 6.1), and spirometry was used to collect data on participant characteristics. These instruments and test were the Seattle Obstructive Lung Disease Questionnaire (SOLQ, Appendix 6.2), COPD Self-Efficacy Scale (CSES, Appendix 6.3), COPD Transitional Care Patient Satisfaction Questionnaire (CTCPSQ, Appendix 6.4), and 6MWT (Appendix 6.5). In order to collect fiscal outcome data occurred outside the study hospital, a health service utilisation and cost record sheet was designed for use in this study (Appendix 6.6). The endpoint measures of the three key outcomes were 6-minute walk distance (6MWD), used to test exercise capacity; the physical function (PF) subscale score of the SOLQ, used to evaluate physical function in relation to HRQOL; and the CSES total score, used to assess self-efficacy. Table 6.3 summarises the aforementioned outcomes and measures. The paragraphs thereafter describe each of them and the baseline measures in detail.

Table 6.3 Study outcomes and measures

Outcomes	Measures
Exercise capacity	6MWD
Quality of life	SOLQ – physical function score SOLQ – emotional function score SOLQ – coping skill score
Self-efficacy	CSES – total score CSES – negative affect score CSES – intense emotional arousal score CSES – physical exertion score CSES – weather/environment score CSES – behavioural risk factors score
Patient satisfaction	CTCPSQ – satisfaction with care score CTCPSQ – satisfaction with health education score
Readmissions and cost	COPD-related readmission – total readmissions COPD-related readmission – time to first readmission COPD-related readmission – direct cost of readmission
Abbreviations: 6MWD = 6-minute walk distance; SOLQ = Seattle Obstructive Questionnaire; CSES = COPD Self-Efficacy Scale; CTCPSQ = COPD Transitional Care Patient Satisfaction Questionnaire.	

6.6.1. Exercise capacity

Exercise capacity was evaluated by a commonly used objective measure of functional exercise capacity, the 6-minute walk test (6MWT). The 6MWT measures the distance covered (in metres) during 6 minutes of walking (6-minute walk distance [6MWD]) with standardised encouragement. The 6MWT resembles a familiar daily activity and involves minimal technical resources (Sciurba et al., 2003). It is recommended by the GOLD guidelines (GOLD, 2006) to assess the exercise capacity of patients with COPD, and is considered useful for measuring outcomes before and after pulmonary rehabilitation (Nici et al., 2006). Change in the 6MWD test is an important indicator of the effectiveness of an intervention in clinical trials

(Holland et al., 2010; Puhan et al., 2008). It has been suggested that a 35-m 6MWD change in patients with moderate to severe COPD would represent an important effect, being indicative of both a significant clinical change and a statistically significant result (Puhan et al., 2008). A more recent study yielded a minimal important difference (MID) of 25 m in COPD patients with a wide range of disease severity after rehabilitation intervention (Holland et al., 2010). The 6MWT has proved since its introduction in 1976 to be reliable, objective, inexpensive and easy to apply (Pinto-Plata, Cote, Cabral, Taylor, & Celli, 2004; Puhan et al; 2008). In this study, the 6MWT was performed according to guidelines (Nici et al, 2006).

6.6.2 Health-related quality of life (HRQOL)

HRQOL was assessed using the Chinese version of the SOLQ (C-SOLQ) developed in the current study. The original SOLQ (Tu et al., 1997) covers four domains: physical function (PF), Emotional function (EF), Coping skills (CS) and Treatment satisfaction (TS). The first three health-related domains were considered in the main study. There were five major reasons for the use of this instrument. First, the SOLQ is a disease-specific questionnaire commonly used to measure HRQOL in the COPD population, and has been demonstrated to be valid and reliable (Curtis & Patrick, 2003; Mahler, 2000; Santo Tomas & Varkey, 2004; Tu et al., 1997; Xu, Ma, & Yang, 2008). Second, it has been shown to be sensitive to change in patients participating in health education, exercise training or pulmonary rehabilitation programmes (Belza et al., 2005; Petty et al., 2006; Steele et al., 2010; Tu et al., 1997). Third, a minimum clinically significant change of approximately 5 points has been established, and can be used to provide guidance on interpreting whether the change in a study is clinically meaningful (Mahler, 2000; Tu et al., 1997). Fourth, it is short, easy to

self-administer and can be completed in 5-10 minutes (Tu et al., 1997). Finally, some of the SOLQ items were adopted from the SF-36, a generic QOL questionnaire commonly used in nursing research. The SOLQ has been shown to be more sensitive to changes than the SF-36, and the three subscales used in the current study have been found to be associated with SF-36 domains (Belza et al., 2005; Curtis & Patrick, 2003; Santo Tomas & Varkey, 2004; Tu et al., 1997). Moreover, the psychosomatic properties of the C-SOLQ were established in the validation study presented in chapter 5.

As noted in that chapter, the reliability of the C-SOLQ was satisfactory in this study. The Cronbach's alpha of the three health-related subscales ranged from 0.73 to 0.92. The test-retest reliability of the three subscales, as indicated by their intraclass correlation coefficients (ICCs), ranged from 0.82 to 0.84. With regard to validity, a change in the C-SOLQ scores was correlated with a corresponding change in the SF-36 items of Physical Function, $r = 0.82$; Role-Physical, $r = 0.40$; Bodily Pain, $r = 0.13$; General Health, $r = 0.42$; Vitality, $r = 0.37$; Social Functioning, $r = 0.64$; Role-Emotional, $r = 0.38$; and Mental Health, $r = 0.40$ (the detailed psychometric testing results of the C-SOLQ are presented in Chapter 5). The three SOLQ domains used in this study, i.e. PF, EF and CS, have 27 items in total. A response to each item was scored from 1-5 or 1-7 on a 5- or 7-point linear scale, where 1 represents the lowest function and 5 or 7 the highest. The score of each response in a scale was summed into a raw score, and then transformed into a normalised score ranging from 0 to 100, a higher score indicating better functioning (Tu et al., 1997).

6.6.3 Self-efficacy

The Chinese version of the CSES was the instrument used to assess the effect of the transitional care intervention on the participants' self-efficacy. This Chinese version (Putonghua version) of the CSES (P-CSES) was revised from the modified Chinese version (Cantonese version) of the CSES (C-CSES) developed in Hong Kong (Wong, Wong, et al., 2005). It has 31 items divided into five subscales. The items concern being able to manage to breathe or avoid breathing difficulty in a particular situation. Individuals respond to each item on a 5-point Likert-type scale ranging from 5 (very confident) to 1 (not at all confident). A higher score indicates a higher level of self-efficacy. The reliability of the Chinese version of the scale was further tested in this study after its revision from the C-CSES (see Chapter 5: Instrument validation). The internal consistency of the Chinese version of the CSES, as indicated by the ICCs, ranged from 0.66-0.85 for each of the five subscales.

6.6.4 Readmissions and cost

Acute exacerbation of COPD is the major cause of hospitalisation in this disease, and thus imposes a heavy direct acute care cost on patients (Chen et al., 2008; Rabe et al., 2007). The effects of the COPD-TCP on COPD-related readmissions and the direct cost of the COPD-readmission were therefore included as an outcome measure in this study. COPD-related readmission herein refers to readmission with a principal diagnosis associated with COPD, including COPD with acute lower respiratory infection (International Classification of Diseases, Tenth Revision, Clinical Modification [ICD-10-CM]: J44.0) and Chronic obstructive pulmonary disease with (acute) exacerbation (ICD-10-CM: J44.1). Measures of readmission included two

most commonly used indicators in transitional care RCTs, the total readmissions and time to first readmission (Naylor et al., 2011).

In this study, the episode of hospital admission when the patient was recruited as subject is defined as “index admission”. A readmission was identified if a patient was readmitted within 6 weeks with a principal diagnosis of COPD to the study hospital or other hospital after discharged from the index admission (for 6-week assessment) or 12 weeks (for 12-week assessment). Time to first readmission was calculated as the number of days between the index discharge date and the readmission date. Direct cost of COPD-related readmission referred to the total amount the hospital charged for the entire hospital stay, which consisted of bed charge, medicine, traditional Chinese medicine, diagnostic investigations, treatment procedures, laboratory, radiology, oxygen and other expenses.

Existing data for the estimation of all these variables were available from the hospital information system, but the health service utilisation and cost record sheet was used to confirm data when the patient was admitted in the study hospital and add information when the patient was admitted to other hospitals.

6.6.5 Patient satisfaction

Patient satisfaction was evaluated using the CTCPSQ to determine patients’ satisfaction with the COPD-TCP. The CTCPSQ is a disease-specific self-reported satisfaction questionnaire that takes approximately five minutes to complete. It comprises 14 items in two domains: service satisfaction (6 items) and education satisfaction (8 items). Each item is rated on a 5-point Likert-type scale with the

following response options: 1 = very satisfied, 2 = satisfied, 3 = neutral, 4 = dissatisfied, 5 = very dissatisfied. The raw score of each item ranges from 1-5. In this study, the scores of individual items were first summed into an actual raw score that was then transformed into a score ranging from 0 to 100. The higher scores represent higher levels of satisfaction.

6.6.6 Baseline sociodemographic and clinical data

The Sociodemographic and Clinical Data Sheet, was used to assess participants' sociodemographic profile and COPD-related clinical characteristics. It consists of two parts. The first part collects data on age, sex, marital status, educational level, employment status, economic status (average household income) and types of healthcare payment. The second part collects data on COPD history, smoking status, pulmonary function, care needs and social support (caregiver and care availability).

Smoking status referred to patients' current smoking status and the number of packs they smoked per day over the course of a year (measured by 'pack-year'). The aim was to determine whether a participant was a current smoker, former smoker or had never smoked. Participants who reported that they had never smoked in their life were defined as never-smokers; those who reported that they used to smoke cigarettes regularly but no longer did so were defined as ex-smokers; and those who reported that they regularly smoke now were defined as current smokers. The number of packs query was intended to estimate the cumulative dose of cigarette smoking. Assuming 20 cigarettes per pack, pack-years were estimated using the following formula: $(\text{cigarettes per day}/20) \times \text{years smoked}$ (Foy, Goff, Bell,

Wagenknecht & Farmer, 2005). One pack-year was regarded as the equivalent of 20 cigarettes per day for a year.

Post-bronchodilator spirometry is the gold standard for diagnosing COPD (GOLD, 2006; Zheng & Gao, 2009). Airflow obstruction was defined as a post-bronchodilator FEV₁ that is less than 80% of that predicted in association with an FEV₁ to forced vital capacity ratio (FEV₁/FVC) of less than 70% (Chinese Medical Association Respiratory Branch COPD group, 2007; GOLD, 2006). In this study, spirometry, a common type of pulmonary function testing was performed to determine the post-bronchodilator FEV₁% predicted and FEV₁/FVC value. According to the GOLD guidelines (GOLD, 2006), spirometric stage of COPD severity was classified into four stages: Stage I: Mild COPD (FEV₁/FVC ratio < 70%, FEV₁ ≥ 80%); Stage II: Moderate COPD (FEV₁/FVC ratio < 70%, 50 ≤ FEV₁ < 80%); Stage III: Severe COPD (FEV₁/FVC ratio < 70%, 30 ≤ FEV₁ < 50%); and Stage IV: Very Severe COPD (FEV₁/FVC ratio < 70%, FEV₁ < 30% or < 50% plus chronic respiratory failure).

6.7 Data collection

In the RCT reported herein, pre- and post-intervention assessments were conducted to obtain reliable and significant data to answer the study's research hypotheses. Data were collected at three time points: T0 – before the intervention (baseline assessment), T1 – immediately following completion of the intervention (6-week assessment) and T2 – at programme exit (12-week assessment). The pre-intervention data collected at T0 provided a baseline for comparison, whilst the post-intervention

data collected at T1 and T2 were compared with the T0 data to detect intervention effects.

A data collector who was not involved in the intervention and was blind to the group assignment and study hypotheses was responsible for data collection. To ensure the quality of data collection, she was trained for two weeks on the performance of the spirometry, 6MWT and questionnaire data collection technique under the supervision of a lung function technician and the doctoral student investigator. The data collection procedure was also tested in a pilot study.

6.7.1 Baseline data collection

Baseline assessment lasted approximately 90 minutes and collected the required data from the Sociodemographic and Clinical Data Sheet, C-SOLQ, CSES, 6MWT and spirometry. The measures were administered in the following order:

- Brief clinical history
- Measurement of body temperature, resting blood pressure, height and weight
- Pre-bronchodilator spirometry trials
- Administration of the Sociodemographic and Clinical Data Sheet
- Post-bronchodilator spirometry trials
- Administration of the CSES and C-SOLQ
- 6MWT

Spirometry

Spirometry was performed in the respiratory unit of the hospital by the data collector using a portable multifunction spirometer (Spirobank II, Medical International

Research, Rome, Italy). The test was conducted according to the national lung function test guidelines (Zheng & Gao, 2009). Participants were asked to withhold administration of bronchodilators, where prescribed, for at least 4 hours prior to testing. The purpose and procedures of the test were explained to them, and the data required by the test software, such as the patient's age, sex, date of birth, ethnic group, height, weight, smoking status and pack-years, were obtained. They were asked for a brief clinical history, and their body temperature, heart rate and blood pressure were taken before the test to ensure that it was safe and appropriate to administer it. The post-bronchodilator spirometry trials were performed 30 minutes after administration of 200 mg of salbutamol.

Six-minute walk test

The 6MWT was conducted according to published guidelines (ATS Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories, 2002; He, 2006). All tests were conducted in the hospital using a straight 30-metre indoor track, with each 0.6 metres of the track length marked by 50 floor tiles. A starting line, which marked both the beginning and end of each 60-m lap, was marked with two small cones indicating the turnaround points. The 6MWT involved a walking phase of 6 minutes and resting phase of 2 minutes. The equipment used in the 6MWT included the following. (1) The Spirobank II, a portable multifunction spirometer with pulse oximetry (the same instrument used in the pulmonary function tests), was used to continuously monitor and record oxygen saturation (SpO₂) and pulse rate during the walk test. (2) A countdown timer was used to measure the time. (3) A mobile phone was available to call for help if needed. (4) A portable oxygen cylinder was on hand for emergency use by participants on oxygen therapy. (5) A first-aid kit

with a digital blood pressure monitor and salbutamol inhaler was available for use. (6) The data collector carried a clipboard to hold the required worksheets. In addition, chairs were made available near each end of the walking course in case participants needed to sit down, and emergency help was available from the nearby outpatient rehabilitation clinic.

Before the start of the test, the participant sat for at least 10 minutes in a chair located near the starting position. During this rest period, his or her blood pressure was taken, and contraindications checked, and he or she was given the following information/instructions.

The purpose of this test is to find out how far you can walk in 6 minutes. This (indicating the spirometer) is a device used to continuously monitor your heart rate and SpO₂. You are required to hold it in your hand while walking. You will start from this point (indicating the marker at one end of the course) and follow the path until the 6-minute period is completed. If you need to stop during this time, please do so, but remain where you are until you can start again. I shall tell you the time at each minute. When the 6 minutes are nearly up, I shall walk towards you and take the device from you. You will keep on walking until I tell you to stop. When I say 'stop', please stop at once and stand still.

The participant was then asked to practise walking and to pivot around a cone briskly by walking for 1-2 laps before the start of the formal test. When the participant was ready to walk, he or she was positioned at the starting line and asked to insert his or her middle finger into the sensor connected to the spirometer. The test began with an

initial rest phase during which the participant's resting pulse rate and SpO₂ were monitored for 2 minutes. During this phase, the participant's baseline ratings of perceived dyspnoea and perceived exertion were measured using the modified Borg scales (on whose use he or she had been given standardised instructions), which were printed on both sides of a laminated card in 28-point SimSun font on a light green or light yellow background.

Once the initial rest phase had been completed, the participant was asked to start walking with the spirometer held in his or her hand, and the data collector switched on the countdown timer at the same time. During the walking phase, the data collector stood near the starting line, monitored the participant's performance, and marked 1 lap on the worksheet whenever the participant returned to the starting point. The data collector provided the participant with feedback on his or her time progression and gave encouragement every minute using the phrase "You are doing well" or "Keep up the good work". The participants who were on chronic oxygen therapy were given supplemental oxygen at the flow rate prescribed by their physician. The data collector carried a portable oxygen cylinder and walked behind these participants during the test. Participants were allowed to stop and rest at any time during the test with the spirometer and timer still running.

When the 6 minutes were nearly up, the data collector walked towards the participant, took over the device, switched it off when its alarm sounded, and instructed the participant to stop. The participant's post-test dyspnoea and fatigue were then rated using the two Borg scales. Finally, the distance walked was counted and data

required by the instrument inserted, and the selected output data were recorded in the spirometer and 6MWT record sheet.

6.7.2 Post-intervention Time 1 (T1) and Time 2 (T2) data collection

Participants were invited back to the hospital for data collection at T1 and T2. Before discharge, they received an appointment sheet with the date of these follow-up visits. One to two days before each follow-up visit, the data collector phoned the participants to reconfirm their availability. During this phone call, the participants were reminded to wear comfortable clothing and appropriate shoes for walking and to bring their appointment sheet along with them. On the day of the visit, the participants came to the respiratory unit for data collection. The required measurements or data were the SOLQ, CSES, 6MWT and COPD-related readmissions and cost at both T1 and T2 and CTCPSQ at T1. Participants were asked to complete all of the self-administered questionnaires and record sheet first and then to perform the 6MWT after their temperature, height and weight had been measured. At the end of T2 data collection, all of the participants in the intervention group submitted their log books and the control group participants submitted their appointment sheets. These log books or sheets contained participants' self-reported information on hospital readmission and direct healthcare costs, with copies of their payment receipt. Their outpatient records (which contained a discharge summary with information on the discharge diagnosis and the time and length of readmission) were also checked as needed. These follow-up hospital visits lasted approximately 40 minutes.

Alternative strategies were adopted for participants who were unable to return for data collection at these time point. The relevant data were collected either at their home (n = 2 at T1, n = 1 at T2) or through the post (n = 2 at T2). For the readmission cases, the data were collected while the participants were in hospital (n = 4 at T1, n = 1 at T2).

In addition to the aforementioned self-reported information on health service utilisation and cost, existing records on hospital readmission, including cost data, were extracted from the hospital information system by a head nurse from the institute. All personal data and information not required for the study were deleted before the data file was given to the doctoral student investigator. The corresponding data that were finally collected included hospital code, age, sex, readmission date, discharge date, length of hospital stay, ICD-10-CM code and treatment outcome. For the dropouts, the project coordinator helped to retrieve the information from hospital records and confirmed the information through telephone call with the patients at the end of the study.

6.8 Data analysis

The data analysis process began with data entry and cleaning, followed by missing data management and, finally, statistical analysis.

6.8.1 Data entry and cleaning

The information collected from the instruments was coded and entered into a computer to establish a database. The entered data were cleaned and verified (Polit & Beck, 2004; Portney & Watkins, 2009). To clean the data, frequency counts were

checked for all categorical variables to identify any mistakes in the codes if the variables had too few entries or were missing. Means, minimums and maximums were run for all continuous variables to make sure that the range of scores was appropriate. For data verification, the data file was printed and visually checked for accuracy against the original. The foregoing procedures were carried out twice by the student investigator and a student helper to ensure the accuracy of the dataset. Any errors discovered were corrected prior to data analysis.

6.8.2 Missing data management

Missing data found in the dataset posed a special challenge to data analysis. Three major tasks were carried out to manage missing data before statistical analysis: identification of the pattern and amount of missing data, assessment of the potential reasons for the data to be missing and determination of a strategy to handle the missing data (Munro, 2005).

6.8.2.1 Identifying amount and pattern of missing data

The missing data rate can be counted at the item, wave and unit level: at the unit level where no information was collected, at the wave level where data are missing from a wave in a longitudinal study and at the item level where partial data are available (Hardy, Allore, & Studenski, 2009). Based on the nature of the data collected in this study, missing data were calculated at the wave level before the final statistical analyses (detailed calculation and results will be given in next chapter). The missing data pattern was identified using the method suggested by Munro (2005); that is, an independent *t*-test was performed to determine whether serious and

significant differences were noted between a two-level grouping variable (cases with missing data versus cases without) and the dependent variables.

6.8.2.2 Assessing potential reasons for missing data

Knowledge of the reasons for missing data is important in determining the method to be used to handle that data and identification of their potential impact on data analysis and interpretation of the results. The reasons for the missing data in this study were examined by reviewing the research records compiled by the research assistant, NCMs and student investigator in their areas of responsibility.

6.8.2.3 Handling missing data

Missing data can be handled in many ways. The most common method is to impute estimated missing values with some predicted values (Armijo-Olivo, Warren, & Magee, 2009). With a missing data rate of 9.03% in the current study (see Chapter 7, Table 7.1), a single imputation method, the last observation carried forward (LOCF) approach, was adopted, as it is suitable for missing random data in a mean comparison when the percentage of missing data is less than 10% (Scheffer, 2002). Using the last observation carried forward approach, missing follow-up values were replaced by the last observation values carried forward from the baseline values, or by any observed intermediate values for drop-outs, based on the assumption that these values represented the intervention effect (Wood, White, & Thompson, 2004).

6.8.3 Statistical analysis

The data were analysed using both per-protocol (PP) analyses and the intention-to-treat (ITT) principle, which is strongly recommended for clinical trials

(Armijo-Olivo et al., 2009; Portney & Watkins, 2009; Schulz et al., 2010). Both descriptive and inferential statistics were used in the data analyses. Table 6.4 summarises the types of analyses and tests conducted at each time point for each measure, and the paragraphs thereafter provide detailed information.

Table 6.4 Summary of data collection and analyses

Measures	Time		Analysis			Statistical Test(s)
	T0	T1	T2	PP	ITT	
Characteristics	✓			✓	✓	Baseline: • Chi-square test • Fisher's exact test • Mann-Whitney U test • Independent t-test
6MWD	✓	✓	✓	✓	✓	Baseline: • Independent t-test T1 or T2: • ANCOVA T0, T1 and T2: • Repeated measures ANCOVA • Bonferroni post-hoc test
SOLQ	✓	✓	✓	✓	✓	Baseline: • Independent t-test T1 or T2: • Independent t-test T0, T1 and T2: • Two-way repeated measures ANOVA • One-way repeated measures ANOVA • Bonferroni post-hoc test
CSES	✓	✓	✓	✓	✓	Baseline: • Independent t-test T1 or T2: • Independent t-test T0, T1 and T2: • Two-way repeated measures ANOVA • One-way repeated measures ANOVA • Bonferroni post-hoc test
CTCPSQ		✓		✓		T1: • Mann-Whitney U test
COPD-related readmissions						T1 or T2:
Total readmissions		✓	✓		✓	• Chi-square test
Time to first readmission		✓	✓		✓	• Mann-Whitney U test
Direct cost of readmission		✓	✓		✓	

6MWD = 6-minute walk distance; SOLQ = Seattle Obstructive Lung Disease Questionnaire; CSES = COPD Self-efficacy Scale; CTCPSQ = COPD Transitional Care Patient Satisfaction Scale; ANOVA: Analysis of variance; ANCOVA: Analysis of covariance.

6.8.3.1 Intention-to-treat (ITT) and Per-Protocol (PP) analysis

The ITT principle is a conservative approach to dealing with missing data. It has been widely recommended as the preferred approach in avoiding bias while analysing the outcomes of randomised trials (Armijo-Olivo et al., 2009; Matilde Sanchez, & Chen, 2006; Peduzzi, Henderson, Hartigan, & Lavori, 2002; Schulz, 2010). In ITT analysis, data are analysed by assuming that each participant received the intervention to which he or she was assigned (Portney & Watkins, 2009). To provide a more valid assessment of the effects of intervention, ITT analysis was regarded as the main analysis in this study, and all recruited participants who began to receive the allocated treatment and were assessed at baseline were included therein. ITT analyses with LOCF were conducted for the outcome measures of 6MWD, CSES (including the overall CSES and NA, IEA, PE, WE, and BRF subscales), SOLQ (including the PF, EF and CS subscales) at T1 and T2 (Table 6.4). It was also suggested that a better application of the ITT approach was possible if complete outcome data were available for the ITT population, and care should be taken to continue to follow up those who withdraw from the study (Gupta, 2011). In the current study, although some patients dropped out the study, complete data on readmissions were accessible through the hospital information system. ITT approach was therefore applied to analyse the data of COPD-related readmissions, including total readmissions and time to first readmission and direct cost of readmission at T1 and T2 using the actual data without the need to impute missing data.

Whilst ITT analysis uses data from all subjects, PP analysis excludes data from subjects who were not fully compliant with the study protocol (Peduzzi et al., 2002). In other words, only data from those subjects who were originally allocated to and

completed the intervention including the prespecified follow-up are used for analysis. PP analysis is assumed to be able to provide information on the maximum treatment effects in patients who adhere fully to the treatment (Armijo-Olivo et al., 2009). However, if this method alone is used, it tends to bias the results in favour of an intervention effect, thereby leading to a misleading interpretation of the results (Portney & Watkins, 2009). In this study, PP analyses were performed in addition to ITT analyses to test the sensitivity of the results for the three key outcomes. Only those participants who had both baseline and all follow-up values for the respective outcomes were included in the PP analyses, which were conducted for 6MWD, CSES and SOLQ at T1 and T2 (Table 6.4). Besides, PP analytic strategy was also applied to analyse the CTCPSQ data, because this outcome measure was evaluated at T1 (immediately after the 6-week intervention) only. As a result, all participants assessed at T1 were included in the analysis.

6.8.3.2 Descriptive and inferential statistical analyses

Statistical analyses were performed using IBM SPSS Statistics version 19 software (SPSS, an IBM company, Chicago, Illinois, USA). Descriptive statistics were first used to describe the participants' characteristics at baseline. The baseline descriptors were summarised as mean and standard deviation (SD) for the continuous variables (e.g. age, smoking pack-years, FVE₁% predicted, FVE₁/FVC), median and range in the case of non-normal distribution, and frequency and percentage for all categorical variables (e.g. sex, marital status, education level). The Shapiro-Wilk test was used to examine the normality of the data distribution. Various inferential statistical tests were conducted to assess the comparability of the control and intervention groups and that of the ITT and PP sample and to test the research hypotheses according to

the nature of the data. All inferential tests were two-tailed. A p -value of less than 0.05 denoted statistical significance.

Baseline data analysis

As shown in Table 4.2, an independent t-test, chi-square test, Fisher's exact test or Mann-Whitney U Test were used to examine the baseline equivalence of the control and intervention groups in both the ITT and PP populations for each variable of participants' demographic and COPD-related clinical and social characteristics. An independent t-test was used to investigate the baseline equivalence of the control and intervention groups in both the ITT and PP populations for the three key outcome measures: 6MWD, SOLQ and CSES.

Follow-up data analyses

Using the information gathered in the baseline measurement, comparisons were then performed using the following specified tests for differences and changes in each outcome variable.

- Independent t-test: used to test the difference between the control and intervention groups at T1 and T2 in SOLQ and CSES scores.
- ANCOVA: used to compare the 6MWD between the two groups at T1 and T2, with the baseline 6MWD as a covariate.
- Repeated measures ANOVA: performed to test the difference in 6MWD for the between-group, within-time and interaction effects, with the baseline 6MWD as a covariate.

- Two-way repeated measures ANOVA: employed to investigate the difference in SOLQ and CSES for the between-group, within-time and interaction effects across the three time periods.
- One-way repeated measures ANOVA: conducted to determine the significant changes occurring over the three time periods for individual groups in 6MWD, SOLQ and CSES. When significant changes were found, a multiple comparison (Bonferroni) test was applied to identify which pairs (T0 vs. T1, T0 vs. T2 and T1 vs. T2) showed the differences.
- Mann-Whitney U-test: used to test the difference in the mean ranks of the CTCPSQ scores in the control and intervention groups at T1 and that in the COPD-related readmission measures and direct cost of readmission in the two groups at T1 and T2.
- Chi-square test: performed to examine the difference in proportions between the control and intervention groups in the total frequency of COPD-related readmission.

6.9 Summary

This chapter describes the full implementation process of the main RCT study. It describes the study setting, participants, sample size estimation, subject randomisation, study intervention, study measures and instruments, and data collection and data analysis methods. The next chapter presents the study's main results.

CHAPTER SEVEN

RESULTS

7.1 Introduction

This chapter consists of two parts. Part 1 presents the quantitative findings of the main study. The subject recruitment process and characteristics of the participants are described before reporting the baseline and follow-up results. The results of the five outcome measures, exercise capacity, HRQOL, self-efficacy, readmissions and cost of readmission and patient satisfaction, are then reported following the baseline findings. Part 2 turns to a discussion of the study's qualitative results, reporting the findings of the focus group interviews and the written responses to the exact questions asked on the focus group from participants who did not join these interviews. This part of the chapter begins with description of the characteristics of the participants following by the presentation of the findings.

Part 1 Quantitative results

7.2 Subject recruitment

Subject recruitment for this study began in November 2008 and continued for 13 months. Data collection for the last participant ended in March 2010. A flow diagram of participant progress through each phase of the trial (Figure 7.1), based on the 2010 updated Consolidated Standards of Reporting Trials (CONSORT) statement (Schulz et al., 2010), shows the flow of subject enrolment, intervention allocation, follow-up and data analysis. Details of each phase are described following the diagram.

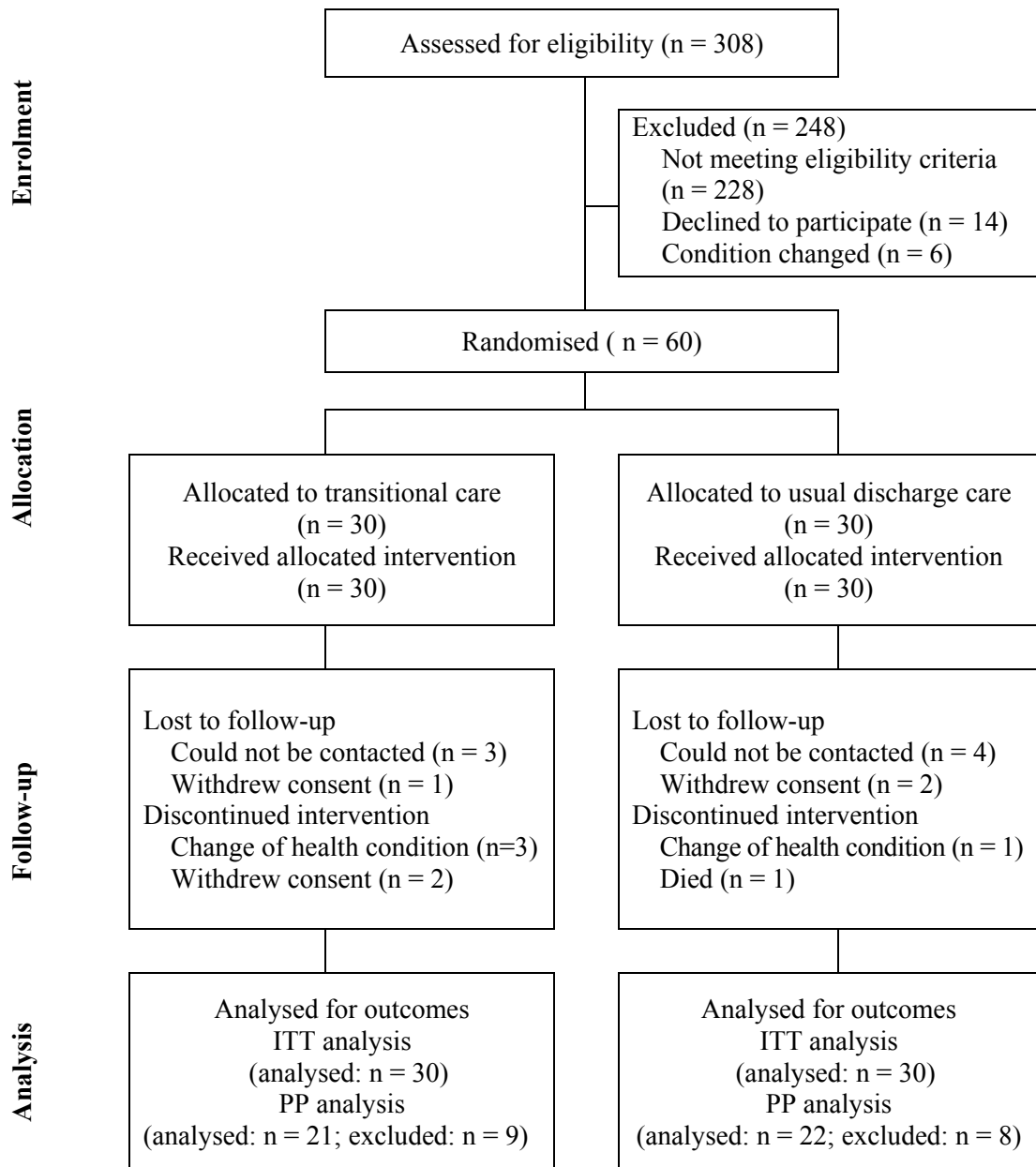


Figure 7.1 CONSORT flow diagram of trial phases

7.2.1 Enrolment

During the 13-month recruitment period, 308 patients with COPD were admitted to the two respiratory wards of the study hospital, of whom 217 were excluded after medical record screening because they did not meet the eligibility criteria. Most of these were excluded because they lived outside the service area, had not been admitted for COPD exacerbation, had a clinical excluding diagnosis such as asthma

or acute congestive heart failure, or had been recruited into another study. The remaining 91 patients were approached for inclusion, but a further 11 cases were excluded for the following reasons. Two patients spoke neither Cantonese nor Putonghua, four were unable to be contacted or to communicate by telephone and five actually lived outside the service area. The 80 remaining potential participants were then invited to join the study. Fourteen of them refused to participate, either because of a lack of time or interest, and another six were lost because their condition changed before allocation. At the end of the recruitment process, 60 participants who fulfilled the eligibility criteria agreed to participate and were subjected to the random allocation process.

7.2.2 Allocation

Participants were randomly allocated to either an intervention or control group after obtaining their written informed consent. Following completion of baseline (T0) data collection, all participants began to receive their allocated intervention. The control group received the usual discharge care, and the intervention group received the usual discharge care plus the 6-week transitional care programme developed for this study. Seven participants (five in the intervention group and two in the control group) discontinued the intervention during the 6-week follow-up period.

7.2.3 Follow-up

During the follow-up phase, 10 subjects were lost to follow-up. Together with the seven lost during the intervention period, a total of 17 of the 60 initial participants (28.3%) dropped out of the study (control 8/30 vs. study 9/30). The reasons for dropout included loss of contact ($n = 7$), withdrawal (refused home visit or follow-up, $n = 2$; work or family role conflict, $n = 3$), change in medical condition (newly

diagnosed pulmonary embolism and thus joined another study, $n = 1$; suffering from low back pain and bed bound from the second day postdischarge, $n = 1$; and diagnosed with lung cancer or tuberculosis and admitted for chemotherapy during the intervention phase, $n = 2$) and death ($n = 1$, at week 6 postdischarge). At the end of the 12-week follow-up, 22 of the 30 subjects (73.3%) in the control group and 21 of the 30 (70.1%) in the intervention group remained to complete the study.

A total of 49 participants (control group: $n = 26$; intervention group: $n = 23$) were assessed at T1 (immediately after the 6-week intervention), although one participant did not complete the questionnaire assessment and eight did not perform the 6MWT because of their condition or did not show up for the tests. All 43 participants who completed the study (control group: $n = 22$; intervention group: $n = 21$) were assessed at T2 (at the exit of the study programme), but three of them did not take the 6MWT. Although the data from the three questionnaires and 6MWT were unobtainable from the withdrawal cases, fiscal data were available from the hospital electronic information system, and those were reconfirmed with the participants. Following completion of the data collection phase, the study moved on to the data analysis phase.

7.2.4 Analysis

This phase began with data management. The steps taken to manage the data are described in Chapter 6, and the related results are presented here. The frequency and percentage of missing values in the data field are shown in Table 7.1. Forty-nine variables were observed across the three time points for 60 participants, including participant characteristics (16 variables), 6MWD (3 variables), CSES (15 variables),

SOLQ (9 variables) and fiscal outcomes (6 variables), and two CTCPSQ variables were observed once at T1 for 48 participants. The total number of values in the data field was 3036, which is equal to the sum of the number of the aforementioned 49 variables multiplied by the number of participants. Missing values accounted for 9.03% (274/3036).

Table 7.1 Frequency and percentage of missing values in the data field

Measurements	Number of variables			Number of values of observations	Number of missing values			Missing values in the data fields in total	Percentage of missing values
	T0	T1	T2		T0	T1	T2		
Participant characteristics	16	0	0	960	0	-	-	0/3036	0.00
6MWD	1	1	1	180	0	19	23	42/3036	1.38
SOLQ	3	3	3	540	0	36	51	87/3036	2.87
CSES	5	5	5	900	0	60	85	145/3036	4.78
Fiscal outcomes	0	3	3	360	-	0	0	0/3036	0.00
CTCPSQ	0	2	0	96	-	0	-	0/3036	0.00
Total	25	14	12	3036	0	115	159	274/3036	9.03

6MWD = 6-minute walk distance, CSES = COPD Self-efficacy Scale, SOLQ = Seattle Obstructive Lung Disease Questionnaire, CTCPSQ = COPD Transitional Care Patient Satisfaction Questionnaire. Participants: (1) 6MWD, SOLQ and CSES, n = 60; (2) CTCPSQ, n = 48.

Total number of values in the data field = the sum of each time point variables*number of participants = (25 + 12 + 12)*60 + 2*48 = 3036.

As it has been specified in the previous chapter, section 6.8.3.1 Intention-to-treat (ITT) and Per-Protocol (PP) analysis, both ITT and PP analyses were performed to evaluate the intervention effects in this study. ITT analysis contained all 60 participants who were originally randomly allocated and assessed at baseline. In contrast to the ITT analysis, the PP analysis included a subset of the ITT population

who completed the study and for which there were no missing values in any of the observations.

7.3 Characteristics of participants

The characteristics of the participants in this study are presented in Tables 7.2 and 7.3. The data of all participants, as well as those of the individual groups, are given in these tables along with the comparison results. Comparisons were conducted in a number of ways: (1) control group versus intervention group (ITT population), (2) control group versus intervention group (PP population), (3) PP population versus dropouts (control group) and (4) PP population versus dropouts (intervention group).

7.3.1 Demographic characteristics

The demographic characteristics of the participants are reported in Table 7.2. Of the 60 participants who completed the baseline assessment, 88.3% ($n = 53$) were male, and their mean age was 71.87 ± 7.1 years, ranging from 52 to 84 years. Most of the participants were married and living with their spouse ($n = 49$, 81.7 %). More than half had a junior high school or below level of education ($n = 38$, 63.3%). Those without a current job (including 53 retired and 3 unemployed) made up 96.7% of the sample. Three-quarters (75.0%) had a monthly income of less than RMB2000, which is below the per capita annual disposable income of urban households in Guangzhou in 2008 (Huang, 2009). Eight (13.3%) participants had their healthcare subsidised in full by the government, whereas the remaining 52 (86.7%) had a partial payment option ($n = 50$) or were responsible for their healthcare costs in full ($n = 2$).

The baseline demographic data of the control and intervention groups were compared by means of an independent *t*-test, chi-square test or Fisher's exact test. Table 7.2 displays the results. The two groups were similar in their demographic characteristics, including age, sex, marital status, education, employment status, average family income and health care payment option.

Table 7.2 Baseline demographic characteristics

Variables	ITT population			PP population		Dropouts		<i>p</i> -value			
	Total n = 60 (%)	Control n = 30 (%)	Intervention n = 30 (%)	Control n = 22 (%)	Intervention n = 21 (%)	Control n = 8 (%)	Intervention n = 9 (%)	A	B	C	D
Age (years)											
Mean ± SD	71.87±7.1	72.13±7.1	71.60±7.2	70.68±7.2	71.95±5.0	76.13±5.3	70.78±11.0	0.773 ^c	0.506 ^c	0.61 ^c	0.767 ^c
Sex											
Male	53 (88.3)	27 (90.0)	26 (86.7)	19 (86.4)	17 (81.0)	8 (100.0)	9 (100.0)	0.999 ^b	0.698 ^b	0.545 ^b	0.287 ^b
Female	7 (11.7)	3 (10.0)	4 (13.3)	3 (13.6)	4 (19.0)	0 (0.0)	0 (0.0)				
Marital status											
Married	49 (81.7)	22 (73.3)	27 (90.0)	15 (68.2)	18 (85.7)	7 (87.5)	9 (100.0)	0.095 ^a	0.281 ^b	0.391 ^b	0.534 ^b
Divorced/Widowed	11 (18.3)	8 (26.7)	3 (10.0)	7 (31.8)	3 (14.3)	1 (12.5)	0 (0.0)				
Education											
≤ Junior high school	38 (63.3)	18 (60.0)	20 (66.7)	12 (54.6)	15 (71.4)	6 (75.0)	5 (55.6)	0.592 ^a	0.252 ^a	0.419 ^b	0.431 ^b
≥ Senior high school	22 (36.7)	12 (40.0)	10 (33.3)	10 (45.4)	6 (28.6)	2 (25.0)	4 (44.4)				
Employment status											
Unemployed/Retired	58 (96.7)	29 (96.7)	29 (96.7)	21 (95.5)	21 (100.0)	8 (100.0)	8 (88.9)	0.999 ^b	0.999 ^b	0.999 ^b	0.300 ^b
Employed	2 (3.3)	1 (3.3)	1 (3.3)	1 (4.5)	0 (0.0)	0 (0.0)	1 (11.1)				
Family average income											
≤ 2000 (RMB)	45 (75.0)	23 (76.7)	22 (73.3)	15 (68.2)	15 (71.4)	8 (100.0)	7 (77.8)	0.766 ^a	0.817 ^a	0.143 ^b	0.999 ^b
≥ 2001(RMB)	15 (25.0)	7 (23.3)	8 (26.7)	7 (31.8)	6 (28.6)	0 (0.0)	2 (22.2)				
Healthcare payment											
Total subsidised	8 (13.3)	5 (16.7)	3 (10.0)	5 (22.7)	3 (14.3)	0 (0.0)	0 (0.0)	0.706 ^b	0.698 ^b	0.287 ^b	0.534 ^b
Self-paid	52 (86.7)	25 (83.3)	27 (90.0)	17 (77.3)	18 (85.7)	8 (100.0)	9 (100.0)				

SD = Standard deviation.

^a Pearson chi-square test, ^b Fisher's exact test, ^c independent t-test; A: control group vs. intervention group (ITT population: 30 vs. 30), B: control group vs. intervention group (PP population: 22 vs. 21), C: PP population vs. dropouts (control group: 22 vs. 8), D: PP population vs. dropouts (intervention group: 21 vs. 9).

7.3.2 COPD-related clinical and social characteristics

Table 7.3 displays the COPD-related clinical and social characteristics of the 60 participants. The median number of years of suffering from COPD was 7, ranging from 1 to 40 years. Fifty-six participants (93.3%) had a history of smoking, including the nine who were current smokers. They had a mean smoking history of 36.60 ± 22.3 pack-years. Their mean FEV₁% predicted and mean FVE₁/FVC ratios were 44.75 ± 17.2 and 44.68 ± 12.1 , respectively. Thirty-nine participants (65.0%) reported that they needed care during their sickness. A majority ($n = 56$, 93.3%) received care from others, including a family member or domestic helper. Care provided by others was available at any time of the day or night for 80% ($n = 48$) of participants, whilst the other 20% ($n = 12$) could access care some of the time.

The chi-square comparisons show the two groups to be similar in smoking status, care needed during sickness, caregiver status and availability of care. There were no significant differences in pack-year history, FEV₁% predicted or FVE₁/FVC, as calculated by independent *t*-tests. The Mann-Whitney U tests revealed no significant differences in COPD history in three comparisons (i.e. control vs. intervention [ITT population], control vs. intervention [PP population], and PP population vs. dropouts [intervention group]), although there was a marginal difference in PP population versus dropouts in the control group. In this control group sample, PP population had a shorter COPD history than the dropouts (5 [range: 1- 30] years vs. 11 [range: 1-40] years; $F = 0.020$, $p = 0.043$).

In summary, the participants in the two groups can be regarded as equivalent in their demographic and COPD-related clinical and social characteristics.

Table 7.3 Baseline COPD-related clinical and social characteristics

Variables	ITT population			PP population		Dropouts		<i>p</i> -value			
	Total n = 60 (%)	Control n = 30 (%)	Intervention n = 30 (%)	Control n = 22 (%)	Intervention n = 21 (%)	Control n = 8 (%)	Intervention n = 9 (%)	A	B	C	D
COPD history (years)											
Median [Range]	7.00 [1-40]	8.5 [1-40]	7.00 [1-21]	5.00 [1-30]	6.00 [1-21]	11.00 [1-40]	8.00 [1-20]	0.846 ^d	0.304 ^d	0.043 ^{d*}	0.665 ^d
Current smoker											
Yes	9 (15.0)	5 (16.7)	4 (13.3)	3 (13.6)	3 (14.3)	2 (25.0)	1 (11.1)	0.999 ^b	0.999 ^b	0.589 ^b	0.999 ^b
No	51 (85.0)	25 (83.3)	26 (86.7)	19 (86.4)	18 (85.7)	6 (75.0)	8 (88.9)				
Smoking history (pack-years[#])											
Mean ± SD	36.60±22.3	40.03±20.8	33.17±23.6	36.95±20.6	32.38±24.4	48.50±20.5	35.00±22.8	0.273 ^c	0.509 ^c	0.184 ^c	0.786 ^c
FEV₁ predicted (%)											
Mean ± SD	44.75±17.2	44.60±17.3	44.90±17.4	42.68±16.8	44.43±16.3	49.88±18.6	46.00±20.7	0.947 ^c	0.731 ^c	0.321 ^c	0.825 ^c
FVE₁/FVC											
Mean ± SD	44.68±12.1	46.17±12.5	43.20±11.7	44.00±12.6	43.52±12.4	52.13±11.0	42.44±10.4	0.347 ^c	0.901 ^c	0.118 ^c	0.821 ^c
Care needs											
Yes	39 (65.0)	22 (73.3)	17 (56.7)	16 (72.7)	12 (57.1)	6 (75.0)	5 (55.6)	0.176 ^a	0.284 ^a	0.999 ^b	0.999 ^b
No	21 (35.0)	8 (26.7)	13 (43.3)	5 (27.3)	9 (42.9)	2 (25.0)	4 (44.4)				
Caregiver											
Self	4 (6.7)	1 (3.3)	3 (10.0)	1 (4.5)	3 (14.3)	0 (0.0)	0 (0.0)	0.612 ^b	0.345 ^b	0.999 ^b	0.534 ^b
Others	56 (93.3)	29 (96.7)	27 (90.0)	21 (95.5)	18 (85.7)	8 (100.0)	9 (100.0)				
Care available											
Some of the time	12 (20.0)	5 (16.7)	7 (23.3)	5 (22.7)	7 (34.3)	0 (0.0)	0 (0.0)	0.519 ^a	0.438 ^a	0.287 ^b	0.071 ^b
All of the time	48 (80.0)	25 (83.3)	23 (76.7)	17 (77.3)	14 (66.7)	8 (100.0)	9 (100.0)				

SD = Standard deviation; [#] Pack-years: a measure of the cumulative dose of cigarette smoking, with 1 pack year = 20 cigarettes/day × 1 year.

^a Pearson chi-square test, ^b Fisher's exact test, ^c independent t-test, ^d Mann-Whitney U test; A: control group vs. intervention group (ITT population: 30 vs. 30), B: control group vs. intervention group (PP population: 22 vs. 21), C: PP population vs. dropouts (control group: 22 vs. 8), D: PP population vs. dropouts (intervention group: 21 vs. 9).

*Significant at *p* < 0.05.

7.4 Baseline outcome measures

The baseline outcome measures of 6MWD, SOLQ and CSES between the control and intervention groups and completers and withdrawals were tested using independent *t*-tests. Four comparisons were carried out for those with baseline characteristics variables: (1) control group versus intervention group (ITT population), (2) control group versus intervention group (PP population), (3) PP population versus dropouts (control group) and (4) PP population versus dropouts (intervention group). Table 7.4 displays the results, and the following sections describe each of the baseline outcomes in detail.

7.4.1 Baseline 6MWD

In Table 7.4, independent *t*-test result showed the mean $\pm$ SD 6MWD performed by ITT population, all 60 participants to be 318 ± 93.1 m, with participants in the control group (313.70 ± 104.3 m) walking slightly less distance than those in the intervention group (322.47 ± 81.8 m). In the PP population, the 18 participants in the control group (354.39 ± 72.0 m) walked more metres than the 19 participants in the intervention group (328.05 ± 76.5 m). Control group PP population (354.39 ± 72.0 m) had better 6MWD results than the dropouts (252.67 ± 117.9 m). The independent *t*-test results revealed no significant differences in 6MWD between the control and intervention groups for ITT population ($t = 0.362$, $p = 0.719$), PP population ($t = -1.077$, $p = 0.289$) or PP population versus dropouts in the intervention group ($t = 0.485$, $p = 0.631$). However, a statistically significant difference was found between PP population and dropouts in the control group (PP population: 354 ± 72.0 m vs. dropouts: 252.67 ± 117.9 m, $t = 2.674$, $p = 0.016$).

7.4.2 Baseline SOLQ

The mean scores of the PF, EF and CS subscales of the SOLQ are shown in Table 7.4. In both the ITT and PP populations, the comparison of two groups showed no significant differences in physical or emotional function or coping skills, as assessed by the SOLQ. In addition, no significant differences in the PF, EF or CS scores were found in either the control or intervention groups when PP population and dropouts were compared.

7.4.3 Baseline CSES

As shown in Table 7.4, the mean $\pm$ SD of the CSES total score between the groups in the different analyses were: control (3.22 ± 0.7) versus intervention (3.31 ± 0.6) in ITT; control (3.21 ± 0.7) versus intervention (3.30 ± 0.6) in PP; PP population (3.21 ± 0.7) versus dropouts (3.23 ± 0.4) in the control group; and PP population (3.30 ± 0.6) versus dropouts (3.29 ± 0.6) in the intervention group. No significant between-group differences were found in other combinations of comparisons.

On the whole, for both the ITT and PP populations, the two groups were equivalent with respect to their baseline COPD self-efficacy (as assessed by the CSES) and HRQOL (as assessed by the SOLQ), but not with exercise capacity tested by 6MWD. To account for this possible baseline difference, covariate adjustment analysis was employed to estimate the adjusted intervention effect on 6MWD, which is reported in Section 7.5.1.

Table 7.4 Baseline outcome measures

Outcome measures	ITT population		PP population		Dropouts		<i>p</i> -value			
	Control (n = 30)	Intervention (n = 30)	Control (n = 22)	Intervention (n = 21)	Control (n = 8)	Intervention (n = 9)	A	B	C	D
6MWD[§] (m)										
Mean ± SD	313.70±104.3	322.47±81.8	354.39±72.0	328.05±76.5	252.67±117.9	312.82±93.4	0.719	0.289	0.016*	0.631
SOLQ										
PF										
Mean ± SD	50.42±17.2	54.08±14.4	49.50±18.9	55.58±15.5	52.96±11.7	50.58±11.6	0.376	0.257	0.634	0.395
EF										
Mean ± SD	65.67±20.0	68.67±20.0	62.88±23.1	67.46±20.8	73.33±17.5	71.48±21.0	0.587	0.499	0.256	0.632
CS										
Mean ± SD	74.07±20.1	76.67±17.9	70.71±21.6	75.40±19.6	83.33±11.8	79.63±13.7	0.599	0.460	0.054	0.526
CSES										
Total										
Mean ± SD	3.22±0.7	3.31±0.6	3.21±0.7	3.30±0.6	3.23±0.4	3.29±0.6	0.589	0.634	0.925	0.951
NA										
Mean ± SD	3.29±0.9	3.52±0.7	3.25±1.0	3.51±0.8	3.40±0.5	3.55±0.5	0.251	0.334	0.568	0.898
IEA										
Mean ± SD	3.45±0.8	3.59±0.8	3.46±0.8	3.58±0.8	3.45±0.7	3.64±1.0	0.485	0.618	0.980	0.858
PE										
Mean ± SD	2.65±0.6	2.68±0.7	2.63±0.7	2.71±0.8	2.70±0.4	2.60±0.7	0.849	0.698	0.782	0.700
WE										
Mean ± SD	3.24±0.7	3.24±0.7	3.21±0.8	3.27±0.6	3.31±0.6	3.19±0.9	0.980	0.793	0.745	0.762
BRF										
Mean ± SD	3.45±0.8	3.48±0.8	3.50±0.9	3.48±0.9	3.31±0.7	3.50±0.7	0.876	0.931	0.590	0.944

6MWD = 6-minute walk distance, m = metre(s), SOLQ = Seattle Obstructive Lung Disease Questionnaire, PF = Physical function, EF = Emotional function, CS = Coping skills, CSES = COPD Self-efficacy Scale, NA = Negative affect, IEA = Intense emotional arousal, PE = Physical exertion, WE = Weather/environment, BRF = Behavioural risk factors, Total = COPD Self-efficacy total score, SD = Standard deviation.

[§]Control group (n = 18), Intervention group (n = 19); A: control group vs. intervention group (ITT population: 30 vs. 30), B: control group vs. intervention group (PP population: 22 vs. 21), C: PP population vs. dropouts (control group: 22 vs. 8), D: PP population vs. dropouts (intervention group: 21 vs. 9).

*Significant at $p < 0.05$.

7.5 Effects of intervention on outcome measures

This section presents the effects of the intervention on exercise capacity, HRQOL, self-efficacy, fiscal outcomes and patient satisfaction. The results of the first three outcome measures are reported in the sequence of: (1) findings of intention-to-treat (ITT) analysis, (2) findings of per-protocol (PP) analysis, and (3) findings of comparison of the ITT and PP results. Only the ITT analysis results are reported for the fiscal outcome measures (including total readmissions, time to first readmission, and direct cost of readmission), whereas only the PP analysis results are reported for the patient satisfaction measures. Partial eta squared effect size statistics is used to indicate whether a difference between groups is statistically significant (Pallant, 2007). The interpretation of the strength of the different effect size statistics is based on Cohen (1988) criteria of 0.1 = small effect, 0.6 = medium effect, 0.138 = large effect. The partial eta squared effect size of the three key outcome valuables, including 6MWD, the SOLD-PF score and the CSES total score are also reported.

7.5.1 Effects of intervention on exercise capacity

Exercise capacity was measured by 6MWD. Accounting for the difference at baseline noted in Section 7.4.1., the T0 value was controlled in the process of data analyses. The three following analyses were performed. First, ANCOVA was conducted to compare the 6MWD scores between the two groups at T1 and T2 separately by adjusting the 6MWD scores at T0 as a covariate. Second, repeated measures ANCOVA based on the Greenhouse-Geisser correction test was employed to examine the between-group and within-time difference in 6MWD and the interaction effects, with the baseline 6MWD scores adjusted as a covariate. Third, repeated measures ANOVA was performed to determine any significant change

occurring over the three time periods for each group. If significant changes were found, multiple comparisons (Bonferroni) were performed to identify which pairs (T0 vs. T1, T0 vs. T2 and T1 vs. T2) exhibited differences.

7.5.1.1 Results using Intention-to-treat (ITT) analysis

As shown in Table 7.5, no significant differences were found between the two groups at T0 ($F_{(1, 57)} = 0.13$, $p = 0.719$, eta squared = 0.00) and T2 ($F_{(1, 57)} = 2.90$, $p = 0.094$, eta squared = 0.05), but patients in the intervention group (359.10 ± 88.5 m) walked a longer distance than those in the control group (309.23 ± 115.1 m) at T1 ($F_{(1, 57)} = 6.73$, $p = 0.012$, eta squared = 0.11). In addition, repeated measures ANCOVA, adjusted by baseline scores, were executed, and the results showed there to be significance differences between the groups ($F_{(1, 57)} = 4.90$, $p = 0.031$, eta squared = 0.08), although no significant differences were found in the time effect ($F_{(1, 57)} = 1.32$, $p = 0.256$, eta squared = 0.02) or interaction effect ($F_{(1, 57)} = 0.30$, $p = 0.589$, eta squared = 0.01). In the intervention group, repeated measures ANOVA showed that there was significant change across the three time points ($F_{(1.361, 39.477)} = 6.71$, $p = 0.008$, eta squared = 0.19), and multiple comparison (Bonferroni) tests further indicated that the mean score of 6MWD increased from T0 (322.47 ± 81.8) to T1 (359.10 ± 88.5 ; $p = 0.005$, eta squared = 0.32), with an average improvement of 36.63 ± 57.7 m. The control group achieved no significant improvement across the three time points ($F_{(1.630, 47.262)} = 0.09$, $p = 0.880$, eta squared = 0.00).

7.5.1.2 Results using Per-Protocol (PP) analysis

Table 7.6 presents the results of PP analysis of the 6MWD scores of the 37 patients (control group, $n = 18$; intervention group, $n = 19$) who completed the study. It can

be seen that there were no significant between-group differences in these scores at T0 ($F_{(1, 35)} = 0.116$, $p = 0.289$, eta squared = 0.03) or T2 ($F_{(1, 34)} = 1.12$, $p = 0.298$, eta squared = 0.03), although the intervention group had significantly higher 6MWD scores (385.89 ± 75.50 m) than the control group (365.50 ± 79.0 m) at T1 ($F_{(1, 34)} = 4.71$, $p = 0.037$, eta squared = 0.12). In addition, the results of repeated measures ANCOVA, adjusted by the baseline score, revealed no significant differences between groups ($F_{(1, 34)} = 2.73$, $p = 0.108$, eta squared = 0.07), over time ($F_{(1, 34)} = 1.67$, $p = 0.205$, eta squared = 0.05) or in the interaction effect ($F_{(1, 34)} = 0.35$, $p = 0.558$, eta squared = 0.01). For the intervention group, repeated measures ANOVA showed that there was a significant change across the three time points ($F_{(1.374, 24.339)} = 8.08$, $p = 0.005$, eta squared = 0.31), and multiple comparison (Bonferroni) tests further showed that the mean 6MWD score increased from T0 (328.05 ± 76.5) to T1 (385.89 ± 75.5 ; $p = 0.003$, eta squared = 0.49), with an average improvement of 57.84 ± 63.8 m. For the control group, there was no significant improvement across time ($F_{(1.347, 24.239)} = 0.50$, $p = 0.612$, eta squared = 0.28).

7.5.1.3 Comparison of ITT and PP analysis results

Table 7.7 summarises the significant results of the two methods of analysis (ITT vs. PP). It can be seen that the two sets of results are similar except for the between-group effect, for which the PP result is insignificant and the ITT result is significant. The two analyses show the same trends of 6MWD changes across the three time periods for the intervention group. The mean 6MWD increased substantially from T0 to T1 in this group, with a minimal decrease from T1 to T2. However, the ITT and PP analyses show different patterns of change in 6MWD for

the control group. As shown in Tables 7.5 and 7.6, 6MWD decreased and then increased in ITT analysis, whilst PP analysis showed it increasing from T0 to T2.

Table 7.5 Comparison of ITT analysis of 6MWD by group and over time

Outcome measure	Time			Between group		Within group		[A,B,C] ^e	Interaction effects	
	T0 ^a Mean±SD	T1 ^b Mean±SD	T2 ^b Mean±SD	<i>F</i>	<i>p</i> -value	<i>F</i>	<i>p</i> -value		<i>F</i>	<i>p</i> -value
6MWD (m) ^c				4.90	0.031*	1.32	0.256		0.30	0.589
Control (n = 30) ^d	313.70±104.3	309.23±115.1	314.17±116.9			0.09	0.880	[0.999, 0.999,0.999]		
Intervention (n=30) ^d	322.47±81.8	359.10±88.5	356.42±99.7			6.71	0.008**	[0.005**, 0.073, 0.999]		
F, <i>p</i> -value	0.13, 0.719	6.73, 0.012*	2.90, 0.094							

SD = Standard deviation, m = metre(s).

^a at T0, ^b at T1 and T2 adjusted by T0, ^c repeated measures ANCOVA adjusted by T0, ^d repeated measures ANOVA, ^e multiple comparison (Bonferroni) [A: *p*-value for T0 vs. T1, B: *p*-value for T0 vs. T2, C: *p*-value for T1 vs. T2].

*Significant at *p* < 0.05; **significant at *p* < 0.01.

Table 7.6 Comparison of PP analysis of 6MWD by group and over time

Outcome measure	Time			Between group		Within group		[A,B,C] ^e	Interaction effects	
	T0 ^a Mean±SD	T1 ^b Mean±SD	T2 ^b Mean±SD	<i>F</i>	<i>p</i> -value	<i>F</i>	<i>p</i> -value		<i>F</i>	<i>p</i> -value
6MWD (m) ^c				2.73	0.108	1.67	0.205		0.35	0.558
Control (n = 18) ^d	354.39±72.0	365.50±79.0	369.50±87.5			0.50	0.612	[0.999, 0.999, 0.999]		
Intervention (n=19) ^d	328.05±76.5	385.89±75.5	382.81±90.3			8.08	0.005**	[0.003**, 0.053, 0.999]		
F, <i>p</i> -value	1.16, 0.289	4.71, 0.037*	1.12, 0.298							

SD = Standard deviation, m = metre(s).

^a at T0, ^b at T1 and T2 adjusted by T0, ^c repeated measures ANCOVA adjusted by T0, ^d repeated measures ANOVA, ^e multiple comparison (Bonferroni) [A: *p*-value for T0 vs. T1, B: *p*-value for T0 vs. T2, C: *p*-value for T1 vs. T2].

*Significant at *p* < 0.05; **significant at *p* < 0.01.

Table 7.7 Comparison of ITT and PP analyses of 6MWD

Outcome measure	Between-group comparison						Between-group effect		Within-group effect		Multiple comparison						Interaction effects	
	T0 ^a		T1 ^b		T2 ^b		PP	ITT	PP	ITT	T0 vs. T1 ^e		T0 vs. T2 ^e		T1 vs. T2 ^e		PP	ITT
	PP	ITT	PP	ITT	PP	ITT					PP	ITT	PP	ITT	PP	ITT		
6MWD^c	NS	NS	S	S	NS	NS	NS	S	NS	NS							NS	NS
Control ^d									NS	NS	NS	NS	NS	NS	NS	NS		
Intervention ^d									S	S	S	S	NS	NS	NS	NS		

NS = Non-significant difference, S = Significant difference.

^a at T0, ^b at T1 and T2 adjusted by T0, ^c repeated measures ANCOVA adjusted by T0, ^d repeated measured ANOVA, ^e multiple comparison (Bonferroni).

7.5.2 Effects of intervention on HRQOL

HRQOL was measured by the three QOL subscales of the SOLQ: physical function (PF), emotional function (EF) and coping skills (CS). Each subscale score ranges from 1 to 100, a higher score representing better functioning. Three statistical tests were conducted for this evaluation: (1) Mean differences on the SOLQ subscales between the two groups at each time point were examined by an independent *t*-test; (2) two-way repeated measures ANOVA was performed to determine the between-group and within-group effects across the three time periods and the interaction effect between group and time in relation to the SOLQ subscales; and (3) for each group, one-way repeated measures ANOVA with a multiple comparison (Bonferroni) test was used to examine the time effect.

7.5.2.1 Results using ITT analysis

As shown in Table 7.8, no significant differences were found between the two groups at T0 in any of the three subscales, PF ($t = 0.89, p = 0.376, \eta^2 = 0.01$), EF ($t = 0.55, p = 0.587$) and CS ($t = 0.53, p = 0.599$), although patients in the intervention group achieved greater improvement on all three subscale scores relative to their control group counterparts at T2 (PF: 59.61 vs. 47.96, $t = 2.70, p = 0.009, \eta^2 = 0.13$; EF: 77.00 vs. 60.78, $t = 2.99, p = 0.004$; CS: 81.81 vs. 69.72, $t = 2.54, p = 0.014$). In addition, the two-way repeated measures ANOVA results revealed a significant between-group difference on PF ($F_{(1,58)} = 5.20, p = 0.026, \eta^2 = 0.08$) and EF ($F_{(1,58)} = 4.58, p = 0.037$), but not on CS ($F_{(1,58)} = 3.23, p = 0.078$), and a significant difference was found on the interaction effect on PF ($F_{(1.568, 90.949)} = 4.47, p = 0.021, \eta^2 = 0.07$) and EF ($F_{(1.531, 88.807)} = 3.53, p = 0.045$). In the intervention group, repeated measures ANOVA showed there to be a significant

change on PF ($F_{(1.513, 43.872)} = 6.01$, $p = 0.009$, eta squared = 0.17) and EF ($F_{(1.570, 45.525)} = 4.46$, $p = 0.024$) across the three time points but not on CS ($F_{(1.411, 40.918)} = 3.03$, $p = 0.076$). Multiple comparison (Bonferroni) tests further showed a significant increase from T0 to T1 on PF ($p = 0.014$) and EF ($p = 0.044$), although the PF ($p = 0.555$) and EF ($p = 0.999$) scores underwent no changes from T1 to T2. In the control group, there was no significant improvement on any of the subscales over time: PF ($F_{(1.613, 46.791)} = 1.30$, $p = 0.279$, eta squared = 0.04), EF ($F_{(1.426, 41.359)} = 0.87$, $p = 0.307$) and CS ($F_{(2, 58)} = 1.70$, $p = 0.192$).

7.5.2.2 Results using PP analysis

As shown in Table 7.9, no significant difference was found between the two groups at T0 on any of the three subscales: PF ($t = 1.15$, $p = 0.257$, eta squared = 0.03), EF ($t = 0.68$, $p = 0.499$) and CS ($t = 0.75$, $p = 0.460$). At T1, patients in the intervention group realised greater improvement than those in the control group on PF (67.54 vs. 50.66, $t = 3.37$, $p = 0.002$, eta squared = 0.22) and EF (82.38 vs. 64.67, $t = 2.37$, $p = 0.023$) but not on CS (86.71 vs. 76.14, $t = 2.01$, $p = 0.052$). The same held true at T2: PF (64.35 vs. 46.41, $t = 3.43$, $p = 0.001$, eta squared = 0.21), EF (81.11 vs. 57.73, $t = 3.70$, $p = 0.001$) and CS (84.72 vs. 67.80, $t = 3.21$, $p = 0.003$). In addition, repeated measures ANCOVA, adjusted by the baseline scores, showed there to be significant between-group differences on all three subscales: PF ($F_{(1, 41)} = 8.51$, $p = 0.006$, eta squared = 0.17), EF ($F_{(1, 41)} = 6.95$, $p = 0.012$) and CS ($F_{(1, 41)} = 5.30$, $p = 0.027$). Further, significant differences were found for the interaction effect on PF ($F_{(1.702, 69.770)} = 5.23$, $p = 0.011$, eta squared = 0.11) and EF ($F_{(1.652, 82)} = 4.54$, $p = 0.020$). In the intervention group, repeated measures ANOVA revealed significant changes on all three subscales over time: PF ($F_{(2, 40)} = 10.37$, $p < 0.001$, eta squared = 0.34), EF

($F_{(2, 40)} = 7.92, p < 0.001$) and CS ($F_{(1.568, 31.367)} = 6.10, p = 0.009$). Multiple comparison (Bonferroni) tests further showed a significant increase from T0 to T1 on PF ($p = 0.001$), EF ($p = 0.004$) and CS ($p = 0.033$), and the PF ($p = 0.036$) and EF ($p = 0.034$) scores continued to increase from T0 to T2, although the CS ($p = 0.062$) scores did not. The control group realised no significant improvement over time on the three subscales in this analysis: PF ($F_{(2, 42)} = 1.07, p = 0.351, \eta^2 = 0.05$), EF ($F_{(1.458, 30.615)} = 1.11, p = 0.339$) and CS ($F_{(2, 42)} = 1.98, p = 0.150$).

7.5.2.3 Comparison of the ITT and PP analyses results

The significant results of the three SOLQ measures in ITT analysis were compared with those in PP analysis. Table 7.10 shows that the two strategies of analysis yielded similar results for most of the comparisons. However, there were significant results in the PP analysis that were not found in the ITT analysis, namely, (1) the t -test results on EF scores at T1; (2) the results of the between-group effects (group) on CS; (3) the results of the within-group (time) effects on PF, EF and CS; (4) the results of the time effect on CS in the intervention group; and (5) the results of pairwise comparisons of the intervention group CS at T0 vs. T1 and PF and EF at T0 vs. T2.

Table 7.8 Comparison of ITT analysis of the SOLQ scores by group and over time

Outcome measures	Time			Between group		Within group		[A,B,C] ^d	Interaction effects	
	T0 ^a Mean±SD	T1 ^a Mean±SD	T2 ^a Mean±SD	<i>F</i>	<i>p</i> -value	<i>F</i>	<i>p</i> -value		<i>F</i>	<i>p</i> -value
PF ^b				5.20	0.026*	2.79	0.079		4.47	0.021*
Control (n=30) ^c	50.42±17.2	50.18±16.1	47.06±16.2			1.30	0.279	[0.999, 0.598, 0.215]		
Intervention (n=30) ^c	54.08±14.4	61.84±20.1	59.61±19.7			6.01	0.009*	[0.014*, 0.144, 0.460]		
<i>t, p</i> -value	0.89, 0.376	2.48, 0.016*	2.70, 0.009**							
EF ^b				4.58	0.037*	1.76	0.185		3.529	0.045*
Control (n=30) ^c	65.67±22.0	65.87±24.9	60.78±22.3			0.87	0.307	[0.999, 0.698, 0.124]		
Intervention (n=30) ^c	68.67±20.6	77.89±22.2	77.00±19.8			4.46	0.024*	[0.044*, 0.143, 0.999]		
<i>t, p</i> -value	0.55, 0.587	1.97, 0.053	2.99, 0.004**							
CS ^b				3.23	0.078	2.15	0.130		2.31	0.113
Control (n=30) ^c	74.07±20.1	75.83±20.1	69.72±19.8			1.70	0.192	[0.999, 0.674, 0.139]		
Intervention (n=30) ^c	76.67±17.9	83.19±16.8	81.81±17.0			3.03	0.076	[0.179, 0.318, 0.999]		
<i>t, p</i> -value	0.53, 0.599	1.54, 0.129	2.54, 0.014*							

SD = Standard deviation, SOLQ = Seattle Obstructive Lung Disease Questionnaire, PF = Physical function, EF = Emotional function, CS = Coping skills.

^aIndependent t-test, ^btwo-way repeated measures ANOVA, ^cone-way repeated measures ANOVA, ^dmultiple comparison (Bonferroni) [A: *p*-value for T0 vs. T1, B: *p*-value for T0 vs. T2, C: *p*-value for T1 vs. T2].

Subscale score ranges from 0-100, a higher score indicates better functioning.

*Significant at *p* < 0.05; **significant at *p* < 0.01.

Table 7.9 Comparison of PP analysis of the SOLQ scores by group and over time

Outcome measures	Time			Between group		Within group			Interaction effects	
	T0 ^a	T1 ^a	T2 ^a	<i>F</i>	<i>p</i> -value	<i>F</i>	<i>p</i> -value ^c	[A,B,C] ^d	<i>F</i>	<i>p</i> -value
	Mean±SD	Mean±SD	Mean±SD							
PF ^b				8.51	0.006**	5.26	0.011*		5.23	0.011*
Control (n=22)	49.50±18.9	50.66±16.2	46.41±16.4			1.07	0.351	[0.999, 0.999, 0.214]		
Intervention (n=21)	55.58±15.5	67.54±17.6	64.35±17.9			10.37	<0.001**	[0.001**, 0.036*, 0.465]		
<i>p</i> -value	1.15, 0.257	3.37, 0.002**	3.43, 0.001**							
EF ^b				6.95	0.012*	3.40	0.048*		4.54	0.020*
Control (n=22)	62.88±23.1	64.67±27.1	57.73±22.9			1.11	0.339	[0.999, 0.961, 0.121]		
Intervention (n=21)	67.46±20.8	82.38±21.6	81.11±18.1			7.92	0.001**	[0.004**, 0.034*, 0.999]		
<i>p</i> -value	0.68, 0.499	2.37, 0.023*	3.70, 0.001**							
CS ^b				5.30	0.027*	4.70	0.012*		2.27	0.091
Control (n=22)	70.71±21.6	76.14±20.7	67.80±19.8			1.98	0.150	[0.717, 0.999, 0.136]		
Intervention (n=21)	75.40±19.6	86.71±13.2	84.72±14.0			6.10	0.009**	[0.033*, 0.062, 0.999]		
<i>p</i> -value	0.75, 0.460	2.01, 0.052	3.21, 0.003**							

SD = Standard deviation, SOLQ = Seattle Obstructive Lung Disease Questionnaire, PF = Physical function, EF = Emotional function, CS = Coping skills.

^aIndependent t-test, ^btwo-way repeated measures ANOVA, ^cone-way repeated measures ANOVA, ^dmultiple comparison (Bonferroni) [A: *p*-value for T0 vs. T1, B: *p*-value for T0 vs. T2, C: *p*-value for T1 vs. T2].

Subscale score ranges from 0-100, a higher score indicates better functioning.

*Significant at $p < 0.05$; **significant at $p < 0.01$.

Table 7.10 Comparison of ITT and PP analyses of SOLQ

Outcome measures	Between-group comparison						Between-group effect		Within-group effect		Multiple comparison						Interaction effects	
	T0 ^a		T1 ^a		T2 ^a		PP	ITT	PP	ITT	T0vsT1		T0vsT2		T1vsT2		PP	ITT
	PP	ITT	PP	ITT	PP	ITT					PP	ITT	PP	ITT	PP	ITT		
PF^b	NS	NS	S	S	S	S	S	S	S	NS							S	S
Control ^c									NS	NS	NS	NS	NS	NS	NS	NS		
Intervention ^c									S	S	S	S	S	NS	NS	NS		
EF^b	NS	NS	S	NS	S	S	S	S	S	NS							S	S
Control ^c									NS	NS	NS	NS	NS	NS	S	S		
Intervention ^c									S	S	S	S	S	NS	NS	NS		
CS^b	NS	NS	NS	NS	S	S	S	NS	S	NS							NS	NS
Control ^c									NS	NS	NS	NS	NS	NS	NS	NS		
Intervention ^c									S	NS	S	NS	NS	NS	NS	NS		

SOLQ = Seattle Obstructive Lung Disease Questionnaire, PF = Physical function, EF = Emotional function, CS = Coping skills, NS = No significant difference, S = Significant.

^aIndependent t-test, ^btwo-way repeated measures ANOVA, ^cone-way repeated measures ANOVA.

7.5.3 Effects of intervention on self-efficacy

The intervention's effects on the participants' self-efficacy were evaluated using the CSES. The scores in this measure range from 1 to 5 with the higher scores indicating the higher level of self-efficacy. The CSES total score, one of the key outcomes of this study, summarises information from the five subscale scores, namely, NA, IEA, PE, WE and BRF. The same statistical analyses conducted for the SOLQ in the previous section were applied to the CSES. These include: (1) an independent t -test to examine the mean differences on CSES between the two groups at each time point; (2) two-way repeated measures ANOVA to determine the between-group (group) effect, within-group (time) effect, and group and time interaction effect in relation to the CSES; and (3) one-way repeated measures ANOVA with the (Bonferroni) post hoc test to examine the within-group (time) effects.

7.5.3.1 Results using ITT analysis

Table 7.11 displays the results of ITT analysis on the CSES.

Comparison between control and intervention groups at each time point

Comparing the differences between the control and intervention groups at T0, T1 and T2, an independent t -test showed there to be no significant differences between them at baseline for any of the CSES measures (NA: $t = 1.16$, $p = 0.251$; IEA: $t = 0.70$, $p = 0.485$; PE: $t = 0.19$, $p = 0.849$; WE: $t = 0.003$, $p = 0.980$; BRF: $t = 0.16$, $p = 0.876$; and Total: $t = 0.54$, $p = 0.589$, eta squared = 0.01). However, significant between-group differences were noted in all of the subscales and the total score at both T1 (NA: $t = 2.89$, $p = 0.005$; IEA: $t = 3.20$, $p = 0.002$; PE: $t = 3.08$, $p = 0.003$; WE: $t = 2.17$, $p = 0.034$; BRF: $t = 2.11$, $p = 0.039$; and Total: $t = 2.98$, $p = 0.004$,

eta squared = 0.13) and T2 (NA: $t = 4.26, p < 0.001$; IEA: $t = 3.67, p = 0.001$; PE: $t = 3.25, p = 0.002$; WE: $t = 3.49, p = 0.001$; BRF: $t = 3.54, p = 0.001$; and Total: $t = 4.05, p < 0.001$, eta squared = 0.22).

Comparison between control and intervention groups over time

Two-way repeated measures ANOVA revealed significant between-group differences in all five subscale measures (NA: $F_{(1, 58)} = 9.87, p = 0.003$; IEA: $F_{(1, 58)} = 8.30, p = 0.006$; PE: $F_{(1, 58)} = 6.87, p = 0.011$; WE: $F_{(1, 58)} = 4.91, p = 0.031$; BRF: $F_{(1, 58)} = 4.84, p = 0.032$) and the CSES total score ($F_{(1, 58)} = 8.39, p = 0.005$, eta squared = 0.13). Similarly, interaction effects between group and time were found in all five subscales (NA: $F_{(1.605, 93.117)} = 9.52, p < 0.001$; IEA: $F_{(1.716, 99.527)} = 8.78, p = 0.001$; PE: $F_{(1.439, 83.450)} = 11.74, p < 0.001$; WE: $F_{(1.743, 101.111)} = 11.19, p < 0.001$; BRF: $F_{(1.737, 100.755)} = 5.98, p = 0.005$) and the CSES total score ($F_{(1.568, 90.927)} = 13.87, p < 0.001$, eta squared = 0.19).

Comparison of individual groups over time

The results of one-way repeated measures ANOVA revealed the intervention group participants to have significant differences over time in all of the subscales (IEA: $F_{(1.392, 40.361)} = 8.17, p = 0.003$; PE: $F_{(1.326, 48.460)} = 9.45, p = 0.002$; WE: $F_{(1.440, 41.747)} = 7.65, p = 0.004$; and BRF: $F_{(2, 58)} = 6.04, p = 0.004$) and CSES total score ($F_{(1.361, 1.678)} = 9.33, p = 0.002$, eta squared = 0.24) except NA ($F_{(1.490, 43.215)} = 3.38, p = 0.056$). Multiple comparison (Bonferroni) tests showed that there was a significant change at T0 versus T1 in the IEA ($p = 0.011$), PE ($p = 0.002$), WE ($p = 0.017$) and BRF ($p = 0.010$) subscale scores and CSES total score ($p = 0.004$) and at T0 versus T2 in the IEA ($p = 0.023$), PE ($p = 0.029$) and WE ($p = 0.019$) subscale scores and

CSES total score ($p = 0.018$). Although no significant differences were detected in any of the measures from T1 to T2, a trend towards improvement in COPD self-efficacy was observed in the intervention group while the control group had a significant decline.

For the control group participants, the results of one-way repeated measures ANOVA revealed there to be significant differences across the three time periods in all of the subscale scores (NA: $F_{(1.613, 46.779)} = 7.14$, $p = 0.004$; IEA: $F_{(2, 58)} = 3.93$, $p = 0.044$; PE: $F_{(2, 58)} = 4.92$, $p = 0.001$; WE: $F_{(2, 58)} = 5.61$, $p = 0.006$; and BRF: $F_{(2, 58)} = 3.87$, $p = 0.026$) and CSES total score ($F_{(2, 58)} = 7.53$, $p = 0.002$, eta squared = 0.21). In addition, the multiple comparison (Bonferroni) tests showed that there was a significant change at T0 versus T2 in the NA ($p = 0.014$), PE ($p = 0.047$) and WE ($p = 0.030$) subscale scores and CSES total score ($p = 0.012$) and at T1 versus T2 on the IEA ($p = 0.023$), PE ($p = 0.023$) and BRF ($p = 0.042$) subscale scores and CSES total score ($p = 0.010$). A decreasing COPD self-efficacy trend was observed in the control group.

7.5.3.2 Results using PP analysis

Table 7.12 displays the results of PP analysis on the CSES.

Comparison between control and intervention groups at each time point

In the PP analysis sample, there were no significant differences between the participants in the control and intervention groups at baseline for any of the CSES measures, although significant differences were demonstrated on all of the subscale and total scores at both T1 (NA: $t = 2.92$, $p = 0.006$; IEA: $t = 3.45$, $p = 0.001$; PE: $t =$

3.54, $p = 0.001$; WE: $t = 3.50$, $p = 0.009$; BRF: $t = 2.75$, $p = 0.025$; and Total: $t = 3.28$, $p = 0.002$, eta squared = 0.21) and T2 (NA: $t = 4.52$, $p < 0.001$; IEA: $t = 3.88$, $p < 0.001$; PE: $t = 3.49$, $p = 0.001$; WE: $t = 4.30$, $p < 0.001$; BRF: $t = 4.05$, $p < 0.001$; and Total: $t = 4.49$, $p < 0.001$, eta squared = 0.33).

Comparison between control and intervention groups over time

The two groups differed significantly on all of the subscale scores (NA: $F_{(1, 41)} = 9.76$, $p = 0.003$; IEA: $F_{(1, 41)} = 8.97$, $p = 0.005$; PE: $F_{(1, 41)} = 8.78$, $p = 0.005$; WE: $F_{(1, 41)} = 8.71$, $p = 0.005$; BRF: $F_{(1, 41)} = 5.18$, $p = 0.028$) and CSES total score ($F_{(1, 41)} = 9.77$, $p = 0.003$, eta squared = 0.19). In addition, significant between-group and time interaction differences were observed in the CSES total scores ($F_{(1, 621, 66, 442)} = 15.90$, $p < 0.001$, eta squared = 0.28) and all five subscale scores (NA: $F_{(1, 687, 69, 180)} = 10.95$, $p < 0.001$; IEA: $F_{(2, 82)} = 9.62$, $p < 0.001$; PE: $F_{(1, 446, 59, 281)} = 11.24$, $p < 0.001$; WE: $F_{(2, 82)} = 10.93$, $p < 0.001$; BRF: $F_{(2, 82)} = 9.02$, $p < 0.001$).

Comparison of individual groups over time

When the individual groups' over-time differences were examined, significant changes were noted in the intervention group in all measures (NA: $F_{(2, 40)} = 5.00$, $p = 0.011$; IEA: $F_{(1, 475, 29, 491)} = 10.41$, $p = 0.001$; PE: $F_{(1, 338, 26, 768)} = 9.94$, $p = 0.002$; WE: $F_{(1, 503, 30, 056)} = 8.53$, $p = 0.003$; BRF: $F_{(2, 40)} = 5.84$, $p = 0.006$), including total CSES ($F_{(1, 419, 28, 370)} = 11.3$, $p = 0.001$, eta squared = 0.36). Participants in the control group also saw a significant change in the CSES total score ($F_{(2, 42)} = 8.89$, $p = 0.001$, eta squared = 0.30) and all subscale scores (NA: $F_{(1, 571, 32, 983)} = 7.43$, $p = 0.004$; PE: $F_{(2, 42)} = 4.35$, $p = 0.019$; WE: $F_{(2, 42)} = 5.23$, $p = 0.009$; BRF: $F_{(1, 580, 33, 177)} = 7.23$, $p = 0.004$) except IEA ($F_{(2, 42)} = 3.05$, $p = 0.058$). Multiple

comparisons also revealed significant differences in the intervention group between T0 and T1 on IEA ($p = 0.005$), PE ($p = 0.002$), WE ($p = 0.014$), BRF ($p = 0.012$) and CSES total score ($p = 0.002$). In addition, three of the subscale scores and the CSES total score were found to differ significantly between T0 and T2 (IEA: $p = 0.012$; PE: $p = 0.034$; WE: $p = 0.019$; and Total: $p = 0.013$). In the control group, no significant differences were found between T0 and T1, but such differences were found between T0 and T2 in NA ($p = 0.020$), BRF ($p = 0.017$) and CSES total score ($p = 0.010$) and between T1 and T2 in NA ($p = 0.020$), PE ($p = 0.020$) and CSES total score ($p = 0.008$). Whilst the control group decreased steadily in the scores for all of the CSES measures, the intervention group showed the reverse trend.

7.5.3.3 Comparison of the ITT and PP analyses results

Table 7.13 presents the comparison results of the ITT and PP analyses on CSES. It can be seen that the two sets of results are very similar. For example, the two analyses reveal similar patterns of between-group over-time changes in the CSES total scores. The average scores of the intervention group increased substantially from T0 to T2, with a substantial increase from T0 to T1 followed by a minimal decrease from T1 to T2, whereas those of the control group decreased from T0 to T2, with a minimal decrease from T0 to T1 followed by a substantial decrease from T1 to T2. The major difference between the two analyses was in the results for the within-group effects of the CSES total score and NA (intervention group) and IEA (control group) subscales. PP analysis detected a significant within-group effect in the CSES total score and NA subscale, whilst ITT analysis showed no significance. By contrast, ITT, but not PP, analysis demonstrated a significant effect in IEA. The same held true for the control group findings. Significant results were revealed for

T0 versus T2 PE and WE and T1 versus T2 BRF in the ITT analysis, but not in the PP analysis. The situation was reversed for BRF, where a significant over-time difference was noted in the PP analysis but not the ITT analysis.

Table 7.11 Comparison of ITT analysis of the CSES scores by group and over time

Outcome measures	Time			Between group		Within group		[A, B, C] ^d	Interaction effects	
	T0 Mean ± SD ^a	T1 Mean ± SD ^a	T2 Mean ± SD ^a	F	p-value	F	p-value ^c		F	p-value
NA ^b				9.87	0.003**	1.00	0.356		9.52	<0.001**
Control (n=30)	3.29±0.9	3.14±0.9	2.86±0.9			7.14	0.004**	[0.459, 0.014*, 0.023*]		
Intervention (n=30)	3.52±0.7	3.75±0.8	3.81±0.8			3.38	0.056	[0.241, 0.136, 0.999]		
t, p-value	1.16, 0.251	2.89, 0.005**	4.26, <0.001**							
IEA ^b				8.30	0.006**	1.25	0.290		8.78	0.001**
Control (n=30)	3.45±0.8	3.30±0.8	3.11±0.9			3.93	0.044*	[0.644, 0.112, 0.376]		
Intervention (n=30)	3.59±0.8	3.97±0.8	3.91±0.8			8.17	0.003**	[0.011*, 0.023*, 0.999]		
t, p-value	0.70, 0.485	3.20, 0.002**	3.67, 0.001**							
PE ^b				6.87	0.011*	4.43	0.025*		11.74	<0.001**
Control (n=30)	2.65±0.6	2.58±0.8	2.37±0.9			4.92	0.001**	[0.999, 0.047*, 0.023*]		
Intervention (n=30)	2.68±0.7	3.25±0.9	3.17±1.0			9.45	0.002**	[0.002**, 0.029*, 0.999]		
t, p-value	0.19, 0.849	3.08, 0.003**	3.25, 0.002**							
WE ^b				4.91	0.031*	1.93	0.156		11.19	<0.001**
Control (n=30)	3.24±0.7	3.17±0.7	2.88±0.8			5.61	0.006**	[0.999, 0.030*, 0.058]		
Intervention (n=30)	3.24±0.7	3.58±0.8	3.61±0.8			7.65	0.004**	[0.017*, 0.019*, 0.999]		
t, p-value	0.03, 0.980	2.17, 0.034*	3.49, 0.001**							
BRF ^b				4.84	0.032*	3.28	0.048*		5.98	0.005**
Control (n=30)	3.45±0.8	3.43±0.8	3.08±0.8			3.87	0.026*	[0.999, 0.144, 0.042*]		
Intervention (n=30)	3.48±0.8	3.85±0.7	3.75±0.7			6.04	0.004**	[0.010*, 0.120, 0.737]		
t, p-value	0.16, 0.876	2.11, 0.039*	3.54, 0.001**							
Total ^b				8.39	0.005**	3.01	0.066		13.87	<0.001**
Control (n=30)	3.22±0.7	3.12±0.7	2.86±0.8			7.53	0.002**	[0.862, 0.012*, 0.010*]		
Intervention (n=30)	3.30±0.6	3.68±0.7	3.65±0.7			9.33	0.002**	[0.004**, 0.018*, 0.999]		
t, p-value	0.54, 0.589	2.98, 0.004**	4.05, <0.001**							

SD = Standard deviation, CSES = COPD Self-Efficacy Scale, NA = Negative affect, IEA = Intense emotional arousal, PE = Physical exertion, WE = Weather/environment, BRF = Behavioural risk factors, Total = CSES total score.

^aIndependent t-test, ^btwo-way repeated measures ANOVA, ^cone-way repeated measures ANOVA, ^dmultiple comparison (Bonferroni) [A: p-value for T0 vs. T1, B: p-value for T0 vs. T2, C: p-value for T1 vs. T2].

Scores of subscales and the total range from 1-5 and a higher score indicating a higher level of self-efficacy.

*Significant at $p < 0.05$; **significant at $p < 0.01$.

Table 7.12 Comparison of PP analysis of the CSES scores by group and over time

Outcome measures	Time			Between group		Within group			Interaction effects	
	T0 Mean $\pm$ SD ^a	T1 Mean $\pm$ SD ^a	T2 Mean $\pm$ SD ^a	<i>F</i>	<i>p</i> -value	<i>F</i>	<i>p</i> -value ^c	[A, B, C] ^d	<i>F</i>	<i>p</i> -value
NA ^b				9.76	0.003**	1.28	0.282		10.95	<0.001**
Control (n=22)	3.25 $\pm$ 1.0	3.12 $\pm$ 0.9	2.74 $\pm$ 1.0			7.43	0.004**	[0.778, 0.020*, 0.020*]		
Intervention (n=21)	3.51 $\pm$ 0.8	3.89 $\pm$ 0.8	3.96 $\pm$ 0.8			5.00	0.011*	[0.104, 0.054, 0.999]		
<i>t, p</i> -value	0.98, 0.334	2.92, 0.006**	4.52, <0.001**							
IEA ^b				8.97	0.005**	2.40	0.097		9.62	<0.001**
Control (n=22)	3.46 $\pm$ 0.8	3.33 $\pm$ 0.8	3.08 $\pm$ 0.9			3.05	0.058	[0.980, 0.149, 0.378]		
Intervention (n=21)	3.58 $\pm$ 0.8	4.12 $\pm$ 0.6	4.05 $\pm$ 0.7			10.41	0.001**	[0.005**, 0.012*, 0.999]		
<i>t, p</i> -value	0.50, 0.618	3.45, 0.001**	3.88, <0.001**							
PE ^b				8.78	0.005**	5.82	0.010*		11.24	<0.001**
Control (n=22)	2.63 $\pm$ 0.7	2.60 $\pm$ 0.8	2.31 $\pm$ 1.0			4.35	0.019*	[0.999, 0.105, 0.020*]		
Intervention (n=21)	2.71 $\pm$ 0.8	3.50 $\pm$ 0.8	3.38 $\pm$ 1.0			9.94	0.002**	[0.002**, 0.034*, 0.999]		
<i>p</i> -value	0.39, 0.698	3.54, 0.001**	3.49, 0.001**							
WE ^b				8.71	0.005**	2.76	0.069		10.93	<0.001**
Control (n=22)	3.21 $\pm$ 0.8	3.18 $\pm$ 0.7	2.80 $\pm$ 0.8			5.23	0.009**	[0.999, 0.061, 0.055]		
Intervention (n=21)	3.27 $\pm$ 0.6	3.75 $\pm$ 0.6	3.79 $\pm$ 0.7			8.53	0.003**	[0.014*, 0.019*, 0.999]		
<i>t, p</i> -value	0.11, 0.793	3.50, 0.009**	4.30, <0.001**							
BRF ^b				5.18	0.028*	4.08	0.020*		9.02	<0.001**
Control (n=22)	3.50 $\pm$ 0.9	3.41 $\pm$ 0.9	2.93 $\pm$ 0.7			7.23	0.004**	[0.999, 0.017*, 0.055]		
Intervention (n=21)	3.48 $\pm$ 0.9	3.98 $\pm$ 0.6	3.83 $\pm$ 0.7			5.84	0.006**	[0.012*, 0.157, 0.746]		
<i>t, p</i> -value	0.87, 0.931	2.75, 0.025*	4.05, <0.001**							
Total ^b				9.77	0.003**	4.42	0.022*		15.90	<0.001**
Control (n=22)	3.21 $\pm$ 0.7	3.13 $\pm$ 0.8	2.77 $\pm$ 0.8			8.89	0.001**	[0.999, 0.010*, 0.008**]		
Intervention (n=21)	3.30 $\pm$ 0.6	3.85 $\pm$ 0.6	3.80 $\pm$ 0.7			11.03	0.001**	[0.002**, 0.013*, 0.999]		
<i>t, p</i> -value	0.52, 0.634	3.28, 0.002**	4.49, <0.001**							

SD = Standard deviation, CSES = COPD Self-Efficacy Scale, NA = Negative affect, IEA = Intense emotional arousal, PE = Physical exertion, WE = Weather/environment, BRF = Behavioural risk factors, Total = CSES total score.

^a Independent t-test, ^b two-way repeated measures ANOVA, ^c one-way repeated measures ANOVA, ^d multiple comparison (Bonferroni) [A: *p*-value for T0 vs. T1, B: *p*-value for T0 vs. T2, C: *p*-value for T1 vs. T2].

Scores of subscales and the total range from 1-5 and a higher score indicating a higher level of self-efficacy.

*Significant at $p < 0.05$; **significant at $p < 0.01$.

Table 7.13 Comparison of ITT and PP analyses of CSES

Outcome measures	Between-group comparison						Between-group effects		Within-group effects		Multiple comparison						Interaction effects	
	T0 ^a		T1 ^a		T2 ^a		ITT	PP	ITT	PP	T0 vs. T1		T0 vs. T2		T1 vs. T2		ITT	PP
	ITT	PP	ITT	PP	ITT	PP					ITT	PP	ITT	PP	ITT	PP		
NA^b	NS	NS	S	S	S	S	S	S	NS	NS							S	S
Control ^c									S	S	NS	NS	S	S	S	S		
Study ^c									NS	S	NS	NS	NS	NS	NS	NS		
IEA^b	NS	NS	S	S	S	S	S	S	NS	NS							S	S
Control ^c									S	NS	NS	NS	NS	NS	NS	NS		
Study ^c									S	S	S	S	S	S	NS	NS		
PE^b	NS	NS	S	S	S	S	S	S	S	S							S	S
Control ^c									S	S	NS	NS	S	NS	S	S		
Study ^c									S	S	S	S	S	S	NS	NS		
WE^b	NS	NS	S	S	S	S	S	S	NS	NS							S	S
Control ^c									S	S	NS	NS	S	NS	NS	NS		
Study ^c									S	S	S	S	S	S	NS	NS		
BRF^b	NS	NS	S	S	S	S	S	S	S	S							S	S
Control ^c									S	S	NS	NS	NS	S	S	NS		
Study ^c									S	S	S	S	NS	NS	NS	NS		
Total^b	NS	NS	S	S	S	S	S	S	S	NS							S	S
Control ^c									S	S	NS	NS	S	S	S	S		
Study ^c									S	S	S	S	S	S	NS	NS		

CSES = COPD Self-Efficacy Scale, NA = Negative affect, IEA = Intense emotional arousal, PE = Physical exertion, WE = Weather/environment, BRF = Behavioural risk factors, Total = COPD Self efficacy total score, NS = Non-significant difference, S = Significant difference.

^aIndependent sample t-test, ^btwo-way repeated measures ANOVA, ^cone-way repeated measures ANOVA.

7.5.4 Effects of intervention on fiscal outcomes

The intervention's effects on fiscal outcomes were assessed in two respects: readmissions and the cost of readmission. All 60 patients in the initial sample (the ITT population) were included in this assessment. Tables 7.14 and 7.15 present the comparison results for the COPD-related readmissions and direct cost of COPD-related readmissions during the 6-week intervention period and follow-up at 12 weeks.

7.5.4.1 COPD-related readmissions

Total readmissions

During the 6-week intervention, 30.0% (10/30) of the control group participants and 13.3% (4/30) of the intervention group participants experienced at least one readmission owing to an exacerbation of their COPD condition, although a Pearson chi-square test detected no statistical difference between the groups ($\chi^2 = 3.35$, $p = 0.067$) in this period. However, a significant difference was found when the 12 weeks' data were compared, with the control group having a higher readmission rate than the intervention group (12/30 [40.0%] vs. 5/30 [16.7%], $\chi^2 = 4.02$, $p = 0.045$). In total, 17 patients (28.3%) were readmitted during the course of the study period for an exacerbation of COPD (see Table 7.14).

Time to first readmission

It can be seen from Table 7.14 that patients in the intervention group had longer median time to first readmission at both 6 weeks and 12 weeks. However, Mann-Whiney U test revealed no significant difference between groups (6 weeks:

Med. = 24.50 vs. 18.00, $U = 16.00$, $z = -0.57$, $p = 0.635$; 12 weeks: Med. = 26.00 vs. Med. = 20.00, $U = 26.00$, $z = -0.42$, $p = 0.721$).

Table 7.14 Comparison of COPD-related readmissions at 6 and 12 weeks

Outcome measures	Control	Intervention	χ^2/U	p -value
6 weeks				
Readmission [n (%)]				
No	20 (70.0)	26 (86.7)	0.125	0.063 ^a
Yes	10 (30.0)	4 (13.3)		
Time to first readmission (days)				
Median (range)	18.00 (6.0-41.0)	24.50 (13.0-31.0)	16.00	0.635 ^b
12 weeks				
Readmission [n (%)]				
No	18 (60.0)	25 (83.3)	4.02	0.045* ^b
Yes	12 (40.0)	5 (16.7)		
Time to first readmission (days)				
Median (range)	20.00 (6.0-69.0)	26.00 (13.0-45.0)	26.00	0.721 ^b

^a Fisher's exact test; ^b Mann-Whiney U test.

* Significant at $p < 0.05$.

7.5.4.2 Cost of COPD-related readmission

Analyses of the data of readmitted participants showed the median cost of COPD-related readmissions during the 6-week intervention to be RMB13,928.88 (interquartile range = 7,638.9) for readmitted participants in the control group and RMB7,117.59 (interquartile range = 5,718.0) for those in the intervention group, with a significant difference between them ($U = 3.00$, $p = 0.014$). No between-group difference was found, however, in the total direct cost of readmissions when the groups were compared at the end of the 12-week follow-up (see Table 7.15).

Table 7. 15 Comparison of cost of COPD-related readmissions at 6 or 12 weeks

Outcome measures	Control	Intervention	<i>U</i>	<i>p</i> -value
6- week cost (RMB)				
n	10	4		
Median	13928.88	7117.59	3.00	0.014*
Interquartile range	7638.9	5718.0		
12-week cost (RMB)				
n	12	5		
Median (range)	19911.07	12170.63	13.00	0.082
Interquartile range	9612.8	2673.3		

* Significant at $p < 0.05$.

7.5.5. Effects of intervention on patient satisfaction

Patient satisfaction was assessed by the CTCPSQ, which has two subscales (service satisfaction and education satisfaction). Subscale scores range from 0 to 100 and a higher score indicates higher level of satisfaction. Data were collected from 48 participants (25 in the control group and 23 in the intervention group) immediately after the 6-week intervention at T1. Results of the Shapiro-Wilk test showed 75% (3/4) of the CTCPSQ subscale scores CTCPSQ in the dataset to be significantly skewed. As a result, a nonparametric test, the Mann-Whitney U test, was performed to evaluate whether the mean ranks for the two groups differed significantly from each other in the CTCPSQ scores. Table 7.16 shows the PP analysis results.

Table 7.16 Comparison of the CTCPSQ scores of the two groups

Domain	Control (n = 25)	Intervention (n = 23)	<i>U</i>	<i>p</i> -value
Service satisfaction				
Median [interquartile range]	75.00 [8.33]	95.83[20.83]	123.00	<0.001**
Education satisfaction				
Median [interquartile range]	56.25 [39.06]	93.75 [18.75]	65.50	<0.001**

Each of the CTCPSQ domain scores ranges from 0 to 100, and the higher the score, the higher the level of satisfaction.

** Significant at $p < 0.01$.

From the above table, it can be seen that the intervention group had a higher median score than the control group in both the service satisfaction and the education satisfaction domains. Significant differences between groups in these two measures were found using the Mann-Whitney U test. The intervention group had a higher median service satisfaction score (Med. = 95.83) than the intervention group (Med. = 75.00, $U = 123.00$, $p < 0.001$), and the same held true for education satisfaction score (Med. = 93.75 vs. Med. = 56.23, $U = 65.50$, $p < 0.001$).

7.6 Summary of Part 1

The first part of this chapter describes the data collection method, baseline data of participants and group comparison results. The results reported thus far reveal the intervention group undergoing transitional care to have had significantly higher exercise capacity, self-efficacy, HRQOL and satisfaction scores and fewer COPD-related readmissions and a lower direct cost of readmission relative to the control group receiving usual care. Although the short-term benefits of the transitional care intervention are demonstrated by these results, no sustained effects were found on exercise capacity and costs once the intervention was completed. The ITT and PA analyses yielded similar results overall.

Part 2 Qualitative results

Two focus group interviews were conducted in November 2009. Each meeting lasted approximately 72.5 minutes (60-85 minutes). All the 21 patients completed the COPD-TCP participated in the qualitative data collection process. Thirteen patients took part in the two focus group meetings. Another eight gave their responses in writing. The following 10 open-ended questions, which were developed to evaluate the effect of the COPD-TCP as experienced by patients who underwent the complete programme served as prompt questions for the interview discussions and the written responses.

1. What were the effects of the home visits that you received from your nurse case manager?
2. What were the effects of the telephone follow-ups that you received from your nurse case manager?
3. How would you assess the effect of daily walking and the upper-arm exercise?
4. How would you assess the effect of the health education offered by your nurse case manager?
5. How would you assess the usefulness of the health education booklet entitled *Rehabilitation Trip: Action Plan Guide* that the programme provided?
6. How would you evaluate the *Rehabilitation Trip: Action Plan Handbook* and the usefulness of the daily record it asked you to keep?
7. How did participating in this programme help you in terms of seeking medical help?
8. How would you assess the nursing care provided by your nurse case manager?

9. What factors affected your ability to carry out the rehabilitation plan?
10. What were the differences between the nursing care you received following your current discharge and that you have received in the past?

7.7 Characteristics of the participants

Table 7.17 summarises the characteristics of the participants. In the total sample (n = 21), 17 (81.0%) were male and four (19.0%) were female. The mean age was 71.95 ± 5.0. All were retired. The majority had a spouse (85.7%), a junior high school or below education level (71.4%), an average family income of less than RMB2000 (71.4%), and a partial health care payment option (85.7%).

Table 7.17 Characteristics of the focus group and written response participants

	Total	Focus Group 1	Focus Group 2	Written response
	n = 21	n = 8	n = 5	n = 8
Age (years)				
Mean ± SD	71.95±5.0	73.00±3.7	71.60±4.4	71.13±6.6
Sex				
Male	17 (81.0)	6 (75.0)	3 (60.0)	8 (100.0)
Female	4 (19.0)	2 (25.0)	2 (40.0)	0 (0.0)
Marital status				
Married	18 (85.7)	7 (87.5)	3 (60.0)	8 (100.0)
Divorced/Widowed	3 (14.3)	1 (12.5)	2 (40.0)	0 (0.0)
Education				
≤ Junior high school	15 (71.4)	5 (62.5)	4 (80.0)	6 (75.0)
≥ Senior high school	6 (28.6)	3 (37.5)	1 (20.0)	2 (25.0)
Employment status				
Retired	21 (100.0)	8 (100.0)	5 (100.0)	8 (100.0)
Employed	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Average family income				
≤ 2000 (RMB)	15 (71.4)	4 (50.0)	4 (80.0)	7 (87.5)
≥ 2001(RMB)	6 (28.6)	4 (50.0)	1 (20.0)	1 (25.5)
Healthcare payment				
Totally subsidised	3 (14.3)	1 (12.5)	2 (40.0)	0 (0.0)
Partial paid	18 (85.7)	7 (87.5)	3 (60.0)	8 (100.0)

SD = Standard deviation.

7.8 Experiences of the participants in the intervention programme

Thematic analysis of the reported experiences of the participants who underwent the COPD-TCP revealed four themes: (1) value of transitional care, (2) intervention effectiveness, (3) support from NCMs and (4) challenge in maintaining health. Each of these four themes had two to four subthemes which were generated from the coding of the data. The following four sections elaborate on these themes and subthemes with illustrative quotes.

7.8.1. Value of transitional care

All of the study participants who took part in the interviews/written responses expressed appreciation for the COPD-TCP implemented in this study. The descriptions of being helpful, a new thing and worth popularising were the values of transitional care commonly recognized by the participants.

Being helpful

“Being helpful” was the description that the participants used most frequently. They regarded the programme as useful to improve their health or disease condition and helped them to reignite hope.

The service provided in this programme is good, and convenient for us as patients, which is indeed helpful for rehabilitation. [Participant WR-7]

Since the very beginning, I've said “thank you all!” It's not only me, but my neighbours [too]. They said, “Your health was so poor previously. You've been

getting better and better since this discharge from the hospital. Was it the outcome of your nurse's help?" [Participant FG1-2]

[The programme] dispelled my doubts about the rehabilitation, and one can be hopeful. [Participant WR-2]

A new thing

Compared with their past experience, the interviewees regarded the transitional care service as "a new thing". The COPD programme connected hospital care with community rehabilitation, which was something they had never experienced before, as the following representative excerpts show.

There was no such service in the past. No follow-up was provided after discharge previously. You had to go back to the hospital whenever you came across any problem. [Participant FG2-1]

This programme is different. Nurses evaluated our health status, taught us what to do, including how to do exercise.... This is great progress that the hospital has made, especially in the psychological aspect.... The continuous follow-ups are new. [Participant FG2-2]

Worth popularising

Some even mentioned their hope that the programme would be popularised and become part of routine COPD care.

My neighbour has a similar disease.... I brought him to see Doctor X [in the study hospital] ... now he wants to have this service. [Participant FG1-8]

It's really good.... This mode of service should be promoted. [Participant FG1-5]

I hope the service can be kept running ... to reduce readmission. [Participants WR-1]

7.8.2. Intervention effectiveness

When asked about the effects of the TCP, participants related their experienced gains or achievements in regard to the interventions they received, including home visit, telephone follow-up, exercise training, health education etc. These interventions were regarded to be effective in improving self-management, confidence, adherence and health status as illustrated in below.

Self-management improvement

The participants commented that the programme had been beneficial in helping them to gain basic knowledge of COPD and self-management skills, such as how to exercise, how to maintain a nutritional balance, how to manage medications and how to cope with the worsening condition. The following are representative comments.

I recognise that this disease is incurable, but this does not mean that there is nothing we can do and [that we must be passive].... I have been following the dietary instructions that the nurse gave me, and everything has gone well. [Participant FG1-3]

If you are short of breath, you can practise breathing techniques. If these are not helpful, you can inhale medications. If you are still short of breath after those two steps, you have to pay close attention to [your symptoms] and consult your doctor or even call the emergency centre. [Participant FG1-7]

Confidence enhancement

Many of the participants highlighted the confidence that they had gained from the programme:

[The programme] provided me with health-related knowledge. Now I can walk and sleep better and feel confident about the rehabilitation. [Participant FG2-4]

I am keeping records every day. The changes observed from the log book make me feel more confident in managing the disease. [Participant WR-3]

Adherence improvement

The necessity of behavioural change was a message that was repeatedly mentioned by the informants during the interviews. They used a number of concrete examples to inform the interviewer of how they were now behaving differently relative to the past:

Previously, I often forgot to take my medication. After participating in this programme, with help from the nurses, I am aware of the importance of the medication ... [and that] exercise is good. No matter how busy I am, I insist on exercising every day. [Participant FG1-8]

Exercise is helpful, I perform every exercise repetitively six times, and I now know that it is effective to inhale medication after washing. I feel uncomfortable if I skip the medication. [Participant FG2-5]

I can take medications and perform exercises regularly now. [Participants FG1-4 and FG2-3]

Better health

When commenting on the effects of the programme, the focus group participants emphasised “improvement in shortness of breath”, “now being in a stable condition”, “reduced readmissions” and “improvement in activity tolerance”. They gave the following examples.

Last year, I was re-hospitalised six times, while it has only happened once this year. Additionally, it was impossible for me to walk across the footbridge without rest in the past, but I can do it now. ...I told my physician that my disease seems to have been cured [Participant FG1-2]

I continue to walk for 30 minutes and to do the upper-arm exercise every day. I feel that my physical condition is much better than before, and my upper and lower extremities are stronger and I have more strength than before. My general condition has also improved greatly. [Participant WR-4]

I was referred to see the nutrition specialist [by the NCM]. ... I gained a few kilograms. ... At the present, I can climb six flights of stairs without any symptoms, which was not possible in the past. [Participant FG1-8]

7.8.3. Support from nurse case managers

Almost every participant expressed their appreciation of the NCMs. Caring, education and guidance and professional help were the support that the participants received from their NCMs, as the following excerpts show.

Caring

I felt that the nurses really cared about me no matter how severe my condition was. I have never met any nurse who would care for me like this before.... This is a good hospital; they do not abandon us. [Participant FG1-6]

Sometimes medication and emotional support is very important. Doctors prescribe you medication, but for nursing, the rehabilitation is the essential part. Caring from nurses makes different. [Participant FG1-1]

The nurse cares for patients very well. ... You can get help from the nurse at any time. [Participant WR-8]

Education and guidance

She [the NCM] visited me at home, explained in words, and taught by demonstration and examples ... how to do the upper-arm exercise at home.... She was able to teach us by words and deeds ... [which] is so-called practical

education. For us as patients, such practical education helped us gain a deeper understanding of the disease, the drugs and the treatment. [Participant FG1-7]

The nurse not only told me the rationale for the exercises, but also demonstrated each exercise for me, through which I gained a deeper understanding of the rehabilitation. On the contrary, doctors just order various tests for us, such as a chest x-ray and electrocardiogram, and we have no idea what happened. [In this program], the nurse emphasised things we should pay attention to after discharge and taught us how to do them. [Participant FG2-2]

Professional help

I was not used to drink alcohol but I drank a little bit on the day discharged home. I felt shortness of breath and called the hotline. ...after carefully assessing my condition, the nurse taught me what to do and explained in detail why not to drink while on medication. ... Since then, I have not consumed alcohol before taking medication. It was an unforgettable experience for me. [Participant FG2-1]

The nurse gave me follow-up calls, and then came to my home for a visit. She knew our conditions and family situation ... and wholeheartedly helped us deal with our problems. The most helpful was the communication between patients and doctors/nurses. [Participant FG2-2]

The nurse is very professional and able to help improve our health. [Participant RW-6]

7.8.4. Challenges in maintaining health

In addition to the positive health outcomes achieved, participants also reported challenges in maintaining health while they were implementing the COPD-TCP. They faced two major challenges: environmental challenge and economic challenge.

Environmental challenge

The environmental challenge came from weather changes and passive smoking as illustrated by two examples below.

Changes in the weather make me short of breath while walking; well, forget it, forget it [I'll think], and then I'll stop walking. [Participant FG1-7]

I feel short of breath when I am around cigarette smoke, but I can't avoid it in public areas. [Participant FG2-3]

Economic challenge

Economic challenge was due to the existing health system defect. This was the most prominent problem, and one that generated a heated discussion, as the following excerpts show.

The disease is incurable. In addition, you cannot afford the treatment without economic support. The prescribed medications alone cost over RMB1,000 per month, accounting for over half of our retirement pension. This is a policy issue. [Participant FG1-4]

To be honest, although I have 100% [reimbursement] ... it is limited to RMB200 per day, and I have to pay the difference if the charge is more than RMB200. For this admission lasting 9 days, I spent over RMB2000 out of my own pocket ... treatment fees, examination fees, inspection fees ... none of these is covered by the RMB200. [Participant FG1-5]

Medical expenses are indeed a burden for me. This morning, I got this box of medicine [Seretide Accuhaler 500/50] by paying more than RMB400. Although I have medical insurance, I still needed to pay RMB250 for it by myself.... I'm using not only this drug but there are other medications as well. I spend several hundred RMB every month. Simply put, I cannot afford this disease! For daily living, I do have a pension. Eating a little better? I cannot do it. I need to save for medical expenses ... one emergency room visit costs me about RMB300. [Participant FG1-6]

7.9 Summary of Part 2

This part of the chapter presents the experiences of the participants who underwent the COPD-TCP, as reported in two focus group interviews and the written responses from those unable to attend the interviews. These qualitative findings provide additional evidence from the patients' perspective to support the quantified benefits of the COPD-TCP reported in the first part of the chapter. Those who took part in the intervention regarded it as novel and helpful and worth to be popularised. The benefits of the programme included the acquisition of knowledge and skills, as well as greater confidence in disease self management, and improved adherence to the treatment regimen and better health status. The participants expressed appreciation

for the effective support they had received from the NCMs, who provided them with caring, education and guidance and professional help. The participants also related their concerns about the challenges they were facing in maintaining and reinforcing health outcomes such as environmental risk factors and unaffordable medical expenses.

CHAPTER EIGHT

DISCUSSION

8.1 Introduction

Chapter 7 reported both the quantitative and qualitative results of the current study, revealing that the COPD-TCP yielded positive results on patients' exercise capacity, HRQOL, self-efficacy and satisfaction, as well as on COPD-related readmission rate and the direct cost of readmission. Although some of these gains could not be sustained for 12 weeks, transitional care was well accepted by the patients who underwent the COPD-TCP. This chapter discusses the research findings from the following perspectives: the effectiveness of transitional care in meeting the unmet needs of patients with COPD (Section 8.2), effectiveness of the COPD-TCP (Section 8.3), challenges in developing transitional care in mainland China (Section 8.4) and methodological considerations (Section 8.5).

8.2 Transitional care in meeting the unmet needs of patients with COPD

The importance of transitional care in meeting the needs of patients with COPD was highlighted in the first chapter of this thesis. Survey studies have reflected upon patients' unmet needs from the perspective of the disease burden (Zhong et al., 2007), economic and societal constraints (He et al., 2009a; Qi, 2009; Yin et al., 2011) and the healthcare system (Guang et al., 2008; Wang et al., 2012). This section further explores the unmet needs of the patients who participated in the current study and addresses the role of transitional care in meeting those needs.

8.2.1 The unmet needs of COPD patients

The 60 participants recruited into the main RCT were aged 71.87 ± 7.1 years, and had a history of COPD ranging from 1-40 years. Their mean FEV₁% predicted and mean FVE₁/FVC ratio were 44.75 ± 17.2 and 44.68 ± 12.1 , respectively, and most of the participants ($n = 57$, 95%) suffered moderate to very severe COPD symptoms according to the GOLD spirometric severity criteria. This study population shares the common demographic characteristics of other studies carried out in mainland China, although the percentage of males was higher than that in earlier studies (Han et al., 2012; Yu et al., 2012; Wang, Zhang et al., 2011). Most of the subjects were retired, and a majority had a low education level and low family average income, and thus out-of-pocket payment for healthcare constituted a considerable burden (the participants partially or fully met the costs of their own healthcare). A readmission rate of 28.33% was noted at 12 weeks, which is comparable to the 25% reported in mainland China (Wang et al., 2012) but lower than the UK statistic (31.40%) reported by Price et al. (2006).

In the main RCT, 65% of the participants indicated that they had care needs during periods of sickness, and 93.3% that they needed care after returning home. Qualitative data from the participants who completed the TCP considered herein further revealed their need for healthcare during their transition from hospital to home after discharge following an acute episode. Participant revealed that to date they had never been followed up after discharge, thus requiring a return to hospital in the face of any subsequent problem. A patient disclosed that he has been hospitalised four to five times, with the recovery never lasting long.

These findings concur with the observations made by other Chinese researchers, indicating that the current practice of COPD management on the mainland still places emphasis on the acute stage of the disease and the hospital setting (Fang et al., 2011; Li & Fu, 2010; Li et al., 2010; Sun, 2010; Zhou et al., 2010). Patients with COPD generally receive inadequate postdischarge care from their healthcare providers. Their unmet needs again highlight the need to provide appropriate healthcare to this patient group, particularly once they have been discharged home after an exacerbation episode.

8.2.2 Transitional care as an efficient modality in COPD management

TCP implementation has been shown to be an effective management strategy in improving patient outcomes and reducing healthcare utilisation and costs in patients with COPD in Hong Kong, Taiwan and elsewhere (Balaban et al., 2008; Neff et al., 2003; Sharma et al., 2010; Shu et al., 2011; Wong et al., 2011). The current study has developed and tested a COPD-TCM which integrated the GOLD guidelines in COPD management with the transitional care model among Chinese COPD patients. The findings support the effectiveness of such programmes.

Seamless care is characterised by comprehensive discharge planning and continuous home follow-up to bridge the service gap after discharge from hospital. This study demonstrates the strengths of such seamless care in COPD management. The COPD-TCP carried out in this study comprised two phases, pre-discharge planning and home follow-up, and the intervention lasted 6 weeks. The care arrangements of the programme involved the identification of individual needs through comprehensive assessment and individual tailored education before patients were

discharged home. Ongoing psychological support and intensive reinforcement to address those needs were provided to patients by the same NCM who performed their initial assessment during each home visit or by telephone follow-up after discharge. During the home visits, any problems related to daily living were further assessed, and support from patient's family members was advocated. In subsequent telephone calls, changes in knowledge, behaviour and status were monitored, and patients were encouraged to maintain changes through feedback designed to reinforce appropriate health practices.

A more effective COPD management programme contains multiple interventions (GOLD, 2011). The current study had four protocols that comprised of multiple elements, including assessment, surveillance, education, guidance and counselling, mutual goal setting, home-based exercise training, hotline and referrals. A more recent study in Hong Kong by Wong and her team (2013) compared the effects between home visits with telephone calls and telephone calls only for transitional discharge support and confirmed that the effects of using bundled interventions involving both home visits and telephone calls were more effective.

The most recent revised GOLD guidelines (GOLD, 2011) place emphasis on the crucial role of pre-discharge preparation and post-discharge follow-up in COPD management. The guidelines propose that the items in Table 8.1 be assessed prior to hospital discharge and during follow-up visits 4-6 weeks after hospitalisation. Most were included in the current intervention, and implemented exactly as recommended, thus strengthening programme efficiency.

Table 8.1 Items for assessment prior to hospital discharge and at follow-up visits 4-6 weeks after hospitalisation with an exacerbation of COPD

At the time of discharge*	At follow-up visits 4-6 weeks postdischarge
• assurance of effective home maintenance pharmacotherapy regimen • reassessment of inhaler technique • education regarding role of maintenance regimen • instruction regarding completion of steroid therapy and antibiotics, if prescribed • assessment of need for long-term oxygen therapy • assurance of follow-up visit in 4-6 weeks • provision of a management plan for comorbidities and their follow-up	• ability to cope in usual environment • measurement of FEV1 • reassessment of inhaler technique • understanding of recommended treatment regimen • reassessment of need for long-term oxygen therapy and/or home nebulizer • capacity to perform physical activities and ADL* • CAT or mMRC* • status of comorbidities*

*Newly recommended item; CAT = COPD Assessment Test; mMRC=Modified British Medical Research Council.

Source: GOLD (2011); *Global Strategy for the Diagnosis, Management and Prevention of COPD (updated 2011)*.

The experience gained during the intervention revealed that continuous assessment through regular follow-ups such as home visits and telephone calls is very important in ensuring that healthcare providers' efforts lead to the desired outcomes. One participant noted in the interview that he had previously often forgotten to take his medication, but with the help of the nurses in the TCP, he became more aware of its importance as well as that of regular exercise. It is clear that transitional care not only provides patients with much needed reinforcement of their efforts to learn the skills of self-management and engage in better health-related behaviour, but also renders some of the assessments (such as those in Table 8.1) more practicable and efficient by locating them within the living environment. For example, NCMs could

detect indoor air pollution when assessing the home environment and could teach patients how to use the oxygen device at home.

8.2.3 The role of NCMs in helping patients with COPD

Collaboration between doctors and allied health professionals, or among a multidisciplinary team, is another typical feature of transitional care. The contribution of the coordinating role played by nurses acting as case manager, care coordinator or coach in COPD care is well documented in transitional care studies (Balaban et al., 2008; Coleman et al., 2006; Daly et al., 2005; Egan, et al., 2002; Kwok et al., 2004; Neff et al., 2003; Shu et al., 2011; Wong et al., 2011). In the current study, four well-trained respiratory ward nurses assumed the role of NCM. They successfully implemented the COPD-TCP among the intervention participants with the support of a clinical team comprising a physician, nutrition specialist, and frontline healthcare providers and in collaboration with the patients and their caregivers (if available). The findings of the focus group interview revealed that the NCMs provided COPD patients with their much needed caring, education and guidance as well as professional help in addressing their problems. The implementation of the COPD-TCP helped the patients to reignite hope, regain confidence, acquire knowledge and skills, cope with their worsening condition, improve adherence to medication, exercise and diet regimens, in addition to the outcome achievements further discussed in coming sections.

8.3 The effectiveness of the COPD-TCP for Chinese patients

The COPD-TCP was found to have positive effects on Chinese patients with COPD in this study. The findings demonstrate the programme's ability to improve exercise

capacity, HRQOL, self-efficacy and patient satisfaction, as well as reduce COPD-related readmission and the direct cost of such readmission.

8.3.1 Effects on functional exercise capacity

The most recent BTS pulmonary rehabilitation guidelines propose that patients be offered pulmonary rehabilitation within one month of discharge (British Thoracic Society Pulmonary Rehabilitation Guideline Development Group, 2012). Physical activity is a key dimension of the functional status of COPD sufferers, and improving exercise tolerance is the central target of pulmonary rehabilitation intervention. The 6MWT is a commonly used test to estimate functional exercise capacity in patients with COPD (ATS Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories, 2002; Jenkins & Cecins, 2010; Puhan et al., 2008).

Change in 6MWD was used as an outcome measure in this study, and both statistically and clinically significant improvements were realised (clinical significance was determined using the MID of 25 m suggested by Holland et al., [2010]). Following transitional care that included daily walking and upper-arm exercises, improvements of 36.63 m (ITT analysis) and 57.84 m (PP analysis) in 6MWD were noted in the intervention group, which comprised patients with varying degrees of disease severity. They were classified as mild ($n = 1$), moderate ($n = 8$), severe ($n = 16$) and very severe ($n = 5$) using the GOLD (2006) criteria. Significant 6MWD differences were noted between the intervention group and control group in both the ITT and PP analyses (ITT analysis: $p = 0.012$; PP analysis: $p = 0.037$). Other studies (Akinci, 2011; Boxall, Barclay, Sayers, & Caplan, 2005; Ghanem, Elaal, Mehany, & Tolba, 2010; Lee et al., 2013; Mendes de Oliveira, 2010; Na et al.,

2005; Oh, 2003; Takigawa et al., 2007) also showed that functional capacity increased after a 6- to 12-week home-based pulmonary rehabilitation programme.

The intervention in this study lasted six weeks, which is the minimum length of an effective rehabilitation programme according to the recently revised GOLD guidelines (2011). Short-term gains in functional exercise capacity were achieved following the 6-week intervention, but these gains were not sustained over 12 weeks. The relatively short duration of the intervention may be one of the factors leading to the non-significant result in terms of a sustained effect. A 6- to 12-week programme is recommended by many guidelines (National Clinical Guideline Centre [NCGC], 2010; Ries et al., 2007). Studies have shown that the longer the programme, the more effective the results (Behnke et al., 2000; Green, Singh, Williams, & Morgan, 2001). However, Brooks, Mangovski-Alzamora and Goldstein (2002) reported that 8 weeks of supervised exercise training in a home maintenance exercise programme (i.e. breathing training, upper extremity exercise, walking and interval training) was inadequate to prevent a decline in functional exercise capacity. Nevertheless, a majority of the patients who completed the COPD-TCP reported improvement in exercise tolerance and health status. One patient reported that she continues to walk for 30 minutes and perform upper-arm exercises every day, and that she feels that both her physical and general conditions have improved as a result of the programme.

Puente-Maestu et al. (2000) conducted an RCT comparing the effects of supervised versus self-monitored training programmes for patients with COPD. They found both types of training to improve exercise tolerance, although the magnitude and extent of

the physiological improvements were greater in patients who trained under supervision. Considering the availability of resources in the mainland setting, the exercise programme in the current study was considered to be practicable and capable of being safely implemented in the home by nurses with little supervision. This was support by the studies done by Na et al. (2005) in Korea and Akinci (2011) in Turkey with the same attempt to improve the accessibility and participation in pulmonary rehabilitation. Na et al.'s (2005) study reported that a simple and easy home-based rehabilitation programme consisting of education and 12 weeks enforced aerobic and muscle-strengthening exercise which was clinically feasible and effective in improving exercise capacity and QOL. Similar gains was demonstrated by a nurse-led, home-based pulmonary rehabilitation programme in which patients received education and performed breathing and aerobic exercise at their home for 12 weeks (Akinci, 2011).

The BTS guidelines regard even relatively low levels of supervised activity as conducive to improved functional performance, as enhanced exercise task capacity can also be achieved through improvements in confidence and ergonomics and/or a reduction in the affective component of dyspnoea (British Thoracic Society Standards of Care Subcommittee on Pulmonary Rehabilitation, 2001). One participant in the current study reported that although he experiences breathlessness when walking for 30 minutes, the more often he walks the more he enjoys doing so. Although the current study did not examine the relationship between all outcome variables, the relationship between functional exercise capacity and self-efficacy was reported by other researchers (Davis, Carrieri-Kohlman, Janson, Gold, & Stulbarg,

2006; Lox & Freehill, 1999). This will be further discussed in a later section of the chapter.

8.3.2 Effects on HRQOL

COPD has significant extrapulmonary consequences that lead to comorbidity conditions that affect patients' quality of life. Improving HRQOL is thus a central goal of COPD management (GOLD, 2001, 2006, 2011). The Chinese version of the SOLQ developed and validated in this study was used to assess the effects of the COPD-TCP on HRQOL. The results suggest that such transitional care has beneficial effects for Chinese patients with COPD. After completion of the COPD-TCP, the intervention realised significant improvements in physical function (PF), emotional function (EF) and coping skills (CS), as assessed by the three health-related subscales of the SOLQ. Compared with the baseline, the mean score in the intervention group increased 7.76 points in PF, 9.22 in EF and 6.52 in CF, a change more than 5 points greater than that which followed the pulmonary programme in the study of Tu et al. (1997).

Significant between-group differences were noted in PF ($p = 0.016$ at week 6 and $p = 0.009$ at week 12), and the between-group/over-time interaction effect was also significant ($F = 4.47$, $p = 0.021$). Echoing the objective 6MWT findings suggesting the programme's positive effect on exercise capacity, the subjective interview findings confirmed its helpful role in improving physical function, with one patient remarking that she was now able to climb six flights of stairs without any symptoms, something that would have been impossible in the past. This study's results also concur with reported evidence showing that pulmonary rehabilitation can lead to

statistically significant and clinically meaningful improvements in HRQOL and functional exercise capacity (Akinci, 2011; Ghanem, ELaal, Mehany, & Tolba; 2010; NCGC, 2010), but is the first study to do so in a Chinese population.

COPD leads to a persistent decline in functional capacity and quality of life. The reduction in physical capacity is frequently associated with psychological impairment and morbidity, including anxiety and depression (GOLD, 2011). Psychosocial well-being is another important aspect that was addressed in the COPD-TCP implemented here, with the NCMs providing ongoing psychological support to patients. The intervention group saw greater EF improvement than their counterparts in the control group at T2 (77.00 vs. 60.78, $t = 2.99$, $p = 0.004$). Two-way repeated measures ANOVA results confirmed the significance difference between the groups in EF ($F_{(1,58)} = 4.58$, $p = 0.037$). A significant difference was also found for the interaction effect ($F_{(1.531, 88.807)} = 3.53$, $p = 0.045$). These findings are comparable to those of another transitional care programme in Guangzhou that was carried out by a group of nurses trained by our research team (Li, Cheng, et al., 2012). That study applied similar intervention strategies to those designed for this study but involved a senior nurse who had been specifically trained in psychological therapy to support patients identified as suffering from psychological distress according to the General Health Questionnaire 12 (GHQ-12). A significant decrease in the incidence of psychological distress post-intervention compared with the baseline data was reported, and the study group had significantly higher quality of life scores, as assessed by the SGRQ (Li, Cheng et al., 2012). Li and her team (2012) focused primarily on the psychological aspects of intervention, whereas this study took a comprehensive and holistic approach to supporting COPD patients.

In the current study, the patients in the intervention group also recorded greater improvement in the CS scores of the SOLQ (81.81 vs. 69.72, $t = 2.54$, $p = 0.014$), which is discussed in greater depth in the coming section.

8.3.3 Effects on COPD self-efficacy

8.3.3.1 The effects and interventions

The effects of the COPD-TCP on self-efficacy were examined using the modified Chinese version of the CSES. The results of both ITT and PP analysis showed significant between-group and time interaction differences in the CSES total scores (ITT analysis: $F_{(1.568, 90.927)} = 13.87$, $p < 0.001$; PP analysis: $F_{(1.621, 66.442)} = 15.90$, $p < 0.001$). Similar to studies focusing on the effects of nursing interventions on self-efficacy in Hong Kong and mainland China (Chen et al., 2012; Ma, Zhao, Liu, & Ai, 2009; Wong, Wong, et al., 2005), the COPD-TCP was found to improve COPD patients' self-efficacy.

In the study carried out by Ma, Zhao, Liu et al. (2009), 30 patients who underwent a health education programme based on self-efficacy theory were compared with 30 patients treated with conventional health education. The results revealed the total self-efficacy score and subscale scores of negative affect (NA) and physical exertion (PE) to be higher in the study group than the control group post-intervention. Self-efficacy in behavioural risk factors (BRF) showed an increasing tendency, and self-efficacy in weather or environment (W/E) a downward trend, although there was no significant difference in intense emotional arousal (IEA) between the two groups.

Another recent transitional care study conducted in China introduced a programme in which the intervention group received discharge planning provided by hospital nurses within 48 hours of readmission and were then followed up by community nurses for 6 months after discharge (Chen et al., 2012). The authors reported that the study group achieved higher scores in total self-efficacy, PE, IEA and W/E than the control group ($p < 0.01$), but there were no significant differences between the two groups in the BRF or NA (Chen et al., 2012).

A Hong Kong study showed the self-efficacy total scores ($U = 272.5$, $p = 0.009$) of patients followed up by telephone to improve significantly relative to patients in a control group (Wong, Mok, et al., 2005). Using mean difference scores to make the comparison, they also found significant differences between the groups in the PE and W/E scores.

The three aforementioned studies reported inconsistent findings for the NA, IEA, W/E and BRF subscales using self-efficacy as the primary goal. Geographic factors may explain the inconsistent W/E results, as this domain contains items related to confidence in coping with climate change. Unlike the other studies (and this one), Ma, Zhao, Liu, et al. (2009) carried out their study in Harbin, in the northern part of China, during the cold winter and spring. Some COPD patients find that inclement weather and temperature changes trigger symptoms. They thus need to learn to cope with these factors. The participants in the current study also mentioned that they were afraid of weather change, with extreme cold and extreme hot leading to colds and dyspnoea, respectively.

Significant improvement was observed in all five dimensions of COPD self-efficacy in the participants receiving transitional care, whereas significant decreases were noted in the control group receiving usual discharge care. Both main group and main time effects were statistically significant ($p < 0.001$). The better outcome found in this study relative to the others discussed may be related to the comprehensive nature of the intervention strategies and the seamless care delivery mode, both of which may have done more to enhance patients' self-efficacy.

8.3.3.2 The role of self-efficacy in programme outcomes

Self-efficacy is defined as “the belief of a person in his or her ability to organize and execute certain behaviours that are necessary in order to produce given attainments” (Bosscher & Smit, 1998, p. 339). According to self-efficacy theory, a change in behaviour and its maintenance are outcomes resulting from a belief in one's ability to perform the given behaviour (Strecher, DeVellis, Becker, & Rosenstock, 1986). Bandura (1997) argued that the degree of physical impairment in chronic disease patients is not predictive of the quality of their functioning. Rather, he stated, “functional limitations may be governed more by beliefs [in] capability than by degree of actual physical impairment” (Bandura, 1997, p. 300). He also suggested that self-efficacy can be enhanced or influenced by four mechanisms: mastery experience, modelling, social persuasion and judgment of bodily states. These four mechanisms, to some extent were applied in the current study.

Self-management education and therapeutic communication between patients and nurses were effective in motivating patients. During the exercise training assessment before and after the walking and upper-arm exercise, a pulse oximeter was placed on

the patient's finger, and he/she was asked to monitor the readings so that he or she would be aware of his or her own condition. Patients who could tolerate only a short distance of walking were instructed to use pursed-lip breathing whenever they decided to stop for a short rest, and these patients would also see a rise in their oximetry readings at the same time. Usually, the SpO₂ readings rose gradually within 1-3 minutes of using the appropriate method of breathing and in such cases patients resumed their walking with confidence. At the same time, the NCM would reinforce the patients' assessment of their own performance accomplishment (Bandura, 1997). Patients were also instructed to use the Borg scale and to make daily records to monitor their progress.

The demonstration and return demonstration teaching method was applied in the teaching of self-management skills or techniques such as inhaler use, pursed-lip breathing, efficient coughing, the breathlessness coping position and upper-arm exercises. When demonstrating the use of the inhaler, the NCM used a placebo inhaler device, and asked the patient to follow her step by step so as to facilitate the learning process.

Moreover, the patient and NCM established mutual goals during the discharge planning phase, and goal achievement was reviewed at the end of each encounter. All of the mutual goals based on individual needs and perceived self-efficacy implicitly included some degree of outcome expectancies because individuals have to believe that they can produce the responses necessary for desired outcomes. The process of having the patient and NCM establish mutual goals may have enhanced the therapeutic alliance and motivated the patients to achieve the goals. Similar to the

findings of this study, Wong et al. (2011) also included collaborative goal-setting in their transitional care interventions and found them to be effective in enhancing patients' self-efficacy.

Although the current study did not examine the relationship between all outcome variables, there is reason to believe that self-efficacy is likely to have played a vital role in eliciting the positive effect for the COPD-TCP. "We have confidence in our disease rehabilitation" was a sentiment commonly expressed by the intervention group participants. They said that the COPD-TCP had helped to reignite hope and confidence. One patient put it this way: "I recognise that this disease is incurable, but that does not mean that there is nothing we can do or that we have to be passive." He said that following the dietary instructions given by the nurse and then finding that all was well helped him to feel that he was "almost cured". In another recent study of Chinese patients with COPD, Yu et al. (2012) explored the relationship between self-efficacy and HRQOL. Using the Chinese version of the CSES to assess self-efficacy and the St George's Respiratory Questionnaire to measure quality of life, they identified significant relationships between the two.

It has been suggested that self-efficacy may act as a mediator between changes in HRQOL and symptoms and physiological outcomes in patients with COPD after pulmonary rehabilitation (Arnold et al., 2006; Kohler, Fish, & Greene, 2002). Kaplan, Atkins, and Reinsch (1984) conducted a study in which 60 patients who had been randomly assigned to an experimental or control group were given a prescription to increase their level of exercise. The experimental group received training to increase their level of exercise in addition to the attention that was given to both groups. After

3 months, the group that had been trained to comply with a walking regimen was found to have significantly increased its level of activity relative to the control group receiving attention alone. The investigators further found this change to have been mediated by changes in perceived efficacy for walking (Kaplan et al., 1984). As discussed in Section 8.3.1, if self-efficacy helps in eliciting optimal outcomes in COPD transitional care, then strategies to improve self-efficacy should be the focus of nursing interventions in this patient group.

8.3.4 Effects on patient satisfaction

Similar to earlier findings revealed in initial transitional care studies carried out on the mainland among patients with coronary heart disease (Zhao, 2004), the findings of this study also showed that patients who underwent the COPD-TCP were more satisfied with the care they had received compared to the control group. The aspects of satisfaction involved both the NCM and the programme, which one informant described as “convenient for patients” and “helpful in rehabilitation”. Studies have shown that time spent with the provider, the provider-patient relationship, communication, information-giving, continuity and nursing intervention all have a positive association with patient satisfaction (Mahomed, St John & Patterson, 2012; Shaw, Williams, & Assassa, 2000). International guidelines emphasise the importance of patient education for patients with COPD, and studies have demonstrated that patient education and postdischarge support improve overall patient satisfaction (Hermiz et al., 2002; Nguyen et al., 2008; Skwarska et al., 2000; Vrijhoef et al., 2007; Wong et al., 2008, 2011).

The four NCMs involved in this study were very effective in building rapport with the patients and their family members and providing them, and caregivers, with self-management knowledge and skills and with consistent psychological support and encouragement during each interaction. The assistance provided by the NCMs was timely, occurring immediately after hospital discharge when patients had just returned home and were attempting to resume normal daily life. Current clinical practice in the mainland healthcare system provides patients with little attention after they are discharged home. It is not surprising to note that the patients in this study regarded transitional care as “a new thing” in their care experience and that most appreciated the care they received. The nurses’ involvement in COPD management was an important factor in rendering that care acceptable to patients.

8.3.5 Effects on readmission and direct cost of readmission

Readmission for patients with COPD is both common and costly. Although transitional care has proved to be a cost-effective care model in chronic disease management, whether a pulmonary rehabilitation programme is effective in reducing healthcare utilisation remains uncertain (NCGC, 2010). However, international guidelines recommend such a programme in COPD management, claiming it to be effective in improving patients’ health status (BTS, 2001; GOLD, 2006; NCGC, 2010; Ries et al., 2007). There is a scarcity of studies carried out in mainland China examining the effects of nursing intervention on healthcare utilisation and cost (Xu, 2012). The current study constitutes the first attempt to look at the effect of a CPOD-TCP on the COPD-related readmission rate and the direct cost of such readmission.

8.3.5.1 COPD-related readmission

Previous studies conducted in Hong Kong (Kowk et al., 2004) and elsewhere (Egan et al., 2002) failed to find any positive effects on readmissions of COPD transitional care. Having benefited from the successful experiences of and lessons learnt from the 22 RCTs reviewed in Chapter 2 of this thesis, the research team involved in this study was able to create a specially designed COPD-TCP, which did prove to reduce the COPD-related readmission rate (five patients in the intervention group were readmitted, compared to 12 in the control group [$p = 0.045$], in the first 12 weeks; no significant differences were found at week 6). These results are similar to the findings of a nurse-led telephone follow-up intervention in Hong Kong carried out among patients with general gastrointestinal/respiratory symptoms after discharge from the emergency room (Wong, Chow, Chang, Lee, & Liu, 2004). Intervention group also had a longer median duration of time to first readmission after the index discharge, though no statistical significance was detected. The following paragraphs discuss the possible reasons for the COPD-TCP's effects on the readmission rate.

Most patients were discharged when their symptoms were improving but not completely resolved. They were discharged home with medication and a follow-up appointment. However, non-adherence is common in China's COPD population. A survey of treatment conditions in patients with stable COPD conducted in six large cities across the country revealed that fully 50% of patients changed their pharmacologic treatment plan and that some even stopped their medication as soon as their condition improved or their symptoms were relieved (He et al., 2009b). Non-adherence to a treatment regimen may result in poor treatment outcomes. In the implementation of the COPD-TCP in the current study, the NCMs continually

monitored patients' signs and symptoms during follow-ups, and closely checked whether they were taking their drugs and using their inhaler correctly.

In addition, for those patients who tended to miss their follow-up appointments, the NCMs urged them to visit their doctor as scheduled. The NCMs also referred patients to doctors for medication adjustment when needed. Sharma, Kuo, Freeman, Zhang, and Goodwin (2010) conducted a retrospective cohort study to determine the risk of a 30-day emergency room visit and readmission in patients with or without a follow-up visit to their primary care physician or pulmonologist in the United States. They found the patients who had made a follow-up visit to have a significantly reduced risk of an emergency room visit (HR = 0.86; 95% CI = 0.83-0.90) and readmission (HR = 0.91; 95% CI = 0.87-0.96). The authors suggested that early follow-up by physicians generally involved an adjustment in medication, thereby avoiding the necessity of an emergency room visit or hospitalisation. Zhao (2004) reported coronary heart disease participants in China who underwent a postdischarge TCP to have more outpatient visits than a usual discharge care group, and Zhao and Wong (2009) found significant differences in medication adherence at 4 and 12 weeks postdischarge between an intervention and control group. The evidence from these two studies underscores the importance of postdischarge surveillance in preventing potential readmission by enhancing patients' adherence to medication and ensuring outpatient follow-up.

In the current study, prior to discharge, patients were instructed to seek timely help if needed, and were prepared for disease self-management at home. A hotline was made available to patients, who could access it at any time of the day or night. The

NCMs took turns answering, and immediate action was taken where necessary, such as the provision of counselling, instruction on medication or referral for medical help. The NCMs referred patients to doctors for medication adjustment and coordinated outpatient or emergency room visits and readmission if necessary. All of these actions may have helped to prevent readmissions.

8.3.5.2 Medical costs

The household income of the majority of participants in this study was low, and only 13.3% enjoyed government-provided healthcare. In other words, a majority was responsible for covering the costs of medical treatment for their disease in full or in part. In the focus group interviews, this economic burden was cited as the most difficult disease-associated problem, and it inspired a heated discussion. Treatment was considered to be much too expensive. One interviewee said that although he was reimbursed for medical expenses up to RMB200 per day, that was rarely sufficient. During his most recent 9-day admission, for example, he had been left more than RMB2,000 out-of-pocket after paying treatment, examination and inspection fees. Another, who was living on a pension, said: “Simply put, I cannot afford this disease!” Although he had insurance, he had a fairly large deductible, having to cover, for example, RMB250 of the cost of a RMB400 box of medicine (Seretide Accuhaler 500/50). Buying healthier food was out of the question, he said, as he had to save his money for medication and potential emergency room visits, which cost him around RMB300 each time.

A detailed cost analysis and evaluation of the patients’ economic burden is outside the scope of this study. However, the descriptive statistics and interview data inform

us that the cost for drug therapy in the maintenance phase of COPD imposes a huge economic burden on families and individuals, with estimates by Fang et al. (2011) suggesting an annual figure of US\$443-738 [RMB2,722.63-4,535.67]. Guo and Wang's (2010) study examining the direct and indirect medical costs of a sample of 668 patients admitted to the Guangzhou Institute of Respiratory Disease (the same research site as that of the current study) in 2008 showed the total economic burden of COPD to be RMB62,844.60 per case, 35.55% (RMB22,342/case) of which was a direct economic burden and 64.45% indirect (RMB40,503/case). Authors insisted that the role played by patients' finances be taken into consideration in COPD management, and that strategies should be taken to improve the affordability of such management in China (Fang et al., 2011; Guo & Wang, 2010).

The medical expenses reflected the effectiveness of COAD-TCP by reducing readmission and thus the cost. Evidence from transitional care studies involving COPD populations in Hong Kong and the United States (Balaban et al., 2008; Coleman et al., 2006; Daly et al., 2005; Parry et al., 2009; Wong, Chau, So, Tam, & McGhee, 2012) suggests that nurses have a role to play in reducing the economic burden imposed by the disease. In Kong Hong, Wong et al. (2012) performed cost-effectiveness analysis of a health-social partnership TCP, and reported the programme to be cost-effective in terms of reducing healthcare costs and attaining quality-adjusted life year (QALY) gains (the intervention had an 89% chance of being cost-effective at the threshold of £20,000[RMB190,000]/QALY). The findings of the current study also hold promise for helping to contain healthcare costs: a significant difference in the direct cost of COPD-related readmission (only the direct cost was calculated) was detected between the intervention and control group at 6

weeks postdischarge (median cost: RMB5,612.62 vs. RMB13,644, $p = 0.009$). Avoiding preventable readmission may reduce economic burden on individuals.

8.4 Challenges in developing transitional care in mainland China

The ongoing Chinese healthcare system reform presents an opportunity for the development of transitional care. The Nursing Development Plan in China (2011-2015) proposed the provision of postdischarge follow-up and transitional care for patients, citing it as one of the key tasks for hospitals in the 12th Five-Year Plan period (Ministry of Health of the People's Republic of China, 2012). Since 2011, transitional care has been one of the research themes of the Ministry of Health. Although current policies support the development of and research on transitional care in mainland China, challenges remain with regard to its implementation. Care providers and clients (patients and their families), government policy, the healthcare system and current clinical practice all have important roles to play if the further development of transitional care is to be realised.

8.4.1 The policy and the system

The authors of previous studies have also cited a number of barriers to the implementation of transitional care in relation to the healthcare delivery system (Li & Fu, 2010; Xu, 2012; Zhang et al., 2012). These authors have criticised the lack of guidelines for transitional care, noting also that nurses have to take risks when dealing with emergent issues as they are not protected by laws or regulations when visiting patients at home (Li & Fu, 2010). In addition, the two-way referral policy (referrals between higher-level hospitals and community health service centres in an attempt to resolve the issue of medical treatment difficulty versus medical treatment

expense) imposes its own challenges. Most patients rely on acute hospital services to treat chronic problems, as there is a great deal of distrust surrounding the services provided by community healthcare service centres (Li & Fu, 2010; Zhang et al., 2012). Furthermore, a payment and compensation mechanism is lacking, and social resources in support of transitional care such as those commonly practised in Hong Kong and elsewhere are inadequate (Li & Fu, 2010; Xu, 2012).

The above mentioned difficulties and challenges were present alongside with the process of conducting the current study. For example, the safety of delivering home visits was a major concern of our research team as well as the nursing director in the site hospital. Soaring medical fees, a lack of access to affordable healthcare services and poor medical insurance coverage were regarded by patients in the intervention group as challenges in maintaining health, with one patient in this study reporting that the prescribed medicines alone accounted for more than half of most people's retirement pension. "This is a policy issue", he said.

8.4.2 The awareness of decision-makers

When considering the development of transitional care, decision-makers seem to have difficulty in committing to this type of service, which is relatively new in mainland China. There are several possible explanations for their reluctance. First, the existing policy and system do not support a smooth interface between hospital discharge and community care. Second, there is little evidence on which the launch of such an initiative could be based (Dong et al., 2012; Xu, 2012; Zhang et al., 2012). Third, no quality appraisal system has been established for transitional care. Fourth, there is a lack of enthusiasm for developing transitional care among hospitals, as the

provision of such care would bring changes and possibly disturb current treatment-orientated practices, thereby increasing the financial allocation to service in the community. Finally, as little attention has been paid to the readmission rate and cost of readmission care by healthcare providers (Zhang et al., 2012), there is little motivation for them to introduce transitional care to combat an overreliance on hospital services.

The findings of this study suggest that transitional care can bring social and economic benefits to hospitals. For example, in the focus-group interviews, a number of the patients said that their experience of the nursing care had made them feel better about the hospital itself, with one reporting: “I feel that the nurses really cared about me no matter how severe my condition was. I have never met a nurse who would care for me like this ... this is a good hospital; they do not abandon us.” Another said that she would recommend the hospital to a neighbour with a similar disease. Moreover, the provision of transitional care can help to change the public image of nurses and nursing in general, thereby improving the social status of these professionals, as indicated by one patient’s remark: “The nurse was very professional and able to help improve our health.”

The hospital involved in this study has continued to provide transitional care to patients with COPD and other respiratory problems using a similar approach to the study’s TCP, and is currently testing a transitional care model for patients with asthma. It has created new positions for two pulmonary rehabilitation nurses, and one of the NCMs in the study reported herein has been assigned to this role and to that of mentor to another new nurse. The study hospital is a key national respiratory

research clinical site, nurses there have helped to train nurses from other parts of the country.

8.4.3 The possibility of bringing changes into current clinical practice

Multidisciplinary collaboration is another typical feature of transitional care delivery. The important contributions made by nurses in the coordinating role of case manager, care coordinator or coach in COPD care are well documented in transitional care studies (Balaban et al., 2008; Coleman et al., 2006; Daly et al., 2005; Egan et al., 2002; Kwok et al., 2004; Neff et al., 2003; Shu et al., 2011; Wong et al., 2011).

In COPD, as in other chronic diseases, a holistic approach is required for optimal management (Garrod, Marshall, & Jones, 2008; GOLD, 2011). The current global trend in COPD management can be characterised as an integrated approach involving treatment, care, self-management and rehabilitation (Nici, ZuWallack, & American Thoracic Society Subcommittee on Integrated Care of the COPD Patient, 2012), as well as a multidisciplinary team comprising doctors, nurses, physiotherapists, occupational therapists, pharmacists, dieticians, and social workers, with mental healthcare workers, behavioural nurse therapists, clinical psychologists and liaison psychiatrists consulted as required (GOLD, 2011; NCGC, 2010). Evidence-based clinical guidelines point out that the success of COPD management interventions in pulmonary rehabilitation programmes is attributable to the collaboration of a multi-profession team (British Thoracic Society Standards of Care Subcommittee on Pulmonary Rehabilitation, 2001).

Several researchers have reported multidisciplinary collaboration to be a great challenge for the delivery of transitional care in mainland Chinese settings (Dong et al., 2012; Li & Fu, 2010; Xu, 2012), a situation experienced in the current study. As previously noted, the management of COPD on the mainland still relies on acute care, and the treatment approach is primarily hospital-based. Pulmonary rehabilitation has been available in the United States, Europe and Hong Kong for some years, but its availability is still limited in mainland China. In Hong Kong and elsewhere, multidisciplinary team involvement is common practice in COPD management, particularly in programmes comprising multiple components of care, such as pulmonary rehabilitation, nutrition intervention, medical treatment, nursing care and social support. In deference to the practical situation in the local setting, the research team involved in this study managed to train clinical nurses to assume the role of NCMs in COPD rehabilitation, and introduced a nurse-led transitional programme with support from the clinical team.

8.4.4 The competence of nurses in the provision of transitional care

Research findings also highlight the vital role played by APNs in the provision of transitional care (Brooten, Youngblut, Deatrick, Naylor, & York, 2003; Naylor, 2012). However, the APN role is underdeveloped in China. Although respiratory ward nurses are competent in COPD care for inpatients, they generally know little about COPD rehabilitation and have no experience in home care. Community nurses are generally less experienced in delivering care to specific disease groups such as COPD patients. Variation in the competence and expertise of nurses has been identified as one of the main factors hindering the development of transitional care (Shi, Wang, & Sun, 2012; Xu, 2012).

However, the research team did meet two groups of nurses from the research site who were willing to dedicate themselves to developing transitional care for people with COPD. After undergoing a specially designed training course provided by our research team, these nurses became competent in the provision of such care to this patient group.

8.4.5 The acceptance of clients

Turning to the receiving end, are patients with COPD and their family members willing to accept transitional care? The literature provides no definitive answer. The authors of a study involving coronary heart disease patients reported that, although the patients were satisfied with the care they received, most were unwilling to pay extra for the service (Zhao & Wong, 2009). In the current study, the COPD-TCP had a very high acceptance rate, with many of the intervention participants expressing their appreciation for the programme. They hoped that the programme could be kept on running and become part of routine COPD care. However, other patients and their family members failed to recognise the value of transitional care, as reflected in their refusal to participate in this study. Unwillingness to accept “new things”, a distorted doctor-patient relationship and the generally low social status of nurses are among the probable causes of the non-acceptance of transitional care by patients (Xu, 2012).

8.5 Methodological considerations

8.5.1 Adopting stringent methodology in study design

To provide evidence of an effective TCP that can meet the needs of Chinese people with COPD, the research team tried to be as meticulous as possible in the experimental design. Randomisation was adopted to control for possible selection

bias, and a control group and repeated measurements were adopted to avoid a biased estimation of the intervention effects. Similarity in participant characteristics was assured (all variables = $p > 0.05$ at baseline between-group comparisons) to minimise confounding effects, and blinded data collection was employed in the outcome assessment to avoid any information bias that may have affected the objectivity of the outcome measures. All instruments and protocols used were validated to confirm their validity, reliability and appropriateness. The inter-rater reliability of the interventionists was examined to ensure intervention consistency, and steps were taken to ensure intervention fidelity, as discussed in the next section. Both objective and subjective outcome measures were included to provide a better understanding of the outcome effects, and both ITT and PP analyses were conducted to deal with variation in the outcome variables (Wang & Bakhai, 2006). Finally, the qualitative method was incorporated to overcome the possible limitations of the use of small datasets in an RCT and to enrich the findings with additional details (Cooke, Moyle, Griffiths, & Shields, 2009).

8.5.2 Fidelity

It is recommended that interventions be implemented with fidelity to successfully produce the desired change in research outcomes and day-to-day practice (Sidani & Braden, 2011). The positive outcomes of the current study are believed to be due to several essential strategies that were employed to ensure intervention delivery in accordance with the original design, namely, the application of an evidence-based intervention, the use of competent nurses for the intervention, and the implementation of structured protocols and manuals.

8.5.2.1 Application of evidence-based interventions

Ensuring the quality of care in meeting the needs of patients with COPD was the core concern in this study. Quality care refers to all systems and processes being geared to meet the needs of the patient through the provision of standardised, evidence-based care in response to individual needs. The literature review for this study revealed many transitional care interventions to provide innovative and evidence-based methods to reduce readmission and cost and to improve the health status of patients with chronic diseases (Chow & Wong, 2010; Coleman et al., 2006; Naylor et al., 1999; Zhao & Wong, 2009; Wong et al., 2011). Several researchers who conducted successful transitional care studies among specific disease groups such as heart failure (Zhao, 2004), renal failure (Chow, 2006) and stroke (Qian et al., 2011; Yeung, 2012) noted that they regarded the key to an efficient TCP to be the development and use of evidence-based protocols to guide intervention implementation. The application of evidence-based interventions was also a key feature in the current study.

Protocols function to guide intervention implementation. They ensure intervention fidelity, as well as the development of evidence-based protocols that address individual needs. The aim of this study was to implement and evaluate a TCP for Chinese patients with COPD. Faced with the challenge of meeting the needs of such patients in a mainland China setting, the COPD-TCP protocols were developed not only on the basis of the best research evidence available but also on clinical expertise and patient preferences. While introducing concepts and practices originally developed overseas, the programme was also modified to suit the Chinese context. Being part of an innovative and evidence-based intervention, or “something new” in

the patients' description, the programme protocols were well accepted by both the NCMs and COPD patients involved.

8.5.2.2 Preparation of competent nurses for intervention

Intervention fidelity requires the careful selection of competent interventionists with the ability and skills to maintain a helpful working alliance with clients, intense training in the specific skills required to provide the intervention and the ability to follow intervention protocols (Forgatch, Patterson, & DeGarmo, 2005; Sidani & Braden, 2011). In the current study, all the four NCMs were RNs, with 6-19 (mean: 11.75) years of clinical experience in respiratory nursing. Two of them had extensive experience in respiratory intensive care. Three held a Bachelor's degree, and one held a Higher Diploma in Nursing, but was studying part-time for a Bachelor's. Before taking up the role of NCM in the COPD-TCP, all four underwent a specially designed outcome-based COPD transitional care training course conducted by the research team. Their contribution in the COPD-TCP was well recognised and appreciated by the patients, as previously discussed.

Neff et al. (2003) conducted an APN-led TCP for patients with COPD in the United States. The patients in their intervention group received care from an APN-directed and -supervised team of nurses with special training in pulmonary disease management, and the programme proved successful in reducing rehospitalisations, acute care visits and depressive symptoms and in improving patients' functional abilities (Neff et al., 2003). The researchers claimed that the outcomes were the result of the APNs and pulmonary disease management team nurses, who possessed

advanced skills, a solid knowledge base, and well-developed competencies and proficiency in caring for patients with COPD.

The difference in effectiveness between APN- and RN-led interventions remains a matter of debate (Delgado-Passler & McCaffrey, 2006; Elkan et al., 2001). Several studies carried out by RNs (Kwok et al., 2004, 2008; Wong et al., 2008) failed to achieve the expected effects of a TCP. The review of the 22 hospital-to-home transitional care studies carried out for the current research found that TCPs for patients with chronic heart disease and COPD seem to be more effective in achieving positive outcomes and reducing readmission and costs when they are run by APNs (Coleman et al., 2006; Daly et al., 2005; Naylor et al., 1994, 2004; Wong et al., 2011) rather than RNs (Egan et al., 2002; Kwok et al., 2004, 2008; Wong et al., 2008). The study published by Neff et al. (2003) also involved the input of an APN who was available as an educational resource for the pulmonary care RNs.

The findings of the current study suggest that TCPs provided by well-trained RNs can bring about the positive effects reported by other researchers (Qian et al., 2011; Zhao & Wong, 2009). In agreement with the recommendations of Forgatch et al. (2005) and Sidani and Braden (2011), for example, this study highlights the importance of a well-designed training programme that equips interventionists with advanced disease-specific knowledge and skills in delivering transitional care to different chronic illness patient groups.

8.5.2.3 Use of structured protocols or manuals

Sidani and Braden (2011) pointed out that the actual implementation of an intervention may fall short of the original plan if there are discrepancies between design and delivery. To avoid deviations from the original plan, the current study adopted a set of structured intervention protocols that meticulously laid out the intervention details step-by-step (Forgatch et al., 2005; Sidani & Braden, 2011). Furthermore, the evidence-based protocols in the TCP and the overall process set by the COPD-TCP were followed, although adjustments were made by competent NCMs to accommodate each subject's unique condition. The intervention fidelity of this study can be affirmed by examining the qualitative data from the intervention participants, particularly their responses to the 10 questions designed to evaluate the COPD-TCP implementation process (see Chapter 7, Part 2: Qualitative results).

Compliance with the COPD-TCP intervention was seen as not only the responsibility of the interventionists but also of the patients. They were expected to collaborate with their NCM in implementing the disease self-management plan. In addition to the structured intervention protocols for the interventionists, the action plan guide and the handbook that served as a manual for the patients may have contributed to intervention adherence, as evidenced by several of the interviewees' remarks. One noted that the materials "have great value; as long as I do what they say, my condition will be controlled". Another noted that he did everything in accordance with the nurses' and programme instructions: "you provided the information, and I reaped the harvest." These findings are consistent with those reported in other transitional care studies using educational tools as an essential means of enhancing

patient adherence (Chow, 2006; Laramée et al., 2003; Yeung, 2012; Zhao & Wong, 2009).

Collaboration between NCMs and patients led to a high rate of adherence with the intervention in this study. As reported in Section 6.5.3 of Chapter 6, the rate of compliance with the 10 intervention items among the 21 participants who completed the COPD-TCP were: (1) disease self-management: 100%; (2) management of worsening symptoms: 95.2% (only one non-adherence was found); (3) medication regimen compliance: 95.2% (oral medication) and 100% (inhalation medication); (4) long-term oxygen therapy: 71.4% (prescribed: $n = 7$; admitted: ≥ 15 hours/day: $n = 5$; non-adherence: 10-11 hours/day: $n = 2$); (5) rehabilitation exercises: 100% (walking: Mean $\pm$ SD: 39.62 ± 3.09 days) and 100% (upper-arm exercise: 40.10 ± 2.74 days); (6) symptom management: 100%; (7) diet management and nutrition: 100% (diet management prescribed: $n = 2$, diet adjustment, as advised by nurse: $n = 11$); (8) smoking cessation: 66.7% (current smoker: $n = 3$, stopped smoking: $n = 2$, reduced smoking: $n = 1$); (9) scheduled outpatient follow-up: 100% (including those persuaded by their case managers, $n = 3$); and (10) documentation: 100%. Smoking cessation had the lowest rate of compliance, as can be seen from the figures. However, only three patients were current smokers, two of whom had stopped smoking and one of whom had reduced the number of cigarettes smoked with encouragement from the NCMs. Although the smoking cessation rate was lowest by means of calculation, in terms of outcome this effect seems quite impressive.

The above findings are similar to the results of a transitional care RCT for Chinese patients with coronary heart disease (Zhao & Wong, 2009). In Zhao and Wong's study,

one hundred patients received a four-week TCP, which consisted of pre- and post-discharge assessment, supported by structured home visits and home follow-ups. The results showed that patients in the study group had significantly better adherence to diet, medication, physical exercise and health-related lifestyle as compared with those in the control group.

8.5.3 Analysis by ITT principles

Like many other COPD studies (Chan, Lee, Suen, & Tan, 2011; Cooke et al., 2009; Garrod, Marshall, & Barley, 2006; Troosters, Gosselink, Janssens, & Decramer, 2010), there were missing data in this study. To manage them, the simple but commonly used strategy of last observation carried forward (LOCF) was employed (Liu-Seifert, Zhang, D'Souza, & Skljarevski, 2010; Scheffer, 2002; Wang & Bakhai, 2006; Wood et al., 2004). In LOCF, the last valid data point replaces all subsequent missing observations, which assumes that there would have been no further improvement or decline in a person's actual condition if he or she had remained in the study. To preserve the strengths of randomisation, ITT analysis was applied in addition to PP analysis in this study, as recommended in Wang and Bakhai (2006).

ITT analysis assumes the dropout rates in both groups to be equal, thus rendering it easier to identify the bias when both ITT and PP analyses are performed using data from the same study (Wang & Bakhai, 2006). When the ITT and PP analysis results of the three key outcome measures (6MWD, SOLQ and CSES) were compared, similar results were found in the majority of comparisons (please refer to Tables 7.7, 7.10 and Table 7.13 Chapter 7). Reverse results were also noted. For example, the results of the between-group comparison of the EF component of the SOLQ at T1

and the between- group/over time comparison of the CS component of the SOLQ revealed no significant differences in the ITT analysis, whereas the PP method produced slightly more significant results. According to Wang and Bakhai (2006), this discrepancy suggests that the dropouts were equally distributed between the groups. Additionally, with regard to the main group effect (between-group effect showed in Table 7.7) of the 6MWD, the PP result was not significant but the ITT result was. There may be a confounding reason for this discrepancy, that is, more participants in the study group dropped out of the study early relative to the control group. Wang and Bakhai (2006) suggested that if a larger number of subjects withdraw from the intervention group than the control group, then the trial will either show no difference in outcomes or an improved outcome in the control arm of the study. With the exception of these three discrepancies, the ITT and PP analyses yielded similarly significant results in all of the between-group comparisons at each time point, as well as in the main time effects (within group effects) and the group and time interactions for the 6MWD, SOLQ and CSES (Table 7.7, Table 7.10 and Table 7.13). The results thus serve as evidence of the intervention's effectiveness.

8.6 Summary

This chapter provides an in-depth discussion of the quantitative and qualitative findings on the COPD-TCP implemented in this study. The unmet needs of Chinese patients with COPD underscore the importance of providing transitional care to reduce the impacts of the disease. By implementing a specially designed evidence-based programme, this study is able to demonstrate that transitional care is an effective care model for addressing the needs of mainland Chinese patients with COPD during the transitional period from hospital to home after acute onset of the

disease. The programme was found to have short-term effects on improving exercise capacity, quality of life, and self-efficacy and reducing COPD-related readmission and costs.

The COPD-TCP was well received by patients, who experienced improvement in their health condition, and successfully implemented in a Chinese healthcare setting, which indicates that transitional care is acceptable to patients with COPD and could be a useful adjunct in COPD treatment in China. However, mainland healthcare providers and decision-makers still have obstacles to overcome to efficiently manage COPD and integrate transitional care into daily practice. The healthcare system reforms in mainland China make it the ideal time to further develop transitional care for patients with chronic diseases and for nurses to take a more active role in the provision of such care.

CHAPTER NINE

CONCLUSION

9.1 Introduction

This concluding chapter begins with a summary of the major outcomes of this study and its contributions to health service research, followed by a discussion of the study's limitations. The chapter next turns to a discussion of the implications of the study results from the perspective of clinical practice, nursing research, staff development and policymaking. It concludes with suggestions for further research and the overall conclusions of the study.

9.2 The major outcomes and contributions to health service research

The aim of this study was to evaluate the effectiveness of a transitional care programme for Chinese people with COPD. Its primary and secondary objectives were as follows. The study's primary objective was to compare exercise capacity, self efficacy, HRQOL and patient satisfaction, as well as readmissions and direct medical costs, in two groups: a intervention group receiving the COPD-TCP outlined in this thesis and a control group receiving usual care. Its secondary objective was to explore the effects of the COPD-TCP on the intervention group patients. This section briefly summarises the major outcomes and findings of the study.

A major part of this study was development of a structured COPD-TCP, which was then successfully introduced into a hospital in China, and the interfacing of inpatient discharge care with home care for patients with COPD. The COPD-TCP was

specially developed to suit the needs of patients with COPD in mainland China, with components and characteristics that are culturally relevant and useful.

Programme development was guided by the 4C's COPD transitional care model that was developed on the basis of three theses: the aforementioned 4C's transitional care model (Wong, Mok, et al., 2005), the Omaha System (Martin, 2005) and the GOLD guidelines (GOLD, 2006). This newly developed model can serve as a framework for other transitional care programmes. It contains the 4C's of the aforementioned transitional care model – comprehensiveness, continuity, coordination and collaboration – which are generic to all transitional care programmes adopting the Omaha System as a framework to construct nursing intervention and the GOLD guidelines to guide COPD management. The integration of the 4C's in an intervention programme can be briefly summarised as follows.

- *Comprehensiveness:* Transitional care intervention is constructed using a comprehensive framework, the Omaha System, and is guided by the integrated disease management strategies specified in the GOLD guidelines. The transitional care intervention is goal-directed and aimed at making an impact on clinical, psychosocial, functional, fiscal and satisfaction outcomes through a comprehensive outcome management process.
- *Continuity:* The care provided to patients is continued from hospital to home immediately following discharge after an episode requiring hospitalisation. The programme begins with discharge planning, followed by a 6-week home follow-up programme. The same NCM who carried out the discharge planning continues with the same patient and provides home follow-up. The

care goals are realised through the ongoing efforts of the individual in COPD self-management with the support of the NCM.

- *Coordination:* The NCMs operate across the spectrum of care, collaborating with a clinical team in response to individual patients' needs. Coordination also concerns managerial coordination in providing support for the delivery of transitional care to the individual patient.
- *Collaboration:* The NCMs receive support from a clinical team, comprising a physician, nutrition specialist, medical and nursing directors, and a project coordinator, to provide optimal care to the individual. Collaboration also involves the nurse partnering with the individual patient and his or her family members or caregiver in the management of COPD, with the aim of moving towards the goals set out at programme inception.

Unlike other programmes, the development of the four intervention protocols in this study was based on evidence from overseas, as well as from Hong Kong and mainland China. Evidence resources included evidence-based clinical guidelines, the opinions of multidisciplinary experts, experiences gleaned from current practice, and patient preferences. The resulting four evidence-based protocols laid the foundation for the study. They standardised the intervention and governed the successful implementation of the COPD-TCP. The protocols were as follows.

- Surveillance protocol: contained the assessment-evaluation framework, as guided by the Omaha System. Assessment covered health problems in the domains of environmental, psychosocial, physical and health-related behaviour, and changes were evaluated and monitored in three aspects: knowledge, behaviour and status.

- Teaching, guidance and counselling protocol: focused on teaching the knowledge and skills necessary for disease self-management, guiding health behaviour change and providing emotional support.
- Treatment and procedures protocol: centred on an individualised nursing care plan with mutual goal setting and a 6-week home-based walking and arm-exercise training programme.
- Case management protocols: specified that nurses act as case managers, offering timely care by referring patients to a physician or other healthcare service whenever required, and that a telephone hotline be available 24 hours a day, 7 days a week.

The protocol-driven intervention implemented in this study was supported in practice by a set of structured documents, including the (1) *COPD Transitional Care Programme Implementation Record*, (2) *COPD Transitional Care Programme Nursing Guideline*, (3) *Rehabilitation Trip: Action Plan Guide* and (4) *Rehabilitation Trip: Action Plan Handbook*. These documents served not only as decision-making guides for appropriate interventions and actions by the NCMs and patients, but also as a structured documentation system that helped to reduce variation in the intervention, thereby ensuring overall study fidelity (Sidani & Braden, 2011).

In addition to programme development, the study's outcome measures were tested for validity and reliability. Three questionnaires were specially developed (see Chapter 5): (1) the Chinese (Putonghua) version of the CSES, which was revised from the modified C-CSES (Cantonese) developed by Wong, Wong, et al. (2005); (2) the C-SOLQ, which was translated from the original English version of the SOLQ

developed by Tu et al. (1997); and (3) a self-developed questionnaire, the COPD Transition Care Patient Satisfaction Questionnaire (CTCPSQ).

A COPD transitional care training course (Appendix 9.1) was carried out prior to study commencement. This course was specially designed for the NCMs on the basis of the Outcome-based Competence Training Model, which places emphasis on the alignment of research, education and practice in preparing nurses who are competent in the provision of transitional care (Wang et al., 2008). Four NCMs (respiratory ward nurses) received this training, and subsequently provided quality care to the intervention group patients in this study.

Such evidence-informed practice contributes to confirmation that this innovative care model is effective and applicable in the healthcare context of mainland China.

The results of the ITT analyses show a significant interaction effect between group and time in the PF and EF subscale scores of the SOLQ ($p < 0.05$), as well as in the total score of the CSES ($p < 0.001$). Although there was no significant interaction effect in 6MWD, a significant between-group difference was found in repeated measures ANCOVA adjusted by the baseline scores ($p < 0.05$). Significant differences were also found between the control and intervention groups in the COPD-related readmission rate at 12 weeks postdischarge ($p < 0.05$) and in the costs of COPD-related readmission at 6 weeks postdischarge ($p < 0.05$). Moreover, compared with the control group, the intervention group was more satisfied with the care and health education received ($p < 0.001$). On the whole, the participants receiving transitional care experienced significant improvement in exercise capacity,

self-efficacy and HRQOL, a reduction in COPD-related readmission and in the direct cost of readmission, and were highly satisfied with their care.

9.3 Limitations of the study

A few limitations should be acknowledged when interpreting the results of this study. The first limitation concerns the generalisability of the research results. Similar to other studies (Cooke et al., 2009; Spaar, Frey, Turk, Karrer, & Puhan, 2009), difficulties were experienced in the recruitment of eligible participants, with the recruitment process yielding fewer cases than planned (60/82, 73.2%). In addition, of the 60 participants, only 71.67% completed the study, although some data on those dropping out were available from other sources. Several factors may have contributed to the recruitment difficulties and high dropouts.

- The healthcare system in mainland China suffers from a disconnection between acute care and post-acute care and from hospital to community and home (Li & Fu, 2010; Wang et al., 2008). Transitional care is thus regarded as ‘a novelty’ on the mainland, and some of the eligible patients approached were either not very accepting of the new service or rejected it outright.
- The study met two unforeseen events during the conduction of the research. One was the imported influenza A (H1N1) outbreak in 2009. The study hospital was prepared to handle cases of H1N1 influenza. This led to fewer beds available for COPD readmission and eight participants withdrew consent or could not be contacted during the outbreak period. Another event was the study hospital’s new building being put into use earlier than planned, which caused subject recruitment to stop while normal services were interrupted during the moving period.

- The study also excluded many patients living outside the service area where patients' home could not be reached by public transport or on foot within 60 minutes.

As a consequence, the sample size (60) is relatively small for detecting change in some of the outcomes. However, the size is comparable to those included in a Cochrane review of pulmonary rehabilitation studies, where the median number of patients included in the nine trials examined was 42 (Puhan et al., 2011). In addition to the small sample size and high dropout rate, the study was also conducted at a single research site with a homogeneous sample population, which further limits the generalisability of the results reported herein and makes it difficult to extrapolate from the experiences of the intervention group patients to the larger population of COPD patients in China.

The second limitation relates to the quality of the data. Missing data are an unavoidable problem that can bias results, reduce generalisability and limit the power of a study (Hardy et al., 2009; Streiner, 2008). As demonstrated by the 6MWD results, missing data in this study may have led to underestimation of the intervention's actual value (Liu-Seifert et al., 2010; Streiner, 2008). Besides, the cost data were collected primarily from the hospital's information system, in which only inpatient information was available, thereby limiting our ability to explore changes in the utilisation of outpatient or emergency room visits and to assess the costs of that utilisation. Furthermore, as data on patient satisfaction were collected at only one time point (immediately after the intervention), we were unable to detect either the within-group time effect or the between-group overtime effects on satisfaction

outcomes, although the focus group interview did provide supplemental qualitative information in this regard.

The third limitation concerns the care-bundled nature of the programme; that is, the programme has multiple components, and thus the effects of the individual elements of the COPD-TCP in isolation could not be readily determined. As discussed in Chapter 8 the focus in COPD management is shifting towards integrated interventions, or the implementation of a care bundle, owing to their proven effects relative to single interventions (Hopkinson et al., 2012; Nici, ZuWallack, & American Thoracic Society Subcommittee on Integrated Care of the COPD Patient, 2012). Most of the intervention group participants appeared to enjoy exercise, particularly daily walking. However, sticking to an exercise plan is also related to the concepts of compliance, behavioural change, self-efficacy and knowledge, which may be affected by other elements, such as mutual goal setting, health education, and the like. The study group participants were highly satisfied with the service and health education they received, and their self-efficacy, HRQOL and exercise capacity all improved. Their COPD-related readmission rate and direct cost of readmission were both less than those of the usual discharge care group. Although these findings suggest that all components of the intervention were beneficial, no attempt was made to identify the relationships and interactions among those components.

The fourth limitation is the relatively short duration of the follow-up period. A recent cohort study in mainland China revealed the recrudescence rate of COPD to be 7.35% in one month, 25% in three months, 55.62% in six months and 88.23% in 12 months (Wang et al., 2012). In other words, the risk of COPD exacerbations

increases over time. However, we were able only to detect the effect of transitional care on readmission within a 12-week period (16.7% of the study group vs. 40% of the control group were readmitted for COPD during this period). Hence, the long-term effects of the COPD-TCP on readmission, as well as those of the other outcomes, remain unclear. The focus group findings suggest that the intervention may have persistent beneficial effects in terms of exercise and physical function related to quality of life, but this study provides no objective data to support that suggestion.

The fifth limitation lies in the research design. In an RCT, blinding helps to avoid observation bias (Wang & Bakhai, 2006). The CONSORT guidelines suggest that all participants, investigators and assessors involved in a study be blinded to the treatment assignment whenever possible (Schulz et al., 2010). However, the current study had to adopt a single-blinded research approach because the NCMs and the patients themselves were aware of the group assignments (although in the case of the nurses, they were aware only of their own patients' assignment). Portney and Watkins (2009) regarded it as impossible to blind participants in many rehabilitation procedures, and thus stated that single-blinded studies can be acceptable.

9.4 Implications of the study

The intention of this study was to use research to inform practice and to suggest applications in clinical practice, nursing research, staff development and policymaking to improve pre- and postdischarge care for patients with COPD and to enhance the development of transitional care in mainland China.

9.4.1 Implications for clinical practice

This research provides empirical evidence to support the provision of transitional care to Chinese patients with COPD to improve their physical and psychosocial well-being. The specially designed COPD-TCP has several beneficial implications for healthcare providers who are interested in providing transitional care to patients with COPD, as well as for patients who are in need of continual care during transition from hospital to home after an acute episode.

A major positive impact of this evidence-based COPD-TCP is that it informs healthcare providers about what interventions should be included in a transitional care programme if certain desirable outcomes are to be realised by patients with COPD. Like other successful COPD management programmes conducted outside mainland China (Akinci & Olgun, 2011; Jack et al., 2009; Neff et al., 2003; Shu et al., 2011; Skwarska et al., 2000), the COPD-TCP developed for this study involves integrated interventions. The core components of the four evidence-based intervention protocols are comprehensive assessment and intensive monitoring, patient education and self-management support, mutual goal setting and exercise training, and the use of an action plan and multidiscipline referrals. As COPD is a complex health problem, multiple interventions used in conjunction may significantly improve patient outcomes (Hopkinson et al., 2012; Monninkhof, van der Valk, van der Palen, van Herwaarden, & Zielhuis, 2003; Nici et al., 2012; Spiliopoulos, Donoghue, Clark, & Dunford, 2008).

The practical experiences gained in this study also yielded information on the benefits of planned nursing interventions. (1) They showed that home visits can help

to detect health problems that individual patients encounter in their real living conditions, thus enabling the provision of more appropriate, targeted advice. (2) Noncompliance with the treatment regimen is common in Chinese patients with COPD (He et al., 2009b). The experiences gleaned in the current study demonstrate that a reminder from a nurse can help to improve adherence. (3) The findings show that nurses can take a more active role in patient education, which should not be conducted in a perfunctory manner. It should be individually tailored with the aim of equipping patients and their caregivers with the knowledge and skills needed for self-management of the disease. (4) A face-to-face demonstration of the inhalation technique can enhance teaching outcomes and medication efficacy, with the patients in this study being unable to use their inhalers properly before such a demonstration by their NCMs. (5) The provision of a teaching booklet was found to be important, with the study participants stating that they regarded it as the most useful tool for disseminating the necessary knowledge and skills. (6) We found that patients' perceived exertion and perceived dyspnoea can be used as a guide to determine the level of exercise intensity. Using these measures not only helps nurses to adjust the intervention dose, but also assists patients in managing their exercise regime. (7) Finally, building confidence was found to be an important motivating factor for Chinese patients with COPD, affecting both their compliance with treatment and ability to self-manage the disease. These key points are worth noting in planning effective nursing interventions in clinical practice.

9.4.2 Implications for nursing research

The development of transitional care and pulmonary rehabilitation is urgently needed in mainland China. To this end, this study documents evidence on the positive effects

of transitional care alongside of home-based rehabilitation on individuals with COPD, which may help other researchers to overcome some of the challenges of conducting this kind of research in the context of the Chinese healthcare system. Chinese researchers have identified a number of barriers to the introduction of transitional care into nursing practice on the mainland, and called for empirical evidence (Dong et al., 2012; Xu, 2012; Zhang et al., 2012), a call this study has answered. Its findings demonstrate that the COPD-TCP outlined herein is effective in improving exercise capacity, self-efficacy, HRQOL, and patient satisfaction and in reducing the readmission rate and service expenditure for readmitted COPD patients suffering an exacerbation of their illness. This study constitutes a groundbreaking effort to provide a framework for other investigators to conduct similar research for other disease groups in China who are greatly in need of hospital-to-home transitional support. Finally, the experience gained in this study illustrates that the alignment of research, education and practice is fundamental to the success of a research project in this arena (Wang et al., 2008).

9.4.3 Implications for staff development

The competence of healthcare providers is an important factor in ensuring the provision of high-quality transitional care. The knowledge and skills taught in the training courses offered to healthcare providers must be appropriate for dealing with all possible intervention measures that may be necessary in managing patients with COPD. The experience gained in this study should help to inform the content of such training. For example, the research team feels that medication knowledge is a very important component for two major reasons: (1) patients are usually discharged home with medications, often with inadequate instructions, meaning they sometimes

do not know how to, or even why they should, take them (Corbett, Setter, Daratha, Neumiller, & Wood, 2010); and (2) although there are no existing medications proven to arrest the long-term decline in lung function in COPD patients, the proper consumption of the ameliorative medications available, whether taken orally or by inhalation, can help to control the symptoms of the disease. Further, some of the most commonly used of these drugs have significant adverse side effects if they are not administered properly (GOLD, 2011). Hence, sound medication knowledge enables nurses to provide individualised education and counselling to patients, to conduct effective assessments and, most importantly, to help their patients to use drugs to achieve optimal outcomes.

Two groups of nurses competent to provide transitional care to mainland Chinese patients with COPD were cultivated in this study. In addition to the four NCMs in the main study, the research team also trained a group of nurses in the hospitals and community health centres that participated in the initial pilot study. Some of these nurses also participated in another study conducted to evaluate the effects of transitional care on quality of life in patients with COPD (Li et al., 2012). The training programme developed for these studies can be used for nursing staff development in hospitals and community care centres that provide COPD care (Wang et al., 2008).

9.4.4 Implications for policy-making

This study provides empirical evidence demonstrating that transitional care can improve the health outcomes of COPD patients and reduce healthcare costs. In addition, the intervention group participants decried their previous healthcare experience, criticising the deficiency of postdischarge support and expressing

satisfaction with the transitional care provided and their hopes that it would soon become a routine service, which should send a strong message to policymakers in the healthcare arena. Enhancing the hospital discharge process and providing follow-up services are new perspectives in COPD management (British Lung Foundation and British Thoracic Society, 2010; GOLD, 2011; O'Reilly et al., 2010). The vital role and contribution of nurses in the provision of community-based care and multidisciplinary pulmonary rehabilitation programmes are well recognised (GOLD, 2011), and further proof is provided by the evidence presented herein. The current study's findings should inform both healthcare providers and policymakers of the need to incorporate nurse-led transitional care into their daily practice. China's healthcare system is currently undergoing reform, and the evidence of this study suggests that the country's policymakers should strongly consider incorporating transitional care into relevant policies.

Staying at the policymaking level, this study also yields research evidence in support of a shift in China's healthcare system from hospital-focused care to community-based care through the provision of effective transitional care. The transitional care model developed in this study should make a substantial contribution to the development of transitional care in mainland China and serve as a useful reference to the country's healthcare policymakers in the course of that development.

9.5 Suggestions for future research

This study has provided a guided TCP for Chinese patients with COPD. It is suggested that this guided COPD-TCP be applied in other settings in future

investigations, both to replicate the results and accumulate a larger knowledge base. There are several ways in which the research design used in this study could be improved to strengthen its validity. First, future studies should recruit a larger sample to achieve adequate power and find ways to entice participants to adhere to the programme until completion.

Second, the sustained benefits of the COPD-TCP remain uncertain, and further research into the effects of transitional care for people with COPD is needed to help to establish a broader evidence base. A longer programme duration should also be considered and tested. The current study delivered a six-week intervention programme and investigated the short-term benefits of the TCP. Although evidence of the programme's effectiveness has been presented in this thesis, there are areas that require further study. For examples, investigation of the possible changes in patient outcomes, or the programme's effects on healthcare utilisation and cost, requires a longer programme duration. The fact that behavioural modification and the development of a healthy lifestyle take time must be taken into consideration. If too many behavioural changes are required of participants, e.g. that they stop smoking, increase physical activities and make dietary change, the cognitive and physical effort required to initiate and maintain those changes may simply be too great, if not impossible. Prioritising a longer intervention according to individual needs would be very helpful in this regard. Additionally, a six-week intervention is the minimum length of an effective programme involved pulmonary rehabilitation as suggested by the guidelines which also proposed that the longer the programme continues, the more effective the results. As previously noted, the benefits gained from a rehabilitation intervention can last for more than 12 months (Ries et al., 2007) and the recrudescence rate among these patients was greater than 88% by twelve months

(Wang et al., 2012). Accordingly, a longer follow-up duration, such as 12 months, is strongly recommended.

Third, further research is needed to examine the inter-relationships of various intervention variables to determine which combination thereof would produce the greatest benefit. Although integrated intervention is a global trend in COPD management, and such an approach was shown in this study to be beneficial in improving patients' health status and satisfaction and reducing healthcare costs, exactly which components in such an integrated programme lead to those benefits remains an open question. Clearly, a better understanding of these components would have important implications for the allocation of resources as transitional care becomes more widespread. The widespread application of such care should be accompanied by trials that allow further evaluation of the specific contribution made by exercise training, patient self-management education and home follow-up, as well as the role of NCMs.

Fourth, further research is needed to test the TCP developed in this study in other settings to determine its potential benefits beyond the patient population considered here. The programme contents could also be further refined to suit different settings with different resources. China is developing community healthcare services, but the best approach is to integrate community care with acute care. We recommend building a team involving both hospital nurses and community nurses and strengthening the collaboration at the two levels of care in the future (Wang et al., 2009).

Finally, in addition to readmission and its costs, future research should consider an evaluation of other fiscal outcomes, such as other types of healthcare utilisation indicators (i.e. emergency room visit and outpatient visits and their cost, the cost of the over-the-counter medications). Furthermore, full cost analysis including the cost of intervention should be considered in the future study.

9.6 Conclusion of the study

This study constitutes one of the first RCTs to evaluate the effects of transitional care programmes for Chinese patients with COPD. Several experimental or non-experimental studies on transitional care have recently been reported in mainland China. Unlike this study, however, those studies targeted specific problems (i.e. sleep or inhalation problem), applied single interventions (i.e. an electronic health record) or tested a single outcome (i.e. sleep quality, quality of life or inhalation use) (Ji, Chen, & Li, 2012; Shen, Liu, Zhang, & Zhao, 2011; Wang & Zhao, 2012). The RCT carried out in this study tested a 4C's COPD-TCP adopting multi-dimensional measures, including exercise capacity, HRQOL, self-efficacy, patient satisfaction, and COPD-related readmissions and the direct cost of readmission. This specially designed COPD-TCP employed a bundle-of-care strategy that incorporated the common features of a popular transitional care programme, the Omaha System nursing care path, and the key components of an effective COPD rehabilitation programme as recommended by the GOLD guidelines. A group of well-trained respiratory ward RNs who acted as case managers successfully implemented four evidence-based protocols, the surveillance protocol, teaching, guidance and counselling protocol, treatment and procedures protocol, and case

management protocol, among patients with COPD with the support of a clinical team.

The evidence presented here demonstrates that the COPD-TCP is effective in COPD management with short-term positive effects. Compared with the control group who received usual discharge care, the patients who underwent the COPD-TCP displayed significant improvements in exercise capacity, HRQOL and self-efficacy, a reduction in COPD-related readmission and the direct cost of readmission, and higher patient satisfaction. These patients were also very accepting of the programme because they experienced an improvement in their health status.

In conclusion, the results of this study suggest that transitional care is of great value to COPD patients during the recovery stage following hospitalisation for an exacerbation episode. They provide evidence to inform healthcare providers involved in the current healthcare reforms in mainland China that transitional care support benefits patients in terms of both health outcomes and healthcare costs. Whilst further study with a larger sample and in different sites is needed to confirm these findings, and a longer follow-up duration is suggested to determine the programme's long-term effects, it is fervently hoped that this study serves as a pioneer model, contributing to the development of transitional care in mainland China to the continued benefit of patients with COPD.

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INFORMATION SHEET

Evaluation of a transitional care program for patients with Chronic Obstructive Pulmonary Disease in Guangzhou China: a randomized controlled trial

You are invited to participate in a research conducted by Professor Frances Kam Yuet WONG and her team, the School of Nursing, The Hong Kong Polytechnic University in The First Affiliated Hospital of Guangzhou Medical College.

The objectives of this research are to evaluate the effectiveness of a transitional care program and to provide evidence on building transitional care model to help Chinese patients with COPD. You will be randomly assigned to two different groups, receiving usual post discharge care service or home visits and telephone follow-up in addition to the usual discharge care service. The telephone follow-up interviews will be tape recorded. You are also invited to participate in three assessment interviews before discharge and at week 7 and 13 after discharged from hospital. The interviews involving questionnaire survey (about 35 minutes) and two tests: Spirometry and 6 minute walk test (An Oximeter will be used to monitor heart rate and Sp O₂ during the test). The tests are free of charge. It is hoped that this information will help us gain a better understanding on the effectiveness of the transitional care service and enhance rehabilitation nursing care for the benefits of all of the patients. This research should not bring about any discomfort.

You have every right to withdraw from the study before or during the measurement without penalty of your treatment and nursing. All information related to you will remain confidential, and will be identifiable by codes known only to the researchers. The results of this research may be used in future research and for publication.

If you have any complaints about the conduct of this research study, please do not hesitate to contact the Secretary of the Human Subjects Ethics Sub-Committee of The Hong Kong Polytechnic University in person or in writing (c/o Human Resources Office in Room M1303 of the University).

If you would like to have more information about this research, please contact Ms Wang Shao Ling, the PhD student in this research team (The Hong Kong Polytechnic University) at tel. no. 852-27664520 or mobile no. 1580022, Ms Zeng Xio Hong (The First Affiliated Hospital of Guangzhou Medical College) at tel. no. 83337750 Ext. 6073, or Professor Frances Wong (The Hong Kong Polytechnic University) at tel. no. 852-27666419.

Thank you for your interest in participating in this study.

Researchers: Professor Frances Wong
Dr. Susan Chow
Shao Ling Wang

Date: _____



有關資料

「慢性阻塞性肺疾病患者出院後延續性護理的成效」研究

誠邀閣下參加黃金月教授負責執行的研究計劃。

這項研究的目的是探討慢性阻塞性肺疾病（COPD）患者延續性護理的成效，為建立 COPD 患者的延續護理模式提供依據。閣下會被隨機分配到研究的兩個不同組別，出院後繼續接受醫院的常規服務或者在醫院常規服務基礎上的家庭探訪和電話隨訪（錄音）。並且在出院前、出院後第七周和第十三周接受 3 次的問卷調查（每次需時約 35 分鐘）和兩項免費測試：肺功能檢查和 6 分鐘步行試驗（包括脈搏和氧飽和度監測，以及氣促和辛苦用力程度自我評估）。希望這些資料能有助於瞭解延續護理成效，從而採用更好的康復護理方法服務於廣大的 COPD 患者。本項研究不會引起任何不適的感覺。

閣下享有充分的權利在研究開始之前或之後決定退出這項研究，而不會受到任何對閣下不正常的待遇或被追究責任。凡有關閣下的資料將會保密，一切資料的編碼只有研究人員得悉。研究的結果只用於未來的研究和學術交流。

如果閣下對這項研究有任何的不滿，可隨時與香港理工大學人事倫理委員會秘書聯絡（地址：香港理工大學人力資源辦公室 M1303 室轉交）。

如果閣下想獲得更多有關這項研究的資料，請與香港理工大學王少玲女士，本項目的博士研究生（電話：852-2766 4520，內地手機：1580022 ）或黃金月教授（電話：852-2766 6419），以及廣州醫學院第一附屬醫院曾小紅女士（電話：83337750 轉 6073）聯絡。

謝謝閣下支持及參與這項研究。

研究員：黃金月、周家儀、王少玲

日期：二零零 年 月 日



CONSENT FORM

Evaluation of a transitional care program for patients with Chronic Obstructive Pulmonary Disease in Guangzhou China: a randomized controlled trial

I _____ hereby consent to participate in the captioned research conducted by Professor Frances Kam Yuet WONG and her team, the School of Nursing, The Hong Kong Polytechnic University in The First Affiliated Hospital of Guangzhou Medical College.

I understand that information obtained from this research may be published and used in future research. However, my right to privacy will be retained such as my personal details will not be revealed.

The procedure as set out in the attached information sheet has been fully explained. My participation in the project is voluntary.

I acknowledge that I have the right to question any part of the procedure and can withdraw at any time without penalty of any kind.

Name of participant:

Signature participant:

Name of researcher:

Signature of researcher:

Date:



參與研究同意書

「慢性阻塞性肺疾病患者出院後延續性護理的成效」研究

本人_____同意參加由香港理工大學護理學院黃金月教授負責執行，在廣州醫學院第一附屬醫院進行的研究項目。

我理解此研究所獲得的資料用於的研究和學術交流。然而我有權保護自己的隱私，我的個人資料將不會被洩漏。

我對所附資料的有關步驟已經得到充分的解釋。我是自願參與這項研究。

我理解我有權在研究過程中提出問題，在任何時候決定退出研究而不會影響任何正常的治療和護理。

參加者姓名:

參加者簽名:

研究人員姓名:

研究人員簽名:

日期:



INFORMATION SHEET

Evaluation of a transitional care program for patients with Chronic Obstructive Pulmonary Disease in Guangzhou China: a randomized controlled trial's Seattle Obstructive Lung Disease Questionnaire Validation Studies

You are invited to participate in a research conducted by Professor Frances Kam Yuet WONG.

This research is aimed at testing the validity and reliability of Seattle Obstructive Lung Disease Questionnaire, so as to check if the questionnaire can accurately evaluate the quality of life in patients with chronic obstructive pulmonary disease. The questionnaire will take around 25 minutes. You simply need to complete the questionnaire according to your actual situation and you are not required to fill in your name. This questionnaire does not cause any discomfort and does not carry any risk.

You have every right to withdraw from the study before or during the measurement without penalty of your treatment and nursing. All information related to you will remain confidential, and will be identifiable by codes known only to the researchers. The results of this research may be used in future research and for publication.

If you have any complaints about the conduct of this research study, please do not hesitate to contact the Secretary of the Human Subjects Ethics Sub-Committee of The Hong Kong Polytechnic University in person or in writing (c/o Human Resources Office in Room M1303 of the University).

If you would like to have more information about this research, please contact Professor Frances Wong (The Hong Kong Polytechnic University) at tel. no. 852-27666419 or Ms Wang Shao Ling at tel. no. 852-27664520 or mobile no. 1361001 .

Thank you for your interest in participating in this study.

Researchers: Professor Frances Wong
Dr. Susan Chow
Shao Ling Wang

Date: _____



有關資料

「慢性阻塞性肺疾病患者出院後延續性護理的成效」研究之

「西雅圖慢性阻塞性肺疾病問卷評定研究」

誠邀閣下參加黃金月教授負責執行的研究計劃。

這項研究的目的是探討西雅圖慢性阻塞性肺疾病問卷的信度和效度，檢定問卷能否正確評價慢性阻塞性肺疾病患者的生命質量。問卷調查需要花費大約 25 分鐘。閣下只需根據實際情況完整地填寫問卷各項，無須填寫姓名。這項調查不會引起任何不適的感覺，也沒有任何風險。

閣下享有充分的權利在研究開始之前或之後決定退出這項研究，而不會受到任何對閣下不正常的待遇或被追究責任。凡有關閣下的資料將會保密，一切資料的編碼只有研究人員得悉。研究的結果只用于未來的研究和學術交流。

如果閣下對這項研究有任何的不滿，可隨時與香港理工大學人事倫理委員會秘書聯絡(地址：香港理工大學人力資源辦公室 M1303 室轉交)。

如果閣下想獲得更多有關這項研究的資料，請與本人聯絡，電話：852-2766 6419 或王少玲女士，電話：852-2766 4520，內地手機：1361001。

謝謝閣下支持及參與這項研究。

研究員

黃金月、周家儀、王少玲

二零零 年 月 日



CONSENT FORM

Evaluation of a transitional care program for patients with Chronic Obstructive Pulmonary Disease in Guangzhou China: a randomized controlled trial's

Seattle Obstructive Lung Disease Questionnaire Validation Studies

I _____ hereby consent to participate in the captioned research conducted by Professor Frances Kam Yuet WONG, at _____ Hospital

I understand that information obtained from this research may be published and used in future research. However, my right to privacy will be retained such as my personal details will not be revealed.

The procedure as set out in the attached information sheet has been fully explained. My participation in the project is voluntary.

I acknowledge that I have the right to question any part of the procedure and can withdraw at any time without penalty of any kind.

Name of participant:

Signature participant:

Name of researcher:

Professor Frances Wong, Dr. Susan Chow, Shao Ling Wang

Signature of researcher:

Date:



參與研究同意書

「慢性阻塞性肺疾病患者出院後延續性護理的成效」研究之

「西雅圖慢性阻塞性肺疾病問卷評定研究」

本人_____同意參加由香港理工大學護理學院黃金月教授負責執行，在_____醫院進行的研究項目。

我理解此研究所獲得的資料用於的研究和學術交流。然而我有權保護自己的隱私，我的個人資料將不能洩漏。

我對所附資料的有關步驟已經得到充分的解釋。這研究並無任何風險。我是自願參與這項研究。

我理解我有權在研究過程中提出問題，在任何時候決定退出研究而不會受到任何不正常的待遇或被追究責任。

參加者姓名:

參加者簽名:

研究人員姓名:

黃金月、周家儀、王少玲

研究人員簽名:

日期:

Assessment and Evaluation Form

護理評估表

第一部分：基本資料

請在適合的項目上“✓”，並按要求填寫空欄：

姓 名：_____	稱 職：_____	住院科室： ☐ 呼吸一區 ☐ 呼吸二區
性 別： ☐ 男 ☐ 女	年 齡：_____	床 號：_____
居住地址：_____		入院日期：_____年____月____日
隨訪電話：_____	聯繫人：_____	出院日期：_____年____月____日

教育程度： ☐ 沒有受過正式教育 ☐ 小學 ☐ 初中 ☐ 高中或中專 ☐ 大專 ☐ 大學或以上	婚姻狀況： ☐ 未婚 ☐ 已婚 ☐ 離異 ☐ 喪偶 職業： _____ 退休： ☐ 已 ☐ 否	醫療費來源： ☐ 公費醫療 ☐ 社會醫療保險 ☐ 自費 ☐ 其他：_____
照顧者：_____	與患者關係：_____	聯絡電話：_____

入院原因： _____ 住院經過： _____ _____ _____
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病史					
診斷	年份	診斷	年份	手術名稱或部位	年份
1. COPD		4.		1.	
2.		5.		2.	
3.		6.		3.	

疾病家族史： ☐ 否認 ☐ 有		過敏史： ☐ 否認 ☐ 有		
疾病名稱		藥物/致敏源		
1.	3.	1.	3.	5.
2.	4.	2.	4.	6.

相關的基線資料	
6-MWD 結果： ☐ 持續 ☐ 間歇行走	SpO ₂ ：測試前： % 測試後： % 測試後氣促評分： 辛苦評分：
肺功能結果：FEV ₁ 預計值： % FEV ₁ /FVC： % ☐ 輕度 ☐ 中度 ☐ 重度 ☐ 極重度氣道阻塞	
SOLQ-EFS 得分：	SOLQ-CSS 得分：

第二部分 評估-評價

請在適合的項目上“✓”出評估發現的問題（□填寫評估發現的其他問題），然後，依據如下評分標準給患者的認知、行為、狀況評分，並標示≤4 的得分：

“K”代表“認知”：1 = 缺乏認知 2 = 少許認知 3 = 基本認知 4 = 足夠認知 5 = 充分認知

“B”代表“行為”：1 = 不恰當 2 = 甚少恰當 3 = 間有恰當 4 = 通常恰當 5 = 一貫恰當

“S”代表“狀況”：1 = 極嚴重的症狀/體征 2 = 嚴重的症狀/體征 3 = 中度的症狀/體征
4 = 輕微的症狀/體征 5 = 沒有症狀/體征

方面	出院前（ 年 月 日）		第一次訪視（ 年 月 日）		第二次訪視（ 年 月 日）	
	問題	評分	問題	評分	問題	評分
環境	1. 收入(Incomes): □ 1.1 低/沒有收入 □ 1.2 沒有醫療保險/自費 □ 1.3	K B S	1. 收入: □ 1.1 低/沒有收入 □ 1.2 沒有醫療保險/自費 □ 1.3	K B S	1. 收入: □ 1.1 低/沒有收入 □ 1.2 沒有醫療保險/自費 □ 1.3	K B S
	2. 衛生: □ 2.1 生活環境骯髒 □ 2.2 食物儲存/棄置不恰當 □ 2.3 有四害 □ 2.4 有臭味/異味 □ 2.5 有致敏源: _____ □ 2.6 有污染/感染源: _____ □ 2.7 有發黴 □ 2.8 汙物處理不當 □ 2.9	K B S	2. 衛生: □ 2.1 生活環境骯髒 □ 2.2 食物儲存/棄置不恰當 □ 2.3 有四害 □ 2.4 有臭味/異味 □ 2.5 有致敏源: _____ □ 2.6 有污染/感染源: _____ □ 2.7 有發黴 □ 2.8 汙物處理不當 □ 2.9	K B S	2. 衛生: □ 2.1 生活環境骯髒 □ 2.2 食物儲存/棄置不恰當 □ 2.3 有四害 □ 2.4 有臭味/異味 □ 2.5 有致敏源: _____ □ 2.6 有污染/感染源: _____ □ 2.7 有發黴 □ 2.8 汙物處理不當 □ 2.9	K B S
	3. 住所環境: □ 3.1 居住在_____層，無電梯 □ 3.2 樓梯陡/不安全 □ 3.3 室溫過冷/過熱 □ 3.4 通風不良 □ 3.5 有油煙/煙霧 □ 3.6 存放有氧氣 □ 3.7 家用電器/設備不安全 □ 3.8 常用物放置過高/過低 □ 3.9 設施/結構障礙: _____ □ 3.10	K B S	3. 住所環境: □ 3.1 居住在_____層，無電梯 □ 3.2 樓梯陡/不安全 □ 3.3 室溫過冷/過熱 □ 3.4 通風不良 □ 3.5 有油煙/煙霧 □ 3.6 存放有氧氣 □ 3.7 家用電器/設備不安全 □ 3.8 常用物放置過高/過低 □ 3.9 設施/結構障礙: _____ □ 3.10	K B S	3. 住所環境: □ 3.1 居住在_____層，無電梯 □ 3.2 樓梯陡/不安全 □ 3.3 室溫過冷/過熱 □ 3.4 通風不良 □ 3.5 有油煙/煙霧 □ 3.6 存放有氧氣 □ 3.7 家用電器/設備不安全 □ 3.8 常用物放置過高/過低 □ 3.9 設施/結構障礙: _____ □ 3.10	K B S
	4. 鄰舍/工作環境的安全: □ 4.1 污染程度高 □ 4.2 活動場地缺乏/不安全 □ 4.3 有引發疾病危險因素: _____ □ 4.4	K B S	4. 鄰舍/工作環境的安全: □ 4.1 污染程度高 □ 4.2 活動場地缺乏/不安全 □ 4.3 有引發疾病危險因素: _____ □ 4.4	K B S	4. 鄰舍/工作環境的安全: □ 4.1 污染程度高 □ 4.2 活動場地缺乏/不安全 □ 4.3 有引發疾病危險因素: _____ □ 4.4	K B S
心理社會	5. 與社區資源的溝通: □ 5.1 不熟悉服務的選擇與程式 □ 5.2 不會表達意願 □ 5.2 資源缺乏/得不到 □ 5.4	K B S	5. 與社區資源的溝通: □ 5.1 不熟悉服務的選擇與程式 □ 5.2 不會表達意願 □ 5.2 資源缺乏/得不到 □ 5.4	K B S	5. 與社區資源的溝通: □ 5.1 不熟悉服務的選擇與程式 □ 5.2 不會表達意願 □ 5.2 資源缺乏/得不到 □ 5.4	K B S
	6. 社交: □ 6.1 缺乏社交 □ 6.2 甚少戶外/消閒活動 □ 6.3	K B S	6. 社交: □ 6.1 缺乏社交 □ 6.2 甚少戶外/消閒活動 □ 6.3	K B S	6. 社交: □ 6.1 缺乏社交 □ 6.2 甚少戶外/消閒活動 □ 6.3	K B S
	7. 角色改變: □ 7.1 不自主的角色反串 □ 7.2 失去原有角色 □ 7.3 承擔新的角色 □ 7.4	K B S	7. 角色改變: □ 7.1 不自主的角色反串 □ 7.2 失去原有角色 □ 7.3 承擔新的角色 □ 7.4	K B S	7. 角色改變: □ 7.1 不自主的角色反串 □ 7.2 失去原有角色 □ 7.3 承擔新的角色 □ 7.4	K B S

第二部分 評估-評價（續）

方面	出院前（ 年 月 日）		第一次訪視（ 年 月 日）		第二次訪視（ 年 月 日）	
	問題	評分	問題	評分	問題	評分
心理社會	8. 人際關係: ☐ 8.1 難以建立/維繫關係 ☐ 8.2 不恰當的價值觀/目標/期望/計畫 ☐ 8.3	K B S	8. 人際關係: ☐ 8.1 難以建立/維繫關係 ☐ 8.2 不恰當的價值觀/目標/期望/計畫 ☐ 8.3	K B S	8. 人際關係: ☐ 8.1 難以建立/維繫關係 ☐ 8.2 不恰當的價值觀/目標/期望/計畫 ☐ 8.3	K B S
	9. 精神/靈性: ☐ 9.1 表達有精神牽掛 ☐ 9.2 信仰與治療護理衝突 ☐ 9.3	K B S	9. 精神/靈性: ☐ 9.1 表達有精神牽掛 ☐ 9.2 信仰與治療護理衝突 ☐ 9.3	K B S	9. 精神/靈性: ☐ 9.1 表達有精神牽掛 ☐ 9.2 信仰與治療護理衝突 ☐ 9.3	K B S
	10. 心理健康: ☐ 10.1 悲傷/絕望/自尊下降 ☐ 10.2 抑鬱/焦慮/恐懼 ☐ 10.3 失去參與活動/自我照顧興趣 ☐ 10.4 無法處理壓力 ☐ 10.5	K B S	10. 心理健康: ☐ 10.1 悲傷/絕望/自尊下降 ☐ 10.2 抑鬱/焦慮/恐懼 ☐ 10.3 失去參與活動/自我照顧興趣 ☐ 10.4 無法處理壓力 ☐ 10.5	K B S	10. 心理健康: ☐ 10.1 悲傷/絕望/自尊下降 ☐ 10.2 抑鬱/焦慮/恐懼 ☐ 10.3 失去參與活動/自我照顧興趣 ☐ 10.4 無法處理壓力 ☐ 10.5	K B S
	11. 性生活: ☐ 11.1 不滿意性關係 ☐ 11.2 危險的性行為 ☐ 11.3	K B S	11. 性生活: ☐ 11.1 不滿意性關係 ☐ 11.2 危險的性行為 ☐ 11.3	K B S	11. 性生活: ☐ 11.1 不滿意性關係 ☐ 11.2 危險的性行為 ☐ 11.3	K B S
	12. 忽略: ☐ 12.1 缺乏生理照顧 ☐ 12.2 缺乏情感支持 ☐ 12.3 缺乏醫療照顧 ☐ 12.4	K B S	12. 忽略: ☐ 12.1 缺乏生理照顧 ☐ 12.2 缺乏情感支持 ☐ 12.3 缺乏醫療照顧 ☐ 12.4	K B S	12. 忽略: ☐ 12.1 缺乏生理照顧 ☐ 12.2 缺乏情感支持 ☐ 12.3 缺乏醫療照顧 ☐ 12.4	K B S
生理	13. 聽覺: ☐ 13.1 弱聽 ☐ 13.2 失聰 ☐ 13.3	K B S	13. 聽覺: ☐ 13.1 弱聽 ☐ 13.2 失聰 ☐ 13.3	K B S	13. 聽覺: ☐ 13.1 弱聽 ☐ 13.2 失聰 ☐ 13.3	K B S
	14. 視覺: ☐ 14.1 看近處物體困難 ☐ 14.2 看遠處物體困難 ☐ 14.3	K B S	14. 視覺: ☐ 14.1 看近處物體困難 ☐ 14.2 看遠處物體困難 ☐ 14.3	K B S	14. 視覺: ☐ 14.1 看近處物體困難 ☐ 14.2 看遠處物體困難 ☐ 14.3	K B S
	15. 口腔衛生: ☐ 15.1 黏膜潰瘍 ☐ 15.2	K B S	15. 口腔衛生: ☐ 15.1 黏膜潰瘍 ☐ 15.2	K B S	15. 口腔衛生: ☐ 15.1 黏膜潰瘍 ☐ 15.2	K B S
	16. 認知: ☐ 16.1 近期記憶受限 ☐ 16.2 遠期記憶受限 ☐ 16.3 難以判別時間/方位/人的身份 ☐ 16.4	K B S	16. 認知: ☐ 16.1 近期記憶受限 ☐ 16.2 遠期記憶受限 ☐ 16.3 難以判別時間/方位/人的身份 ☐ 16.4	K B S	16. 認知: ☐ 16.1 近期記憶受限 ☐ 16.2 遠期記憶受限 ☐ 16.3 難以判別時間/方位/人的身份 ☐ 16.4	K B S
	17. 疼痛: ☐ 17.1 主訴不適/疼痛 ☐ 17.2	K B S	17. 疼痛: ☐ 17.1 主訴不適/疼痛 ☐ 17.2	K B S	17. 疼痛: ☐ 17.1 主訴不適/疼痛 ☐ 17.2	K B S
	18. 神志: ☐ 18.1 混亂 ☐ 18.2 嗜睡 ☐ 18.3	K B S	18. 神志: ☐ 18.1 混亂 ☐ 18.2 嗜睡 ☐ 18.3	K B S	18. 神志: ☐ 18.1 混亂 ☐ 18.2 嗜睡 ☐ 18.3	K B S
	19. 皮膚: ☐ 19.1 破損/壓瘡: _____ ☐ 19.2 皮疹: _____ ☐ 19.3	K B S	19. 皮膚: ☐ 19.1 破損/壓瘡: _____ ☐ 19.2 皮疹: _____ ☐ 19.3	K B S	19. 皮膚: ☐ 19.1 破損/壓瘡: _____ ☐ 19.2 皮疹: _____ ☐ 19.3	K B S

第二部分 評估-評價（續）

方面	出院前（ 年 月 日）		第一次訪視（ 年 月 日）		第二次訪視（ 年 月 日）	
	問題	評分	問題	評分	問題	評分
	20. 神經肌肉骨骼功能: ☐ 20.1 活動範圍受限 ☐ 20.2 肌肉強度下降 ☐ 20.3	K B S	20. 神經肌肉骨骼功能: ☐ 20.1 活動範圍受限 ☐ 20.2 肌肉強度下降 ☐ 20.3	K B S	20. 神經肌肉骨骼功能: ☐ 20.1 活動範圍受限 ☐ 20.2 肌肉強度下降 ☐ 20.3	K B S
生理	21. 呼吸: R: _____次/分鐘 SpO ₂ : _____ % 吸氧: _____升/分鐘 ☐ 21.1 呼吸型態異常: _____ ☐ 21.2 呼吸音異常: _____ ☐ 21.3 咳嗽 ☐ 21.4 咳痰: _____毫升/天 ☐ 21.4.1 白色粘液痰 ☐ 21.4.2 漿液泡沫痰 ☐ 21.4.3 膿痰 ☐ 21.4.4 ☐ 21.5 氣短: ☐ 21.5.1 靜息時 ☐ 21.5.2 活動時 ☐ 進食 ☐ 沐浴 ☐ 排便 ☐ 用力 ☐ 21.6 紫紺: ☐ 唇周 ☐ 肢端 ☐ 21.7 呼吸困難分級: _____ ☐ 21.8	K B S	21. 呼吸: R: _____次/分鐘 SpO ₂ : _____ % 吸氧: _____升/分鐘 ☐ 21.1 呼吸型態異常: _____ ☐ 21.2 呼吸音異常: _____ ☐ 21.3 咳嗽 ☐ 21.4 咳痰: _____毫升/天 ☐ 21.4.1 白色粘液痰 ☐ 21.4.2 漿液泡沫痰 ☐ 21.4.3 膿痰 ☐ 21.4.4 ☐ 21.5 氣短: ☐ 21.5.1 靜息時 ☐ 21.5.2 活動時 ☐ 進食 ☐ 沐浴 ☐ 排便 ☐ 用力 ☐ 21.6 紫紺: ☐ 唇周 ☐ 肢端 ☐ 21.7 呼吸困難分級: _____ ☐ 21.8	K B S	21. 呼吸: R: _____次/分鐘 SpO ₂ : _____ % 吸氧: _____升/分鐘 ☐ 21.1 呼吸型態異常: _____ ☐ 21.2 呼吸音異常: _____ ☐ 21.3 咳嗽 ☐ 21.4 咳痰: _____毫升/天 ☐ 21.4.1 白色粘液痰 ☐ 21.4.2 漿液泡沫痰 ☐ 21.4.3 膿痰 ☐ 21.4.4 ☐ 21.5 氣短: ☐ 21.5.1 靜息時 ☐ 21.5.2 活動時 ☐ 進食 ☐ 沐浴 ☐ 排便 ☐ 用力 ☐ 21.6 紫紺: ☐ 唇周 ☐ 肢端 ☐ 21.7 呼吸困難分級: _____ ☐ 21.8	K B S
	22. 循環: P: _____次/分 BP: _____/_____mmHg ☐ 22.1 胸悶 ☐ 22.2 下肢水腫 ☐ 22.3	K B S	22. 循環: P: _____次/分 BP: _____/_____mmHg ☐ 22.1 胸悶 ☐ 22.2 下肢水腫 ☐ 22.3	K B S	22. 循環: P: _____次/分 BP: _____/_____mmHg ☐ 22.1 胸悶 ☐ 22.2 下肢水腫 ☐ 22.3	K B S
	23. 消化-水合: ☐ 23.1 食欲減退 ☐ 23.2 電解質紊亂 ☐ 23.3	K B S	23. 消化-水合: ☐ 23.1 食欲減退 ☐ 23.2 電解質紊亂 ☐ 23.3	K B S	23. 消化-水合: ☐ 23.1 食欲減退 ☐ 23.2 電解質紊亂 ☐ 23.3	K B S
	24. 排便功能: ☐ 24.1 便秘 ☐ 24.2 腹瀉 ☐ 24.3	K B S	24. 排便功能: ☐ 24.1 便秘 ☐ 24.2 腹瀉 ☐ 24.3	K B S	24. 排便功能: ☐ 24.1 便秘 ☐ 24.2 腹瀉 ☐ 24.3	K B S
	25. 泌尿功能: ☐ 25.1 尿量異常 ☐ 25.2 失禁 ☐ 25.3	K B S	25. 泌尿功能: ☐ 25.1 尿量異常 ☐ 25.2 失禁 ☐ 25.3	K B S	25. 泌尿功能: ☐ 25.1 尿量異常 ☐ 25.2 失禁 ☐ 25.3	K B S
	26. 傳染和感染情況: ☐ 26.1 發熱 _____° C ☐ 26.2 感染: _____ ☐ 26.3 不遵循預防措施 ☐ 26.4	K B S	26. 傳染和感染情況: ☐ 26.1 發熱 _____° C ☐ 26.2 感染: _____ ☐ 26.3 不遵循預防措施 ☐ 26.4	K B S	26. 傳染和感染情況: ☐ 26.1 發熱 _____° C ☐ 26.2 感染: _____ ☐ 26.3 不遵循預防措施 ☐ 26.4	K B S

第二部分 評估-評價 (續)

方面	出院前 (年 月 日)		第一次訪視 (年 月 日)		第二次訪視 (年 月 日)	
	問題	評分	問題	評分	問題	評分
健康行為	27. 營養: 體重: _____ Kg 身高: _____ cm 理想體重的百分數: _____ % 體重指數: _____ kg/m ² 血清白蛋白: _____ g/L 空腹血糖: _____ mmol/L	K B S	27. 營養: 體重: _____ Kg 身高: _____ cm 理想體重的百分數: _____ % 體重指數: _____ kg/m ² 血清白蛋白: _____ g/L 空腹血糖: _____ mmol/L	K B S	27. 營養: 體重: _____ Kg 身高: _____ cm 理想體重的百分數: _____ % 體重指數: _____ kg/m ² 血清白蛋白: _____ g/L 空腹血糖: _____ mmol/L	K B S
	☐ 27.1 營養不良: ☐ 輕 ☐ 中 ☐ 重 ☐ 27.2 體重下降 ☐ 27.3 飲食不均衡 ☐ 27.4 不遵循飲食指導 ☐ 27.5		☐ 27.1 營養不良: ☐ 輕 ☐ 中 ☐ 重 ☐ 27.2 體重下降 ☐ 27.3 飲食不均衡 ☐ 27.4 不遵循飲食指導 ☐ 27.5		☐ 27.1 營養不良: ☐ 輕 ☐ 中 ☐ 重 ☐ 27.2 體重下降 ☐ 27.3 飲食不均衡 ☐ 27.4 不遵循飲食指導 ☐ 27.5	
	28. 睡眠與休息型態: ☐ 28.1 夜間常醒 ☐ 28.2 身體狀況致睡眠/ 休息不足 ☐ 28.3 失眠 ☐ 28.4	K B S	28. 睡眠與休息型態: ☐ 28.1 夜間常醒 ☐ 28.2 身體狀況致睡眠/ 休息不足 ☐ 28.3 失眠 ☐ 28.4	K B S	28. 睡眠與休息型態: ☐ 28.1 夜間常醒 ☐ 28.2 身體狀況致睡眠/ 休息不足 ☐ 28.3 失眠 ☐ 28.4	K B S
	29. 身體活動: ☐ 29.1 久坐的生活方式 ☐ 29.2 缺乏/沒有堅持運動 ☐ 29.3	K B S	29. 身體活動: ☐ 29.1 久坐的生活方式 ☐ 29.2 缺乏/沒有堅持運動 ☐ 29.3	K B S	29. 身體活動: ☐ 29.1 久坐的生活方式 ☐ 29.2 缺乏/沒有堅持運動 ☐ 29.3	K B S
	30. 個人照顧: ☐ 30.1 洗熨衣服困難 ☐ 30.2 沐浴困難 ☐ 30.3 如廁困難 ☐ 30.4 穿衣褲困難 ☐ 30.5 梳理頭髮困難 ☐ 30.6 洗漱困難 ☐ 30.7 不願/不能/忘記完成 個人照顧 ☐ 30.8	K B S	30. 個人照顧: ☐ 30.1 洗熨衣服困難 ☐ 30.2 沐浴困難 ☐ 30.3 如廁困難 ☐ 30.4 穿衣褲困難 ☐ 30.5 梳理頭髮困難 ☐ 30.6 洗漱困難 ☐ 30.7 不願/不能/忘記完成 個人照顧 ☐ 30.8	K B S	30. 個人照顧: ☐ 30.1 洗熨衣服困難 ☐ 30.2 沐浴困難 ☐ 30.3 如廁困難 ☐ 30.4 穿衣褲困難 ☐ 30.5 梳理頭髮困難 ☐ 30.6 洗漱困難 ☐ 30.7 不願/不能/忘記完成 個人照顧 ☐ 30.8	K B S
	31. 藥物濫用: ☐ 31.1 過量服用處方藥物 ☐ 31.2 吸煙: 支/天 ☐ 31.3 酗酒 ☐ 31.4 吸二手煙 ☐ 31.5	K B S	31. 藥物濫用: ☐ 31.1 過量服用處方藥物 ☐ 31.2 吸煙: 支/天 ☐ 31.3 酗酒 ☐ 31.4 吸二手煙 ☐ 31.5	K B S	31. 藥物濫用: ☐ 31.1 過量服用處方藥物 ☐ 31.2 吸煙: 支/天 ☐ 31.3 酗酒 ☐ 31.4 吸二手煙 ☐ 31.5	K B S
	32. 健康照顧督導: ☐ 32.1 沒有尋求症狀所需的監 測和治療 ☐ 32.2 沒有按要求復診 ☐ 32.3 不能配合綜合治療計畫 ☐ 32.4	K B S	32. 健康照顧督導: ☐ 32.1 沒有尋求症狀所需的監 測和治療 ☐ 32.2 沒有按要求復診 ☐ 32.3 不能配合綜合治療計畫 ☐ 32.4	K B S	32. 健康照顧督導: ☐ 32.1 沒有尋求症狀所需的監 測和治療 ☐ 32.2 沒有按要求復診 ☐ 32.3 不能配合綜合治療計畫 ☐ 32.4	K B S
	33. 遵從醫囑用藥: ☐ 33.1 不遵從劑量/時間用藥 ☐ 33.2 出現藥物副作用/ 不良反應 ☐ 33.3 藥物儲存不當 ☐ 33.4 依賴別人協助用藥 ☐ 33.5	K B S	33. 遵從醫囑用藥: ☐ 33.1 不遵從劑量/時間用藥 ☐ 33.2 出現藥物副作用/ 不良反應 ☐ 33.3 藥物儲存不當 ☐ 33.4 依賴別人協助用藥 ☐ 33.5	K B S	33. 遵從醫囑用藥: ☐ 33.1 不遵從劑量/時間用藥 ☐ 33.2 出現藥物副作用/ 不良反應 ☐ 33.3 藥物儲存不當 ☐ 33.4 依賴別人協助用藥 ☐ 33.5	K B S

**慢性阻塞性肺疾病患者延續護理項目
康復訓練運動量評估**

一、出院前/第一次訪視

200 年 月 日

項目	T	P	R	BP	SpO ₂	辛苦程度	氣促程度
上肢運動前	℃	次/分	次/分	/ mmHg	%		
1 級練習後	不需	次/分	次/分	不需	%		
2 級練習後	不需	次/分	次/分	不需	%		
3 級練習後	不需	次/分	次/分	不需	%		
步行前	℃	次/分	次/分	/ mmHg	%		
步行後	不需	次/分	次/分	不需	%		
持續步行時間	最長： 分鐘		備註：				

注：1. 運動量確定標準：運動後 SpO₂ ≥ 90%，下降 ≤ 5%，氣促和辛苦程度得分 ≤ 3。
2. 每級練習之間間隔 1 分鐘，此時測量上述數據。

二、第二次訪視

200 年 月 日

項目	T	P	R	BP	SpO ₂	辛苦程度	氣促程度
上肢運動前	℃	次/分	次/分	/ mmHg	%		
__級練習後	不需	次/分	次/分	不需	%		
4 級練習後	不需	次/分	次/分	不需	%		
5 級練習後	不需	次/分	次/分	不需	%		
6 級練習後	不需	次/分	次/分	不需	%		
步行前*	不需	次/分	次/分	不需	%		
步行後*	不需	次/分	次/分	不需	%		
持續步行時間*	最長： 分鐘		備註：				

注：1. 運動量確定標準：運動後 SpO₂ ≥ 90%，下降 ≤ 5%，氣促和辛苦程度得分 ≤ 3。
2. 每級練習之間間隔 1 分鐘，此時測量上述數據。
3. *需調整運動量者測量。

慢性阻塞性肺疾病延續護理項目

健康教育（知識部分）記錄表

請在適合的項目上“✓”，並評價患者或照顧者健康教育前後的知識水準，如教育對象為照顧者時，請加上“*”號，如：“* 4”。

1 = 缺乏認知 2 = 甚少認知 3 = 基本認知 4 = 足夠認知 5 = 充分認知

項 目 \ 日 期	教育前	出院日	第一次訪視	第二次訪視
	月 日	月 日	月 日	月 日
1. 疾病的名稱和特徵※	☐	☐	☐	☐
2. 慢阻肺的主要病因※	☐	☐	☐	☐
3. 慢阻肺的典型症狀和體征※	☐	☐	☐	☐
4. 疾病自我照顧的重要性與常識※	☐	☐	☐	☐
5. 家庭康復訓練的意義和方法※	☐	☐	☐	☐
6. 藥物治療※	☐	☐	☐	☐
7. 症狀急性加重及其應對※	☐	☐	☐	☐
8. 《COPD 康復之旅行動計畫》的使用※	不適用	☐	☐	☐
9. 戒煙的方法（適用於吸煙者）※☆	☐	☐	☐	☐
10. 飲食與營養△	☐		☐	☐
11. 日常生活的安排與節省體能的方法△	☐		☐	☐
12. 戶外或消閒活動△	☐		☐	☐
13. 尋求醫療幫助與健康服務資源利用△	☐		☐	☐
14. 身心鬆弛△☆	☐		☐	☐

指引：①出院前教導 ※ + ※☆ 項目 → 訪視時教導 △ + △☆ 項目 + 強化教導 ※☆ + 4 以下得分 ※ 項目；②首次教育前需先評價原有知識水準

跟進問題：_____

（出院日填寫） _____年____月____日

跟進記錄：_____

（第一次訪視時填寫） _____年____月____日

跟進記錄：_____

（第二次訪視時填寫） _____年____月____日

慢性阻塞性肺疾病延續護理項目

健康教育（技能部分）記錄表

請在適合的項目上“✓”，並評價患者或照顧者健康教育前後的技能水準，如教育對象為照顧者時，請加上“*”號，如：“* 4”。

1 = 不掌握 2 = 少許掌握 3 = 部分掌握 4 = 基本掌握 5 = 熟練掌握

項 目 \ 日 期	教育前	出院日	第一次訪視	第二次訪視
	月 日	月 日	月 日	月 日
1. 步行※	不適用	☐	☐	☐
2. 上肢運動※	不適用	☐	☐	☐
3. 有效的咳嗽排痰技巧※	☐	☐	☐	☐
4. 氣霧劑使用（適用者）※☆	☐	☐	☐	☐
5. 輕易吸器的使用（適用者）※☆	☐	☐	☐	☐
6. 准納器使用（適用者）※☆	☐	☐	☐	☐
7. 旋渦式吸入器使用（適用者）※☆	☐	☐	☐	☐
8. 吸入器的清潔和保養（適用者）※☆	☐	☐	☐	☐
9. 減輕氣喘的方法△	☐		☐	☐
10. 體溫測量與監測（適用者）△☆	☐		☐	☐
11. 安全使用家庭氧療（適用者）△☆	☐		☐	☐
12. 縮唇呼吸（適用者）△☆	☐			☐
13. 日常活動的呼吸配合（適用者）△☆	☐			☐
14. 肌肉鬆弛練習（適用者）△☆	☐			☐

指引：①出院前教導 ※ + ※☆ 項目 → 訪視時教導 △ + △☆ 項目 + 強化教導 4 以下得分 ※ + ※☆ 項目；②首次教導前需先評價原有技能水準

跟進問題：_____

（出院日填寫）_____年____月____日

跟進記錄：_____

（第一次訪視時填寫）_____年____月____日

跟進記錄：_____

（第二次訪視時填寫）_____年____月____日

Telephone Follow-up Record

慢性阻塞性肺疾病患者延續護理項目

電話隨訪記錄單（第 2/3/5 周）

日期：____年__月__日

時間：__時__分

共____分鐘

自我介紹用語：（稱暱）早晨/午安，我是廣醫附一院延續護理項目的護士（名字）

護理評估和監測	
1. COPD 的症狀和體征 1.1 咳嗽有否增加？ ☐ 否 ☐ 有 1.2 咳痰情況如何？ 1.2.1 痰量增加？ ☐ 否 ☐ 有 1.2.2 痰液的顏色有否改變？ ☐ 否 ☐ 有： 什麼顏色？ _____ 1.3 氣喘有否加劇？ ☐ 否 ☐ 有：☐ 活動時 ☐ 靜息時 1.4 上述症狀變化已持續多久？ ____/□小時□天 1.5 有否看醫生？ ☐ 否 ☐ 有 _____ 有否服用藥物？ ☐ 否 ☐ 有 _____ 2. 併發症狀/新出現的症狀 2.1 體溫如何？ ☐ 正常 ☐ 發熱 ____℃ 2.2 下肢有否水腫？ ☐ 否 ☐ 有 或加重？ ☐ 否 ☐ 有 2.3 有否覺得胸悶？ ☐ 否 ☐ 有 2.4 身體有否其他不適？ ☐ 否 ☐ 有 _____ 3. 環境 3.1 訪視時建議改善的家居環境危險因素有否落實？ （適用者） ☐ 有 ☐ 否：原因： _____ 4. 心理社交方面 4.1 有否參與一些社交活動？ ☐ 有 ☐ 否 原因： _____ 4.2 心情如何？判斷：情緒低落： ☐ 否 ☐ 有： 原因： _____	5. 家庭康復訓練 5.1 有否按協定計畫堅持每日步行 30 分鐘？ ☐ 有 ☐ 否：原因： _____ 5.2 每次可以持續步行 ____分鐘？ 5.3 步行後一般的辛苦程度： ____ 氣促程度： ____ 5.4 有否按協定計畫堅持每日做上肢運動？ ☐ 有 ☐ 否：原因： _____ 5.5 運動時身體有否不適？ ☐ 否 ☐ 有 _____ 5.6 上肢運動後一般的辛苦程度： ____ 氣促程度： ____ 6. 健康行為 6.1 復診醫生有否處方藥物？（復診者適用） ☐ 有 ☐ 否 6.2 有否按醫生處方服藥（次數、時間、劑量）？ ☐ 有 ☐ 否：原因： _____ 6.3 服藥後效果如何？副作用： ☐ 否 ☐ 有 _____ 6.4 氣喘時有否使用霧化吸入藥物？ ☐ 有 ☐ 否 用量 ____噴/次？ ____次/日？ 6.5 遇到呼吸困難時有否採用減輕氣喘的方法？ ☐ 有 ☐ 否：原因： _____ 6.6 飲食方面如何？ 判斷： ☐ 不恰當 _____ 6.7 有否按協定計畫戒煙？（適用者） ☐ 有 ☐ 否：原因： _____ 6.8 有否每日按醫生處方吸氧？（適用者） ☐ 有 ☐ 否：原因： _____ 每天吸氧 ____小時？

主要問題或特別的護理需要：

情況	護理干預
1. ☐ 一切如常、依從治療、依從康復訓練 2. ☐ 一切如常、知識缺乏： 3. ☐ 疾病常識 ☐ 藥物治療 ☐ 康復訓練 ☐ 飲食營養 4. ☐ 身心健康 ☐ 家庭氧療 ☐ 戒煙 ☐ 5. ☐ 不能依從藥物治療： ☐ 知識/信念缺乏 ☐ 未掌握技能 6. ☐ 不能依從運動訓練： ☐ 知識/信念缺乏 ☐ 未掌握技能 7. ☐ 不能依從家庭氧療： ☐ 知識/信念缺乏 ☐ 未掌握技能 8. ☐ 不能依從營養治療： ☐ 知識/信念缺乏 ☐ 未掌握技能 9. ☐ 不依從行為沒有改善 10. ☐ 多種疾病護理需要	1. ☐ 護理 0 級： ☐ 讚賞、鼓勵 + 原計畫 ☐ 對因教育、指導 + 原計畫 ☐ 對因教育、指導 + 調整計畫 ☐ 間歇步行 30 分鐘 ☐ 持續步行 30 分鐘 ☐ 上肢運動__級 ☐ 2. ☐ 護理 1 級：+ 電話跟進 3. ☐ 護理 2 級：+ 訪視跟進 + 電話跟進 4. ☐ 護理 3 級：共同訪視 5. ☐ 護理 4 級：護理會診 電話跟進： 月 日 時 分 訪視跟進： 月 日 時 分
11. ☐ 症狀轉變超過 24 小時： ☐ 氣喘增加 ☐ 應付日常活動時氣短加重 ☐ 咳嗽比平常多 ☐ 痰量比平常增加，出現膿痰 ☐ 使用短效氣霧劑次數增加 ☐ 較平常的活動能力減低 ☐ 較易疲倦或不能入睡 ☐ 發熱 $\geq 38.8^{\circ}\text{C}$ 12. ☐ 出現併發症狀超過 24 小時： ☐ 胸悶 ☐ 雙下肢浮腫 ☐ 13. ☐ 尋求醫生協助確定藥物治療方案 14. ☐ 嚴重藥物副作用 _____ 15. ☐ 出現危險訊號： ☐ 極度氣喘，休息和停止活動不能緩解 ☐ 嗜睡或神志混亂	6. ☐ 自我監測： ☐ 症狀 ☐ 藥物副作用 7. ☐ 護理 5 級 R：門診轉介 + 電話跟進 電話跟進： 月 日 時 分 8. ☐ 護理 6 級：急診室轉介 + 電話跟進 電話跟進： 月 日 時 分 9. ☐ 護理 7 級：經門診住院轉介 + 訪視跟進 訪視跟進： 月 日 時 分

結尾鼓勵用語：慢性阻塞性肺疾病是慢性病，不容易處理，您有沒有一些什麼事情想做來提升自己的健康？現在，我們一起來定一下目標，讓我給您打打氣，下次探訪您的時候和您跟進。

與患者協定的共同目標：

目標	內 容
1	
2	
3	

詢問患者下星期最適合的 ☐ 致電 ☐ 訪視時間：__月__日__時__分

如有問題可隨時致電我們的熱線：_____，再見！

電話隨訪記錄單 (第 6 周)

共 分

自我介紹用語: (稱曙) 早晨/午安, 我是廣醫附一院延續護理項目的護士 (名字)

護理評估和監測	
1. COPD 的症狀和體征 1.1 咳嗽有否增加？ ☐ 否 ☐ 有 1.2 咳痰情況如何？ 1.2.1 痰量增加？ ☐ 否 ☐ 有 1.2.2 痰液的顏色有否改變？ ☐ 否 ☐ 有： 什麼顏色？ _____ 1.3 氣喘有否加劇？ ☐ 否 ☐ 有： ☐ 活動時 ☐ 靜息時 1.4 上述症狀變化已持續多久？ ____/□小時 □天 1.5 有否看醫生？ ☐ 否 ☐ 有 _____ 有否服用藥物？ ☐ 否 ☐ 有 _____ 2. 併發症狀/新出現的症狀 2.1 體溫如何？ ☐ 正常 ☐ 發熱 ____℃ 2.2 下肢有否水腫？ ☐ 否 ☐ 有 或加重？ ☐ 否 ☐ 有 2.3 有否覺得胸悶？ ☐ 否 ☐ 有 2.4 身體有否其他不適？ ☐ 否 ☐ 有 _____ 3. 環境 3.1 訪視時建議改善的家居環境危險因素有否落實？ （適用者） ☐ 有 ☐ 否：原因： _____ 4. 心理社交方面 4.1 有否參與一些社交活動？ ☐ 有 ☐ 否 原因： _____ 4.2 心情如何？判斷：情緒低落： ☐ 否 ☐ 有： 原因： _____	5. 家庭康復訓練 5.1 有否按協定計畫堅持每日步行 30 分鐘？ ☐ 有 ☐ 否：原因： _____ 5.2 每次可以持續步行____分鐘？ 5.3 步行後一般的辛苦程度： ____ 氣促程度： ____ 5.4 有否按協定計畫堅持每日做上肢運動？ ☐ 有 ☐ 否：原因： _____ 5.5 運動時身體有否不適？ ☐ 否 ☐ 有 _____ 5.6 上肢運動後一般的辛苦程度： ____ 氣促程度： ____ 6. 健康行為 6.1 復診醫生有否處方藥物？（復診者適用） ☐ 有 ☐ 否 6.2 有否按醫生處方服藥（次數、時間、劑量）？ ☐ 有 ☐ 否：原因： _____ 6.3 服藥後效果如何？副作用： ☐ 否 ☐ 有 _____ 6.4 氣喘時有否使用霧化吸入藥物？ ☐ 有 ☐ 否 用量__噴/次？ __次/日？ 6.5 遇到呼吸困難時有否採用減輕氣喘的方法？ ☐ 有 ☐ 否：原因： _____ 6.6 飲食方面如何？ 判斷： ☐ 不恰當 _____ 6.7 有否按協定計畫戒煙？（適用者） ☐ 有 ☐ 否：原因： _____ 6.8 有否每日按醫生處方吸氧？（適用者） ☐ 有 ☐ 否：原因： _____ 每天吸氧____小時？

主要問題或特別的護理需要：

情況	護理干預
1. ☐ 一切如常、依從治療、依從康復訓練 2. ☐ 一切如常、知識缺乏： 3. ☐ 疾病常識 ☐ 藥物治療 ☐ 康復訓練 ☐ 飲食營養 4. ☐ 身心健康 ☐ 家庭氧療 ☐ 戒煙 ☐ 5. ☐ 不能依從藥物治療： ☐ 知識/信念缺乏 ☐ 未掌握技能 6. ☐ 不能依從運動訓練： ☐ 知識/信念缺乏 ☐ 未掌握技能 7. ☐ 不能依從家庭氧療： ☐ 知識/信念缺乏 ☐ 未掌握技能 8. ☐ 不能依從營養治療： ☐ 知識/信念缺乏 ☐ 未掌握技能 9. ☐ 不依從行為沒有改善 10. ☐ 多種疾病護理需要	1. ☐ 護理 0 級： ☐ 讚賞、鼓勵 + 原計畫 ☐ 對因教育、指導 + 原計畫 ☐ 對因教育、指導 + 調整計畫 ☐ 間歇步行 30 分鐘 ☐ 持續步行 30 分鐘 ☐ 上肢運動__級 ☐ 2. ☐ 護理 1 級：+ 電話跟進 3. ☐ 護理 2 級：+ 訪視跟進 + 電話跟進 4. ☐ 護理 3 級：共同訪視 5. ☐ 護理 4 級：護理會診 電話跟進： 月 日 時 分 訪視跟進： 月 日 時 分
11. ☐ 症狀轉變超過 24 小時： ☐ 氣喘增加 ☐ 應付日常活動時氣短加重 ☐ 咳嗽比平常多 ☐ 痰量比平常增加，出現膿痰 ☐ 使用短效氣霧劑次數增加 ☐ 較平常的活動能力減低 ☐ 較易疲倦或不能入睡 ☐ 發熱 $\geq 38.8^{\circ}\text{C}$ 12. ☐ 出現併發症狀超過 24 小時： ☐ 胸悶 ☐ 雙下肢浮腫 ☐ 13. ☐ 尋求醫生協助確定藥物治療方案 14. ☐ 嚴重藥物副作用 _____ 15. ☐ 出現危險訊號： ☐ 極度氣喘，休息和停止活動不能緩解 ☐ 嗜睡或神志混亂	6. ☐ 自我監測： ☐ 症狀 ☐ 藥物副作用 7. ☐ 護理 5 級 R：門診轉介 + 電話跟進 電話跟進： 月 日 時 分 8. ☐ 護理 6 級：急診室轉介 + 電話跟進 電話跟進： 月 日 時 分 9. ☐ 護理 7 級：經門診住院轉介 + 訪視跟進 訪視跟進： 月 日 時 分

與患者協定的共同目標：

目標	內 容
1	
2	
3	

結尾鼓勵用語：到__月__日，您就成功完成 6 個星期的出院後延續護理項目了，祝賀您！慢性阻塞性肺疾病是慢性病，需要長時間的治療和疾病的自我管理，請多加努力！努力！

提醒回醫院做問卷調查和肺功能等檢查的時間：__月__日__時__分

如有問題可隨時致電我們的熱線：_____，再見！

Individualised Care Plan

慢性阻塞性肺疾病患者延續護理項目

護理計畫表

一、出院護理計畫

200 年 月 日

主要問題	護理目標
1.	協議目標：_____ _____ _____ _____ 患者目標：_____ _____
2.	
3.	
4.	
5.	
護理幹預	健康教育、指導和諮詢： 必備知識、必備技能(見第 9-10 頁) 治療和程式： 康復訓練：步 行：☐持續 ☐間歇：30 分鐘，qd 上肢運動：____級， 不負重，qd 家庭氧療：☐壓縮氧氣 ☐制氧機： 升/分鐘 小時/日 出院帶藥： 200 年 月 日 —— 200 年 月 日 支氣管舒張劑：口服_____ 霧化_____ 糖皮質激素： 口服_____ 霧化_____ 抗菌素：_____ 祛痰藥：_____ 其 他：_____ _____ 備用藥物：☐無 ☐有_____ 監 測：☐運動訓練 ☐藥物治療 ☐症狀 ☐家庭氧療 ☐戒煙 ☐_____ 個案管理：☐護理 0 級：家庭隨訪 ☐護理 5 級 N：營養師轉介

慢性阻塞性肺疾病患者延續護理項目

護理計畫表（續）

二、第一次家庭訪視修訂計畫

200 年 月 日

新問題		護理目標
1.		協議目標：
2.		_____
3.		患者目標：
護理 幹 預	☐ 執行原計畫 ☐ 新增： 健康教育、指導和諮詢：必備知識、必備技能（見第 9-10 頁）及 _____ 治療和程序： _____ 監 測： _____ 個案管理： ☐ 追加電話隨訪：跟進： ☐ 康復訓練 / ☐ 藥物治療 / ☐ _____ ☐ 追加家庭訪視：技能指導： ☐ 上肢運動 / ☐ 藥物吸入 / ☐ 家庭氧療 ☐ 指導照顧者： _____ ☐ 護理轉介（見第 16 頁）	

三、第二次家庭訪視修訂計畫

200 年 月 日

新問題		護理目標
1.		協議目標：
2.		_____
3.		患者目標：
護理 幹 預	健康教育、指導和諮詢：必備知識、必備技能（見第 9-10 頁） 治療和程序：步 行： ☐ 持續 ☐ 間歇：30 分鐘，qd 上肢運動： _____ 級， ☐ 不負重，qd ☐ 負重： _____ kg，qd 新處方藥物 _____ _____ 其他 _____ 監 測： ☐ 運動訓練 ☐ 藥物治療 ☐ 症狀 ☐ 家庭氧療 ☐ 戒煙 ☐ _____ 個案管理： ☐ 追加電話隨訪：跟進： ☐ 康復訓練 / ☐ 藥物治療 / ☐ _____ ☐ 追加家庭訪視：技能指導： ☐ 上肢運動 / ☐ 藥物吸入 / ☐ 家庭氧療 ☐ 指導照顧者： _____ ☐ 護理轉介（見第 16 頁）	

Referral Records

慢性阻塞性肺疾病延續護理項目

護理轉介記錄表

一、護理 3-4 級轉介

轉介原因	轉介至 / 給	轉介：日期 / 時間	執行：日期 / 時間
☐ 依從行為疑難個案 ☐ 多種疾病護理需要	☐ 共同訪視 ☐ 會診會議	 	

二、護理 5 級 N 轉介

轉介原因	轉介至 / 給	聯絡轉介	轉介
		日期/時間	日期/時間
☐ 有重度營養不良危險	☐ 營養科門診		

三、護理 5 級 R 轉介

轉介原因	轉介至 / 給	患者求助	聯絡轉介	轉介
		日期/時間	日期/時間	日期/時間
☐ 出現症狀轉變 ☐ 出現併發症狀 ☐ 有關治療方案	☐ 呼吸科門診 醫生：	 	 	
☐ 出現症狀轉變 ☐ 出現併發症狀 ☐ 有關治療方案	☐ 呼吸科門診 醫生：	 	 	
☐ 出現症狀轉變 ☐ 出現併發症狀 ☐ 有關治療方案	☐ 呼吸科門診 醫生：	 	 	

四、護理 6-7 級轉介

轉介原因	轉介至 / 給	患者求助	聯絡轉介	轉介
		日期/時間	日期/時間	日期/時間
出現危險訊號 ☐ 極度氣喘，休息和停止活動不能緩解 ☐ 嗜睡或神志混亂	☐ 急診室 ☐ 經門診入院	 	 	
出現危險訊號 ☐ 極度氣喘，休息和停止活動不能緩解 ☐ 嗜睡或神志混亂	☐ 急診室 ☐ 經門診入院	 	 	

慢性阻塞性肺疾病患者延續護理項目
轉介處理意見及護理記錄單

[illegible]

* 本記錄單供書寫轉介處理意見和護理記錄用（包括附加電話和訪視跟進、特別護理問題等）。

慢性阻塞性肺疾病患者延續護理項目

(護理轉介單)

姓名: _____ 性別: ☐ 男 ☐ 女 年齡: _____

轉介護士: _____

轉介時間: _____年____月____日____時____分

轉介原因:

- | | | |
|---|--------------------------------------|---------------------------------------|
| 1. ☐ 依從行為疑難個案 | 2. ☐ 多種疾病護理需要 | 3. ☐ 有重度營養不良危險 |
| 4. ☐ 出現症狀轉變 | 5. ☐ 出現併發症狀 | 6. ☐ 有關治療方案 |
| 7. ☐ 極度氣喘, 休息和停止活動不能緩解 | 8. ☐ 嗜睡或神志混亂 | |

轉介要求:

- | | |
|---|---|
| 1. ☐ 護理 3 級: 共同訪視 | 2. ☐ 護理 4 級: 會診會議 |
| 3. ☐ 護理 5 級: 營養科門診 | 4. ☐ 護理 5 級 R: 呼吸科門診 |
| 5. ☐ 護理 6 級: 急診室 | 5. ☐ 經門診入院 |

接收科室: _____

接收醫生/護士: _____

接收時間: _____年____月____日____時____分

慢性阻塞性肺疾病患者延續護理項目

(護理轉介單)

姓名: _____ 性別: ☐ 男 ☐ 女 年齡: _____

轉介護士: _____

轉介時間: _____年____月____日____時____分

轉介原因:

- | | | |
|---|--------------------------------------|---------------------------------------|
| 1. ☐ 依從行為疑難個案 | 2. ☐ 多種疾病護理需要 | 3. ☐ 有重度營養不良危險 |
| 4. ☐ 出現症狀轉變 | 5. ☐ 出現併發症狀 | 6. ☐ 有關治療方案 |
| 7. ☐ 極度氣喘, 休息和停止活動不能緩解 | 8. ☐ 嗜睡或神志混亂 | |

轉介要求:

- | | |
|---|---|
| 1. ☐ 護理 3 級: 共同訪視 | 2. ☐ 護理 4 級: 會診會議 |
| 3. ☐ 護理 5 級: 營養科門診 | 4. ☐ 護理 5 級 R: 呼吸科門診 |
| 5. ☐ 護理 6 級: 急診室 | 5. ☐ 經門診入院 |

接收科室: _____

接收醫生/護士: _____

接收時間: _____年____月____日____時____分

COPD Transitional Care Programme Nursing Guideline

臨床實施指引

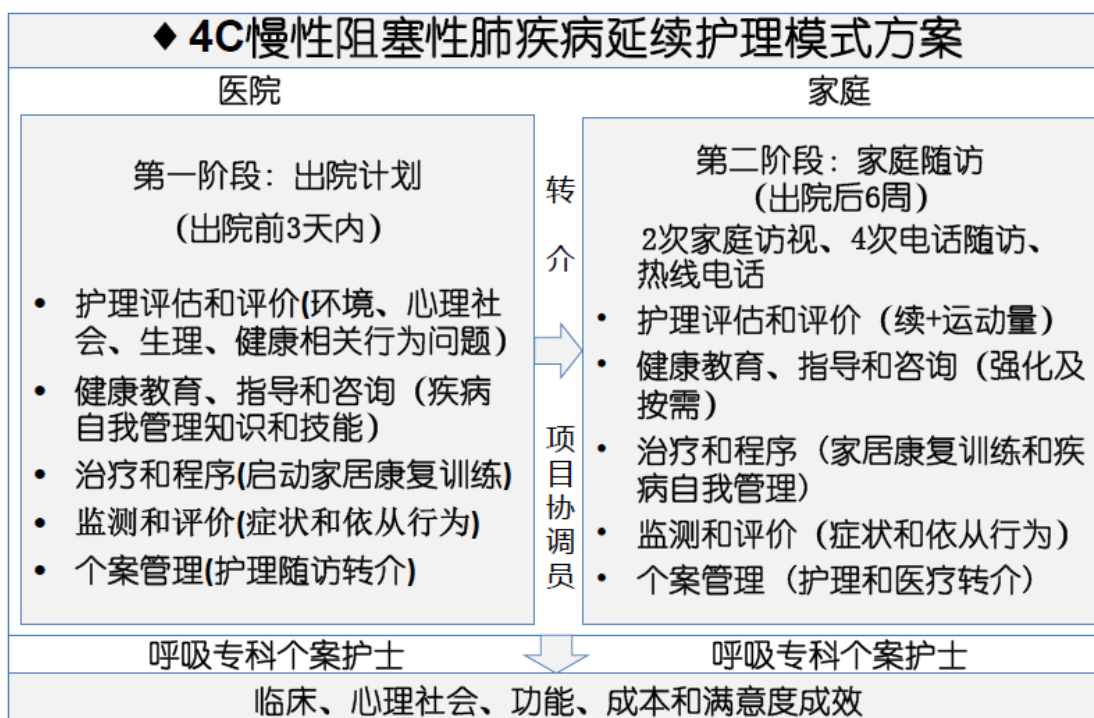


表 1 隨訪時間安排

星期日	星期一	星期二	星期三	星期四	星期五	星期六	周次
		訪視 1	訪視 1	訪視 1	訪視 1		1
	訪視 1	電話 1	電話 1	電話 1	電話 1		2
	電話 1	電話 2	電話 2	電話 2	電話 2		3
	電話 2	訪視 2	訪視 2	訪視 2	訪視 2		4
	訪視 2	電話 3	電話 3	電話 3	電話 3		5
	電話 3	電話 4	電話 4	電話 4	電話 4		6
	電話 4	回院 1	回院 1	回院 1	回院 1		7
	回院 1						8
							9
							10
							11
							12
		回院 2	回院 2	回院 2	回院 2		13
	回院 2						
	週五出院	週一出院	週二出院	週三出院	週四出院		出院時間

注：1. 第一次訪視必須在患者出院後 72 小時內執行；必要時，其余隨訪安排可順延 2 天。

2. 回院日安排患者回到醫院收集問卷資料和進行 6-分鐘步行試驗。

表 2 護理干預實施流程一覽表

項 目 \ 時 間		出 院 前	出 院 後					
		3d	72h	W2	W3	W4	W5	W6
護理評估	測量 T、P、R、BP、SpO ₂	✓	✓			✓		
	測量身高、體重	✓				✓*		
	奧瑪哈架構的全面評估	✓	✓			✓		
	居所和社區環境評估		✓			✓		
	康復訓練運動量評估	✓	✓*			✓		
	電話定期追蹤評估			✓	✓		✓	✓
健康教育	必備知識 1-8，選擇必備知識 9	✓	✓*	✓*	✓*	✓*	✓*	✓*
	必備知識 10-13，選擇知識 14		✓	✓*	✓*	✓*	✓*	✓*
	必備技能 1-3，選擇必備技能 4-8	✓	✓			✓		
	必備技能 9、選擇必備技能 10-14		✓			✓*		
	選擇技能 12-14					✓		
治療和程式	家庭訪視		✓			✓		
	電話隨訪			✓	✓		✓	✓
	步行訓練（30min/d）		✓	✓	✓	✓	✓	✓
	上肢運動（不負重）		✓	✓	✓			
	上肢運動（負重 0.4-1.2kg）					✓	✓	✓
	疾病自我管理		✓	✓	✓	✓	✓	✓
	家庭訪視或電話跟進		✓*	✓*	✓*	✓*	✓*	✓*
	熱線電話		✓	✓	✓	✓	✓	✓
監測和評價	藥物治療	✓	✓	✓*	✓*	✓*	✓*	✓*
	步行訓練		✓	✓	✓	✓	✓	✓
	上肢運動		✓	✓	✓	✓	✓	✓
	家庭氧療		✓*	✓*	✓*	✓*	✓*	✓*
	急性症狀加重	✓	✓	✓	✓	✓	✓	✓
	健康行為的建立（飲食、戒煙等）	✓	✓	✓	✓	✓	✓	✓
	護理轉介：共同訪視/會診會議			✓*	✓*	✓*	✓*	✓*
	護理轉介：營養師	✓*						
	護理轉介：門診		✓*	✓*	✓*	✓*	✓*	✓*
	護理轉介：急診/住院		✓*	✓*	✓*	✓*	✓*	✓*

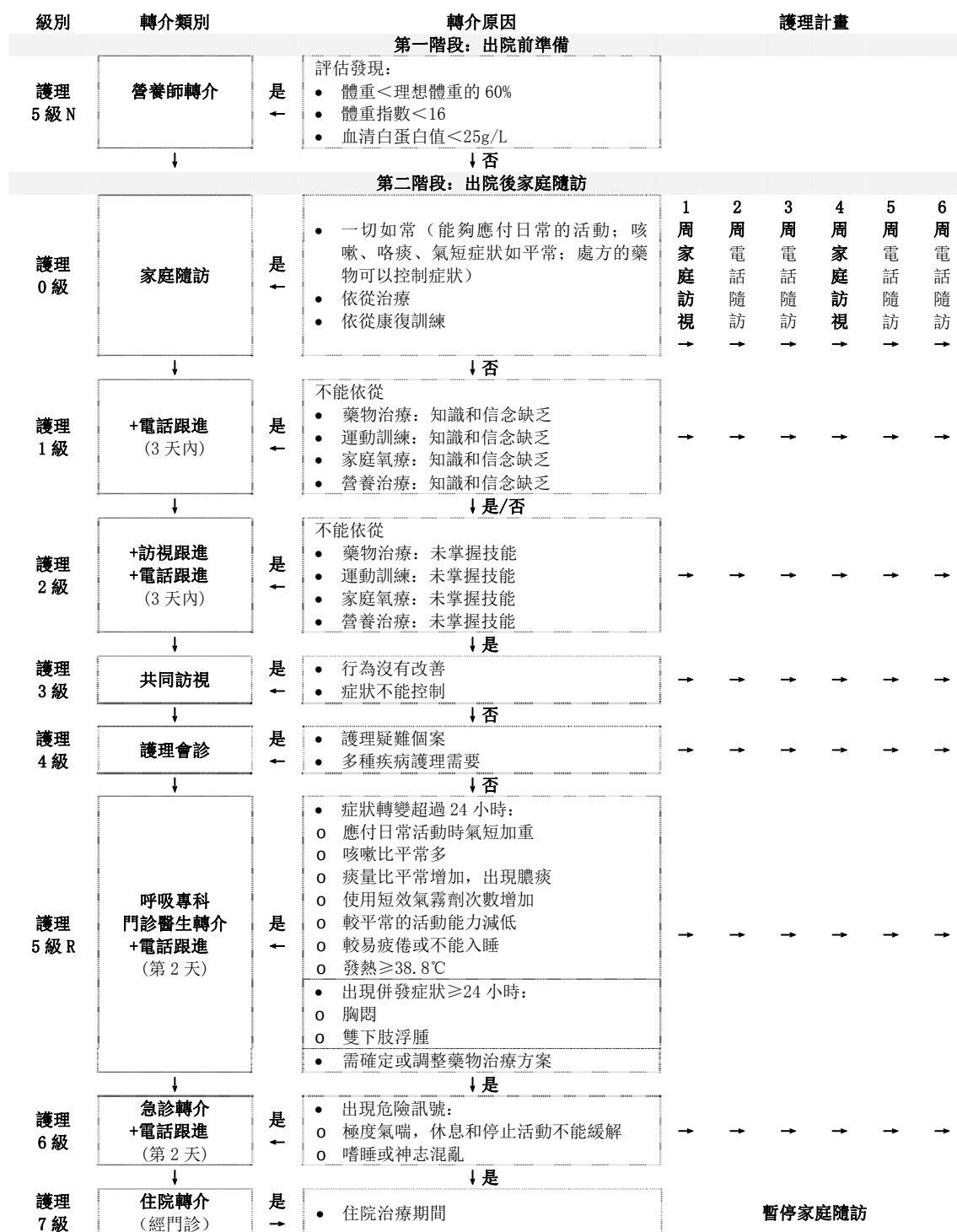
注： * 必要時，根據醫囑或病人的實際需要選擇。

表 3 護理實施記錄一覽表

編號	表格名稱	填寫時間	出院前	出院後					
			3d	72h	W2	W3	W4	W5	W6
F1	護理評估表第一部分: 基本資料		✓						
F2	護理評估表第二部分: 評估-評價		✓	✓			✓		
F3	護理計畫表		✓	✓			✓		
F4	康復訓練運動量評估及運動處方		✓	✓*			✓		
F5	健康教育（知識部分）記錄表		✓	✓			✓		
F6	健康教育（技能部分）記錄表		✓	✓			✓		
F7	上肢運動評估表		✓	✓			✓		
F8	氣霧劑使用評估表		✓*	✓*			✓*		
F9	輕易吸入器使用評估表		✓*	✓*			✓*		
F10	准納器使用評估表		✓*	✓*			✓*		
F11	渦流式吸入器使用評估表		✓*	✓*			✓*		
F12	護理及醫療轉介記錄表		✓*	✓*	✓*	✓*	✓*	✓*	✓*
F13	轉介處理意見及附加項目記錄單		✓*	✓*	✓*	✓*	✓*	✓*	✓*
F14	電話隨訪記錄單				✓	✓		✓	✓
F15	轉介單		✓*	✓*	✓*	✓*	✓*	✓*	✓*
16	康復之旅行動計畫手冊 護士填寫 2-4、7、13-15、17 和 19 頁		✓	✓			✓		
	康復之旅行動計畫手冊 病人填寫 1、5-9、12-14、16-17 和 20 頁		✓	✓	✓	✓	✓	✓	✓

注： * 按需要填寫。

護理轉介路徑：



注：隨訪過程若患者複住院 ≤ 7 天，出院後繼續完成隨訪方案。

護理轉介程序：

共同訪視程式（護理 3 級）	
步驟一	個案護士填寫轉介單 → 通知項目協調員
步驟二	項目協調員聯絡有關人員 → 確定訪視日期、時間 → 通知有關人員參加共同訪視
步驟三	進行共同訪視 → 個案護士按護理共同訪視意見調整護理計畫 → 完成護理轉介記錄表和轉介處理意見及附加項目記錄單的填寫

護理會診會議程式（護理 4 級）	
步驟一	個案護士填寫轉介單 → 通知項目協調員
步驟二	項目協調員聯絡研究員確定會診需要 → 安排護理會診具體事項（日期、時間、地點、參加者） → 通知有關人員參加會診會議
步驟三	進行護理會診會議 → 個案護士按護理會診意見調整護理計畫 → 完成護理轉介記錄表和轉介處理意見及附加項目記錄單的填寫

營養師轉介程式（護理 5 級 N）	
步驟一	個案護士填寫轉介單 → 聯絡專責營養師預約就診 → 安排病人就診
步驟二	個案護士跟進轉介處理意見 → 完成護理轉介記錄表和轉介處理意見 和附加記錄單的填寫

呼吸專科門診轉介程式（護理 5 級 R）	
步驟一	個案護士填寫轉介單 → 聯絡門診醫生或專責醫生預約就診 → 電話通知病人就診
步驟二	病人就診後第二天電話跟進 → 完成護理轉介記錄表和轉介處理意見 和附加記錄單的填寫

急診室轉介程式（護理 6 級）	
步驟一	個案護士接到病人求助電話 → 判斷急診室轉介需要 → 建議即到急診室求診
步驟二	24 小時內電話跟進 → 完成護理轉介記錄表和轉介處理意見 和附加記錄單的填寫

住院轉介程式（護理 7 級）	
步驟一	個案護士接到病人求助電話 → 判斷住院轉介需要 → 建議即到門診求診
步驟二	聯絡門診醫生診視病人 → 接收病人入院治療
步驟三	完成轉介記錄表、轉介處理意見和附加記錄單的填寫 → 暫停家庭訪視
步驟四	病人出院後，在不影響研究干預的情況下 → 繼續家庭訪視

臨床實施方法或決策參考資料

1. 慢性阻塞性肺疾病臨床嚴重程度的肺功能分級（吸入支氣管舒張劑後）：

- I 級(輕度)： $FEV_1 / FVC < 70\%$ ， FEV_1 占預計值百分比 $\geq 80\%$
II 級(中度)： $FEV_1 / FVC < 70\%$ ， $50\% \leq FEV_1$ 占預計值百分比 $< 80\%$
III 級(重度)： $FEV_1 / FVC < 70\%$ ， $30\% \leq FEV_1$ 占預計值百分比 $< 50\%$
IV(極重度)： $FEV_1 / FVC < 70\%$ ， FEV_1 占預計值百分比 $< 30\%$ 或 FEV_1 占預計值百分比 $< 50\%$ ，或伴有慢性呼吸衰竭

2. 慢性阻塞性肺疾病急性期住院病人病情穩定判斷標準（需要專責醫生協助確認）：

- 吸入 β_2 受體激動劑頻率少於每四小時一次；
- 病人可在病房下床行走；
- 病人進食時沒有氣喘，睡眠過程沒有因氣喘而醒；
- 臨床情況已穩定 12-24 小時；
- 血氣分析結果已穩定 12-24 小時。

3. 功能性呼吸困難分級：

- 0 級：除非劇烈活動，無明顯呼吸困難
1 級：當快走或上緩坡時有氣短
2 級：由於呼吸困難比同齡人步行得慢，或者以自己的速度在平地上行走時需要停下來呼吸
3 級：在平地上步行 100 米或數分鐘後需要停下來呼吸
4 級：明顯的呼吸困難而不能離開房屋或者當穿脫衣服時氣短

4. 營養狀態的評價：

4.1 營養不良的判斷標準：

	營養狀況良好	輕度營養不良	中度營養不良	重度營養不良
理想體重的百分數	90-110%	80%-90%	60%-80%	60%以下
體重指數	$> 21 \leq 22$	18.5-21	16-18.4	16 以下
血清白蛋白值	$\geq 35g/L$	30-34.9g/L	25-29.9g/L	25g/L 以下

4.2 計算公式：

- ① 理想體重 (IBW, kg) = 身高 (cm) - 105
② 理想體重的百分數 (PIBW) = 體重 (BW) $\div$ 理想體重 (IBW) $\times 100\%$
③ 體重指數 (BMI) = 體重 (kg) $\div$ 身高 (m)²

5. 能量需要量的確定

- 5.1 按照三大產熱營養素供熱比例確定能量的需要量：穩定期：碳水化合物占 50%～60%，脂肪占 20%～30%，蛋白質占 15%～20%；急性期：脂肪、蛋白質所占比例按穩定期上限供給。
- 5.2 採用 Moore-Angelillo 公式計算，確定患者的能量需要量：
男性：REE (kcal/d) = 11.5 × Wt + 952
女性：REE (kcal/d) = 14.1 × Wt + 515
公式中，Wt：體重 (kg)
COPD 穩定期營養治療原則：無營養不良患者，能量 1.3×REE；存在營養不良的患者，能量 1.5×REE，同時應注意考慮到應疲乏、氣促及胃腸道功能障礙等影響食欲及營養成分吸收

6. 家庭氧療

家庭氧療必須按醫囑執行。

7.1 適應症

- ① PaO₂ ≤ 55mmHg 或 SaO₂ ≤ 88%，有或沒有高碳酸血症。
② PaO₂ 55–60mmHg，或 SaO₂ < 89%，並有肺動脈高壓、心力衰竭水腫或紅細胞增多症。

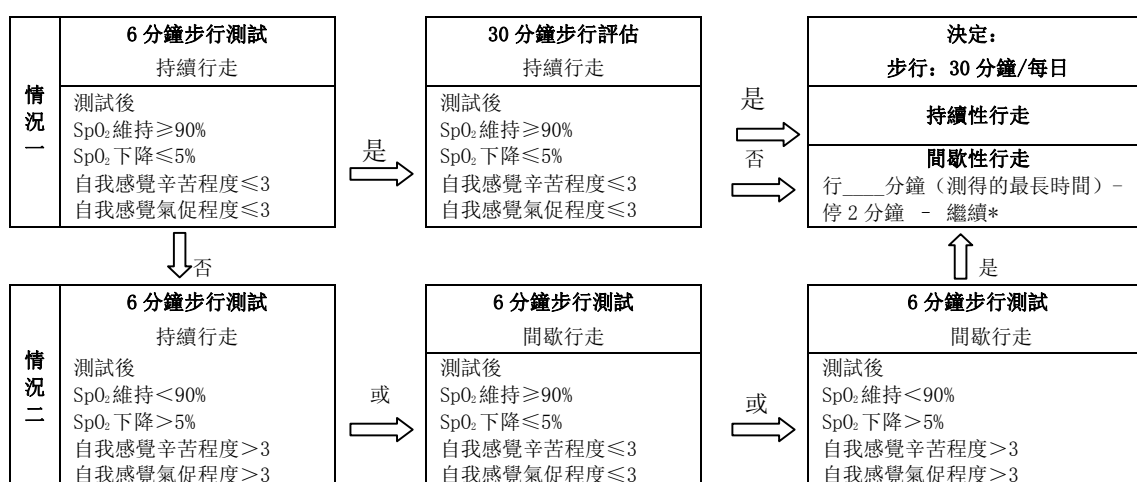
7.2 吸氧的劑量

- ① 氧流量：1.0～2.0 升/分鐘；
② 吸氧濃度 = 21 + 4 × 氧流量；
③ 吸氧時間：每日 15 小時以上才能達到治療的目的。

8. 家居康復訓練指導和運動量的確定

8.1 步行：

- 8.1.1 訓練指導：指導患者盡自己最大的能力，每天堅持步行 30 分鐘。不能安全地持續性步行 30 分鐘者，開始時可以採用間歇的方式：運動直至出現活動無耐力症狀和體征時，停下來休息約 2 分鐘，然後再繼續運動；逐漸增加到能持續運動 30 分鐘。
- 8.1.2 運動量的確定：依據 6 分鐘步行測試和 30 分鐘步行評估結果，確定採用持續性行走或間歇性行走的方式，以及間歇性行走的時間如下：



注：* 行走的時間（行____分鐘）為所測得的 30 分鐘內或 6 分鐘內最長的持續行走時間，且 SpO₂維持 ≥ 90%，SpO₂下降 ≤ 5%，自我感覺辛苦程度 ≤ 3，自我感覺氣促程度 ≤ 3。

8.2 上肢運動：

8.2.1 訓練指導：

- 練習前的準備：選擇一張有靠背的椅子，舒適地坐在椅子上，髖關節與膝關節均呈 90 度角，背部放一小枕承托，雙腳平踏在地面上。
- 練習一：①開始動作：雙手交叉放在膝上，肘關節伸直，掌心向下；②伸展動作：雙手向外向上抬舉至頭的斜上方，與身體中線呈 45 度角停下來；反掌使手心向後。還原動作：③回復到開始時的動作。
- 練習二：①開始動作：雙手放在身體的兩側，肘關節伸直，掌心向後。②伸展動作：雙手向外向上抬舉至頭頂停下來；反掌使手心向後。③還原動作：回復到開始時的動作。
- 練習三：①開始動作：雙手放在身體的兩側，肘關節伸直，掌心向後。②伸展動作：雙手向外向上抬起，直至肩胛水準。③反掌使手心向前方停下來。④雙手向前至身體的中線對合。⑤然後還原動作。⑥回復到開始時的動作。
- 練習要領：① 在吸氣時，做舉手的動作；② 每一呼吸週期完成一套練習動作 1 次，盡可能配合呼吸連續完成 6 次的每套練習動作；③ 每套練習動作之間休息 1 分鐘；④ 做舉手動作時必須保持肘關節伸直，但不致引起疼痛或不適。

8.2.2 運動量的確定：運動量的級別共 6 級（見表 3），運動量的確定標準：完成 1/2/3 套練習後，測試後 SpO_2 維持 $\geq 90\%$ ；且與運動前比較下降 $\leq 5\%$ ，自我感覺辛苦程度 ≤ 3 ，自我感覺氣促程度 ≤ 3 ，運動後沒有身體不適的症狀和體征。當患者能夠連續完成 3 套練習動作，每套動作練習 6 次，至少 7 天時，從第四周開始進行負重的訓練，每手的負重量為 0.2-0.6 公斤。個案護士在患者出院前或第一次訪視時（計畫外出院者適用）評估確定前三周的運動級別，第四周訪視時評估調整訓練量，確定後三周的運動級別。

上肢運動訓練量

分級	負重量（公斤）	練習套數	重複次數
1	0	1	6
2	0	2	6
3	0	3	6
4	0.2	3	6
5	0.4	3	6
6	0.6	3	6

- 8.3 運動訓練注意事項：①穿著舒適的衣服；②運動前不要過饑過飽；③運動前後分別做 5 分鐘的熱身運動和平息運動；④天氣轉壞時，可選擇在室內做運動；⑤運動前，如有需要可按照指示適量提高氧流量，運動後需調回原來的氧流量；⑥運動後可能會出現短暫性的疲勞、肌肉酸痛、氣喘及痰液增加。

9. 常用的治療藥物

種類	通用名	商品名	用法用量	藥理及臨床應用	副作用	注意事項
支氣管舒張劑	短效 B_2 受體激動劑	沙丁胺醇	舒喘靈 口服 2-4mg/次 每日3次	使支氣管平滑肌鬆弛，解除痙攣 口服後15-30min起效，2-3h達到峰值，持續6h以上	常見噁心、頭痛，心悸、手指震顫等 劑量過大時，可見胸痛、持續的心率增快或心博強烈、情緒煩躁不安等	心得安等 β 受體阻滯劑可拮抗本品的支氣管擴張作用 有心血管病史或使用後有明顯心悸者，須在醫生指導下使用 甲亢、糖尿病、高血壓、心血管功能不全患者慎用
		萬托林	氣霧吸入 100-200 μ g/次 (100 μ g/噴) 24h內不超過8-12噴	主要用於緩解症狀 吸入後數分鐘內開始起效，15-30min達到峰值，持續療效4-5h		
		博利康尼	口服 2.5-5mg 每日3次	擴張支氣管 作用可達8小時		
	長效 B_2 受體激動劑	沙美特羅	施立穩 氣霧吸入 50 μ g/次 每日2次 嚴重者可加至100 μ g/次	舒張支氣管 作用持續12小時		不能緩解急性發作 甲亢患者慎用
		福莫特羅	奧克斯 乾粉吸入 4.5-9 μ g/次 每日2次(早、晚)	吸入後1-3 min起效 作用持續12 h以上	常見頭痛、心悸、震顫、心動過速 偶見急躁、不安、失眠、皮疹	對福莫特羅或吸入乳糖過敏者禁用 甲狀腺功能異常和嚴重心血管病患者慎用
		丙卡特羅	美普清 口服 50 μ g /次 每日1次(晚) 或每日2次(早、晚)	擴張支氣管，促進支氣管的纖毛作用	偶見心悸、面色潮紅、震顫、頭痛、目眩、失眠、耳鳴、胃部不適、皮疹發生、口渴、周身倦怠、鼻塞	甲亢、高血壓、心臟病、糖尿病患者慎用
		異丙托溴銨	愛喘樂 氣霧吸入 40-80 μ g/次(20 μ g/噴) 每天3-4次	抑制支氣管收縮，使氣道擴張 吸入後15-30min起效，30-90min達最大效果，作用維持6-8小時	口幹、咽幹、心率增加、視力模糊、青光眼、排尿困難、尿潴留和便秘	重複用藥必須間隔2小時以上 有青光眼、尿潴留等疾病的患者需慎用
	抗膽鹼藥	噻托溴銨	思力華 氣霧吸入 18 μ g/次 每天1次	減輕氣短，提高深吸氣能力和運動耐量，同時減少痰液分泌	同上	窄角型青光眼、前列腺增生、或膀胱頸梗阻患者應慎用 對噻托溴銨，阿托品或其衍生物過敏者禁用
支氣管舒張劑	茶鹼類	氨茶鹼	口服 0.1g/次 每日3次	直接擴張支氣管，改善心排血量，擴張全身血管和肝血管，增加水鈉排出，改善呼吸肌功能	常有噁心、嘔吐、頭痛、失眠，嚴重者心動過速、精神失常、驚厥、昏迷等	活動性消化性潰瘍和未經控制驚厥性疾病患者禁用 空腹服用，避免吸煙、香煙、咖啡因、巧克力會增加茶鹼副作用，應避免食用 定期監測血清茶鹼濃度，避免血藥濃度過高
		緩釋放茶鹼	舒弗美 口服 0.1-0.2g 每12小時1次			

9. 常用的治療藥物（續）

種類	通用名	商品名	用法用量	藥理及臨床應用	副作用	注意事項
糖皮質激素	布地奈德	普米克	乾粉吸入 輕症：400-800 ug/日，重症：800-1600ug/日 每日 2-4 次	局部對抗非特異炎症和抗過敏	少數患者發生聲音嘶啞和口腔咽喉部念珠菌感染	吸入後用淨水漱洗口腔和咽喉部，以防真菌感染 肺結核患者及氣道真菌、病毒感染者慎用
			氣霧吸入 初始劑量：200-800ug/次，每日 2 次 維持劑量：200-400ug			
	倍氯米松	必可酮	氣霧吸入 維持：100 μg/次 (50 μg/噴)，每日 3-4 次 嚴重者，開始劑量 600-800 μg/日，見效後漸減劑量	抗炎作用		
祛痰藥	鹽酸氨溴索	沐舒坦	口服 15-30mg/次，每日 2 次或者每日 3 次	促進粘液的排出 溶解分泌物	胃部灼熱、消化不良和偶爾出現的噁心、嘔吐	1. 與抗生素有協同作用 2. 不宜與城液混合，避免同阿托品、強鎮咳藥連用 3. 飯後服
	溴己新	必漱平	口服 16mg/次 每日 3 次	直接作用於支氣管腺體使痰液變稀易於咳出	偶見胃部不適、胃痛、腹瀉	胃潰瘍者慎用
	桃金娘油	吉諾通	口服 300mg/次 每日 3 次	溶解粘液、調節分泌，主動刺激粘液纖毛運動，使粘液易於排出	罕有	餐前 30 分鐘，用較多的涼開水送服
	沙雷肽酶	達先	口服 5-10mg/次 每日 3 次	抗炎消腫，分解緩激肽、溶解纖維蛋白，可緩解腫脹，溶除粘性膿液，潔化病灶	過敏反應、腹瀉、食欲不振、胃部不適、噁心、嘔吐，偶見鼻出血及血痰	飯後服 凝血功能異常及嚴重的肝腎功能障礙者慎用
	乙醯半胱氨酸	富露施	口服 600mg/次 每日 3 次	分解粘蛋白複合物，降低痰液粘度，使粘痰容易咳出	可引起嗆咳、支氣管痙攣、噁心、嘔吐、胃炎、皮疹等	避免與硝酸甘油、酸性藥物合用，用 40℃ 以下溫開水中溶解後飲用
	沙雷肽酶	達先	口服 10mg/次 每日 3 次	抗炎消腫，分解緩激肽，溶解纖維蛋白。	過敏、腹瀉、食欲不振、噁心嘔吐等	凝血功能異常及嚴重的肝腎功能障礙者慎用

參與研究項目臨床干預方案實施人員的職責

一、 研究項目協作負責人

- (一) 負責項目在研究場所實施過程的各項協調和管理；
- (二) 確保研究獲得所需的資源和支持；
- (三) (另參考研究協定書)。

二、 研究項目統籌員

- (一) 起橋樑作用，負責協調研究團隊之間以及各部門之間的各項事務，使得研究能順利進行；
- (二) 負責協助組織研究參與人員的培訓；
- (三) 處理研究對象對研究的諮詢；
- (四) 保持與項目研究組人員溝通，及時回饋研究的進展和遇到的問題；
- (五) 參與雙方管理層的協調會議和研究人員的工作會議。

三、 資料收集員

- (一) 接受項目研究員的培訓以瞭解研究的目的，並掌握各種研究工具的使用；
- (二) 按指引收集入選個案的基線和隨訪資料，以及回收病人手冊（資料收集完畢後）；
- (三) 妥善保管研究資料，定期交給研究員；
- (四) 妥善保管和安全使用研究測量儀器和用具；
- (五) 與研究員、項目協調員和病房護士長保持密切的聯絡和溝通。

四、 項目協調員（病房護士長）

- (一) 參加項目專項培訓；
- (二) 負責個案的篩選、隨機分組、簽署參與研究同意書、通知資料收集員收集資料等程序；
- (三) 安排個案護士執行干預組患者的延續護理方案，並給予必要的指導；
- (四) 統籌患者的護理轉介和醫療轉介；
- (五) 協調與多專業團隊的各項工作，獲得他們對項目的支持；
- (六) 協調護患關係；
- (七) 負責收集和保管研究實施記錄，並定期交給研究員；
- (八) 及時向項目統籌員和研究員回饋實施的情況和需協助解決的問題，提出意見和建議；
- (九) 定期參與項目的個案研討會和工作會議；
- (十) 負責在患者出院前發放和回收滿意度問卷（用信封封好）。

五、 呼吸專科個案護士

- (一) 參加項目培訓課程的培訓並考核合格；
- (二) 作為個案管理護士，除執行常規護理外，根據項目指引實施干預組患者的延續護理方案；

- (三) 按護理實施記錄要求進行資料收集和記錄;
- (四) 與多團隊專業人員密切合作, 按需進行護理或醫療轉介;
- (五) 參與護理會診會議和共同訪視;
- (六) 妥善保管和安全使用項目所配備的儀器和用具;
- (七) 妥善保管研究實施記錄;
- (八) 與項目協調員和研究員保持良好的溝通, 及時回饋實施情況;
- (九) 定期參與項目的個案研討會和工作會議。

六、專責醫生

專責醫生在本研究項目多專業團隊中的重要一員, 是護士的支持者和密切合作夥伴, 他/她將會:

- (一) 協助確認納入個案符合入選條件;
- (二) 當主管醫生休假期間協助確定個案資料收集和護理干預時機;
- (三) 當個案需要進行醫療轉介(門診或住院)時, 提供協調、配合和幫助;
- (四) 向個案護士提供諮詢和幫助;
- (五) 應邀參加護理會診會議, 並提供專業的意見和建議。

取樣條件核對表

姓名： 性別：☐男 ☐女 床號： 病區：☐一區 ☐二區
 入院時間：200 年 月 日 時 分 當天入院序號：
 住址： 聯絡電話：

（符合入選條件「是」排除條件「否」者，請在「☐」內打鉤）

入選條件	排除條件
入院診斷為： AECOPD 或 慢性支氣管炎急性發作+COPD 或 慢性支氣管炎急性發作+肺氣腫+ COPD 或 肺炎/肺部感染+COPD 或 慢性支氣管炎急性發作+支氣管哮喘+COPD 年齡≥40 歲	患有： 既往有哮喘史(診斷為 COPD 前) 缺血性心臟病(需服用藥物治療) 充血性心力衰竭 老年癡呆症 肺癌
☐ 是	☐ 否
清醒、合作	出院後入住老人院
☐ 是	☐ 否
能閱讀和書寫中文	目前正參加其他肺康復項目
☐ 是	☐ 否
居住在乘坐公共交通工具 1 小時可達到的範圍內	有影響訓練的身體障礙： 四肢活動障礙或受限 疼痛導致活動障礙或受限 由於疾病入院前已不能參加運動
☐ 是	☐ 否
能以電話聯絡	住院期超過一個月
☐ 是	☐ 否
	臨終患者
	☐ 否
願意參加本項研究	不能提供知情同意者
☐ 是	☐ 否

注明：當個案符合上述所有項目時，納入該個案→簽署參與研究同意書→揭曉隨機分組結果→記錄：

納入研究：☐是 ☐否 原因 _____ 組別：☐實驗組 ☐對照組

編號： _____

取樣時間：200 年 月 日

通知資料收集員：☐是

通知個案護士： _____/護士長 ☐是

Letter to expert panel and Research Protocol Review Feedback Form

致慢性阻塞性肺疾病延續護理項目“研究議定書”

廣州醫學院第一附屬醫院專家評定小組成員

各位尊敬的專家：

在廣州醫學院第一醫院護理部、呼吸疾病研究所、科研管理科和醫院領導的大力支持下，我在香港理工大學護理學院黃金月教授和周家儀博士指導下的博士研究課題：“中國廣州慢性阻塞性肺疾病患者延續護理項目效果評價：隨機控制實驗”將在貴院進行臨床干預階段的研究。

該項研究的目的是發展適合廣州地區慢性阻塞性肺疾病（COPD）患者的出院後延續護理模式，並測試該模式的應用在臨床、功能、成本和滿意度方面的成效。為使研究具有科學性和可行性，確保研究在貴院能順利實施，我誠邀閣下作為該項目的中國內地專家審定組的成員，審核將在貴院實施的研究議定書（research protocols），包括項目的《實施指引》、《護理實施記錄》、《康復之旅行動計劃指引》、《康復之旅行動計劃》和《資料記錄》等研究用資料。專家組審定會議將在 2008 年 10 月 22 日上午舉行（具體時間和會議地點另行通知）。敬請各位專家在與會前，完成專家審核意見表的填寫，並在與會時提交。十分感謝閣下的配合和支持！

如對資料有任何疑問，請隨時與我聯繫。我的聯絡電話：852-27664520；電郵：
hsslwong@（請用附件形式發送）。

順祝：工作愉快！

香港理工大學護理學院研究生

王少玲

2008 年 10 月 8 日

(廣州醫學院第一附屬醫院專家組)

工作部門：_____ 職務：_____ 工作經驗：_____ 年

本表格是用以收集各位專家小組成員對慢性阻塞性肺疾病延續護理項目的研究議定書（research protocols），包括項目的《實施指引》、《護理實施記錄》、《康復之旅行動計劃指引》、《康復之旅行動計劃》和《資料記錄》等研究用資料的審核意見。請在空欄填寫您的意見和建議。

[illegible]

慢性阻塞性肺疾病患者延續護理項目

研究議定書專家審核意見表（續）

[illegible]

簽署:

謝謝您的寶貴意見！

研究議定書專家審核項目

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4.6 專責醫生

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Questionnaire for Expert Panel 1 Review – P-CSES

Questionnaire on Equivalence of Putonghua Version of the COPD Self-Efficacy Scale to the modified Cantonese Version

(Administered by the authors of the modified Cantonese Version CSES)

Name of the Review: _____

Date of Review: _____

慢性阻塞性肺疾病自我效用量表

慢性阻塞性肺疾病自我效能量表

Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)

1	Strongly disagree	2	Disagree	3	Agree	4	Strongly agree
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Please justify your rating and giving relevant suggestion or modification, if any.

閱讀以下列舉的項目，並決定在這些情況下你有多少信心去應付或避免呼吸困難。請用下列的量表作為基礎回答你的問題：

填表說明：閱讀以下列舉的項目，並決定在這些情況下，您有多大的信心去應付或避免呼吸困難。請按如下尺度作答：

(1) = 非常有信心 (2) = 相當有信心 (3) = 有少許信心

(4) = 無信心 (5) = 非常無信心

Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)

1	Strongly disagree	2	Disagree	3	Agree	4	Strongly agree
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Please justify your rating and giving relevant suggestion or modification, if any.

1. 當我感到太疲勞時。(When I become too tired.)

Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)

1	Strongly disagree	2	Disagree	3	Agree	4	Strongly agree
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Please justify your rating and giving relevant suggestion or modification, if any.

2. 當四周的空氣都濕氣時。

當四周的空氣潮濕時。(When there is humidity in the air.)

Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)

1	Strongly disagree	2	Disagree	3	Agree	4	Strongly agree
---	-------------------	---	----------	---	-------	---	----------------

Please justify your rating and giving relevant suggestion or modification, if any.

3. 當我從溫暖的天氣/環境，進入寒冷的天氣/環境時。

當我從溫暖的地方，進入寒冷的地方時。(When I go into cold weather from a warm place.)

Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)

1	Strongly disagree	2	Disagree	3	Agree	4	Strongly agree
---	-------------------	---	----------	---	-------	---	----------------

Please justify your rating and giving relevant suggestion or modification, if any.

4. 當我經歷情緒的壓力和苦惱時。

當我覺得情緒緊張或不開心時。(When I experience emotional stress or become upset.)

Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)

1	Strongly disagree	2	Disagree	3	Agree	4	Strongly agree
---	-------------------	---	----------	---	-------	---	----------------

Please justify your rating and giving relevant suggestion or modification, if any.

5. 當我上樓梯上得太快時。(When I go up stairs too fast.)

Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)

1	Strongly disagree	2	Disagree	3	Agree	4	Strongly agree
---	-------------------	---	----------	---	-------	---	----------------

Please justify your rating and giving relevant suggestion or modification, if any.

6. 當我否認我有呼吸困難時。(When I try to deny that I have respiratory difficulties.)

Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)

1	Strongly disagree	2	Disagree	3	Agree	4	Strongly agree
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Please justify your rating and giving relevant suggestion or modification, if any.

7. 當我周圍都有香煙的煙霧時。(When I am around cigarette smoke.)

Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)

1	Strongly disagree	2	Disagree	3	Agree	4	Strongly agree
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Please justify your rating and giving relevant suggestion or modification, if any.

8. 當我生氣時。(When I become angry.)

Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)

1	Strongly disagree	2	Disagree	3	Agree	4	Strongly agree
---	-------------------	---	----------	---	-------	---	----------------

Please justify your rating and giving relevant suggestion or modification, if any.

9. 當我運動或付出很大的體力時。(When I exercise or physically exert myself.)

Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)

1	Strongly disagree	2	Disagree	3	Agree	4	Strongly agree
---	-------------------	---	----------	---	-------	---	----------------

Please justify your rating and giving relevant suggestion or modification, if any.

10. 當我感到我的生活難過時。

當我為我的生活而感到苦惱時。(When I feel distressed about my life.)

Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)

1	Strongly disagree	2	Disagree	3	Agree	4	Strongly agree
---	-------------------	---	----------	---	-------	---	----------------

Please justify your rating and giving relevant suggestion or modification, if any.

11. 我性交不足或不舉時。

當我感到性交力不從心時。(When I feel sexually inadequate or impotent.)

Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)

1	Strongly disagree	2	Disagree	3	Agree	4	Strongly agree
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Please justify your rating and giving relevant suggestion or modification, if any.

12. 當我感到無奈時。(When I am frustrated.)

Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)

1	Strongly disagree	2	Disagree	3	Agree	4	Strongly agree
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Please justify your rating and giving relevant suggestion or modification, if any.

13. 當我舉起重物件時。(When I lift heavy objects.)

Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)

1	Strongly disagree	2	Disagree	3	Agree	4	Strongly agree
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Please justify your rating and giving relevant suggestion or modification, if any.

14. 當我呼喊或呼叫。

當我叫喊或大聲說話時。(When I yell or scream.)

Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)

1	Strongly disagree	2	Disagree	3	Agree	4	Strongly agree
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Please justify your rating and giving relevant suggestion or modification, if any.

15. 當我躺床上休息時。(When I am lying in bed.)

Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)

1	Strongly disagree	2	Disagree	3	Agree	4	Strongly agree
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Please justify your rating and giving relevant suggestion or modification, if any.

16. 在非常熱或寒冷的天氣。

在非常炎熱或寒冷的天氣裡。(During very hot or very cold weather.)

Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)

1	Strongly disagree	2	Disagree	3	Agree	4	Strongly agree
---	-------------------	---	----------	---	-------	---	----------------

Please justify your rating and giving relevant suggestion or modification, if any.

17. 當我笑得很多時。(When I laugh a lot.)

Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)

1	Strongly disagree	2	Disagree	3	Agree	4	Strongly agree
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Please justify your rating and giving relevant suggestion or modification, if any.

18. 當我沒跟隨合當的日常飲食。

當我沒有跟隨恰當的日常飲食時。(When I do not follow a proper diet.)

Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)

1	Strongly disagree	2	Disagree	3	Agree	4	Strongly agree
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Please justify your rating and giving relevant suggestion or modification, if any.

19. 當我感到無助時。(When I feel helpless.)

Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)

1	Strongly disagree	2	Disagree	3	Agree	4	Strongly agree
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Please justify your rating and giving relevant suggestion or modification, if any.

20. 當我受到感染(喉嚨、鼻竇、傷風感冒等)。

當我受到感染(喉嚨、鼻竇感染，傷風感冒等)時。(When I get an infection [throat, sinus, clods, the flu, etc.])

Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)

1	Strongly disagree	2	Disagree	3	Agree	4	Strongly agree
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Please justify your rating and giving relevant suggestion or modification, if any.

-
21. 當我感到孤主而不想理會所有人或所有事時。
當我對人或事有疏離感時。(When I feel detached from everyone and everything.)
Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)
- | | | | | | | | |
|---|-------------------|---|----------|---|-------|---|----------------|
| 1 | Strongly disagree | 2 | Disagree | 3 | Agree | 4 | Strongly agree |
|---|-------------------|---|----------|---|-------|---|----------------|
- Please justify your rating and giving relevant suggestion or modification, if any.
-

22. 當我覺得憂慮時。
當我覺得焦慮時。(When I experience anxiety.)
Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)
- | | | | | | | | |
|---|-------------------|---|----------|---|-------|---|----------------|
| 1 | Strongly disagree | 2 | Disagree | 3 | Agree | 4 | Strongly agree |
|---|-------------------|---|----------|---|-------|---|----------------|
- Please justify your rating and giving relevant suggestion or modification, if any.
-

23. 當我在污染的環境中。(When I am around pollution.)
Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)
- | | | | | | | | |
|---|-------------------|---|----------|---|-------|---|----------------|
| 1 | Strongly disagree | 2 | Disagree | 3 | Agree | 4 | Strongly agree |
|---|-------------------|---|----------|---|-------|---|----------------|
- Please justify your rating and giving relevant suggestion or modification, if any.
-

24. 當我吃得過多時。(When I overeat.)
Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)
- | | | | | | | | |
|---|-------------------|---|----------|---|-------|---|----------------|
| 1 | Strongly disagree | 2 | Disagree | 3 | Agree | 4 | Strongly agree |
|---|-------------------|---|----------|---|-------|---|----------------|
- Please justify your rating and giving relevant suggestion or modification, if any.
-

25. 當我感到沮喪或意志消沉時。(When I feel down or depressed.)
Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)
- | | | | | | | | |
|---|-------------------|---|----------|---|-------|---|----------------|
| 1 | Strongly disagree | 2 | Disagree | 3 | Agree | 4 | Strongly agree |
|---|-------------------|---|----------|---|-------|---|----------------|
- Please justify your rating and giving relevant suggestion or modification, if any.
-

26. 當我在空氣不流通的房間運動時。(When exercise in room that is poorly ventilated.)
Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)
- | | | | | | | | |
|---|-------------------|---|----------|---|-------|---|----------------|
| 1 | Strongly disagree | 2 | Disagree | 3 | Agree | 4 | Strongly agree |
|---|-------------------|---|----------|---|-------|---|----------------|
- Please justify your rating and giving relevant suggestion or modification, if any.
-

27. 當我害怕時。(When I am afraid.)
Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)

1	Strongly disagree	2	Disagree	3	Agree	4	Strongly agree
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Please justify your rating and giving relevant suggestion or modification, if any.

28. 當我經歷到失去重要的物件或愛人時。

當我經歷到失去重要的物件或摯愛時。(When I experience the loss of a valued object or a loved one.)

Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)

1	Strongly disagree	2	Disagree	3	Agree	4	Strongly agree
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Please justify your rating and giving relevant suggestion or modification, if any.

29. 當我家中有問題時。(When there are problems in the home.)

Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)

1	Strongly disagree	2	Disagree	3	Agree	4	Strongly agree
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Please justify your rating and giving relevant suggestion or modification, if any.

30. 當我感到不能勝任時。

當我感到沒有能力（做事）時。(When I feel incompetent.)

Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)

1	Strongly disagree	2	Disagree	3	Agree	4	Strongly agree
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Please justify your rating and giving relevant suggestion or modification, if any.

31. 當我匆忙時。(When I hurry or rush around)

Are the words used in the translated version of the CSES presented fluently and accurately as in the Chinese version (HK.)? (Please circle your best answer.)

1	Strongly disagree	2	Disagree	3	Agree	4	Strongly agree
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Please justify your rating and giving relevant suggestion or modification, if any.

—The End—

**** Thanks for Your Comments!****

Questionnaire for Expert Panel 2 Review — P-CSES

Questionnaires for the evaluation on the Chinese (Putonghua) Version of the COPD Self-Efficacy Scale (P-CSES)

(Administered by expert panel 2)

Name of the Expert Panel Member: _____

Work Setting: _____

Year of Working Experience in COPD (Medicine/Nursing/Research/Rehabilitation)

Field: _____ Date of Review: _____

Information and Instructions to all panel members

The purpose of this study is to establish the psychometric evidence for the translated Chinese (Putonghua) version of the Modified COPD Self-Efficacy Scale (P-CSES) before the application to people with Chronic Obstructive Pulmonary Disease (COPD) in Guangzhou China.

CSES is a questionnaire to assess self-efficacy in patients with COPD. It was translated into Chinese (Cantonese with modification and applied to research study in Hong Kong. As CSES will be used in China setting, it is necessary to revise this modified Cantonese version of CSES to suit the language usage in Mainland China and to ensure the validation before actual use.

As panel members, you are invited to participate in this validation processes to evaluate the language equivalence as well as the relevance and representativeness of the translated version of P-CSES. Two questionnaires are designed to guide you through the evaluation. Further instruction is as following:

- Please respectively fill in the two questionnaires: Q1 for the evaluation on the language equivalence of the Chinese version of the P-CSES and Q2 for the evaluation on the relevance and representativeness of the translated version of the P-CSES.
- A four-point Likert scale is used. It ranges from “4” **strongly agree** to “1” **strongly disagree** for Q1 and from “4” **excellent** to “1” **poor** for Q2 respectively. Please circle the number that you think is the most appropriate to your evaluation.
- Please also provide your comments, justifications or suggestions; especially when you have rated “2” **disagree** or “1” **strongly disagree** on Q1, and “2” **fair** or “1” **poor** on Q2.
- Please be reminded to work independently.
- If you have any quires on the reviewing process, please do not hesitate to ask investigator for clarification.

Questionnaire on Equivalence of the Putonghua Version of the COPD Self-Efficacy Scale to the Original English Version

THE COPD SELF-EFFICACY SCALE

慢性阻塞性肺疾病自我效能量表

Read each numbered item below, and determine how confident you are that you could manage breathing difficulty or avoid breathing difficulty in that situation. Use the following scale as a basis for your answer:

填表說明：閱讀以下列舉的項目，並決定在這些情況下，您有多大的信心去應付或避免呼吸困難。請按如下尺度作答：

- | | |
|-------------|----------------------------|
| (1) = 非常有信心 | (a) = Very confident |
| (2) = 相當有信心 | (b) = Pretty confident |
| (3) = 有少許信心 | (c) = Somewhat confident |
| (4) = 無信心 | (d) = Not very confident |
| (5) = 非常無信心 | (e) = Not at all confident |

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

1. 當我感到太疲勞時。(When I become too tired.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

2. 當四周的空氣潮濕時。(When there is humidity in the air.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

3. 當我從溫暖的環境，進入寒冷的環境時。(When I go into cold weather from a warm place.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

4. 當我覺得情緒緊張或不開心時。(When I experience emotional stress or become upset.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

5. 當我上樓梯上得太快時。(When I go up stairs too fast.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

6. 當我否認我有呼吸困難時。(When I try to deny that I have respiratory difficulties.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

7. 當我周圍都有香煙的煙霧時。(When I am around cigarette smoke.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

8. 當我生氣時。(When I become angry.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

9. 當我運動或付出很大的體力時。(When I exercise or physically exert myself.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

10. 當我為我的生活而感到苦惱時。(When I feel distressed about my life.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

11. 當我感到性交力不從心時。(When I feel sexually inadequate or impotent.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

12. 當我感到無奈時。(When I am frustrated.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

13. 當我舉起重的物件時。(When I lift heavy objects.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

14. 當我叫喊或大聲說話時。(When I yell or scream.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

15. 當我躺床上休息時。(When I am lying in bed.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

16. 在非常炎熱或寒冷的天氣裡。(During very hot or very cold weather.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

17. 當我笑得很多時。(When I laugh a lot.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any

18. 當我沒有跟隨合當的日常飲食時。(When I do not follow a proper diet.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

19. 當我感到無助時。(When I feel helpless.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

20. 當我受到感染(如：喉嚨、鼻竇感染，傷風感冒等)時。 When I get an infection (throat, sinus, clods, the flu, etc).

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

21. 當我感到疏離所有的人或所有事時。(When I feel detached from everyone and everything.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

22. 當我覺得焦慮時。(When I experience anxiety.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

23. 當我在污染的環境中。(When I am around pollution.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

24. 當我吃得過多時。(When I overeat.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

25. 當我感到沮喪或意志消沉時。(When I feel down or depressed.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

26. 當我在空氣不流通的房間運動時。(When exercise in room that is poorly ventilated.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

27. 當我害怕時。(When I am afraid.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

28. 當我經歷到失去重要的物件或摯愛時。(When I experience the loss of a valued object or a loved one.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

29. 當我家中有問題時。(When there are problems in the home.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

30. 當我感到沒有能力（做事）時。(When I feel incompetent.)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

31. 當我匆忙時。(When I hurry or rush around)

Are the words used in the translated version of the P-CSES presented fluently and accurately as in the original version?

1 Strongly disagree 2 Disagree 3 Agree 4 Strongly agree

Please justify your rating and giving relevant suggestion or modification, if any.

—The End of Questionnaire 1—

**** Thanks for Your Comments!****

—Please Go on to Questionnaire 2—

Questionnaire for the evaluation of the content validity of the Putonghua version of the COPD SELF-EFFICACY SCALE

A. CONTENT RELEVACY

How the content of each of the following 31 items is relevant to the assessment of its related domain (negative affect, intense emotional arousal, physical exertion, weather/environmental, and behavioural risk factors respectively) for people with COPD? Please justify your rating and give suggestions:

Domain One Negative Affect

Item	Poor	Fair	Good	Excellent	Suggestions
6. 當我否認我有呼吸困難時。	1	2	3	4	
11. 當我感到性交力不從心時。	1	2	3	4	
12. 當我感到無奈時。	1	2	3	4	
15. 當我躺床上休息時。	1	2	3	4	
19. 當我感到無助時。	1	2	3	4	
21. 當我對人或事有疏離感時。	1	2	3	4	
22. 當我覺得焦慮時。	1	2	3	4	
25. 當我感到沮喪或意志消沉時。	1	2	3	4	
28. 當我經歷到失去重要的物件或摯愛時。	1	2	3	4	
29. 當我家中有問題時。	1	2	3	4	
30. 當我感到沒有能力（做事）時。	1	2	3	4	

Domain Two Intense Emotional Arousal

Item	Poor	Fair	Good	Excellent	Suggestions
1. 當我感到太疲勞時。	1	2	3	4	
4. 當我覺得情緒緊張或不開心時。	1	2	3	4	
8. 當我生氣時。	1	2	3	4	
14. 當我叫喊或大聲說話時。	1	2	3	4	
17. 當我笑得很多時。	1	2	3	4	
27. 當我害怕時。	1	2	3	4	

Domain Three Physical Exertion

Item	Poor	Fair	Good	Excellent	Suggestions
5. 當我上樓梯上得太快時。	1	2	3	4	
9. 當我運動或付出很大的體力時。	1	2	3	4	
13. 當我舉起重物件時。	1	2	3	4	
26. 當我在空氣不流通的房間運動時。	1	2	3	4	
31. 當我匆忙時。	1	2	3	4	

Domain Four Weather/environmental

Item	Poor	Fair	Good	Excellent	Suggestions
2. 當四周的空氣潮濕時。	1	2	3	4	
3. 當我從溫暖的環境，進入寒冷的環境時。	1	2	3	4	
7. 當我周圍都有香煙的煙霧時。	1	2	3	4	
16. 在非常炎熱或寒冷的天氣裡。	1	2	3	4	
20. 當我受到感染(如：喉嚨、鼻竇感染，傷風感冒等)時。	1	2	3	4	
23. 當我在污染的環境中。	1	2	3	4	

Domain Five Behavioural Risk Factors

Item	Poor	Fair	Good	Excellent	Suggestions
10. 當我為我的生活而感到苦惱時。	1	2	3	4	
18. 當我沒有跟隨恰當的日常飲食時。	1	2	3	4	
24. 當我吃得過多時。	1	2	3	4	

B. CONTENT REPRESENTATIVENESS

How well is the content of each of the following 31 items representing the domain of negative affect, intense emotional arousal, physical exertion, weather/environmental, and behavioural risk factors respectively, when assessing the people with COPD?

Please justify your rating and give suggestions:

Domain One Negative Affect

Item	Poor	Fair	Good	Excellent	Suggestions
6. 當我否認我有呼吸困難時。	1	2	3	4	
11. 當我感到性交力不從心時。	1	2	3	4	
12. 當我感到無奈時。	1	2	3	4	
15. 當我躺床上休息時。	1	2	3	4	
19. 當我感到無助時。	1	2	3	4	
21. 當我對人或事有疏離感時。	1	2	3	4	
22. 當我覺得焦慮時。	1	2	3	4	
25. 當我感到沮喪或意志消沉時。	1	2	3	4	
28. 當我經歷到失去重要的物件或摯愛時。	1	2	3	4	
29. 當我家中有問題時。	1	2	3	4	
30. 當我感到沒有能力（做事）時。	1	2	3	4	

Domain Two Intense Emotional Arousal

Item	Poor	Fair	Good	Excellent	Suggestions
1. 當我感到太疲勞時。	1	2	3	4	
4. 當我覺得情緒緊張或不開心時。	1	2	3	4	
8. 當我生氣時。	1	2	3	4	
14. 當我叫喊或大聲說話時。	1	2	3	4	
17. 當我笑得很多時。	1	2	3	4	
27. 當我害怕時。	1	2	3	4	

Domain Three Physical Exertion

Item	Poor	Fair	Good	Excellent	Suggestions
5. 當我上樓梯上得太快時。	1	2	3	4	
9. 當我運動或付出很大的體力時。	1	2	3	4	
13. 當我舉起重物件時。	1	2	3	4	
26. 當我在空氣不流通的房間運動時。	1	2	3	4	
31. 當我匆忙時。	1	2	3	4	

Domain Four Weather/environmental

Item	Poor	Fair	Good	Excellent	Suggestions
2. 當四周的空氣潮濕時。	1	2	3	4	
3. 當我從溫暖的環境，進入寒冷的環境時。	1	2	3	4	
7. 當我周圍都有香煙的煙霧時。	1	2	3	4	
16. 在非常炎熱或寒冷的天氣裡。	1	2	3	4	
20. 當我受到感染(如：喉嚨、鼻竇感染，傷風感冒等)時。	1	2	3	4	
23. 當我在污染的環境中。	1	2	3	4	

Domain Five Behavioural Risk Factors

Item	Poor	Fair	Good	Excellent	Suggestions
10. 當我為我的生活而感到苦惱時。	1	2	3	4	
18. 當我沒有跟隨恰當的日常飲食時。	1	2	3	4	
24. 當我吃得過多時。	1	2	3	4	

—The End—

**** Thanks for Your Comments!****

Questionnaire for Expert Panel 1 Review – SOLQ

Evaluation Questionnaire on Language Equivalence and Cultural Relevance of the Chinese Version Seattle Obstructive Lung Disease Questionnaire (SOLQ)

(Administered by Expert Panel 1)

Name of the Expert Panel Member: _____

Work Setting: _____

Year of Working Experience in COPD (Medicine/Nursing/Research/Rehabilitation)

Field: _____ Date of Review: _____

Information and Instructions to all panel members

The purpose of this study is to establish the psychometric evidence for the translated Chinese version of the SOLDQ before the application of this Chinese version to people with Chronic Obstructive Pulmonary Disease in Guangzhou China.

SOLDQ is a questionnaire to monitor health-related quality of life in patients with COPD. As SOLDQ is newly introduced from US to China, therefore, it is necessary to translate SOLDQ into Chinese version and ensure the validation before actually using it in China setting.

As panel members, you are invited to participate in this validation processes to evaluate the language equivalence and cultural relevance of the translated version of the SOLQ. A questionnaire is designed to guide you through the evaluation. Further instruction is as following:

- Please read the original version and the Chinese version of the SOLQ before filling in this questionnaire.
- This questionnaire consists of two parts: Part one for language equivalence evaluation and Part two for cultural relevance evaluation of the translated version of the SOLQ. A four-point Likert scale is used. Please circle the number that you think is the most appropriate to your evaluation.
- Please also provide your comments, justifications or suggestions on the remarks column; especially when you have rated “2” disagree / irrelevant, or “1” strongly disagree / very irrelevant.
- Please be reminded to work independently.
- If you have any quires on the reviewing process, please do not hesitate to ask for investigator for clarification.

Part One: Evaluation of Language Equivalence

Are the words used in the translated version of the SOLDQ presented fluently and accurately as in the original version? Please justify your rating and giving relevant suggestion or modification on the remarks column, if any.

	Strongly disagree	Disagree	Agree	Strongly agree														
1. Seattle Obstructive Lung Disease Questionnaire 西雅圖阻塞性肺部疾病調查問卷 (SOLDQ)	1	2	3	4														
2. During the <u>past 4 weeks</u> , how often have your lung problems caused you to feel... <i>(fill in one oval on each line.)</i> <u>過去 4 周內</u> ，由於肺部問題使您感到不適的頻率..... (把每一行中的一個圓圈填滿)	1	2	3	4														
<table><tr><th>Never</th><th>Almost Never</th><th>A Little of the Time</th><th>Some of the Time</th><th>A good bit of the time</th><th>Most of the Time</th><th>All of the Time</th></tr><tr><td>從不</td><td>幾乎 不</td><td>少數 時間</td><td>部分 時間</td><td>比較多 時間</td><td>大部分 時間</td><td>所有 時間</td></tr></table>	Never	Almost Never	A Little of the Time	Some of the Time	A good bit of the time	Most of the Time	All of the Time	從不	幾乎 不	少數 時間	部分 時間	比較多 時間	大部分 時間	所有 時間	1	2	3	4
Never	Almost Never	A Little of the Time	Some of the Time	A good bit of the time	Most of the Time	All of the Time												
從不	幾乎 不	少數 時間	部分 時間	比較多 時間	大部分 時間	所有 時間												
4. Low in energy or tired 無精力或疲倦	1	2	3	4														
5. Frightened when you had difficulty breathing 呼吸困難時感到驚恐	1	2	3	4														
6. Embarrassed by your coughing or heavy breathing 咳嗽或沉重的呼吸聲令您感到尷尬	1	2	3	4														
7. You could not enjoy life 不能享受生活	1	2	3	4														

Remarks (Please specify for which item):

			Strongly disagree	Disagree	Agree	Strongly agree
8. The following items are about activities you might do during a typical day. Does <u>your lung disease now limit you</u> in these activities? If so, how much? 以下的項目是您日常可能進行的活動。您的肺部問題有否限制您進行這些活動？如果有的話，程度如何？			1	2	3	4

						Strongly disagree	Disagree	Agree	Strongly agree
Activities	Extremely Limited	Quite a Bit Limited	Moderately Limited	Slightly Limited	Not at All Limited	1	2	3	4
活動	極度限制	相當限制	中度限制	輕度限制	完全不限制	1	2	3	4
9. Vigorous activities , such as running, participating in strenuous sports (e.g., swimming, jogging, tennis) 重體力活動如跑步，參加劇烈的運動(如游泳、慢跑、打網球)						1	2	3	4
10. Lifting or moving heavy objects (e.g. furniture, children) 提舉或搬移重物（如傢俱、小孩）						1	2	3	4
11. Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling or playing golf 中等強度活動，如移動桌子、推動吸塵器、打保齡球或高爾夫球						1	2	3	4
12. Climbing <u>several</u> flights of stairs 上幾層樓梯						1	2	3	4
13. Lifting or carrying groceries 提或攜帶日雜用品						1	2	3	4
14. Climbing a hill or one flight of stairs 上坡或上一層樓梯						1	2	3	4
15. Bending, kneeling or stooping 俯身、跪下、或彎腰						1	2	3	4
16. Walking more than a mile 步行超過一英里						1	2	3	4
17. Walking several blocks 步行幾條馬路						1	2	3	4
18. Walking one block 步行一條馬路						1	2	3	4
19. Bathing or dressing yourself 自己洗澡或穿衣						1	2	3	4
20. Getting in or out of bed 上床或下床						1	2	3	4

Remarks (Please specify for which item):

					Strongly disagree	Disagree	Agree	Strongly agree
21. During the <u>past 4 weeks</u> , how <u>short of breath</u> were you while doing your...					1	2	3	4
<u>過去 4 周</u> ，當您進行以下活動時感到氣促的程度如何								
Not at All	Mildly	Somewhat	Moderately	Severely	1	2	3	4
完全無	輕度	一些	中度	重度				
22. Normal daily activities					1	2	3	4
日常生活活動								
23. Most strenuous activities					1	2	3	4
大多數劇烈的活動								
24. During the <u>past 4 weeks</u> , did your shortness of breath <u>limit you</u> while doing your...					1	2	3	4
<u>過去 4 周內</u> ，您的氣促是否限制您進行活動.....								
Not at All	Mildly	Moderately	Severely	I Couldn't Do Activities at All	1	2	3	4
完全無	輕度	中度	重度	我根本無法進行活動				
25. Normal daily activities					1	2	3	4
日常生活活動								
26. Most strenuous activities					1	2	3	4
大多數劇烈的活動								

Remarks (Please specify for which item):

							Strongly disagree	Disagree	Agree	Strongly agree
27. During the <u>past 4 weeks</u> , how often did you feel...							1	2	3	4
<u>過去 4 周內</u> ，您產生以下感受的頻率.....										
Never	Almost Never	A Little of the Time	Some of the Time	A Good Bit of Time	Most of the Time	All of the Time	1	2	3	4
從不	幾乎不	少數時間	部分時間	比較多時間	大部分時間	所有時間				
28. Short of breath							1	2	3	4
氣促										
29. Afraid to exercise							1	2	3	4
害怕活動										

	Strongly disagree	Disagree	Agree	Strongly agree
30. Afraid getting angry would worsen your breathing 害怕生氣會影響呼吸	1	2	3	4
31. Worried you wouldn't be able to breathe at all 擔心您根本不能呼吸	1	2	3	4
32. Your breathing problems were out of control 您難以控制呼吸問題	1	2	3	4
33. You were a burden on your family and friends 您是家庭和朋友的負擔	1	2	3	4

Remarks (Please specify for which item):

	Strongly disagree	Disagree	Agree	Strongly agree
34. How would you rate the following? 您如何評價下列問題?	1	2	3	4
Poor	1	2	3	4
Fair				
Good	1	2	3	4
Very Good				
Excellent	1	2	3	4
很差				
一般	1	2	3	4
好				
很好	1	2	3	4
極好				
35. The explanation given by your doctor or health care provider about your breathing problems 您的醫生或醫護人員對您呼吸問題的解釋	1	2	3	4
36. The current treatment for your breathing problems overall 目前針對您呼吸問題的整體治療措施	1	2	3	4
37. During the <u>past 4 weeks</u> , how often did you feel confident dealing with your breathing problems? 過去 4 周內，您對處理您的呼吸問題感到有信心的頻率?	1	2	3	4
All of the time	1	2	3	4
Most of the time				
A good bit of the time	1	2	3	4
Some of the time				
A Little of the Time	1	2	3	4
Almost never				
Never	1	2	3	4
所有 時間				
大部分 時間	1	2	3	4
比較多 時間				
部分 時間	1	2	3	4
少數 時間				
幾乎 不	1	2	3	4
從不				

Remarks (Please specify for which item):

Part Two: Evaluation of Cultural Relevancy

Are the content of the translated version of the SOLDQ relevant to the Chinese culture when assessing the COPD patient's quality of life? Please justify your rating for each item and giving relevant suggestion or modification on the remarks column, if any.

過去4周內，由於肺部問題使您感到下列不適的頻率.....					
	Very irrelevant	Irrelevant	Relevant	Very relevant	Remarks
1.無精力或疲倦	1	2	3	4	
2.呼吸困難時感到驚恐	1	2	3	4	
3.咳嗽或沉重的呼吸聲令您感到尷尬	1	2	3	4	
4.不能享受生活	1	2	3	4	
以下的項目是您日常可能進行的活動。您的肺部問題有否限制您進行這些活動？如果有的話，程度如何？					
5.重體力活動如跑步，參加劇烈的運動（如游泳、慢跑、打網球）	1	2	3	4	
6.提舉或搬移重物（如傢俱、小孩）	1	2	3	4	
7.中等強度活動，如移動桌子、推動吸塵器、打保齡球或高爾夫球	1	2	3	4	
8.上幾層樓梯	1	2	3	4	
9.提或攜帶日雜用品	1	2	3	4	
10.上坡或上一層樓梯	1	2	3	4	
11.彎腰、跪下、或俯身	1	2	3	4	
12.步行超過一英里	1	2	3	4	
13.步行幾條馬路	1	2	3	4	
14.步行一條馬路	1	2	3	4	

	Very irrelevant	Irrelevant	Relevant	Very relevant	Remarks
15.自己洗澡或穿衣	1	2	3	4	
16.上床或下床	1	2	3	4	
過去4周，當您進行以下活動時感到氣促的程度如何？					
17.日常生活活動	1	2	3	4	
18.大多數劇烈的活動	1	2	3	4	
過去4周內，您的氣促是否限制您進行活動.....					
19.日常生活活動	1	2	3	4	
20.大多數劇烈的活動	1	2	3	4	
過去4周內，您產生以下感受的頻率.....					
21.氣促	1	2	3	4	
22.害怕活動	1	2	3	4	
23.害怕生氣會影響呼吸	1	2	3	4	
24.擔心您根本不能呼吸	1	2	3	4	
25.您難以控制呼吸問題	1	2	3	4	
26.您是家庭和朋友的負擔	1	2	3	4	
您如何評價下列問題？					
27.您的醫生或醫護人員對您呼吸問題的解釋	1	2	3	4	
28.目前針對您呼吸問題的整體治療措施	1	2	3	4	
29.過去4周內，您對處理您的呼吸問題感到有信心的頻率？	1	2	3	4	

**** Thanks for Your Comments! ****

Questionnaire for Expert Panel 2 Review – SOLQ

Evaluation Questionnaire on Content Validity of the Chinese Version Seattle Obstructive Lung Disease Questionnaire (SOLQ)

(Administered by Expert Panel 2)

Name: _____

Work Setting: _____

Years of Working Experience in COPD Field: _____ Years

Date of Review:

Information and Instructions to all panel members

The purpose of this study is to establish the psychometric evidence for the translated Chinese version of the SOLQ before the application of this Chinese version to people with Chronic Obstructive Pulmonary Disease in Guangzhou China.

SOLQ is a questionnaire to monitor health-related quality of life in patients with COPD. As SOLQ is newly introduced from US to China, therefore, it is necessary to translate SOLQ into Chinese version and ensure the validation before actually using it in China setting.

As panel members, you are invited to participate in this validation processes to evaluate the content relevance and representativeness of the translated version of the SOLDQ. A questionnaire is designed to guide you through the evaluation. Further instruction is as following:

- A four-point Likert scale is used. Please circle or highlight the number that you think is the most appropriate to your evaluation.
- Please also provide your comments, justifications or suggestions on the remarks column, especially when you have rated “2” irrelevant / fair, or “1” very irrelevant / poor.
- Please be reminded to work independently.
- If you have any quires on the reviewing process, please do not hesitate to ask for investigator for clarification.

Evaluation of Content Relevancy and Content Representativeness

SOLQ consists of 29 items measuring four health dimensions: physical function, emotional function, coping skills, and treatment satisfaction. The physical function scale assesses the degree of dyspnea and the extent of physical limitation. The emotional function scale measures the impact of the disease on patients' psychological well-being. The coping skills scale measures self-efficacy. The treatment satisfaction, measures how satisfied patients are with the care they have received specifically for their pulmonary disease.

Domain One Physical Function

A. CONTENT RELEVANCY

Please indicate how well each of the following 18 items is relevant to the domain “physical function” and give your comments on the remarks column, if any:

Item	Very irrelevant	Irrelevant	Relevant	Very relevant
1. 過去 4 周內，有多少時間您因肺部問題而感到.....				
1A. 乏力或疲倦	1	2	3	4
2. 以下的項目是您日常可能進行的活動。您目前的肺部疾病有否限制您進行這些活動？ 如果有的話，程度如何？				
2 A. 劇烈活動如跑步，參加費力的運動（如游泳、慢跑、打網球）	1	2	3	4
2 B. 提舉或搬動重物（如傢俱、小孩）	1	2	3	4
2 C. 中等強度活動，如移動桌子、推動吸塵器、做操或打太極拳	1	2	3	4
2 D. 上幾層樓梯	1	2	3	4
2 E. 提舉或攜帶雜貨用品	1	2	3	4
2 F. 上坡或上一層樓梯	1	2	3	4
2 G. 彎腰、跪下、或俯身	1	2	3	4
2 H. 步行超過1公里	1	2	3	4
2 I. 步行幾個街區（500米）	1	2	3	4
2 J. 步行一個街區（100米）	1	2	3	4
2 K. 自己洗澡或穿衣	1	2	3	4
2 L. 上床或下床	1	2	3	4
3. 過去 4 周，當進行以下活動時，您感到氣促的程度如何？				
3 A. 日常生活活動	1	2	3	4
3 B. 大多數費力的活動	1	2	3	4
4. 過去 4 周內，氣促有否限制您進行以下活動？				
4 A. 日常生活活動	1	2	3	4
4 B. 大多數費力的活動	1	2	3	4
5. 過去 4 周內，有多少時間您有以下的感受？				

5 A. 氣促	1	2	3	4
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Remarks (Please specify for which item):

B. CONTENT REPRESENTATIVENESS

Please indicate how well these items under this domain adequately represent the assessment of physical function, when assessing COPD patient's quality of life and give your comments on the remarks column, if any:

1	Poor	2	Fair	3	Good	4	Excellent
---	------	---	------	---	------	---	-----------

Remarks:

Domain Two Emotional Function

A. CONTENT RELEVANCY

Please indicate how far each of the following 5 items is relevant to the domain "emotional function" and give your comments on the remarks column, if any:

Item	Very irrelevant	Irrelevant	Relevant	Very relevant
1. 過去 4 周內，有多少時間您因肺部問題而感到.....				
1 C. 咳嗽或費力的呼吸令您感到尷尬	1	2	3	4
1 D. 您不能享受生活的樂趣	1	2	3	4
5. 過去 4 周內，有多少時間您有以下的感受？				
5 B. 害怕運動	1	2	3	4
5 C. 害怕生氣會影響呼吸	1	2	3	4
5 F. 您是家庭和朋友的負擔	1	2	3	4

Remarks (Please specify for which item):

B. CONTENT REPRESENTATIVENESS

Please indicate how well these items under this domain adequately represent the assessment of emotional function, when assessing COPD patient's quality of life and give your comments on the remarks column, if any:

1	Poor	2	Fair	3	Good	4	Excellent
---	------	---	------	---	------	---	-----------

Remarks:

Domain Three Coping Skills

A. CONTENT RELEVANCY

Please indicate how far each of the following 4 items is relevant to the domain "coping skills" and give your comments on the remarks column, if any:

Item	Very irrelevant	Irrelevant	Relevant	Very relevant
1. 過去 4 周內，有多少時間您因肺部問題而感到.....				
1B. 呼吸困難時感到驚恐	1	2	3	4
5. 過去 4 周內，有多少時間您有以下的感受？				
5 D. 擔心您完全無法呼吸	1	2	3	4
5 E. 難以控制您的呼吸問題	1	2	3	4
7. 過去 4 周內，有多少時間您感到有信心去應對您的呼吸問題？				
所有時間 大部分時間 比較多時間 部分時間 少數時間 極少數時間 從不	1	2	3	4

Remarks (Please specify for which item):

B. CONTENT REPRESENTATIVENESS

Please indicate how well these items under this domain adequately represent the assessment of coping skills, when assessing COPD patient's quality of life and give your comments on the remarks column, if any:

1	Poor	2	Fair	3	Good	4	Excellent
---	------	---	------	---	------	---	-----------

Remarks:

Domain Four Treatment Satisfaction

A. CONTENT RELEVANCY

Please indicate how well each of the following 2 items is relevant to the domain “treatment satisfaction” and give your comments on the remarks column, if any:

Item	Very irrelevant	Irrelevant	Relevant	Very relevant
6. 您如何評價下列情況？				
6 A. 醫生或醫護人員針對您的呼吸問題給予的解釋	1	2	3	4
6 B. 目前針對您呼吸問題的整體治療	1	2	3	4

Remarks (Please specify for which item):

B. CONTENT REPRESENTATIVENESS

Please indicate how well these items under this domain adequately represent the assessment of treatment satisfaction, when assessing COPD patient’s quality of life and give your comments on the remarks column, if any:

1	Poor	2	Fair	3	Good	4	Excellent
---	------	---	------	---	------	---	-----------

Remarks:

C. Please indicate how well these four domains as a whole adequately represent the assessment of health related quality of life for patient with COPD and give your comments on the remarks column, if any:

1	Poor	2	Fair	3	Good	4	Excellent
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Remarks:

**** Thanks for Your Comments! ****

The Chinese Version SF-36

健康狀況調查表 (SF-36)

說明：下面的問題是詢問您對自己健康狀況的看法、您的感覺如何及您進行日常生活的能力如何。如果您沒有把握如何回答問題，儘量作一個最好的答案，並在第 10 個問題之後的空白處寫上您的建議。

請打一個鉤

1. 總體來講，您的健康狀況是：	非常好	☐
	很好	☐
	好	☐
	一般	☐
	差	☐
2. 跟一年前相比，您覺得您現在的健康狀況是：	比一年前好多了	☐
	比一年前好一些	☐
	和一年前差不多	☐
	比一年前差一些	☐
	比一年前差多了	☐

健康和日常活動

3. 以下這些問題都與日常活動有關。您的健康狀況是否限制了這些活動？如果有限制，程度如何？

請打一個鉤

	有很多 限制	有一點 限制	根本沒 有限制
(1) 重體力活動（如跑步、舉重物、激烈運動等）	☐	☐	☐
(2) 適度活動（如移桌子、掃地、做操等）	☐	☐	☐
(3) 手提日雜用品（如買菜、購物等）	☐	☐	☐
(4) 上幾層樓梯	☐	☐	☐
(5) 上一層樓梯	☐	☐	☐
(6) 彎腰、曲膝、下蹲	☐	☐	☐
(7) 步行 1500 米左右的路程	☐	☐	☐
(8) 步行 800 米左右的路程	☐	☐	☐
(9) 步行約 100 米的路程	☐	☐	☐
(10) 自己洗澡、穿衣	☐	☐	☐

4. 在過去四個星期裏，您的工作和日常活動有沒有因為身體健康的原因而出現以下這些問題？

每個問題都回答有或沒有

	有	沒有
(1) 減少了工作或其他活動的 <u>時間</u>	☐	☐
(2) 本來想要做的事情只能完成一部分	☐	☐
(3) 想要做的工作或活動的 <u>種類</u> 受到限制	☐	☐
(4) 完成工作或其他活動有 <u>困難</u> （比如，需要額外的努力）	☐	☐

5. 在過去四個星期裏，您的工作和日常活動有沒有因為情緒（如感到消沉或憂慮）而出現以下問題？

每個問題都回答有或沒有

	有	沒有
(1) 減少了工作或其他活動的 <u>時間</u>	☐	☐
(2) 本來想要做的事情只能完成一部分	☐	☐
(3) 做工作或其他活動不如平時仔細	☐	☐

請打一個鉤

6. 在過去的四個星期裏，您的身體健康或情緒不好在多大程度上影響了您與家人、朋友、鄰居或集體的正常社交活動？	根本沒有影響	☐
	很少有影響	☐
	有中度影響	☐
	有較大影響	☐
	有極大影響	☐
7. 在過去四個星期裏，您有身體上的疼痛嗎？	根本沒有疼痛	☐
	有很輕微疼痛	☐
	有輕微疼痛	☐
	有中度疼痛	☐
	有嚴重疼痛	☐
	有很嚴重疼痛	☐
8. 在過去四個星期裏，身體上的疼痛影響您的正常工作嗎（包括上班工作和家務活動）？	根本沒有影響	☐
	有一點影響	☐
	有中度影響	☐
	有較大影響	☐
	有極大影響	☐

您的感覺

9. 以下這些問題有關過去一個月裏您的感覺如何以及您的情況如何。

（對每一條問題，請鉤出最接近您的感覺的那個答案）

請在每一行打一個鉤

	所有的 時間	大部分 時間	比較 多 時間	一部分 時間	小部分 時間	沒有 此 感覺
(1) 您覺得生活充實嗎？	☐	☐	☐	☐	☐	☐
(2) 您是一個精神緊張的人嗎？	☐	☐	☐	☐	☐	☐
(3) 您感到垂頭喪氣，什麼事都不能使您振作嗎？	☐	☐	☐	☐	☐	☐
(4) 您覺得平靜嗎？	☐	☐	☐	☐	☐	☐
(5) 您精力充沛嗎？	☐	☐	☐	☐	☐	☐
(6) 您的情緒低落嗎？	☐	☐	☐	☐	☐	☐
(7) 您覺得筋疲力盡嗎？	☐	☐	☐	☐	☐	☐
(8) 您是個快樂的人嗎？	☐	☐	☐	☐	☐	☐
(9) 您感覺疲勞嗎？	☐	☐	☐	☐	☐	☐
(10) 您的健康限制了您的社交活動（如走親訪友）嗎？	☐	☐	☐	☐	☐	☐

總的健康情況

10. 請對下面的每一句話，選出最符合您情況的答案

每一橫行只打一個鉤

	絕對 正確	大部分 正確	不能 肯定	大部分 錯誤	絕對 錯誤
(1) 我好像比別人容易生病	☐	☐	☐	☐	☐
(2) 我跟我認識的人一樣健康	☐	☐	☐	☐	☐
(3) 我認為我的健康狀況在變壞	☐	☐	☐	☐	☐
(4) 我的健康狀況非常好	☐	☐	☐	☐	☐

您的批評或建議：

**** 問卷完，謝謝您的合作！ ****

Questionnaire for Expert Panel Review – CTCPSQ

致慢性阻塞性肺疾病延續護理項目“病人滿意度調查問卷”

專家評定小組成員

各位尊敬的專家：

誠意地邀請閣下參與香港理工大學護理學院慢性阻塞性肺疾病延續護理項目的成效評估工具之一——“病人滿意度調查問卷”之專家小組的評定工作。本次專家問卷的評定目的是建立“病人滿意度調查問卷”的內容效度，使該問卷能應用於慢性阻塞性肺疾病延續護理項目的研究之中。

該“病人滿意度調查問卷”是本課題組自行設計的結構式問卷，共 14 個條目，用以評估 COPD 患者延續護理項目在健康照顧方面的成效。具體測量出院病人對所獲得的護理服務和健康教育，以及對出院後護理（控制組）或參與延續護理計劃（干預組）3 個方面的滿意程度。

煩請閣下根據問卷填寫指引，獨立完成如下的評定問卷的填寫。在問卷填寫過程如有任何疑問，請致電（852）27664520，或發送郵件到：hsslwong@
向香港理工大學護理學院研究生王少玲查詢。

衷心感謝您的鼎力支持！

香港理工大學護理學院

研究生：王少玲

二零零七年九月二十七日

慢性阻塞性肺疾病延續護理項目
“病人滿意度調查問卷——專家評定問卷”

專家姓名：_____

問卷填寫日期：2007 年____月____日

工作單位和部門：_____

職務：_____

呼吸科臨床護理☐/社區護理☐/護理教育☐/護理研究☐之工作經驗：_____年

問卷填寫指引

本問卷是用以收集各位專家小組成員對慢性阻塞性肺疾病延續護理項目的成效評估工具“病人滿意度調查問卷”之內容效度的評定意見。

請您選擇對如下各部分之特定內容的同意程度，並在選項數字上打一個“√”。如您選擇了“不同意”或“非常不同意”，請在“意見或建議”欄填寫您的意見和建議。

病人滿意度調查問卷

一．問卷說明的描述的恰當性

問卷填寫指引

本問卷是了解你對出院後獲得的護理或醫院和社區護理人員聯合提供之慢性阻塞性肺疾病延續護理服務的滿意程度。請仔細閱讀下列各項提問，然後，在所提供的選項中“√”出你的選擇。

非常不同意 ☐

不同意 ☐

同意 ☐

非常同意 ☐

意見或建議：

二．以下對各條目回答之選擇項的恰當性

非常滿意= 5 滿意= 4 沒有意見= 3 不滿意= 2 非常不滿意= 1

非常不同意 ☐

不同意 ☐

同意 ☐

非常同意 ☐

意見或建議：

三．各條目與所屬方面在內容上的相關性和代表性

	相關性				代表性			
	非常不同意	不同意	同意	非常同意	非常不同意	不同意	同意	非常同意
<u>對所獲得護理服務的滿意程度</u>								
你對如下各項滿意嗎？								
1. 護士提供之護理服務的及時性	1	2	3	4	1	2	3	4
2. 護士提供之護理服務在解決我的呼吸問題方面	1	2	3	4	1	2	3	4
3. 護士提供之護理服務的方便性	1	2	3	4	1	2	3	4
4. 護士與我之間的溝通	1	2	3	4	1	2	3	4
5. 護士的服務態度	1	2	3	4	1	2	3	4

意見或建議：

	相關性				代表性			
	非常不同意	不同意	同意	非常同意	非常不同意	不同意	同意	非常同意
對健康教育的滿意度								
你對護士所提供的如下方面健康教育或指導滿意嗎？								
6. 慢性阻塞性肺疾病的自我照顧常識（如：預防感染、消除疾病的危險因素等）	1	2	3	4	1	2	3	4
7. 康復訓練（如：帶氧運動、上肢運動、放鬆練習）	1	2	3	4	1	2	3	4
8. 藥物應用（如：氣霧劑的使用、服藥）	1	2	3	4	1	2	3	4
9. 有效的咳痰方法	1	2	3	4	1	2	3	4
10. 控制呼吸困難的方法	1	2	3	4	1	2	3	4
11. 急性症狀加重時的應對和求醫方法	1	2	3	4	1	2	3	4
12. 營養（飲食）指導	1	2	3	4	1	2	3	4
13. 家庭氧氣治療（適用者填寫）	1	2	3	4	1	2	3	4

意見或建議：

	相關性				代表性			
	非常不同意	不同意	同意	非常同意	非常不同意	不同意	同意	非常同意
對出院後護理或延續護理計劃的滿意度								
14. 總體來說，你對出院後的護理服務滿意嗎？	1	2	3	4	1	2	3	4

意見或建議：

四. 本問卷條目數量的恰當性

	條 目 數	非 常 不 同 意	不 同 意	同 意	非 常 同 意
本問卷的如下各組成部分之條目數量恰當					
1. 對所獲得護理服務的滿意程度	5	1	2	3	4
2. 對健康教育的滿意度	8	1	2	3	4
3. 對出院後護理或延續護理計劃的滿意度	1	1	2	3	4

意見或建議:

五. 問卷對慢性阻塞性肺疾病出院後護理病人滿意度的反應性

總體上，本問卷足以反映病人對出院後護理或慢性阻塞性肺疾病延續護理的滿意度:

非常不同意 ☐

不同意 ☐

同意 ☐

非常同意 ☐

意見或建議:

****問卷完，謝謝您的寶貴意見！****

Sociodemographic and Clinical Data Sheet

1. Sex: ☐ Male ☐ Female
2. Age: _____
3. Date of birth: _____
4. Education level: ☐ No-schooling ☐ Primary ☐ Junior high school
☐ Senior high school or vocational Training
☐ Higher diploma or above
5. Marital Status: ☐ Single ☐ Married ☐ Divorced ☐ Widowed
6. Employment status: ☐ Unemployed ☐ Retired
☐ Retired with illness ☐ Currently employed: _____
7. Average monthly family individual incomes:
☐ ≤¥430 ☐ ¥431-2000 ☐ ¥2001-3000 ☐ ≥¥3001
8. Source of medical expenditure: ☐ Self paid ☐ Social Medical Insurance
☐ Free ☐ Others: _____
9. Who is responsible for the daily: ☐ Self ☐ Spouse ☐ Maid
☐ Others: _____
10. History of COPD (years) : _____
11. Do you need the provision of care by others while you are ill? ☐ Yes ☐ No
12. Who will take care of you? ☐ None ☐ Family member ☐ Friend
☐ Main ☐ Others: _____
13. The care available to you is: ☐ At night only ☐ Occasionally
☐ All the time ☐ Others: _____
14. Are you a smoker? ☐ No
☐ Ever been, for _____ years, _____ Cigarettes/day
☐ Yes, for _____ years, _____ Cigarettes/day

個人資料及臨床情況記錄表

1. 您的性別：☐男☐女
2. 您的年齡：____歲
3. 您的出生日期：____年____月____日
4. 您的教育程度：☐沒有受過正式教育☐小學
☐初中☐高中或中專☐大專以上
5. 您的婚姻狀況：☐未婚☐已婚☐離異☐喪偶
6. 您的職業是：☐無業☐退休☐病退
☐在聘_____（請說明您的職業）
7. 您的家庭人均月收入：☐430元以下☐431-2000元
☐2001-3000元☐3001元以上
8. 您的醫療費來源：☐自費☐社會醫療保險金
☐公費醫療☐其他_____
9. 家庭的起居飲食由誰照顧：☐自己☐配偶☐保姆
☐其他_____
10. 您已經患有慢性阻塞性肺疾病：_____年
11. 您有病時，是否需要他人照顧：☐需要☐不需要
12. 有什麼人照顧您：☐無人☐親人_____
☐朋友☐保姆☐其他_____
13. 您所得到的照顧是：☐只在晚上☐間中的☐隨時的
☐其他_____
14. 您有無吸煙：☐無
☐曾有，吸煙_____年，每日_____支
☐有，已吸煙_____年，每日_____支

Seattle Obstructive Lung Disease Questionnaire*(Please fill in one circle on each line accordingly)*

1. During the <u>past 4 weeks</u> , how often have your lung problems caused you to feel...?							
	Never	Almost Never	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
(1) Low in energy or tired	☐	☐	☐	☐	☐	☐	☐
(2) Frightened when you had difficulty breathing	☐	☐	☐	☐	☐	☐	☐
(3) Embarrassed by your coughing or heavy breathing	☐	☐	☐	☐	☐	☐	☐
(4) You could not enjoy life	☐	☐	☐	☐	☐	☐	☐
2. The following items are about activities you might do during a typical day. Does <u>your lung disease now limit you</u> in these activities? If so, how much?							
Activities	Extremely Limited	Quite a Bit Limited	Moderately Limited	Slightly Limited	Not at all Limited		
(1) Vigorous activities , such as running, participating in strenuous sports (e.g., swimming, jogging, tennis)	☐	☐	☐	☐	☐		
(2) Lifting or moving heavy objects (e.g., furniture, children)	☐	☐	☐	☐	☐		
(3) Moderate activities , such as moving a table, pushing a vacuum cleaner, doing daily exercise or practicing Tai chi chuan	☐	☐	☐	☐	☐		
(4) Climbing <u>several</u> flights of stairs	☐	☐	☐	☐	☐		
(5) Lifting or carrying groceries (e.g. buying fresh produce, shopping)	☐	☐	☐	☐	☐		
(6) Climbing a hill or <u>one</u> flight of stairs	☐	☐	☐	☐	☐		
(7) Bending, kneeling or stooping	☐	☐	☐	☐	☐		

Please turn to next page to continue

Activities	Extremely Limited	Quite a Bit Limited	Moderately Limited	Slightly Limited	Not at all Limited
(8) Walking more than 1000 meters	☐	☐	☐	☐	☐
(9) Walking 500 meters	☐	☐	☐	☐	☐
(10) Walking 100 meters	☐	☐	☐	☐	☐
(11) Bathing or dressing yourself	☐	☐	☐	☐	☐
(12) Getting in or out of bed	☐	☐	☐	☐	☐
3. During the <u>past 4 weeks</u> , how <u>short of breath</u> were you while doing your...					
	Not at All	Mildly	Somewhat	Moderately	Severely
(1) Normal daily activities	☐	☐	☐	☐	☐
(2) Most strenuous activities	☐	☐	☐	☐	☐
4. During the <u>past 4 weeks</u> , did your shortness of breath <u>limit you</u> while doing your...					
	Not at All	Mildly	Moderately	Severely	I Couldn't Do Activities at All
(1) Normal daily activities	☐	☐	☐	☐	☐
(2) Normal daily activities	☐	☐	☐	☐	☐

Please turn to next page to continue

5. During the <u>past 4 weeks</u> , how often did you feel...							
	Never	Almost Never	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
(1) Short of breath	☐	☐	☐	☐	☐	☐	☐
(2) Afraid to exercise	☐	☐	☐	☐	☐	☐	☐
(3) Afraid getting angry would worsen your breathing	☐	☐	☐	☐	☐	☐	☐
(4) Worried you wouldn't be able to breathe at all	☐	☐	☐	☐	☐	☐	☐
(5) Your breathing problems were out of control	☐	☐	☐	☐	☐	☐	☐
(6) You were a burden on your family and friends	☐	☐	☐	☐	☐	☐	☐
6. How would you rate the following?							
	Poor	Fair	Good	Very good	Excellent		
(1) The explanation given by your doctor or health care provider about your breathing problems	☐	☐	☐	☐	☐		
(2) The current treatment for your breathing problems overall	☐	☐	☐	☐	☐		
7. During the <u>past 4 weeks</u> , how often did you feel confident dealing with your breathing problems?							
All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	Almost Never	Never	
☐	☐	☐	☐	☐	☐	☐	

** Thank you for your participation!**

西雅圖阻塞性肺部疾病問卷

（請在下列每一行選擇一相應的圓圈，並將其塗黑）

1. <u>過去4周內</u> ，有多少時間您因肺部問題而感到.....							
	從不	極少數時間	少數時間	部分時間	比較多時間	大部分時間	所有時間
(1) 乏力或疲倦	☐	☐	☐	☐	☐	☐	☐
(2) 當呼吸困難時感到驚恐	☐	☐	☐	☐	☐	☐	☐
(3) 因咳嗽或沉重呼吸聲而感到尷尬	☐	☐	☐	☐	☐	☐	☐
(4) 您不能享受生活的樂趣	☐	☐	☐	☐	☐	☐	☐
2. 以下的項目是您日常可能進行的活動。 <u>您目前的肺部疾病有否限制您進行這些活動？</u> 如果有的話，程度如何？							
<i>活動</i>	極大限制	較大限制	中度限制	輕微限制	根本沒有限制		
(1) 劇烈活動 ，如跑步；參加費力的運動，如游泳、慢跑、打網球	☐	☐	☐	☐	☐		
(2) 提舉或搬動重物，如傢具、小孩	☐	☐	☐	☐	☐		
(3) 中等強度活動 ，如移動桌子、推吸塵器、做操或打太極拳	☐	☐	☐	☐	☐		
(4) 上幾層樓梯	☐	☐	☐	☐	☐		
(5) 提舉或攜帶雜貨用品（如買菜、購物等）	☐	☐	☐	☐	☐		
(6) 上坡或上一層樓梯	☐	☐	☐	☐	☐		
(7) 彎腰、跪下或俯身	☐	☐	☐	☐	☐		

續下頁

活動	極大 限制	較大 限制	中度 限制	輕微 限制	根本 沒有限制
(8) 步行超過1000米	☐	☐	☐	☐	☐
(9) 步行500米	☐	☐	☐	☐	☐
(10) 步行100米	☐	☐	☐	☐	☐
(11) 自己洗澡或穿衣	☐	☐	☐	☐	☐
(12) 上床或下床	☐	☐	☐	☐	☐
3. <u>過去4周內</u> ，當進行以下活動時，您感到 <u>氣促</u> 的程度如何？					
	完全 無	輕微	有些	中度	極度
(1) 日常生活活動	☐	☐	☐	☐	☐
(2) 很費力的活動	☐	☐	☐	☐	☐
4. <u>過去4周內</u> ，氣促有否 <u>限制您</u> 進行以下活動？					
	完全 無	輕度	中度	極度	我根本無法進行活動
(1) 日常生活活動	☐	☐	☐	☐	☐
(2) 很費力的活動	☐	☐	☐	☐	☐

續下頁

5. 過去4周內，有多少時間您有以下的感受？							
	從不	極少數時間	少數時間	部分時間	比較多時間	大部分時間	所有時間
(1) 氣促	☐	☐	☐	☐	☐	☐	☐
(2) 害怕運動	☐	☐	☐	☐	☐	☐	☐
(3) 害怕生氣會影響呼吸	☐	☐	☐	☐	☐	☐	☐
(4) 擔心您完全無法呼吸	☐	☐	☐	☐	☐	☐	☐
(5) 難以控制您的呼吸問題	☐	☐	☐	☐	☐	☐	☐
(6) 您是家庭和朋友的負擔	☐	☐	☐	☐	☐	☐	☐
6. 您如何評價下列情況？							
	差	一般	好	很好	極好		
(1) 醫護人員針對您呼吸問題給予的解釋	☐	☐	☐	☐	☐		
(2) 目前針對您呼吸問題的治療總體來說	☐	☐	☐	☐	☐		
7. 過去4周內，有多少時間您感到有信心去應對您的呼吸問題？							
所有時間	大部分時間	比較多時間	部分時間	少數時間	極少數時間	從不	
☐	☐	☐	☐	☐	☐	☐	

**** 謝謝您的參與！ ****

The COPD Self-Efficacy Scale

Read each numbered item below, and determine how confident you are that you could manage breathing difficulty or avoid breathing difficulty in that situation. Use the following scale as a basis for your answer:

(1) = Very confident (2)= Pretty confident (3)= Somewhat confident
(4)= Not very confident (5) = Not at all confident

	Very confident	Pretty confident	Somewhat confident	Not very confident	Not at all confident
1. When I become too tired.	1	2	3	4	5
2. When there is humidity in the air.	1	2	3	4	5
3. When I go into cold weather from a warm place.	1	2	3	4	5
4. When I experience emotional stress or become upset.	1	2	3	4	5
5. When I go up stairs too fast.	1	2	3	4	5
6. When I try to deny that I have respiratory difficulties.	1	2	3	4	5
7. When I am around cigarette smoke.	1	2	3	4	5
8. When I become angry	1	2	3	4	5
9. When I exercise or physically exert myself.	1	2	3	4	5
10. When I feel distressed about my life.	1	2	3	4	5
11. When I feel sexually inadequate or impotent.	1	2	3	4	5
12. When I am frustrated.	1	2	3	4	5
13. When I lift heavy objects.	1	2	3	4	5

	Very confident	Pretty confident	Somewhat confident	Not very confident	Not at all confident
14. When I yell or scream.	1	2	3	4	5
15. When I lying in bed.	1	2	3	4	5
16. During very hot or very cold weather.	1	2	3	4	5
17. When I laugh a lot.	1	2	3	4	5
18. When I do not follow a proper diet.	1	2	3	4	5
19. When I feel helpless.	1	2	3	4	5
20. When I get an infection (throat, sinus, clods, the flu, etc).	1	2	3	4	5
21. When I feel detached from everyone and everything.	1	2	3	4	5
22. When I experience anxiety.	1	2	3	4	5
23. When I am around pollution.	1	2	3	4	5
24. When I overeat.	1	2	3	4	5
25. When I feel down or depressed.	1	2	3	4	5
26. When exercise in room that is poorly ventilated.	1	2	3	4	5
27. When I am afraid.	1	2	3	4	5
28. When I experience the loss of a valued object or a loved one.	1	2	3	4	5
29. When there are problems in the home.	1	2	3	4	5
30. When I feel incompetent.	1	2	3	4	5
31. When I hurry or rush around.	1	2	3	4	5

慢性阻塞性肺疾病自我效能量表

填表說明：閱讀以下列舉的專案，並決定在這些情況下，您有多大的信心去應付或避免呼吸困難。請按如下尺度作答：

- (1) = 非常有信心 (2) = 相當有信心 (3) = 有少許信心
(4) = 無信心 (5) = 非常無信心

請打一個鉤

	非常有信心 (1)	相當有信心 (2)	有少許信心 (3)	無信心 (4)	非常無信心 (5)
1. 當我感到太疲勞時。	1	2	3	4	5
2. 當四周的空氣潮濕時。	1	2	3	4	5
3. 當我從溫暖的環境，進入寒冷的環境時。	1	2	3	4	5
4. 當我覺得情緒緊張或不開心時。	1	2	3	4	5
5. 當我上樓梯上得太快時。	1	2	3	4	5
6. 當我否認我有呼吸困難時。	1	2	3	4	5
7. 當我周圍都有香煙的煙霧時。	1	2	3	4	5
8. 當我生氣時。	1	2	3	4	5
9. 當我運動或付出很大的體力時。	1	2	3	4	5
10. 當我為我的生活而感到苦惱時。	1	2	3	4	5
11. 當我感到性交不足或不舉時。	1	2	3	4	5
12. 當我感到無奈時。	1	2	3	4	5
13. 當我舉起重物件時。	1	2	3	4	5
14. 當我叫喊或大聲說話時。	1	2	3	4	5

請打一個鉤

	非常有信心 (1)	相當有信心 (2)	有少許信心 (3)	無信心 (4)	非常無信心 (5)
15. 當我躺床上休息時。	1	2	3	4	5
16. 在非常炎熱或寒冷的天氣裏。	1	2	3	4	5
17. 當我笑得很多時。	1	2	3	4	5
18. 當我沒有跟隨恰當的日常飲食時。	1	2	3	4	5
19. 當我感到無助時。	1	2	3	4	5
20. 當我受到感染(如：喉嚨、鼻竇感染，傷風感冒等)時。	1	2	3	4	5
21. 當我感到孤立而不想理會所有人或所有事時。	1	2	3	4	5
22. 當我覺得焦慮時。	1	2	3	4	5
23. 當我在污染的環境中。	1	2	3	4	5
24. 當我吃得過多時。	1	2	3	4	5
25. 當我感到沮喪或意志消沉時。	1	2	3	4	5
26. 當我在空氣不流通的房間運動時。	1	2	3	4	5
27. 當我害怕時。	1	2	3	4	5
28. 當我經歷到失去重要的物件或摯愛時。	1	2	3	4	5
29. 當我家中有問題時。	1	2	3	4	5
30. 當我感到不能勝任時。	1	2	3	4	5
31. 當我匆忙時。	1	2	3	4	5

**** 問卷完，謝謝您的合作！ ****

Appendix 6.4

COPD Transitional Care Patient Satisfaction Questionnaire

This questionnaire aims at understanding your degree of satisfaction with the post-discharge care or transitional care. Please read the items below carefully and indicate your degree of satisfaction by ticking the number accordingly.

Items	very satisfied	satisfied	neutral	dissatisfied	very dissatisfied
<u>Satisfaction with nursing service</u>					
My degree of satisfaction towards the following items is:					
1. Timeliness of the care provided by nurse(s)	5	4	3	2	1
2. Care provided by nurse(s) on solving one's breathing problem	5	4	3	2	1
3. Convenience of the care provided by nurse(s)	5	4	3	2	1
4. Communication between nurse(s) and oneself	5	4	3	2	1
5. service attitude of the nurse(s)	5	4	3	2	1
<u>Satisfaction with health education</u>					
My degree of satisfaction with the health education or guidance provided by nurses is:					
6. COPD self-management knowledge (e.g. infection prevention, elimination of disease risk factors etc.)	5	4	3	2	1
7. Rehabilitation training (e.g. aerobic exercise, upper-arm exercise, relaxation exercise)	5	4	3	2	1
8. Medication regimen (e.g. use of inhalation drug, oral medication)	5	4	3	2	1
9. Coughing technique	5	4	3	2	1
10. Breathing control technique	5	4	3	2	1
11. Coping with worsening symptom	5	4	3	2	1
12. Nutrition(diet) instruction	5	4	3	2	1
13. Home oxygen therapy (if applicable)	5	4	3	2	1
Overall satisfaction with the post-discharge care or transitional care					
14. Overall, I consider that nursing service is:	5	4	3	2	1

**** Thank you for your participation!****

慢性阻塞性肺疾病延續護理計畫病人滿意度問卷

本問卷是瞭解你對出院時或/和出院後所獲得的護理護理服務的滿意程度。請仔細閱讀下列各項提問, 然後, 在所提供的選項中「✓」出你的選擇。

項目內容	非常滿意	滿意	不適用	不滿意	非常不滿意
對所獲得護理服務的滿意程度					
我對下列各方面的滿意程度：					
1. 護士提供之護理服務的及時性	5	4	3	2	1
2. 護士提供之護理服務在解決我的呼吸問題方面	5	4	3	2	1
3. 護士提供之護理服務的方便性	5	4	3	2	1
4. 護士與我之間的溝通交流	5	4	3	2	1
5. 護士的服務態度	5	4	3	2	1
對健康教育的滿意度					
我對護士所提供的如下方面健康教育或指導的滿意程度：					
6. 慢性阻塞性肺疾病的自我照顧常識(如:預防感染、消除疾病的危險因素等)	5	4	3	2	1
7. 康復訓練(如:帶氧運動、上肢運動、放鬆練習)	5	4	3	2	1
8. 藥物應用 (如:氣霧劑的使用、服藥)	5	4	3	2	1
9. 有效的咳痰方法	5	4	3	2	1
10. 控制氣喘的方法	5	4	3	2	1
11. 急性症狀加重時的應對和求醫方法	5	4	3	2	1
12. 營養(飲食)指導	5	4	3	2	1
13. 家庭氧氣治療(適用者填寫)	5	4	3	2	1
對所獲得的護理服務的整體滿意度(出院時或/和出院後)					
14. 總體來說, 我對整體護理服務的滿意程度：	5	4	3	2	1

問卷完,謝謝您的參與!

Spirometry and Six-Minute Walk Test Report

*Name:	Gender: ☐ Male ☐ Female	Age:
T: °C	BP: / mmHg	Height: cm Weight: kg
Smoking Status: ☐ Non-smoker ☐ Smoker: cigarette/day (in past 4 weeks)		
Symptoms: ☐ Caught ☐ Sputum ☐ dyspnea		

* With two coppices, name only shown on the one kept by patients.

Pulmonary Function Test Results

Mild		Time: :		
	FEV ₁ /FVC	FEV ₁ % predicted	Bronchodilator Trail	Level of airflow limitation
PRE-BEST			☐ Negative ☐ Positive	☐ Mild ☐ Moderate ☐ Severe ☐ Very Severe
POST-BD				

6MWT Results

Date:			☐ O ₂ during walking: L/m		
	Time	P	SpO ₂ %	Dyspnea	Fatigue
Pre	:				
Post	:				
60m	120m	180m	240m	300m	
360m	420m	480m	540m	600m	

Walking duration:	Stopping Duration:	Distance walked in 6 minutes: M
		Distance predicted: %
		Minimal SpO₂: %
		☐ Continue ☐ interval
		Maximal distance: m/times

肺功能檢查和六分鐘步行試驗結果

編號： 年 月 日	性別： ☐ 男 ☐ 女	出生日期：
體溫： ℃ cm	血壓： / mmHg	身高： cm
體重： kg		
吸煙情況： ☐ 無吸煙 ☐ 吸煙：	支/日（過去四周內平均數）	
症狀現況： ☐ 咳嗽 ☐ 咯痰 ☐ 氣短/呼吸困難		

肺功能測試

測試日期：200 年 月 日	時 間：
FEV ₁ /FVC %	FEV ₁ %預計值
支氣管擴張試驗	氣流受限
吸藥前	☐ 輕 ☐ 中 ☐ 重 ☐ 極重
吸藥後	☐ 輕 ☐ 中 ☐ 重 ☐ 極重

六分鐘步行試驗

測試日期： 日	年 月	☐ 步行過程吸氧：	升/分
時間	P 次/分	SpO ₂ %	氣促程度
測試前	:		辛苦程度
測試後	:		
60m	120m	180m	240m
360m	420m	480m	540m
			300m
			600m

行走時間	暫停/停止時間	6 分鐘步行總距離： 米 佔正常預測的： % SpO ₂ 最低值： % ☐ 持續步行 ☐ 間歇步行 最長步行距離： 米/次
0 0 : 00	0 :	
0 :	0 :	
0 :	0 :	
0 :	0 :	
0 :	0 :	

Health service utilization and cost record sheet

醫療資源運用及醫療費用記錄單

(出院後第 6 或 12 周)

1. 醫療系統外的成本

1.1 在過去 6 或 12 周,你有否因你的呼吸問題而看過私家醫生?如果有,多少次?花費多少?

- ☐ 無;
- ☐ 有, 次數:____; 診金連藥費共花費: ¥_____

1.2 在過去 6 或 12 周,你有否自己買藥服用(包括中藥和西藥)來治療你的呼吸問題?如果有,多少次?花費多少?

- ☐ 無;
- ☐ 有, 次數:____; 共花藥費: ¥_____

2. 醫療系統內的資源運用

2.1 在過去 6 或 12 周,你有否因你的呼吸問題而看過急診?如果有,多少次?花費多少(含自費、記帳、醫保、報銷部分)?

- ☐ 無;
- ☐ 有, 次數:____; 費用共:¥_____

2.2 在過去 6 或 12 周,你有否因你的呼吸問題而看過門診(正常門診隨訪除外,含社區醫生)?如果有,多少次?花費多少(含自費、記帳、醫保、報銷部分)?

- ☐ 無;
- ☐ 有, 次數:____; 費用共:¥_____

2.3 在過去 6或12 周,你有否因COPD而再次住院?如果有,多少次?花費多少(含自費、記帳、醫保、報銷部分)?

- ☐ 無;
- ☐ 有, 次數:____; 天數:____; 費用共:¥_____

(出院後第 12 周)

3. 社區醫療資源利用

3.1 您出院後護士有否來探訪您? 無;

☐ 有: ☐ 社區護士 ☐ 醫院護士

3.3 今後,您願意接受出院後的護士探訪嗎?

- ☐ 非常願意
- ☐ 無所謂
- ☐ 不願意
- ☐ 非常不願意

3.4 您是否願意支付護士探訪的費用?

- ☐ 是,您心理能夠承受的護士訪視費用是:¥_____ (不包括各種治療費用)
- ☐ 否

****問卷完成。謝謝您的合作! ****

COPD transitional care training course Outlines

慢性阻塞性肺疾病延續護理培訓課程大綱

課程目標：通過本課程的教學,使學員具備慢性阻塞性肺疾病患者延續護理所需的態度、知識和技能;並具有參與實施慢性阻塞性肺疾病延續護理項目的專業才能。

課程學時：162（授課：42，含課堂練習及技能考核；理論考試/能力評價：4；自學/課後練習：32；臨床、社區實習：40（含綜合技能考核）；香港參觀交流：44）

培訓時間：2008年9月3日——2008年10月8日

培訓地點：廣州醫學院第一附屬醫院,香港理工大學護理學院

主辦單位：香港理工大學護理學院 協辦單位：廣州醫學院第一附屬醫院

學員：參與慢性阻塞性肺疾病患者出院後延續性護理成效研究項目的護士

培訓人數：正式學員:4, 旁聽學員:6

入讀條件：

1. 大專以上學歷；
2. 具有5年以上呼吸內科臨床護理經驗；
3. 對護理慢性阻塞性肺疾病患者有抱負；
4. 有興趣並自願參與是項研究。

培訓目標：學員在完成課程後,能夠表現出COPD患者延續護理的專業才能,包括：

1. 評估護理需要能力
 - 1) 採用恰當的評估工具(表格、量表、儀器)和檢查方法收集資料和資料

- 2) 正確地獨立完成患者的身體健康情況評估、心理和社會評估、居家環境評估和健康行為評估
 - 3) 全面評估患者的疾病自我管理能力和
 - 4) 準確地評估患者的居家康復訓練準備狀態 準確地評估患者及其照顧者的健康教育需要
 - 5) 依據指引,持續性地評估患者及照顧者的護理需要
 - 6) 準確地評估患者的護理/醫療轉介需要
 - 7) 系統並正確地記錄評估資料
2. 計劃護理能力
- 1) 分析評估所得資料,確定患者及其照顧者的健康和康復需要
 - 2) 依據指引評估結果,制定居家康復護理幹預計劃
 - 3) 與患者共同協商擬定具體的行動目標和方案
 - 4) 配合患者出院後治療方案,計劃護理幹預措施
 - 5) 合理安排出院護理轉介/出院後隨訪
 - 6) 根據實際情況的變化/護理評價結果修改護理計劃
3. 實施護理能力
- 1) 健康教育、指導和勸導能力
 - 給予恰當的個體化健康教育
 - 清楚解釋疾病的特徵、預後、生理限制和其自身參與疾病管理的重要作用
 - 勸導患者建立健康生活方式(如:堅持鍛煉、均衡飲食、戒煙)
 - 指導患者正確地執行居家肺康復訓練(步行訓練、呼吸訓練、身體活動的呼吸調節)
 - 指導患者執行疾病自我管理(避免感染、藥物治療、有效咳嗽排痰、氣喘的控制、身心鬆弛、家庭氧療、監測和應對急性發作)
 - 2) 治療和處置能力
 - 依指引執行出院前護理計劃和出院後隨訪計劃

- 運用綜合的方法使患者獲得疾病自我管理的信心和能力
- 通過臨床護理/家庭訪視和電話隨訪, 及時發現患者病情變化
- 判斷患者在家居康復訓練和疾病自我管理上遇到的問題並提供及時的說明(如即時指導、心理支援、安排跟進)

3) 個案管理能力

- 應用綜合知識和循證依據指導實踐
- 向所負責的個案提供身心社靈的整合護理
- 洞悉患者在疾病自我管理上的信念和價值觀
- 與服務物件進行有效的溝通
- 與臨床護士/社區護士進行有效的溝通
- 與多專業醫療團隊的成員達成有效的溝通和協調
- 充分且合理地運用人、財、物和社區資源
- 協助患者尋求相應的說明和支援
- 準確地判斷患者的護理和醫療轉介需要並協調轉介

4) 監測能力

- 正確地應用體查方法及輔助儀器測量生理變化
- 持續監測患者居家肺康復訓練計劃的執行情況
- 持續監測患者疾病自我管理的實施情況
- 持續監測急性發作的症狀和體征

4. 評價護理成效能力

- 1) 明確並採用恰當的成效評價指標
- 2) 依據指引, 持續收集主觀的和客觀的評價資料和資料
- 3) 及時、準確記錄干預過程及其效果
- 4) 與患者及其照顧者以及多專業醫療團隊的成員討論評價結果

評 估: 由以下項目組成: 100%

1. 技能考核:30%;
2. 理論考試:30%;

3. 護理個案實踐報告:40%。

獲得的資格：凡完成課程並考核合格者，將獲得香港理工大學護理學院的課程結業證書(正式學員)或繼續教育證書(旁聽學員)。

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2. 馮正儀(2002)・社區護理・上海:復旦大學出版社。
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4. Global Initiative for Chronic Obstructive Lung Disease (2006). *Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (updated 2006)*. Retrieved from: <http://www.goldcopd.org/>.
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教學計劃

上課時間	學習目標	教學內容	教學活動	教學時數
03-09-08 08:30-10:30 14:30-15:00		課前評估	問卷 考試	2
		開班儀式 1. 主辦單位項目負責人講話 2. 協辦單位負責人講話 3. 課程引介		
15:00-17:00 (星期三)	1. 說出延續護理的定義及在整體醫療服務中的價值; 2. 描述延續護理的特徵; 3. 描述如何為延續護理建立循證的依據; 4. 舉例說明護理計量; 5. 描述延續護理的成效指標。	延續護理的發展與實踐	討論	2
04-09-08 14:30-17:30	1. 說出護理研究在 COPD 延續護理中的重要意義; 2. 說出 COPD 延續護理研究項目的目的; 3. 描述 COPD 延續護理模式的特徵; 4. 敘述 COPD 延續護理實驗方案的內容; 5. 說出護理研究的倫理原則; 6. 表現出以嚴謹的科學態度參與 COPD 延續護理項目的實施。	COPD 延續護理的應用研究	講授 討論	4
18:30-21:30 (星期四)	1. 說出 COPD 的定義和分級; 2. 簡述 COPD 的臨床表現和體征; 3. 描述疾病的危險因素; 4. 說出 COPD 的治療原則; 5. 說出家居肺康復治療護理的目的; 6. 描述家居肺康復治療護理的項目; 7. 解釋疾病自我管理的重要性; 8. 描述 COPD 自我管理的內容;	慢性阻塞性肺疾病基本醫學知識 1. 呼吸系統的應用解剖與生理 2. 疾病的定義和危險因素 3. 臨床表現和診斷 4. 疾病的治療 4.1 藥物治療與非藥物治療 4.2 穩定期的治療 (肺康復) 4.3 急性症狀加重的處理 5. 疾病的預防 (疾病自我管理)	講授 示教	4
	9. 歸納常用 COPD 藥物種類、藥名、藥理及臨床應用、副作用、注意事項; 10. 根據現行臨床常用的藥物治療方案, 研討如何指導患者正確執行藥療。	6. 臨床常用 COPD 藥物治療方案	自學	4
05-09-08 14:30-17:30 (星期五)	1. 解釋營養治療與 COPD 康復的關係; 2. 簡述 COPD 飲食原則; 3. 建議 COPD 患者可選擇的食物、食譜。	COPD 患者的營養評估 COPD 營養指導	講授 練習	2
	1. 描述 COPD 患者的心理特徵; 2. 說出 COPD 患者的心理護理的重要性; 3. 討論減輕患者焦慮、抑鬱情緒的護理措施; 4. 實施指導患者進行鬆弛訓練。	COPD 患者的心理特徵和護理 鬆弛技巧	講授 示教 練習	2

教學計劃(續)

上課時間	學習目標	教學內容	教學活動	教學時數
05-09-08 18:30-21:30 (星期五)	1. 說出家庭氧療的重要性; 2. 說出家庭氧療的適應症、流量、注意事項; 3. 回復示範制氧機的使用方法。	家庭氧療 1. 適應症、流量、注意事項 2. 吸氧裝置的選擇和使用指導	講授 示範 練習	2
	1. 解釋影響臨床決策的因素; 2. 討論 COPD 患者護理評估、診斷、計劃、實踐和評價過程的思考過程; 3. 舉例說明關護概念在延續護理中的應用; 4. 在 COPD 延續護理中表現出對患者的關愛。	COPD 患者延續護理中的臨床思考 關護概念在 COPD 患者延續護理中的應用	講授 個案 研討	2
10-09-08 14:30-17:30 (星期三)	1. 說出霧化吸入藥物的藥名、作用原理、劑量、使用方法、副作用及注意事項; 2. 回復示範指導患者使用吸入器(吸入技巧及效果評價);	霧化吸入 1. 常用霧化吸入藥物 2. 各種吸入器的使用和清潔	講授 示範 練習 考核	4
	3. 示範指導患者霧化吸入。	3. 指導患者使用吸入器霧化吸入	課後 練習	8
10-09-08 18:30-21:30 (星期三)	1. 說出 COPD 延續護理中健康教育的目的和意義; 2. 識別 COPD 患者的健康教育需要; 3. 列出 COPD 的健康教育內容;	健康教育 1. 健康教育基本知識與技能 2. COPD 延續護理中的健康教育(目的、意義、內容、方法)	授課 討論	4
	4. 製作健康教育資料; 5. 運用知識技巧實施 COPD 患者健康教育。	3. COPD 健康教育資料製作 4. COPD 患者的健康教育	自學 課後 實踐	8
11-09-08 14:30-17:30 (星期四)	1. 討論護理個案管理的定義; 2. 分析各類個案管理模式; 3. 描述個案管理的步驟; 4. 簡述個案管理在臨床上的應用。	個案管理在 COPD 患者護理中的應用	講授 討論	2
	1. 簡述 Omaha 系統的組成; 2. 在 COPD 患者延續護理中的應用以 Omaha 系統為架構的實施記錄系統。	Omaha 系統在 COPD 患者延續護理中的應用	講授 討論 練習	2
11-09-08 18:30-21:30 (星期四)	1. 解釋康復治療(教學內容所列各項)的原理和作用; 2. 描述康復治療(教學內容所列各項)的方法; 3. 識別患者康復治療的需要; 4. 回復示範教學內容所列各項康復治療; 5. 回復示範訓練量的評估。	COPD 的家居康復治療技巧 1. 有效咳嗽與排痰 2. 呼吸訓練 3. 氣喘的控制 4. 體力鍛煉(步行、上肢運動) 5. 日常生活活動的應對技巧	講授 示範 練習 考核	4
	6. 示範指導患者進行家居康復治療。	6. 訓練量的評估 7. COPD 家居康復治療技巧指導	自學 課後 練習	8

教學計劃（續）

上課時間	學習目標	教學內容	教學活動	教學時數
12-09-08 14:30-17:30	1. 說出 COPD 患者的出院計劃的目的； 2. 簡述 COPD 患者出院計劃的護理內容； 3. 列出 COPD 患者的個人、家庭和住所的健康評估項目； 4. 識別住所環境中的危險因素； 5. 識別促進或阻礙 COPD 患者康復的家庭和社會因素及資源； 6. 評估 COPD 患者自我照顧的實際能力；	COPD 患者的出院計劃 COPD 病患者的個人、家庭和住所的健康評估	講授 討論 練習	4
12-09-08 18:30-21:30 (星期五)	7. 提出改善或避免危險因素的合理建議； 8. 依據評估實證或實際情況的變化制定或修改干預措施； 9. 填寫各種護理表格或檔。	電話隨訪		2
	1. 簡述 COPD 延續護理效果評價的重要性； 2. 討論各項評價指標的應用； 3. 概述 COPD 延續護理項目的實施要求； 4. 說出護士在項目中的角色責任； 5. 準備執行 COPD 延續護理方案。	COPD 延續護理的效果評價 COPD 延續護理項目的組織實施		2
			自學 課後 練習	4
08-10-08 14:30-16:30		考試 問卷調查		2
16:45-17:45 (星期三)		結業儀式 1. 彙報學習心得 2. 課程總結 3. 頒發結業/繼續教育證書 4. 合照		

臨床實習周

(2008 年 09 月 16 日——09 月 20 日)

上課 時間	學習目標	教學內容	教學 活動	教學 時數
16-09-08 至 20-09-08	1. 熟悉血氣分析、肺功能檢查等實驗室檢查報告的基本判斷; 2. 掌握慢性阻塞性肺疾病患者的臨床觀察; 3. 掌握肺部聽診的方法; 4. 掌握 Omaha 體系記錄系統的臨床應用; 5. 掌握有效的護患溝通和關係建立的技巧; 6. 掌握與多專業團隊成員溝通協調的技巧; 7. 每位學員完成 1 例個案的評估與計劃。	1. COPD 患者的臨床觀察 2. 肺部聽診 3. 實驗室檢查結果的判斷 4. 護理評估、健康問題的診斷與家居護理計劃的制定 5. 護患溝通與護患關係建立 6. 多專業團隊的協調與合作 7. 個案隨訪	帶教 實踐	40

備註：①每天上午隨醫生查房（COPD 患者）；②19-09-08 下午：個案隨訪實踐；③20-09-08 上午：綜合實踐技能考核；④臨床實習周反思小結在香港學習周進行。

香港學習周

(2008 年 09 月 21 日——2008 年 09 月 28)

上課 時間	教學目標	教學內容	教學 活動	教學 時數
22-09-08 或 25-09-08	1. 見習 COPD 患者家庭訪視過程，包括： • 家庭和住所環境和危險因素的評估 • 個人健康狀況的物理評估及健康需要評估 • 患者既照顧者 COPD 自我管理知識水準及技能掌握程度的評估 • 根據評估發現實施健康教育及指導 • 與患者及家人協議確定康復計劃 2. 見習與患者及家人的有效溝通； 3. 體驗在訪視過程中對患者及家人的關愛。	家庭訪視 溝通技巧在 COPD 患者延續護理中的運用	帶教	8
22-09-08 或 25-09-08	1. 瞭解香港的醫療護理服務； 2. 瞭解香港的社康護理服務的管理和護理運作模式；	香港醫院社康護理服務	參觀 交流	8
23-09-08 24-09-08 26-09-08	1. 見習 COPD 病人的住院、出院後胸肺複康服務； 2. 思考中國內地的延續護理發展。	COPD 患者的胸肺複康計劃	參觀 交流 授課 臨床 見習	8 8 8
27-09-08	1. 瞭解香港健康教育資源 2. 瞭解香港的護理教育的現狀和發展	健康教育資源（參觀香港醫院管理局健康資訊天地） 香港的護理教育（參觀香港理工大學）	參觀	4

香港理工大學護理學院 COPD 延續護理課題組

二零零八年八月二十二日