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EFFECTS OF A TRANSITIONAL RENAL PALLIATIVE PROGRAMME FOR PATIENTS WITH END-STAGE RENAL FAILURE: A PILOT RANDOMISED CONTROLLED TRIAL

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PhD

THE HONG KONG POLYTECHNIC UNIVERSITY

2022

THE HONG KONG POLYTECHNIC UNIVERSITY SCHOOL OF NURSING

Effects of a Transitional Renal Palliative Programme for Patients with End-stage Renal Failure: A Pilot Randomised Controlled Trial

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Tam Mee Ling Bonnie

A thesis submitted in partial fulfilment of the requirements for the

degree of Doctor of Philosophy

December 2019

CERTIFICATE OF ORIGINALITY

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ABSTRACT

Background:

Globally, chronic kidney disease (CKD) is a common prevalence with a mortality rate of 33.7%. In Hong Kong, end-stage renal failure (ESRF) accounted for the 6th leading cause of death. Previous studies have shown the positive effects of palliative care with palliation of symptoms and improved quality of life for cancer patients. Recently there have been recommendations to extend transitional palliative care to end-stage organ failure patients including ESRF patients. Despite renal palliative service being available to end-stage renal failure patients, empirical evidence is not available for reference. This study was therefore launched to fill this service and knowledge gap.

Aims:

The study aimed to examine the feasibility of the study and preliminary effects of the transitional renal palliative programme (TRPP) among patients with ESRF.

Methods:

In the first stage of the study, a 4Cs nurse-led multidisciplinary support TRPP was developed based on research evidence, clinical expertise and patient preference. It included three sets of standardised protocols: (1) pre-discharge assessment and planning, (2) post-discharge follow-up and (3) assessment and surveillance. A pilot randomised controlled trial was conducted in the second stage with participants recruited from August 2014 to September 2016 for palliative care in a Renal Unit of a regional hospital in Hong Kong. All participants received customary palliative care and the intervention group underwent the TRPP which had bi-monthly home visits and weekly telephone follow-ups in addition to customary care. The primary outcome measures included non-scheduled readmission, length of hospital stay, and Accident and Emergency Department attendance, and secondary outcomes included health-related quality of life, symptom manifestation, palliative performance scale, anxiety and depression, patient satisfaction and burden of caregivers and were assessed at baseline (T0), and at 1, 3, 6 and 12 month(s) after recruitment into the study (T1, T3, T6 and T12). Chi-square or fisher's exact test, Mann Whitney U test or independent t-test and repeated measure of analysis of variance were applied where appropriate in testing the outcomes of the TRPP. Missing data was managed by multiple imputations. Intention-to-treat (ITT) analysis and per-protocol (PP) analysis were performed. Alongside the pilot trial, continued face-to-face interviews were conducted to explore the experience of patients with ESRF and their caregivers regarding the transitional palliative care program and thematic analysis was conducted for qualitative data.

Results:

This study was undertaken according to the study plan with approximately 6 patients referred per month, 48.73% eligibility rate, and 52.63% attrition rate. A total of 76 patients with ESRF were randomly assigned to the intervention group (n=38) and control group (n=38). The baseline demographic characteristics of the two groups were comparable. The results of ITT analysis and PP analysis were similar. The chi-square test showed the intervention group had fewer unplanned readmission rate at T6 (control: 39.47% vs intervention: 18.42%, χ^2 =7.67, *p*=0.02) and at T12 (control: 31.58 % vs intervention: 26.32%, χ^2 =12.22, *p*=0.002. The Mann Whitney U test revealed significant differences in the intervention group with shortened length of hospitalisation at T6 (*p*=0.04) and T12 (*p*<

0.01), and significant fewer Accident and Emergency Department visits at T1 (p<0.001), T3 (p<0.001), T6 (p<0.001) and T12 (p=0.02) when compared with the control group.

The intervention group further revealed better secondary outcome measures than those in the control group. Employing ITT analyses, the 2-ways repeated measure of analysis of variance showed significant interaction effects between group and time in all the five domains of the Kidney Disease Quality of Life-36, Hong Kong (including Symptom Problem List, Effects of Kidney Disease, Burden of Kidney Disease, Physical Composite Score, and Mental Composite Score; all *ps*<0.001), Palliative Performance Scale (*p*<0.001), Hospital Anxiety and Depression Scale - Anxiety (*p*=0.01), Patient Satisfaction (*p*=0.001) and ZBI (*p*=0.01), while insignificant interactions were noted in Symptoms Manifestation (*p*=0.08), and Hospital Anxiety and Depression Scale – Depression (*p*=0.05). Participants in the intervention groups perceived improvement in quality of life, physical function, satisfaction with care and less degree of burden on informal caregivers. Regarding the qualitative information from the patients and their caregivers, thematic analysis of their experiences was aggregated into four themes: (1) positive value of TRPP, (2) preparation of self-management of ESRF, (3) support of nurse case manager and (4) scope of services. Participants appraised transitional palliative care positively.

Conclusion:

The study results provide strong support for the feasibility and acceptability of the study design, instrumentation and interventions. This pilot study provides the groundwork for a future main study and has demonstrated that the nurse-led transitional home-based palliative care produced significant effects in reducing the utilisation of health services. Furthermore, this trial exhibits improved patient outcomes in terms of improved quality of life, control of

symptom intensity, improved functional status, less anxiety and depression, increased satisfaction rate, and less burden on the informal caregiver.

The encouraging results of this trial show healthcare providers that TRPP benefits ESRF patients in terms of improved clinical outcomes and fewer healthcare expenditures. The provision of current strategies is the future trend of care. The limitations in this trial include the high attrition rate due to the high mortality, which suggests modification of the study duration for a future main study. A large trial using a similar methodology and instrumentation would help produce stronger evidence in supporting the effectiveness of the TRPP in clinical practice. To conclude, the encouraging preliminary findings of the pilot study could inform the renal specialty of the integration of transitional care into conventional renal care for the population of ESRF patients with non-dialysis therapy.

Trial registration: The United States Clinical Trials Registration, ClinicalTrials.gov Identifier: NCT02139917

Keywords: chronic kidney disease, end-stage renal failure, nurse case manager, selfmanagement, transitional palliative care

LIST OF PRESENTATIONS AND PUBLISHED WORK

Publications (from the thesis)

- Chow, S.K.Y. & Tam, B.M.L. (2014). Is the Kidney Disease Quality of Life-36 (KDQOL-36) a valid instrument for Chinese dialysis patients? *BMC Nephrology*, 15(199), 1-7. DOI:10.1186/1471-2369-15-199
- Tam, B.M.L., Wong, F.K.Y., & Wang, S. (2022). Effects of a Transitional Palliative Care Model for End-stage Renal Failure Patients: A Randomised Controlled Trial. *Journal of Advanced Nursing* (under review by the editorial board).

Presentation (from the thesis)

- Tam, B.M.L. & Wong, F.K.Y. (2017). A pilot study of lived experiences of Endstage Renal Failure patients with palliative care. Proceeding of the 5th Asian Nephrology Nurses Symposium, September 2017, Hong Kong (Oral Presentation)
- Tam, B.M.L., Chan, J.H.W., Cheung, S.C.Y., Chan, T.Y.M., Yip, M.K., Yip, R., Li, C.S., Chau, K.F., & Wong, F.K.Y. (2018). 3A approach of symptoms encountered by End-stage Renal Failure (ESRF) patients with Renal Palliative Care (RPC) – Awareness, Assessment and Address of symptoms. Proceedings of 21st East Asia Forum of Nursing Scholars (EAFONS). January 2018, Taiwan. (Poster presentation)
- Tam, B.M.L. & Wong, F.K.Y. (2019). Effects of transitional palliative care model for patients with end-stage renal failure. International Conference on Innovation in Nursing Education and Patient Care. March 2019, Hong Kong. (Poster Presentation Award).
- Tam, B.M.L. & Wong, F.K.Y. (2019). Effects of transitional palliative care model for patients with end-stage renal failure. World Nursing Congress. June 2019, Brisbane. (Oral Presentation).

- Tam, B.M.L. & Wong, F.K.Y. (2020). Effects of transitional palliative care model for patients with end-stage renal failure. 18th Asian Pacific Conference of Nephrology (APCN). October 2020, Hong Kong. (Poster Presentation).
- Tam, B.M.L. & Wong, F.K.Y. (2021). Effects of a home-based renal palliative program on quality of life, symptom intensity, and health services utilisation among patients with end-stage kidney disease: a randomised controlled trial. JCECC Conference. June 2021, Hong Kong. (Poster Presentation).

ACKNOWLEDGEMENTS

In preparing for this trial, I am truly grateful to all the experts who gave me valuable comments on the study design and the validity of the study protocol.

Data analysis was the essential process of this study after data collation. I would like to extend my sincere thanks to Dr. Paul Lee for providing his important feedback on data analysis.

I would like to express my sincere gratitude to the staff of the Renal Palliative Unit at Queen Elizabeth Hospital for their exceptional support of the transitional palliative care programme. Besides, sincere thanks also go to the patients and their families who participated in this clinical trial.

A heartfelt appreciation is extended to the Associate Consultant Dr. Jennifer Chan, in charge of Renal Palliative Care, for her guidance and enthusiasm for this study and her generous facilitation to make my dream come true. Her encouragement and the extraordinary arrangement helped me overcome the challenges encountered.

I would also like to extend my heartfelt gratitude to Dr. Shaoling Wang, Research Fellow at the Hong Kong Polytechnic University, for her in-depth comments and unfailing assistance on this dissertation.

I would like to extend my heartfelt gratitude to my supervisor Professor Frances Wong, the pioneer of transitional care and patient advocate. She has offered me a generous backup during my deferment of study. Very deep appreciation for her support, wisdom, expertise, and guidance throughout this study in which I can taste the real meaning of transitional palliative care. Her encouragement and constructive comments helped me tremendously throughout my study, especially at the time when I encountered challenges and felt helpless.

Finally, special and earnest gratitude to my parents for their endless and infinite support. I would like to convey my appreciation to my beloved and respectful father who had gone to a peaceful place a year ago. Most importantly, I would like to dedicate this work to my dearest siblings and sister-in-law. Without your faith, support, and continuous encouragement, I could not have completed this study.

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GIOSSARY OF COMMONLY USED ABBREVIATIONS AND SYMBOLS

ADL	Activities of daily living
ACKD	Advanced Chronic Kidney Disease
AED	Accident and emergency department
ANOVA	Analysis of variance
APN	Advanced Practice Nurse
BP	Blood pressure
BKD	Burden of Kidney Disease
CAPD	Continuous Ambulatory Peritoneal Dialysis
CHF	Congestive heart failure
CI	Confidence interval
CKD	Chronic kidney disease
COPD	Chronic obstructive pulmonary disease
CVI	Content validity index
Df	Degree of freedom
DM	Diabetic mellitus
EKD	Effect of Kidney Disease
eGFR	Estimated glomerular filtration rate
EOL	End of life
ESRD	End-stage renal disease
ESRF	End-stage renal failure
g/L	Grams per litre

HADS	Hospital Anxiety and Depression Scale
HD	Haemodialysis
HR	Hazard ratio
NDMT	Non-dialysis medical therapy
ITT	Intention-to-treat
KDQOL-36 (HK)	Kidney Disease Quality of Life-36, Hong Kong
LOS	Length of stay
MCAR	Missing complete at random
MCS	Mental composite score
MD	Mean difference
MI	Multiple imputation
n	Number
NC	Nurse Consultant
NP	Nurse Practitioners
OR	Odds ratio
OS	Omaha System
р	Probability
PD	Peritoneal dialysis
PP	Per-protocol
PPS	Palliative Performance Scale
QOL	Quality of life
RCT	Randomised controlled trial
RM-ANOVA	Repeated measures analysis of variance
SD	Standard deviation
SPL	Symptom Problem List

SPSS	Statistical Product and Service Solutions
SM	Symptom manifestation
t	T-test value
TRPP	Transitional Renal Palliative Programme
TPC	Transitional Palliative Care
vs	Versus
χ^2	Chi-square
ZBI	Zarit Burden Index

CHAPTER ONE: INTRODUCTION

1. Introduction

This chapter provides the context of the study. The first section provides an introduction to the background of this study. The second section provides an overview of chronic kidney disease (CKD) and end-stage renal failure (ESRF) and the various supportive interventions. The third section explores the different needs and unmet needs of ESRF patients with conservative therapy. The fourth section introduces palliative care for non-dialysis patients with ESRF including the implications of palliative care over customarily conservative care. The effects and implications of transitional palliative care (TPC) are discussed in the fifth section. The sixth section is the statement of purpose. At the end of this chapter, the significance of this study and the outline of this thesis are presented.

1.1 Background

ESRF is an irreversible and advanced chronic disease. The effects of renal impairment at a later stage will affect multi-organs and lead to comorbidities such as cardiac dysfunction, osteoporosis, bleeding tendency, neurological defect, skin integrity, and compromised immunity (Mahon et al., 2013). In reaching the ESRF stage, patients require dialysis or kidney transplantation (Chambers et al., 2010). When replacement treatment brings no additional benefits for the patients, palliative care is a good option (Murtagh et al., 2016). ESRF patients continuously present diverse comorbidities with diverse and complicated needs of care, which can be effectively managed by palliative care, especially with regard to psychosocial and spiritual support (Brumley et al., 2007; Brown & Johansson, 2011).

Palliative care is a medical specialty that focuses on caring for the whole person including the physical, emotional, and spiritual needs of those with a serious illness, a life-threatening injury, or other medical conditions. The goal of palliative care is to improve the quality of life (QOL) by minimising distressful suffering while maintaining functioning status according to the patient's values and concerns, regardless of the patient's stage of disease or the requirement for other therapies (Davis & Hui, 2017). Palliative care also aims to ensure that the holistic needs of individuals, including physical, psychological and spiritual care are met in maintaining patients' comfort as much as possible, regardless of their age or life expectancy, and to provide emotional support for patients and families (National Academies of Sciences, 2003).

The approach of palliative care, traditionally applied to oncology patients, is now advocated for patients with end-stage organ failure. The benefits of palliative care include symptom palliation, appropriate communication regarding advanced care planning, various backup systems for patients and families, and patient education for self-management of symptoms (National Institute for Health and Clinical Excellence, 2015). Home-based palliative care has become an emerging need nowadays as the existing conventional hospital-based health care facilities play only a limited role in caring for the chronically ill in society (Santha, 2011). There is a need for shifting conventional hospital-based palliative care to home-based palliative care. Various studies of home-based palliative care have provided evidence indicating positive outcomes such as improved utilisation of Accident and Emergency Department (AED) services (Brumley et al., 2003; Brumley et al., 2007), and improved satisfaction with care (Brumley et al., 2007; Wentlandt et al., 2016).

More aggressive interventions seem to effectively reduce short-term readmissions (Verhaegh et al., 2014). The research results indicate that the high-intensity interventions of transitional care have the components of a nurse coordinator, interchanging of information between the primary care provider and the hospital, and a home visit arranged within three days after discharge (Verhaegh et al., 2014). However, there has been no definite home-based palliative care program reported with confirmed evidence, thus there is a gap to be filled.

1.2 CKD and ESRF

CKD is defined as impaired kidney function and presentation of proteinuria over at least 3 months and is often present along with cardiovascular disease and diabetes (Levin et al., 2008). Estimated glomerular filtration rate (eGFR) of <60mL/min/1.73m² is regarded as a gauge/measure of impaired kidney function, which is accompanied by the presence of albuminuria, abnormal histological findings (as detected through kidney tissue biopsy) or urine sediment abnormalities are used to diagnose CKD (National Kidney Foundation, 2002; Stevens & Levins, 2013).

Based on eGFR measures, CKD is classified into 5 stages. Among them, earlier stages (stages 1, 2 and 3) can be asymptomatic and the renal function may be sustained with medical management (Stevens & Levins, 2013). CKD stage 4 (eGFR 15-29 mL/min/1.73m2) indicates severe loss of kidney function and CKD stage 5 (eGFR < 15 mL/min/1.73m2) indicates kidney failure which is also called advanced chronic kidney disease (ACKD) or end-stage renal disease (ESRD) (Stevens & Levin., 2013). ESRF is the term used in this study to describe participants with advanced renal function impairment.

1.2.1 Prevalence and mortality of CKD

CKD is a growing global problem affecting around 10% of many countries' populations (Chambers et al., 2018). In Canada, CKD affected 12.5% (around 3 million Canadians) in 2007-2009 (Arora et al., 2013). In the United States, 14.8% prevalence of CKD in stages 1-5 from 2011 to 2014 was reported, in addition, there were 120,688 new cases of ESRD in 2014 (1% increase compared to 2013) and a total of 678,383 ESRF patients were treated in 2014 (Saran et al., 2017). Globally, in 2017, for all age groups and both gender, the prevalent cases of CKD were 6.98 billion as reported by the Global Burden of Disease Study 2017 (Saran et al., 2017). The increasing prevalence of CKD has been attributed to a growing elderly population and increasing rates of diabetes, hypertension and other cardiovascular risk factors (Fox et al., 2012).

According to the estimations of the Global Burden of Diseases, Injuries, and Risk Factors Study (GBD) 2017, CDK resulted in the mortality of 1.23 million globally in 2017, of which 23.2% were from type 1 diabetes, 40.5% from type 2 diabetes, 41.4% from hypertension, 25.5% from glomerulonephritis and 25.9% from other unspecified causes. Total deaths from CDK increased by 33.7% from 2007 to 2017 (Saran et al., 2017).

ESRF is a leading cause of morbidity and mortality worldwide (Luyckx et al., 2018). Hong Kong is no exception. In Hong Kong, ESRF accounted for the 6th leading cause of death from 2001 to 2019 (Centre of Health Protection, 2020). There was an increased prevalence of ESRF with 1400 patients requiring RRT in 2017 (Tang, 2018).

1.2.2 Treatment of CKD

When the renal function approaches the end-stage, treatment options are limited to renal replacement therapy (RRT) utilising haemodialysis (HD), peritoneal dialysis (PD) or renal transplantation or conservative management (CM)/palliative care (Central Renal Registry, 2020). There is an estimation that more than 5 million patients may require RRT globally by 2030 (Tang, 2018). As ESRF is a global health issue affecting around 0.7 million people in the United States, more than 500,000 patients received dialysis and 215,000 people are living with kidney transplants (Saran et al., 2017). Hong Kong practices the 'PD first' policy and the majority of the patients are on continuous ambulatory peritoneal dialysis treatment. In 2013, there were 3817 PD, 1192 HD and 3501 renal transplant patients in Hong Kong, and the ratio of PD to HD was 76.2% to 23.8% (Leung et al., 2015).

ESRF therapy is considered care intensive and related to high healthcare expenditure as well (Canadian Institute for Health Information, 2016). Dialytic therapy involves several measures and risks including the establishment of dialysis access, risk of treatment complications and disease, disturbance of daily life patterns as well as a decline in functional status. The dialytic treatment options pose a higher stress level for the elderly with other comorbidities (Kurella et al., 2016; Morton et al., 2012). Regarding the pros and cons of dialysis therapy, patients of advanced age, in frail conditions with multiple comorbidities may gain no benefit of prolonged life expectancy from dialysis therapies (Murtagh et al., 2016).

1.2.3 Conservative therapy

Conservative care, supportive care, non-dialysis care or palliative care constitute conservative therapy for individuals with non-dialysis treatment. Given no benefit from dialysis, conservative care is an alternative viable treatment option for older patients with comorbidity (Verberne et al., 2020). In recent years, it has been suggested that non-dialytic therapy can be a desirable option of therapy for older people as those who are on dialysis would experience significantly more negative effects of kidney disease and advanced psychological stress than those with non-dialysis (Central Renal Committee, 2018; Shah, et al., 2019).

Positive results from conservative therapy in terms of conservative care, non-dialysis therapy or palliative care have been reported. Verberne, et al. (2020) found that older patients with conservative care may achieve similar QOL and symptom intensity compared with those with dialysis therapy. Non-dialysis care patients experienced fewer hospitalisation days (Jassal et al., 2011). Making use of the skills of palliative medicine enhances symptom control and QOL, resulting in non-dialysis elderly patient survival of a median of 16 months (Brown et al., 2015). Given these research findings, ESRF patients receiving conservative therapy have similar outcomes when compared to those receiving dialysis therapy. (Central Renal Committee, 2018; Tang, 2018).

1.3 Needs of ESRF Patients with Conservative Therapy

Although conservative therapy may have similar outcomes for those who do not benefit from dialysis therapy, these patients undergoing conservative therapy still have their needs in physical, psycho-emotional, communication and QOL needs.

1.3.1 Needs for physical distress

Patients with ESRF often have a severe level of comorbidity, a complex/refractory system burden, and shortened life expectancy. The inherent nature of ESRF is related to different complications such as fluid retention, electrolyte imbalance, acid-base imbalance, cardiovascular disease, anaemia, and azotemia. In assessing the symptom burden of ESRF patients, pain (32%), anxiety (44%) and other symptoms (55% – 84%) were partially relieved or not reduced at all during the final week of life and end-of-life (EOL) in patients with ESRF (Axelsson et al., 2019).

1.3.2 Needs for the psycho-emotional distress

Psychological disorders commonly co-exist with CKD (Goh & Griva, 2018). It is common to note persistent emotional distress of depression and anxiety with fluctuating in severity during CKD due to chronic disease burden, clinical status, treatment issues, daily life circumstances, and other stressful circumstances (Goh & Griva, 2018). The prevalence rate of anxiety in patients with ESRD was estimated at approximately 12% to 52% (Murtagh et al., 2007). Besides, the risk of depression and anxiety in patients with CKD has also been linked to demography such as sociodemographic factors (Hou et al., 2014), gender (Veater & East, 2016), and clinical parameters of sleep quality, employment and financial status (Veater & East, 2016).

Many studies have shown that depression is more prevalent in those with CKD and that ESRF is a strong risk factor for adverse outcomes such as hospitalisation and mortality (Palmer et al, 2013; Murtagh et al., 2007; Veater & East, 2016). However, depression is often underdiagnosed because of the overlapping signs and symptoms of complications of CKD and depression (Goh & Griva, 2018). Besides, the need of accepting a critical

diagnosis of irreversible chronic disease that requires lifelong treatment, adaptation to readjustment of daily life and treatment, and coping with the complications can prove extremely challenging for ESRF patients (Cukor et al., 2007).

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1.3.3 Needs for effective communication

To achieve good clinical results with patient-centred care there must be effective channels of communication between the patient and the healthcare team. Concerning the nature of the disease trajectory of CKD, the need for advanced care planning and treatment decision making are critical, and the main components of palliative care. Patients' treatment preferences and expectations should be acknowledged and patients must be involved and empowered in treatment decision making (Hargie, 2006). However, there is little information regarding organ failure patients (Rodriguez et al., 2005; Sakr et al., 2018).

Information communication of treatment programs of health care is fundamental and crucial in patient-centred care. The trajectory of ESRF involves treatment decision making, advancing physical and psychosocial suffering, individual vulnerability and existential
issues, yet, is seldom offered to patients with ESRF (Allen et al., 2014; Cohen et al., 2007; Wong et al., 2012). ESRF patients expect prognosis communication initiated by health providers in relation to disease trajectory (Rodriguez et al., 2005) because they often embrace extensive and complex medical decision-making on treatment options including treatment modalities, strategies of symptom management and end of life (EOL) plans (Allen et al., 2014; Meyers & Goodlin, 2006). To facilitate patient-centred care, the care provider should acknowledge and respond to individual patients' requirements and preferences (Winakur, 2012). Yet, the practice of referral and management of ESRF in the existing healthcare system is inconsistent, contributing to varied supportive services for organ failure patients (Lindvall et al., 2014).

1.3.4 Needs on QOL

ESRF patients are challenged with various distress symptoms of distress, consequently, burden and psychological stress may result from poorly managed symptoms that negatively influence the QOL (Thomas & Noble, 2007). As the symptoms are poorly controlled, the patient will be frustrated physically and psychologically. Patients will be repeatedly admitted into the hospital for investigation and interventions. The uncertain prognosis and unstable disease trajectory will adversely affect QOL (Dalgaard et al., 2014).

With the unmet needs of physical and psychological symptom care, effective communication about treatment, and QOL at the EOL for older and sicker people with ESRF is very important. The integration of palliative care with supportive care is brought about, which addresses the complex symptom and psychological issues required to improve QOL and plan EOL care for patients and their families (Smith et al., 2015).

1.4 Palliative Care

According to the fact sheet of the World Health Organisation, 2020,

"Palliative care improves the quality of life of patients and that of their families who are facing challenges associated with life-threatening illness, whether physical, psychological, social or spiritual. The quality of life of caregivers improves as well." Palliative care is special and individualised care management to improve QOL and alleviate distress and suffering along with other medical treatments. It is appropriate for both those undergoing dialysis and non-dialysis therapy (Holley et al., 2007). Palliative care is characterised by advanced planning of care, management of symptoms, hospice referral and patient and family support (Brown et al., 2008). It is typically offered using an interdisciplinary team approach including physicians, nurses, social workers, chaplains, and specialists in other disciplines to manage pain and symptoms. Adequate communication between healthcare professionals and the patient and family is the key to a better collaboration of care (Hashim, 2017). In the pursuant chapters in this thesis, the undermentioned palliative care refers to ESRF patients who undergo conservative care with physical, and psychosocial support without any RRT.

1.4.1 Preferences of ESRF patients and the existing gaps in palliative care

Non-dialytic ESRF patients may survive days to weeks (Schmidt & Moss, 2014). Patients' preferences for treatment, plan of care, and place of death are honoured and respected as they have the right to their preferred choice of treatment. A study by O'Connor & Corcoran (2012) invited 50 subjects to reflect on their preferred treatment once ESRF was diagnosed. The findings revealed that their considered main goals of treatment considered, were to be independent and free from major symptoms of disease or treatment, and the older ESRF patients on palliative care preferred good QOL and dignified death.

Swindler (2012) emphasised that palliative care patients with non-dialysis therapy were intently focused on QOL over the length of life, while simultaneously receiving targeted medical renal therapy. However, with inadequate communication between patients and healthcare providers, there is mounting potential for intensive and complex patterns of care provided to the majority of the population of patients with organ failure, which are not aligned with their desires and values (Sanders et al., 2018). The nephrology community has identified that there are explicit unmet palliative care needs in this population with advanced kidney impairment (O' Hare et al., 2017). Service gaps do exist on the best time for improving the EOL experience of older patients with ESRF and their caregivers, the effectiveness of palliative care in improving QOL of patients' and caregivers' satisfaction with care as well as aligning treatment decisions with patient concerns.

1.4.2 Integration of palliative care into the conventional care

People with ESRF gain benefits from palliative care including improved symptom control, psychological support, care coordination, satisfaction with care and QOL during the end phase of life (Wachterman et al., 2016). The goal of integrating palliative care along with routine kidney care has become crucial to improving the QOL and relatively peaceful death for ESRF patients (Wasylynuk, 2015).

Home-based palliative care improved symptom control (Evangelista et al., 2012; Rabow et al., 2004) and reduced depressive distress (Evangelista et al., 2012), improved QOL (Bakitas et al., 2009; Evangelista et al., 2012; Rabow et al., 2004), lengthen survival (Temel et al., 2010; Rabow et al., 2004), reduced healthcare utilisation (Lukas et al., 2013; Rabow et al., 2014), reduced healthcare utilisation (Lukas et al., 2013; Rabow et al., 2014), reduced healthcare utilisation (Lukas et al., 2014), reduced

2004), shortened hospitalisation stay (Lukas et al., 2013), and more appropriate decision making (Ciemins et al., 2006).

However, there are no standardised interventions of palliative care in the studies mentioned above, nor are they specifically designed for ESRF patients. Despite high levels of morbidity and mortality in patients with CKD, the utilisation of palliative care in ESRF is still being developed in Hong Kong (Chan et al., 2018; Yong et al., 2009).

1.4.3 Making a difference through palliative care

As described in the background section, palliative care involves physical, psychological, and spiritual care. It provides physical support such as medication for pain and constipation. It also assists patients and their families in getting emotional support if needed (The National Academies of Sciences, Engineering & Medicine, 2003).

Along the aggressive disease trajectory, patients and family members who need psychosocial support and standard goals of care are emphasised. palliative care enables the review of the changing goals of patients especially when serious events and declines in functional level have occurred. There has been an increasing recognition of the impacts of palliative care as mentioned above, however, there has been no evidence of the best model for guiding the caring services of the population with CKD. Concerning the palliative care of ESRF patients, the type of transition care that can offer optimal patient and clinical outcomes is not yet established.

1.5 Transitions in the Healthcare Services for Patients with ESRF

Among ESRF patients, repeated hospitalisations are associated with increased morbidity and mortality, and reduced QOL. Repeated unplanned admissions also increase distress to patients' well beings and daily living patterns, as well as causing a financial burden on health. Recurrent hospitalisations also result in significant societal and health expenditures (Saran et al., 2017). With quality pre-discharge planning and continuous home-based support, a proportion of unplanned readmissions could be avoided with optimised transitional care (Mathew et al., 2015).

The transitional approach of continuous home-based support and palliative care is in alignment with the theme of symptom management and psychological support (National Institute for Health and Clinical Excellence, 2015). With timely identification of abnormality and appropriate treatment, home-based palliative care focuses on symptom management, psychosocial and spiritual care, and home-based support has minimised this symptom distress by employing regular telephone follow-up and home visits during the post-discharge and inter-medical consultation period.

1.5.1 Components of transitional care

According to Coleman (2003), transitional care includes both the sending and receiving aspects of the transfer, it is critical for patients with complex healthcare needs. Transitional care is provided and designed based on a comprehensive plan of care and the availability of health care providers with clinical competence. It covers early identification of symptoms with appropriate and timely interventions, support arrangement, patient education, and care coordination (Coleman, 2003). An adequate intervention dose is ensured which aims at a high-quality outcome.

1.5.2 Outcomes of transitional care

Evidence has shown that a multi-disciplinary care team improves the post-discharge support to patients with chronic illness in the effective control of pain (Hughues et al., 2000); improved social function (Hughues, et al., 2000); improved health-related QOL (Hughues, et al., 2000; Wong et al., 2010), increased satisfaction with care (Wong, et al., 2010) and reduced readmission (Brumley et al., 2007).

The concept of TPC within the context of elderly patients with ACKD and life-limiting conditions is shifting from the hospital to the community and its goals of care are shifting from curing disease to a high QOL with PC needs. The framework of transitional care not only includes an effort to transfer patient services from hospital-based care to home-setting care, but it is also a process of tailoring and adapting for older patients to manage changes in the treatment trajectory of ESRD with a specific approach and healthcare providers. The transition from active curing care to palliation of symptoms is a significant challenge (Butcon & Chan, 2017) for elderly patients and their families who have to adapt to the changes in clinical conditions and their outcomes. Little is known about the correlation between the QOL, caregivers' burden, and satisfaction of care.

1.5.3 Development of palliative care in Hong Kong

In the last two decades, the concept of transitional care has been recognized and shared in healthcare practice. Various studies adopting a transitional care model have demonstrated positive evidence of clinical outcomes in COPD, heart failure, and cancer patients with a high satisfaction rate of care, and even in terminally ill patients (Brumley et al., 2007). A pilot study aimed to examine if the role development of clinical nurse specialists in Hong Kong could reduce lower limb oedema of ESRF patients on Continuous Ambulatory Peritoneal Dialysis (CAPD) therapy with an initial approach of transitional care (Wong, 2001). However, the model of transitional care including regular follow-up by telephone outreach and periodic home visit still needs further investigation among the population of non-dialysis ESRF patients.

1.6 Statement of Purpose

This was the first randomised controlled trial (RCT) on non-dialytic patients with ESRF in Hong Kong. The purpose of this pilot study was to evaluate the feasibility of the process of conducting transitional home-based renal palliative programs in terms of the recruitment process, randomization of groups, implementation of interventions and response to intervention. This pilot RCT also aimed at evaluating the preliminary effectiveness of a transitional home-based renal palliative program. In this pilot RCT, TPC comprised a set of strategies and interventions designed to ensure the coordination and continuity of health care for ESRF patients transferred from hospital-based to home setting care. The primary outcomes of this pilot RCT were unplanned readmission, length of stay (LOS) during hospitalisation and AED attendance. The secondary outcomes included symptoms intensity, physical function, satisfaction with care, psychological distress, QOL and the burden on caregivers.

1.7 Significance of the study

Palliative care service under Hospital Authority is organised and coordinated on a cluster basis. Currently, palliative care services are provided locally in all seven clusters. In-patient palliative care service is mainly for patients with severe or complex symptoms and needs. A range of ambulatory Palliative care services is also available including outpatient, daycare and home care services to reduce unnecessary hospitalisation and better support patients in the community with unique and individual features services and post-discharge support and continuous follow-up (Hospital Authority, n.d.).

In recent decades, the care delivery model has shifted from hospital-based to home-based due to overwhelming public demand in Hong Kong. Transitional care was repeatedly applied in different studies for different groups of patients with chronic diseases. The effects and outcomes of these studies are non-inclusive. In addition, relatively little attention has been directed toward caregivers who are negatively influenced by the challenges of the caregiver role as well as the progressive clinical status of patients (Wong et al., 2020). The importance of filling the service gap is very clear and the development of the Transitional Renal Palliative Programme (TRPP) to address the supportive care requirement of patients and caregivers is indicated.

With the goal of high-quality patient care, healthcare providers have endeavoured to plan and implement the care program for patients with ESRF. This is the first local pilot RCT of patients with ESRF which evaluated the effects of a TPC program. With the appropriate treatment protocol and post-discharge support, patients with ESRF may better control their symptoms and reduce the complications of the disease, including emotional depression and anxiety. The exploration of the transitional model provides significant crucial information, may improve patient-centred clinical outcomes, support the family caregivers, minimise healthcare utilisation with reduced non-schedule readmission, inform the hospital policy and inspire healthcare providers of the possible needs for further development of palliative care services in Hong Kong.

1.8 Thesis Outline

This thesis has seven chapters. Chapter 1 is the introduction. Chapter 2 provides an overall report of the literature reviews on CKD, treatment of ESRF, palliative care for ESRF patients and effects of transitional care. Chapter 3 presents the research questions, aim and objectives and describes the stages of this study and the context of this trial, including the design, methods, and procedures adopted in this pilot RCT. Chapter 4 outlines the structural concept of this study and describes the development of study protocols including telephone follow-up, home visits, patient-initiated telephone calls, and referral protocol. The role of the nurse case manager (NCM) is also described. In preparing the protocol and the interventions, searching for research articles, consideration of the patient's preference, expert recommendations and validation are all included and considered. Chapter 5 reports the results of the study. Chapter 6 presents a discussion of the main findings, and Chapter 7 describes challenges encountered, limitations, and implications for clinical practice, and concludes this doctoral thesis.

CHAPTER TWO: LITERATURE REVIEW

2. Introduction

The objectives of the literature review are to evaluate, summarise and synthesise the information from published studies and evidence-based guidelines, core curriculum, position statements and standards of palliative care in ESRF for the development of this study. The first section details CKD and ESRF including diagnosis, epidemiology, prevalence, morbidity, mortality and its treatment. Palliative care will be described in section two, including the terminology of terms, definition, and effects of palliative care. The third section explores the concepts of transitional care in a heterogeneous population with chronic diseases, including a critical review of the study interventions involving the patients and care. Finally, the characteristics of a multidisciplinary team approach and nurse-led TRPP with clinical outcomes are elaborated on.

2.1 Overview of ESRF and their Symptoms

CKD is defined as compromised renal function denoted by eGFR of less than 60 ml/min/1.73 m², or gross kidney damage, sustained for three months duration, regardless of the underlying factor (Webster et al., 2017). CKD can be classified into five stages delineated according to the level of the GFR as shown in Table 2.1 (National Kidney Foundation, 2017; Lamb et al., 2013). The renal function of patients experiencing chronic renal failure will eventually progress to ESRF and require RRT to sustain life.

Stage	Description	eGFR* (l/minute/1.73m ²)
1	Slight kidney damage with normal or high filtration	> 90
2	Mild decrease in kidney function	60-89
3a	Mild to moderate decrease in kidney function	45-59
3b	Moderate to a severe decrease in kidney function	30-44
4	Severe decrease in kidney function	15-29
5	Kidney failure; requiring dialysis or kidney transplantation	< 15

Table 2.1 Stages of Chronic Kidney Disease

*Estimated Glomerular Filtration Rate

National Kidney Foundation (2017)

There are four renal therapy options for ESRF namely hemodialysis, peritoneal dialysis, renal transplantation, and palliative care (Tang, 2018). Patients presenting with CKD stages 1-3 can be managed within their primary care settings. They have to approach nephrology care for the preparation of dialysis access when they approach or reach CKD stages 4-5. This enables them to have fewer complications and effective control of renal disease progression.

ESRF is an irreversible chronic disease with an advanced renal dysfunction where the body cannot maintain acid-base balance and electrolyte balance, and excrete nitrogenous waste and excess water, resulting in uremia, electrolyte imbalance, metabolic acidosis and hormonal disturbance with nephropathy anaemia (Go et al., 2004). The diversified physical symptoms and complications of ESRF impose a psychological burden on ESRF patients who experience various levels of psychological stress. Peptide and steroid hormones that are metabolised are circulated at low levels in ESRF patients who commonly experience chronic stress (Stenvinkel & Larsson, 2013).

2.1.1 Impacts of ESRF on psychosocial symptoms

Irreversible end-stage renal impairment influences multi-organ function and requires adherence to treatment for positive clinical outcomes. Lifestyle restrictions significantly impact psychosocial functioning during treatment. It is common for patients with ESRF to encounter psychosocial symptoms during the disease trajectory. The study of Yong et al. (2009) described that there was no difference in the QOL and symptom burden experienced by ESRF patients between dialysis therapy and palliative care. These findings were echoed by a systematic review (O'Connor & Kumar, 2012) that the level of symptom burden was comparable in these groups and the QOL was significantly compromised in both palliative care and the group with dialysis therapy.

Depression and anxiety

Depression is the most common psychological symptom which affects the QOL of ESRF patients and their families (Gerogianni et al., 2016). It adversely affects their social, economic, and psychological health (Anees et al., 2011; Shirazian et al., 2017). Besides, depression has been associated with negative clinical outcomes (Cukor et al., 2012; Fischer et al., 2011; Tsai et al., 2012), high mortality (Tsai et al., 2012; Fischer et al., 2011) and a high prevalence of inflammation in patients with ESRF (Di Lullo et al., 2016). Palmer et al. (2013) have found that non-dialytic patients with ESRF have three times higher rates of depression than those in the general population. The presence of depression in patients with ESRF may be under-diagnosed due to the overlapping of somatic symptoms of depression with uraemic symptoms, including fatigue, poor appetite and poor quality of sleep (Hedayati et al., 2012). Depression is also manifested in sadness, anxiety, depressive mood, poor self-esteem, sleep disorder, pessimism about the future, and poor appetite (Economidou et al., 2005).

Anxiety disorders in the ESRF population have received sparse clinical attention compared with depression. Self-report scales have been the main source of information, giving a general measure of anxiety level (Martin et al., 2004). The negative impact of anxiety on the QOL and disability has been indicated in multiple illnesses, however, effects specific to ESRF have not been identified (Goh & Griva, 2018).

Depression, anxiety, and other psychiatric conditions may indicate an additional risk for patients as serious physiological abnormalities and treatment resistance have been associated with comorbid depression (Goh & Griva, 2018; Pollack, 2005). Uncontrolled cognitive impairment and psychiatric disorders can b be contributing factors to poor QOL in patients with ESRF (Moreira et al., 2015).

Sleep disturbance

Insomnia is a common sleep disorder in ESRF patients (Maung et al., 2016) which is associated with morbidity and mortality (Harris et al., 2012). The prevalence of insomnia ranges from 50 to 75% in ESRF patients and the presence of insomnia symptoms reduces the QOL (Merlino et al., 2006; Theofilou, 2013). These sleep disorders may contribute to cardiovascular disease and cause the substantial morbidity and mortality found in patients with ESRF (Mavanur et al., 2010). The diagnosis and treatment of sleep disorders are problematic by overlapping clinical features of ESRF and other comorbid symptoms (Maung et al., 2016).

2.1.2 Impacts of ESRF on physiological symptoms

Researchers reported that the symptom burden was high for patients at CKD stages 4 and 5 (Almutary et al., 2013; Murphy et al., 2009). The most commonly reported symptoms were severe weakness (81%), poor sleep (70%), muscle and joint ache (69%) (Brown et al., 2017). No significant relationship between the frequency of symptoms perceived and the severity of ESRF or comorbidity status was reported (Murphy et al., 2009).

Researchers have revealed that renal patients are included in the symptomatic populations with irreversible chronic illness (Ammirati, 2020; Germain & McCarthy, 2004). The symptom distress and compromised QOL of ESRF patients are similar to those with terminal malignancy (Ren et al., 2019; Saini et al., 2006). Various studies have indicated that persons approaching the end phase of life will encounter multiple chronic symptoms, which can be worsened if the individual has unsolved psychological distress (Morrison & Meier, 2003; Kazanowski, 2003; National Consensus Project for Quality Palliative Care, 2004; Warraich, 2017).

Fatigue

Fatigue is one of the most widespread but commonly under-recognized and under-treated symptoms (Ahlberg et al., 2005; Almutary et al., 2013, 2016; Kirshbaum, 2012). Fatigue can be viewed as a multi-faceted concept (Artom et al., 2014; Joshwa & Campbell, 2017) which is fluctuating in duration and intensity and is affected by circadian rhythms (Piper et al., 1998) and is associated with sleep disorders and anaemia, malnutrition and weakness (Artom et al., 2014; Harrington, 2012). Symptom management of fatigue is critical given that fatigue has been associated with compromised QOL and higher mortality rates (Davey et al., 2019).

Dyspnea

Dyspnea is a highly prevalent and complex symptom of patients with ESKD, which may persist despite optimal care (Almutary et al., 2013; Chilvers et al., 2020). The distress of dyspnoea may be exaggerated with a comorbid condition such as anaemia, malnutrition, inflammation and muscle wasting (Salerno et al., 2017). Concurrent diseases with acidosis, angina, respiratory infection, and renal failure provoke dyspnea (Segall et al., 2014).

Anaemia

Anaemia is the most common complication of CKD (Marinakis & Xanthopoulos, 2009; Batchelor et al., 2020). It is presented clinically as fatigue and/or depression and negatively affects the QOL of patients with decreased motor activity, sleep disturbance, altered social activity, anxiety, and depression (Kastrouni et al., 2010; Moreira et al., 2015). Treatment with pharmacological interventions is prescribed for anaemic patients with the injection of erythropoietin stimulating hormone if indicated (Palmer et al., 2013). There is an association between iron deficiency anaemia and increased risk of mortality and cardiovascular problems (Awan et al., 2021), but absolute iron deficiency anaemia is only associated with the chance of hospital admission.

Pain

Pain is one of the most distressing symptoms among patients with ESRF. The prevalence of pain has been associated with psychosocial distress, poor sleep, depressive symptoms and lower health-related QOL (Davison et al., 2019; Santoro et al., 2013). Pain is extremely common in ESRF due to cardiovascular insufficiency and accumulation of metabolic wastes and is the most distressing symptom approaching the last phase of life (Morrison & Meier, 2003). Pain severity and symptom distress in CKD patients are under-estimated (Gamondi

et al., 2013; Ng et al., 2020a). In addition to pharmacological treatment of the WHO threestep analgesic ladder, non-pharmacological strategies including electrotherapy and high tone external muscle stimulation are effective in neuropathic pain management in ESRF patients (Santoro et al., 2013).

Gastrointestinal Symptoms

There is a prevalence of constipation in ESRF patients with palliative support. Causes of constipation are directly related to physical inactivity, weakness, poor nutrition, inadequate fibre intake and dehydration (Morrison & Meier, 2003). The lack of appetite is common in the final stages of illness. Anorexia is accompanied by compromised physical functions and often causes grave concern in patients and family caregivers (Morrison & Meier, 2003). The medical complications of anorexia may lead to weight loss and malnutrition. A high serum uraemic level is attributed to an unpleasant sense of smell and oral sensation leading to anorexia in ESRF patients (Santacoloma Osorio & Camilo Giraldo, 2017). Severe starvation induces protein and fat metabolism leading to adverse effects on the functions of various vital organs such as the heart, liver, kidney, brain, and gastrointestinal tract (Mehler & Brown, 2015).

Pruritus

Pruritus is another common but distressing symptom in the uremic patient which needs intervention. This distress significantly affects the ESRF patient due to the accumulation of nitrogenous waste in the skin together with inadequate sebaceous secretion. Common pharmacological treatment includes diphenhydramine (Sara et al., 2015). Poorly managed skin itchiness greatly affects insomnia, social life and health-related QOL (Santoro et al., 2013).

Thirst

The symptoms of thirst are commonly reported by the patient taking anticholinergic medications and opiate treatment (Wiffen et al., 2014). Symptoms of thirst are common and exaggerated in renal failure patients who require dietary compliance with fluid restrictions.

Delirium

In kidney failure patients, delirium may be associated with the accumulation of nitrogenous waste products and the effects of electrolyte imbalances. Early identification and assessment can improve outcomes (Kurella & Yaffe, 2011; Mayo clinic staff, 2017).

Poor appetite

Poor appetite is common during the late stage of CKD as there is an accumulation of nitrogenous waste within systemic circulation which affect food taste deviant and creates foul breath and poor appetite or anorexia. The development of poor appetite may result in weight loss and malnutrition. Appetite suppression in uraemia is multifactorial and may be associated with adverse clinical outcomes such as increased hospitalisation rate and death in patients with CKD (Ikizler, 2013).

2.1.3 Challenges in symptom management for ESRF patients

The general symptoms of CKD can often be managed by adjustment of behaviour and lifestyle such as dietary modification and limitation of fluid intake. However, the uncontrolled symptoms will create refractory distress, which acts adversely on other systemic functions. Whilst multiple organ manifestations will lead to further progression of residual renal function (Kallenbach et al., 2005).

2.1.3.1 Management of high-risk factors

High-risk factors for CKD are uncontrolled hypertension, hyperglycemia, and dyslipidemia. Different modes of strategic treatment are suggested for the prevention of the progression of chronic nephropathies such as ruling out the underlying cause with treatment (American Kidney Fund, 2015), anti-hypertensive treatment (American Kidney Fund, 2015; Jackson & Bellamy, 2015), good glycaemic control (American Kidney Fund, 2015; Fioretto & Solini, 2005), reno-protection with angiotensin-converting enzyme inhibitors and angiotensin II receptor blockers (Jackson & Bellamy, 2015; Nakao et al., 2003), low protein diet for non-dialysis patients and healthy lifestyle (American Kidney Fund, 2015; Riegersperger & Sunder-Plassmann, 2007).

Hypertension is the most common cardiovascular complication in patients' experiencing ESRF. Optimal blood pressure is below 130/80 mmHg in patients with CKD and/or diabetes (Bakris et al., 2000), and even less than 120 mm Hg using standardised office reading for most adults with CKD not receiving dialysis as suggested by the most updated international guideline (Cheung at al., 2021). Ideally, blood pressure monitoring should be carried out by patients at home (Agarwal et al., 2009). Good control of fluid volume and sodium with an appropriate dosage of antihypertensive medications can facilitate the control of hypertension (Jackson & Bellamy, 2015; Wright & Hutchison, 2009).

2.1.3.2 High mortality

People with ACKD have high mortality from the progression of renal dysfunction which contributes to death from cardiovascular and cancer disease (Webster et al., 2017). Patients with supportive care have a 1-year survival of 70.6% (95% CI 63.3-78.0%) (Foote et al.,

2016). Comorbidities such as cardiac disease and advanced depression are closely associated with morbidity and mortality for patients with ESRF (Segall et al., 2014).

2.1.3.3 Increasing burden on healthcare service utilisation

Readmissions for patients with non-dialysis-dependent CKD and kidney failure are common and are associated with significant morbidity, mortality, and economic consequences (Doshi & Wish, 2021). Approximately 50% of 30-days readmission is avoidable with timely follow-up care, optimal nutrition, and availability of palliative care consultation with goal-orientated care planning (Doshi & Wish, 2021).

In Hong Kong, a study found that 40.8% of the unplanned readmissions due to medical conditions within 30-days were deemed to be preventable (Yam et al., 2010). Reasons for unscheduled readmission were due to clinical factors (42.3%) including the low threshold for admission and premature discharge; patient factors (41.9%) including medical and health factors such as relapse of the previous complaint, compliance problems, followed by system factors (14.6%) including inadequate discharge planning, inadequate palliative care support, and social factors (1.2%) such as compromised caregiver system, lack of support and community services (Yam et al., 2010).

The findings of Taylor & Gutteridge (2013) reported that there was a connection between depression and increased hospitalisation rates in ESRD patients. Approximately 722,692 (7.78%) out of 92,899,685 annual emergency department visits were ESRD patients. ESRF patients were prone to have hospitalization after the visit to AED [odds ratio (OR): 2.70; 95% confidence interval (CI): 2.13–3.41] and intensive care unit (OR: 2.21; 95% CI: 1.45–3.38) than patients without ESRF in the United States (Wang & Heidt, 2021).

2.1.3.4 Impaired QOL

QOL includes parameters such as physical function, psychological well-being, social interaction, cognition, emotion, strength and energy, sleep quality and general life satisfaction. Health-related QOL declined emphatically with more advanced stages of CKD. Other parameters including female gender, diabetic mellitus (DM), and cardiac problems were associated with compromised QOL (Mujais & Finkelstein, 2009). The status of QOL of individuals with ESRF was further associated with the condition of disease which is linked to risks of hospitalisation and premature death. The QOL of ESRF patients was substantially lower than that of the general population (Webster et al., 2017).

2.1.3.5 Inadequate symptom control

A national registry study in Sweden revealed the unmet care needs of 472 ESRF patients in their last week of life (Axelsson et al., 2019). Of six predefined symptoms, the pain was the most prevalent (69%), followed by respiratory secretion (46%), anxiety (41%), confusion (30%), shortness of breath (22%), and nausea (17%). The symptoms noted in the study of

Axelsson et al. (2019) reflected that patients with pain 32% and/or anxiety 44%, were only partly relieved or not relieved at all. In addition, bereavement support was offered to only 38% of the families with deceased. Even if death was expected, most patients dying with ESRF had unmet palliative care needs regarding symptom control, advance care planning, and bereavement support (Axelsson et al., 2019).

Because of the unmet needs for physical and psychological symptom care at the EOL for older and sicker people with ESRF, the need for palliative care with supportive care is advocated. Palliative care aims to address the complex symptoms and psychological issues of ESRF patients to enhance QOL and plan EOL care (Smith et al., 2015).

2.1.4 Non-dialysis conservative care

Conservative care is an alternative treatment for persons who do not view dialysis as a variable treatment option. For instance, patients over 80 years of age would present no survival benefit with dialysis (Van Loon et al., 2019). Data suggest that conservative care may bring similar symptom distress and QOL that are comparable with those on maintenance dialysis (Song, 2016). The non-dialysis pathway of care with symptom management and services coordination to assist patients in staying at home as long as possible is an option of care.

Opting for non-dialytic treatment has been a common, recognized, and significant treatment modality in certain groups of patients with ESRF (Wong et al., 2007). The prognosis of this group of non-dialytic treatment patients is not known in terms of hospitalisation rates and survival status (Wong et al., 2007). Palliative care in local hospitals can be delivered hospital-based or home-based (Chan et al., 2015; Yong et al., 2009). There is no well-definite recommendation of a care model available for reference. Locally, the development of palliative services for organ failure patients of different systems is in the early stage. The need for palliative care is being considered by the renal team with the increased prevalence of CKD (Leung et al., 2015; Tang, 2018).

2.2 Palliative Care for ESRF

The objective of palliative care is to achieve the optimum QOL attainable for patients and their relatives. Various approaches to palliative care can be implemented from the diagnosis of the illness in alignment with transitional therapies. Palliative care considers dying as a normal process without accelerating or postponing death. It provides alleviation of distressing symptoms both physically and psychologically. Palliative care offers support to the patient to live as actively as possible by integrating physical, psychological, social, and spiritual care in the process of care delivery (Kidney Disease Fund, 2007; WHO, 2020). ESRF is complicated with multi-organ involvement if a patient goes further into the process of care and encounters a refractory system that may be better treated in the hospital. Because of this, the dynamic end phase of life care described in the earlier phase of the process of treatment, palliative care may minimize the symptom distress that requires hospitalization and better-advanced symptoms management (Chambers et al., 2018).

2.2.1 Palliative care and associated terms

Different terms describing the care provided for advanced, irreversible chronic diseases are used. Medical oncologists and mid-level providers consider that the term 'palliative care is discouraging and distressing to patients. In most cases, they prefer the term 'supportive care' and are more likely to refer patients on primary and advanced cancer treatments to 'supportive care' (Fadul et al., 2009).

A range of alternative terms have been adopted clinically in describing non-dialysis nephrology care, for example, conservative care, maximal conservative management, supportive care, renal supportive care or renal palliative care, Non-dialysis Medical Therapy (NDMT) is also called "maximum conservative management" or "active medical management without dialysis" has been used in addressing non-dialysis care in the ESRF population (Murtagh et al., 2016). NDMT is a treatment plan for CKD patients who forgo the initiation of dialysis (Renal Association, 2002), which is also described as an alternate therapy for stage 5 CKD patients (Kilshaw et al., 2016).

Dialysis does not significantly prolong life and it may significantly impact the QOL. Conservative management is offered to these patients, employing a multi-disciplinary team to provide holistic care with active management which addresses symptoms to improve function to preserve independence (Kilshaw et al., 2016). However, the undefined terms of care for the ESRF population have hindered studies from providing the evidence way to enhance patient care and clinical outcomes (Murtagh et al., 2016).

The term "palliative care" inclines to imply a negative belief and may discourage patients from accepting palliative care (Dai et al., 2017). Palliative care is often underutilized due to the stigmatization of palliative care with the sense of giving up on a struggling individual's illness (Shen & Wellman, 2019). Rebranding has thus been proposed as a strategy to minimise negative perceptions. Instead, the term "supportive care" mentioned earlier in the section is used in naming palliative care units as proposed in several studies (Dai et al., 2017).

Inappropriate perception of the term "palliative care" adversely affects the time of referral and clinical outcomes. Vissers et al. (2013) evidenced the benefits of early referral for palliative care with fewer investigations. The focus was on the early identification of patients in a palliative trajectory with effective prevention of irritating symptoms. Consequently, there was an improved QOL and better EOL care with less demand for clinical investigations (Vissers et al., 2013). The term palliative care is more commonly applied in day-to-day patient care services. There was an increase in palliative care for CKD patients with an understanding of palliative care services. Non-dialysis conservative care is integrated into the holistic management of ESRF patients throughout their disease trajectory (Brown, 2012; David et al., 2018; Qazi et al., 2018).

As denoted by National Kidney Foundation (2017), palliative care is a special planned medical care that assists CKD patients by alleviating pain, other symptoms of distress, and psychosocial stress simultaneously as they continue to receive treatment for their disease. The objective of palliative care is to improve the QOL for both the care recipient and caregiver with comprehensive medical care focusing on pain and symptom management. Healthcare providers have acknowledged the benefits of palliative care for non-dialysis ESRF patients (Brown et al., 2015). However, few CKD patients and family caregivers are aware of the offer and effects of palliative care. Palliative care empowers patients and families with better management of their conditions, and it can prolong the lives of patients (National Kidney Foundation, 2017).

2.2.2 Impacts of palliative care on ESRF patients

Palliative care strategies have been developed and gradually integrated into the normal routine care framework. A range of empirical evidence shows the clinical treatment of ESRF towards the EOL focuses on the demands of the clinical conditions rather than the treatment of the disease. ESRF patients will benefit from early intervention utilising palliative care (Chiu et al., 2021; Germain et al., 2011; Hong Kong College of Physicians, 2008). In recent decades, various approaches to palliative care programs have been applied to a diverse

patient population with effective clinical outcomes (Luckett et al., 2014; Chettiar et al., 2018; Kao et al., 2013). Frail elderly patients with ESRF presented with comorbid clinical status managed with early palliative care may live as long as patients who rely on RRT (Kasiske & Wheeler, 2013). Evidence has shown that early palliative care has been related to less hospitalisation, less AED attendance, and better QOL (Germain et al., 2011; Kasiske & Wheeler, 2013).

A comprehensive picture of palliative care was synthesized from a collective review of efficiency programs, perspectives of patients and their caregivers, and views of healthcare providers in palliative care (Seow & Bainbridge, 2017). The key components of quality home-based palliative care which emerged are composed of teamwork within and across settings, holistic management of nonphysical and physical symptoms, timely and responsive interventions, and patient and family preparedness (Seow & Bainbridge, 2017).

2.2.3 Impacts of holistic management on alleviation of symptoms

CKD is a complex medical condition that is associated with several comorbidities and requires comprehensive medical management. The risk of death increases with a decreased eGFR below 60 ml/minute per 1.73 m² of body surface area, while the high hospitalisation rate is also associated with decreased GFR (Go et al., 2004; Nitsch et al., 2011). In traditional modes of therapy, all renal failure related signs and symptoms are actively managed for the alleviation of symptoms of the disease by all possible strategies, while the CKD related symptoms are actively managed using the palliative approach (Brumley et al., 2007; Brown et al., 2015). Palliative treatment aims at meeting the needs of patients with the prevention of complications, slowing the decline of clinical status and better control of symptoms with early identification, appropriate intervention and evaluation of interventions implemented and their surveillance.

Dialysis for ESRF will no longer prolong life or even improve QOL in some patients with severe comorbidity. Instead, non-dialytic management is now an established treatment option in most renal units in the United Kingdom (Alston, 2013). Conservative management is a commonly adopted treatment option nowadays with the provision for control of symptoms, prevention of complications by controlling acid-base, electrolyte and hydration balance through a non-dialytic approach, correction of anaemia and effective management of EOL (Carson et al., 2009; Chandna et al., 2011; Murtagh et al., 2007; Portolés et al., 2021). For instance, anaemia among patients with stage 4-5 CKD was treated by blood transfusion therapy and repeated hospitalisation, both of which were shown to be ameliorated significantly by Erythropoietin Stimulating Agent (Palmer et al., 2014). Conservative management allows the maintenance of the QOL for the patient and their significant others. In addition, empowering caregivers, as an alternative strategy, to provide symptom control is emphasised (Mechler & Liantonio, 2019).

2.2.4 Holistic management in meeting the needs of patients with ESRF

In addition to related physical symptoms and treatment choice preference, the burden of ESRF can be heavy in terms of emotional, spiritual, and practical concerns. Holistic management of physical and non-physical symptoms is crucial and requires support from multidisciplinary professionals. The palliative teams can assist in customising care plans and addressing patients' diverse needs. They can provide appropriate conventional therapies as well as additional care such as relaxation techniques including massage, and relaxation exercises to relieve emotional and spiritual stress (Davison & Jassal, 2016; Murtagh et al., 2016, Henson et al., 2020). The holistic care approach may enhance patients' peace of mind

and ability to handle personal affairs, improve QOL and relieve all forms of suffering (Seow & Bainbridge, 2017).

The goal and purposes of TPC are to improve the QOL for patients and their families by treating the pain, symptoms and emotional stress of the illness, and providing important support for decision making (Davison & Jassal, 2016). Palliative care provides emotional support for both patients and their families. The purpose of social support is targeted at the provision of psychological and material resources enabling a person's ability to deal with stress (Davison & Jassal, 2016; Kimmel et al., 2001).

2.2.5 The importance of seamless teamwork in health-related communications

Adequate communication between healthcare providers and patients plays an important role in achieving good clinical feedback in patient-oriented care and improving patient engagement in their care. Appropriate communications underpin the quality of palliative care (Murray et al, 2015) and are linked with better QOL of patients with palliative care (Walczak et al., 2016). Good communication requires bundles of behaviours, attitudes, values, traits, and techniques to transfer information both verbally and non-verbally. During the complex care delivery process, patients with ESRF often encounter numerous and complex treatment options and decision-making, which constitute treatment modalities, care strategies, and system control (Meyer & Goodlin, 2016; LeMond et al., 2015). In the delivery of palliative care, it is important to communicate the disease trajectory, dying trajectory, and treatment options among patients, family members and healthcare providers (Allan & Killick, 2009; Barclay et al, 2011). Honest and appropriate communication facilitates the patients and families in understanding treatment options, priorities of care setting, and EOL planning in the disease trajectory of irreversible and advanced kidney disease (Eneanya et al., 2015).

Communication and coordination of care between providers, competent skills, and the ability to address individuals' changing needs are treated as critical attributes of palliative care models (Luckett et al., 2014). Advanced knowledge and extensive clinical experiences are beneficial for meeting the needs of individuals with ESRF. Fitzsimons et al. (2007) conducted an interview with organ failure patients about their family caregivers about their perspectives on palliative care. The study revealed inadequate hospital and community support and the informants suggested that organ failure patients deserved more coordinated and continuous care.

A team approach to palliative care can facilitate patients making critical decisions about treatment options including pharmacological and non-pharmacological management (World Health Organization, 2016). The palliative care team empowers patients to understand and determine what treatment to choose. Whatever the treatment options that patients receive, the palliative care team will work along with the nephrologist in supporting the ESRF patient. A clear explanation of the expected outcomes of the disease trajectory of ESRF is emphasised. Patients and families have different needs along the disease trajectory of CKD. The palliative care team will work together with the patient and family members to better realise their condition and treatments (Bslohun et al., 2019). Overall, communication is one of the key components of palliative care. In caring for CKD patients receiving palliative care, good coordination of care, comprehensive planning of care, and collaborative team effort is emphasised to optimise care.

In summing up, seamless teamwork within and across settings will result in smooth transitions between settings and providers, improved communication and more effective collaboration. The smooth connections facilitate sharing of patient health-related information (Seow and Bainbridge, 2017).

2.2.6 Challenges in the integration of palliative care in Hong Kong

Advanced technology, a healthy lifestyle, improved public health awareness and requirements, and medical interventions have contributed to an extended life expectancy (Lynn & Forlini, 2001; Mishra, 2016). As people with chronic illnesses are living longer, there is an increasing concern about the burden of chronic illness on individuals, families, and the healthcare system (Glare & Virik, 2001; Hajat & Stein, 2018). During the long duration of the disease trajectory, people with a life-threatening illness will experience pain, various physical burdens, and other psychosocial and spiritual symptoms (Bookbinder & Glajchen, 2010). Hence, palliative care is acknowledged as a more acceptable treatment strategy to preserve the QOL (Higginson & Donaldsen, 2004; Sleeman et al., 2021).

In Hong Kong, according to the local practice of managing the population of ESRF, especially for frail patients who opt for palliative services, dialysis therapy is suspended. The trajectory of the disease will worsen and the patient will encounter repeated hospitalisation, prolonged LOS at the hospital and poor QOL when the distress symptoms are not well controlled (Whitney & Chuang, 2016). Conventional medical care for patients cannot meet the needs of patients with satisfactory clinical outcomes. On the other hand, the population of ESRF without dialysis therapy can receive proactive care to effectively control the symptom burden and maintain their psychological well-being with various modes of ongoing support (Abdel-Rahman et al., 2010; Brown et al., 2015; Crawford et al., 2014).

Comprehensive supportive care involves interventions to defer the declination of renal function and minimise the degree of adverse conditions or complications, active symptom management and appropriate communication, which includes advanced care preparation, psychosocial and family support, and cultural and spiritual support (Davison et al., 2015). As with other chronic diseases, the inadequacy of supportive strategies to sustain the continuity of care may increase the episodes of unplanned readmission during the transition of care from hospital to home-based for ESRF patients (Mathew et al., 2015). Researchers in Hong Kong have indicated that the leading causes of readmission include inadequate discharge planning, piecemeal care with inadequate hospital and community support, non-recognition of newly developed symptoms, declined condition, and complications of the disease (Wong et al., 2010). Various studies of home-based or community-based palliative care evidenced optimal clinical effects with fewer readmissions (Morrison et al., 2011; Ranganathan et al., 2013), increased satisfaction of care (Wentlandt et al., 2016; Wong et al., 2016) and improved QOL (University of Pittsburgh Medical Center, 2016).

The integration of the palliative care approach into chronic disease management contributes to the enhancement of care quality and reduction of healthcare expenditure (Murray et al., 2005; Teruel et al., 2015; Wong et al., 2018). With palliative care, people with advanced chronic disease can benefit from psychosocial support and better symptom management instead of waiting until the unpredictable last weeks or months of life are encountered (Bookbinder, & McHugh, 2010; Gillick, 2005; Sleeman et al., 2021). Coordinated input from both nephrology and palliative care teams will ultimately improve EOL care for ESRF patients (Teruel et al., 2015).

In the recent decades, an enhancement program of intensified follow-up has led to fewer acute hospital admissions and AED visits for non-dialytic ESRD patients (Chan et al., 2015) and psychoeducational services could significantly improve non-dialytic ESRF patient symptoms and reduce acute hospital admissions (Chan et al., 2020) in the local context. However, overarching guidelines and policies for the provision of palliative care are inadequate in Hong Kong (Wong et al., 2020). Fragmented palliative care programs are established by different organisations, with different service guidelines and structures resulting in fragmentation of services and inadequate coverage of all patients' needs for community-based care leading to high demand for inpatient palliative care (Wong et al., 2020). The provision of person-centred palliative care does not adequately meet the needs of patients under non-hospital based care.

While palliative care services have typically focused on patients, relatively little attention has been directed to family caregivers, who are profoundly challenged by their caregiving roles (Hudson & Payne, 2011), for instance, the positive effects of psychosocial support on the caregivers were significantly illustrated locally in an RCT on patients with CKD with no dialysis (Chan et al., 2016). As caring for a patient with an irreversible disease at home is physically and emotionally demanding, most informal caregivers experience higher levels of stress and thus have unmet support needs (Hudson et al., 2004; Ullrich et al., 2017; Wallerstedt et al., 2014). Stress on caregivers can negatively impact their health (Tripodoro et al., 2015) and the results of physical, mental and socio-economic problems of caregivers can manifest in physical disorders and poor QOL (Choi & Seo, 2019; Zavagli et al., 2019). However, very few studies examining the informal caregivers of non-dialytic patients are available for reference.

In the recent decade, various literature focused on palliative care in the home-hospice or acute care setting (Morrison e al., 2011; Taylor et al., 2017). Very little has been written about palliative care services for the benefit of non-dialytic ESRF patients. There is no evidence of studies showing what approach to palliative care will result in definite improved clinical outcomes or standardised palliative care interventions. Despite high rates of morbidity and mortality in patients with CKD, the integration of supportive care in chronic kidney disease CKD remains in its infancy, with exceedingly few studies having been performed (Davison & Jassal, 2016). The demand for palliative care has risen consistently risen with the increased prevalence of CKD. The demand for palliative care has consistently risen with the escalated prevalence of CKD, and palliative and supportive components of renal services should be enhanced to underpin ESRF patients (Hussain et al., 2013; Kavalieratos, 2016).

2.3 Literature Review on Transitional Care Strategies

This study proposes the use of the TRPP in palliative care delivery to ESRF patients. A TRPP is specially designed to promote the safe transition of patients from hospital to home (Naylor & Sochalski, 2011; Hung & Leidig, 2015). In transitional care, it is planned to transfer the patient from one care setting to another such as a hospital, institution home or an assisted living facility (Coleman & Boult, 2003). According to the National Transition of Care Coalition (2019), transitional care can occur specifically within settings (e.g. from the intensive care unit to the general ward), between settings (e.g. from acute hospital care to palliative care), across health states (e.g. from curative care to palliative care), and between providers (e.g. from generalist to an acute care provider). Changing from curing care to palliative care can be a confusing and traumatic process for patients, who may experience anxiety, helplessness and a sense of abandonment (Sinuff et al., 2015).

2.3.1 Aim and objectives

This literature review on the TRPP aimed at searching for relevant information for the development of the TRPP in this study. The specific objective was to explore the best appropriate model of transitional care for patients with renal palliative care discharged from the hospital to the home environment. The specifications of transitional care study inferred characteristics of study including the type of study, patient group and the number of participants, morbidity/type of disease and outcomes of the study. The characterised TRPP involved: (1) structural framework of transitional mode (2) types of intervention/modes of strategies, (3) care provider/care coordinator, (4) dose of interventions, and (5) outcome variables.

2.3.2 Methods

Data sources and searches: Literature was searched through electronic databases Cumulative Index to Nursing and Allied Health Literature (CINAHL), the Index Medicus (MEDLINE), the Social Science Citation Index (SSCI), Elsevier Scopus, PubMed, Clinical Key and the Cochrane Central Register of Controlled Trials (CENTRAL, The Cochrane Library), and Excerpta Medica database (EMBASE) from 1999 to 2014 were searched. The keywords for online searching included "transitional care", "home-based care", "discharge patient", "discharge planning", "post-discharge support", "telephone follow-up", "home visit", "referral", "protocol-driven program", "Omaha System (OS)".

Inclusion criteria: A considerable number of transitional care studies were carried out globally and locally with an extensive body of evidence on transitional care. Those meeting the following inclusion criteria have been included in this review: (1) study design: RCT;

(2) study population: adult (18 years of age or older) with chronic diseases; (3) study intervention: discharge plan (e.g. assessment, coaching, education) plus post-discharge supportive interventions (e.g. telephone follow-up, home visits, referral); and (4) the study targeted in the following categories of intervention outcomes:

- Clinical outcomes: physiological presentation, symptom control, mortality rate and others
- Psychosocial outcomes: coping management, anxiety or depression, adherence to treatment, knowledge and others
- Functional outcomes: QOL, self-care functional status, and others
- Healthcare cost: readmission, emergency department visit, days of hospitalisation and others
- Satisfaction: patient or caregivers and others

Process of data screening: A total of 85 studies and 9 systematic reviews covering the period from 1999 to 2014 were retrieved by the doctoral student investigator for the abovementioned databases. In the first filtering process, 34 articles, 4 quasi-experimental studies and 5 systemic reviews were shortlisted. In addressing the inclusion criteria, the search was narrowed down to 34 RCTs (Andersen et al., 2002; Blakeman et al., 2014; Blue et al., 2001; Boult et al. 2011; Bouman et al., 2008; Brumley et al., 2007; Buurman et al., 2010; Caplan et al., 2004; Coleman et al., 2006; Daly et al., 2005; Egan et al., 2002; Forster et al., 2005; Hanssen et al. 2007; Hermiz et al., 2002; Jack et al., 2009; Kwok et al., 2004; Kwok et al., 2008; Laramee et al., 2003; Lim et al., 2003; Naylor et al., 2004; Naylor et al., 1999; Saleh et al., 2012; Sinclair et al., 2005; Stewart et al., 1999; Wong et al., 2004; Thomson et al., 2005; Wong et al., 2008; Wong et al., 2010; Wong et al., 2011; Wong et al., 2014; Wong et al., 2005; Young et al., 2003; Zhao & Wong, 2009; Zwar et al., 2012). *Data analysis*: Two tables were used to present the review results. Table 2.2 presents a summary of the reviewed studies. Effects of various modes of TRPP present a review of citations, study participants, delivery mode of intervention (dose, way, provider and coordinator), duration of follow-up, initiation of telephone call and intervention, intervention strategies (care categories and quality assurance), and intervention effectiveness (clinical and functional outcomes, psychosocial outcomes, health utilisation and cost outcomes, and satisfaction).

No	Study Author(s) (year)	Subjects	Design of study	Types of interventions	Outcome measurements	Key findings
1	Naylor et al. (1999) United States	Mixed diagnosis patients (N =363) C (n = 186) I (n=177) Discharged from hospital to home	RCT	 Protocol-derived; nurse-led program comprehensive discharge assessment and planning Protocol-derived post-discharge home-based follow-up APNs as the project coordinator Intervention: Discharge planning Home visit Telephone out-reach 	 Readmission rate Length of hospitslisation Acute care visits Functional status Depression Patient satisfaction rate Health cost 	 The intervention group had: Fewer readmission The shorter length of hospitalisation Fewer health services reimbursement Control group: Increased Medicare reimbursement No differences between the group in: Acute care visit Functional status Depression Patient satisfaction
2	Stewart et al. (1999) Australia	Chronic HF patients (N=200) C $(n = 100)$ I $(n = 100)$ Discharged from hospital to community	RCT	 Program component: discharge planning and post- discharge telephone follow up at 3rd & 6th month Interventions: Home visit by cardiac specialty nurse 7-14 days Healthcare cost assessment 	 Readmission rate Healthcare cost QOL Mortality rate 	In the intervention group:Less readmissionReduced associated healthcare costsProlong survival rateImproved QOL
3	Blue et al. (2001) United Kingdom	Heart failure patients (N=165) C (n=83) I (n=82) Discharged from hospital to home	RCT	 Cardiac specialty nurse coordinated program Nurse-led program Home visits for up to 1 year Patient education: promotion of optimal cardiac drug Family education Telephone follow-up (12 weeks) 	MortalityReadmission	 In the intervention group: Take the target dose of a drug Less readmission Fewer days in the hospital Fewer chronic heart failure events
4	Andersen et al. (2002) Denmark	Stroke patients (N = 155) C (n = 48) I (doctor)(n=54) I (physiotherapist) (n=53) Discharged from hospital to home	RCT	 Multidisciplinary: doctor, physiotherapist Program structure: phone follow-up, home visit if necessary Interventions: Health monitoring Referral to community resources 	The functional quality of movement Barthel indexFrenchay activity index	 No differences between the 3 groups in physical function. Three groups got improvement in the physical function

Table 2.2 Review of study setting and findings of the transitional care for chronic disease

Notes: RCT = randomised controlled trial; I= intervention group; C= control group; AED = Accident and Emergency Department; ADL= activities of daily living; CDSES = Career Decision Self-efficacy Scale; IADL=independent activities of daily living; SF= short form; QOL= quality of life; TV= trained volunteers

#11 diagnoses include stroke, chronic heart failure, Cardiac Arterial Disease, cardiac arrhythmias, Chronic Obstructive Pulmonary Disease, diabetic mellitus, hip fracture, spinal stenosis; Peripheral vascular disease, deep vein thrombosis, Pulmonary embolism
No	Study Author(s) (year)	Subjects	Design of study	Types of interventions	Outcome measurements	Key findings
5	Hermiz et al. (2002) Australia	COPD patients (N=177) C (n=84) I (n=93) Discharged from hospital to home	RCT	 Intervention structure: Discharge planning Telephone follow-up Health assessment Patient education: ADL, exercise, drugs 	 Readmission rate AED visit Frequency of general physician consultation QOL Satisfaction rate 	In the intervention group: Increased patient satisfaction Higher knowledge score
6	Egan et al. (2002) Australia	COPD patients (N=66) I (n = 33) C (n = 33) Discharged from hospital to home	RCT	 NCM program Program structure: discharge planning and post-discharge telephone follow up Interventions: Assessment of health Patient education 	 Anxiety Depression Physical symptoms Social support Subjective wellbeing 	 A non-significant difference in key outcome variables between groups: readmission, depression, symptoms The positive impact on psychological wellbeing (less anxiety) faded out over time in the intervention group:
7	Laramee et al. (2003) United States	CHF patients (N=287) C (n=146) I (n=141) Discharge from hospital to home	RCT	 Hospital-based NCM Multidisciplinary team Discharge planning Telephone follow-up: 12 weeks Patent initiated call 	 Symptom surveillance Readmission LOS in hospital Healthcare cost Patient satisfaction Treatment adherence 	 In the intervention group: Increased patient satisfaction No significant difference between groups: Readmission LOS in hospital
8	Lim et al. (2003) Australia	Post-acute care patients (N=598) C (n=287) I (n=311) Discharged from hospital to community	RCT	 6-month Follow-up Education of patient	 Readmission Mortality rate Use of community service QOL Stress 	 Better outcomes in the intervention group: Enhanced QOL Total health cost No differences between the group in: Unplanned readmission

Notes: RCT = randomised controlled trial; I= intervention group; C= control group; AED = Accident and Emergency Department; ADL= activities of daily living; CDSES = Career Decision Self-efficacy Scale; IADL=independent activities of daily living; SF= short form; QOL= quality of life; TV= trained volunteers

No.	Study Author(s) (year) Place	Subjects	Design of study	Types of interventions	Outcome measurements	Key findings
9	Young (2003) Canada	CHF & COPD patients (N=146) C(n=75) I(n=71) Discharged from hospital to home	RCT	 Disease management program Cardiac specialty nurse Home visit Education 	ReadmissionAED visit	Significant differences between groups: • Readmission • Less AED visit
10	Naylor et al. (2004) United States	Heart failure older patients (N = 239) I $(n = 118)$ C $(n = 121)$ Discharged from hospital to home	RCT	 APN-led Transitional Care Protocol guided, APN case manager and interventions based on national guidelines Program structure: discharge plan and follow-up Interventions: Health assessment Monitor medication Symptoms management Coordinate care 	 Non-scheduled readmission Mortality rate Cost QOL for heart failure Functional status Satisfaction with care 	 A longer time of post-discharge since inception readmission in the intervention group Fewer readmissions, lower mean total health cost in the intervention group Short-term improvement in QOL, functional status and patient satisfaction in the intervention group
11	Caplan et al. (2004) Australia	Elderly>75 (N=739) C(n=370) I(n=369) Discharged from Emergency Department to home	RCT	 Comprehensive geriatric assessment:18-months Home visit weekly Mortality rate Physical function (Barthel index) Activities of daily living 	 Readmission AED visit Mortality Physical function ADL Cognitive function 	 No difference in readmission rate between both groups. Improvement in the intervention group: Low AED visit in the intervention group Great physical function Better mental function
12	Kwok et al. (2004) Hong Kong	COPD patients (N = 157) I (n = 77) C (n =80) Discharged from hospital to community	RCT	 Community nurse-led (CN) home visit program Program structure: home visits Intervention: Review patient health condition Health counselling Psychosocial support Health & social resources referral Telephone hotline 	 Unplanned readmission AED visits 6-minutes walking test Psychosocial score Multidimensional Health Locus of Control Scale Carer burden 	 Intervention group subjects had a higher rate of unplanned readmission within 6 months than control group subjects CN interventions might have effects on supervised physical exercise, stress management and referrals to effective resources

Notes: RCT = randomised controlled trial; I= intervention group; C= control group; AED = Accident and Emergency Department; ADL= activities of daily living; CDSES = Career Decision Self-efficacy Scale; IADL=independent activities of daily living; SF= short form; QOL= quality of life; TV= trained volunteers

No	Author Study (year) Place	Subjects	Design o study	of Types of interventions	Outcome measurements	Key findings
13	Wong et al. (2004) Hong Kong	Emergency room patients (N=795) C (n=400) I (n=395) Discharged from Emergency Department to home	RCT	 Protocol-driven: O Telephone follow-up: 2 times by AED nurse O Education 	AED visitClinical condition	In the intervention group:Improvement of conditionReduction of AED visit
14	Daly et al. (2005) United States	Chronic ill patient on ventilator (N=334) C (n=103) I (n=231) Discharged from hospital to home	RCT 2 months	 Disease management program Care coordination patient/family support Multidisciplinary team: APN, Geriatrician, Pulmonologist 	 Readmission cost Length of hospitalisation Mortality rate Associated costs 	 Reduction of readmission in the study group Time-to-first rehospitalisation LOS Mortality No differences in readmission, cost & death
15	Forster et al. (2005) Canada	General medical disease patients (N=620) C (n=307) I (n=313) Discharged from hospital to home	RCT	 CNS led discharge program In-hospital consultation Post-discharge visit Post-discharge telephone follow-up 	 Mortality rate Readmission rate Patient satisfaction LOS 	Improved patient satisfactionImproved patient safety
16	Sinclair et al. (2005) United Kingdom	Myocardial Infarction, elderly patients (N=324) C (n=163) I (n=161) Discharged from hospital to home	RCT	Home visitEducationPsychosocial supportActivities of daily living resumption	 Readmission LOS in hospital	• Reduction in readmission in the study group
17	Thompson et al. (2005) Australia	CHF patients (N = 106) I (n = 48) C (n = 58) Discharged from hospital to home	RCT	 Nurse-led program Protocol driven intervention Home visit Education Psychosocial support 	ReadmissionSurvival rateLOS in hospital	• Reduction in readmission in the study group

Notes: RCT = randomised controlled trial; I= intervention group; C= control group; AED = Accident and Emergency Department; ADL= activities of daily living; CDSES = Career Decision Self-efficacy Scale; IADL=independent activities of daily living; SF= short form; QOL= quality of life; TV= trained volunteers

No.	Study Author(s) (year) Place	Subjects	Design of study	Types of interventions	Outcome measurements	Key findings
18	Wong, et al. (2005a) Hong Kong	Diabetic Mellitus patients (N = 120) I $(n = 60)$ C $(n = 60)$; Discharged from hospital to home	RCT	 Protocol-derived transitional care program Program structure: pre-discharge planning telephone follow-up Interventions: Assessment Education on medication, diet, exercise and health-related lifestyle Health counselling 	 Health assessment of HbA1c Level of understanding and adherence Healthcare utilisation: readmission, Satisfaction with care 	 The intervention group had a greater decrease in HbA1c, better adherence, shorter LOS of stay and cost than those in the control group No significant differences in readmission, AED visits and patient satisfaction Nurse-led transitional care: a practical and cost-effective model
19	Coleman et al. (2006) United Stats	Chronically ill older patients with 1 of 11 diagnoses# (N = 750) I (n = 379) C (n = 371) Discharged from hospital to community	RCT	 A protocol-guided care transitions program Program structure: hospital visit, personal health record, case managers, telephone follow-up, home visits Interventions: Self-management of drugs Monitoring of symptoms Education 	 Comorbidity index Readmission rate Non-elective hospital cost 	The intervention group had: • Lower readmission rates at 30 days and 90 days • Reduced hospital cost at 180 days
20	Brumley et al. (2007) Australia	Terminally ill (COPD, RCT CHF or cancer) patients (N=298) I (n=149) C (n=149) Discharged from hospital to home		 Usual care plus interdisciplinary team care of Pain and symptom relief Patient and family education and training Medical and social support services. 	Satisfaction with careUtilisation of health servicesHealthcare cost	 Increased satisfaction Less readmission (36% of the palliative group and 59% of the controlled group were hospitalized.) Less use of AED services
21	Hassen et al. (2007) Norway	Myocardial Infraction patients (N = 288) I (n = 156 C (n = 132 Discharged from hospital to home	RCT	 Program structure: Telephone follow-up and telephone hotline Interventions Repeated health information Emotional support Provide coping strategies 	 Health-related QOL Lifestyle outcomes: Smoking Exercise 	 Significant improvement of QOL over time for both groups Significant differences between study and control groups in the physical activity and smoking cessation after 6 months

Notes: RCT = randomised controlled trial; I= intervention group; C= control group; AED = Accident and Emergency Department; ADL= activities of daily living; CDSES = Career Decision Self-efficacy Scale; IADL=independent activities of daily living; SF= short form; QOL= quality of life; TV= trained volunteers

No.	Study Author(s)(year) Place	Subjects	Design of study	Types of interventions	Outcome measurements	Key findings
22	Bouman et al. (2008) Netherlands	Older patients with poor health (N= 330) I (n=160) C (n=170) Discharged from hospital to elderly home	RCT	 Program structure: Protocol-driven O Interventions: O Home visit O Health assessment O Individual plan in agreement O Coordination with participant's GP once 	 Functional status: ADL, IADL Health-related outcomes: MOS SF-20 Mortality rate Health complaints 	 No effect of home visiting program on the health status of the older people with poor health The home visit program has no benefit to the subjects
23	Wong et al., (2008) Hong Kong	Chronic disease patient (N = 332) I(n=166) C(n=166) Discharged from hospital to home	RCT	 Program component: protocol-driven home visit Interventions: Routine care plus post-discharge home visits Health assessment Intervention scheme in the Omaha System 	 Re-hospitalisation rate ADL index Self-perceived health Self-perceived life satisfaction General symptoms 	 No significant effect of home-visit Self-perceived life satisfaction and health were statistically significant predictors of readmission
24	Kwok et al. (2008) Hong Kong	Chronic Heart Failure (N = 105) I $(n = 49)$ C $(n = 56)$ Discharged from hospital to home	RCT	 6-months program Home visit: weekly for 4, monthly for 5 Protocol driven intervention Education Psychosocial support 	 readmission walking exercise health cost personal care cost 	 Reduction in readmission in the study group No difference in: Walking exercise Health cost Personal care cost
25	Jack et al. (2009) United States	Chronic disease patients (N = 749) I (n=373) C(n=376) Discharged from hospital to home	RCT	 Community nurse-led post-discharge care program Program structure: discharge advocate, discharge planning home visits, telephone call Interventions: Medication follow-up Health information Reminder of follow-up Pharmacist telephone consultation 	 Health-related QOL: SF-12 Charlson Comorbidity Index Readmission rate Emergency visits 	Lower hospital utilization rate at 6-month in the intervention group
26	Buurman et al. (2010) The Netherland	Acute admission to medical patients (N= 674) I (n= 337) C(n=337) Discharged from hospital to home	RCT	 Community Nurse-led program Protocol-derived transitional care program program structure: Pre-discharge planning 5 times home visits patient education on medication, diet and exercise 	 ADL assessment Satisfaction Caregiver satisfaction Survival rate Cognitive function QOL 	 The intervention group had a better level of understanding of diet, medication, and health-related lifestyle No difference between groups in readmission

 Table 2.2 Review of study setting and findings of the transitional care for chronic disease (continued)

Notes: RCT = randomised controlled trial; I= intervention group; C= control group; AED = Accident and Emergency Department; ADL= activities of daily living; CDSES = Career Decision Self-efficacy Scale;

IADL=independent activities of daily living; SF= short form; QOL= quality of life; TV= trained volunteers

No.	Study Author(s) (vear)	Subjects	Design of study	Types of interventions	Outcome measurements	Key findings
27	Zhao & Wong (2009) China	Coronary heart disease patients (N= 200) I(n= 100) C(n=100) Discharged from hospital to home	RCT	 Protocol-derived Transitional Care program OS-based program structure: Pre-discharge planning Home visits Telephone follow up Interventions: nursing assessment patient education on medication, diet, exercise and health-related lifestyle, health counselling 	 Health assessment Level of understanding and adherence Healthcare utilisation Satisfaction with care 	 The intervention group had a better level of understanding of diet, medication, and health-related lifestyle No difference between groups in readmission
28	Wong et al. (2010) Hong Kong	CKD on CAPD patients (N= 94) I(n)= 47) C(n)=47) Discharged from the clinic to home	RCT	 Nurse-led program (7th & 13th week) Telephone follow-up Education Structure documentation: OS Self-management involves an information guidebook 	 Adherence to treatment: diet, fluid, dialysis, drug QOL Satisfaction Symptom control Health services utilisation 	Differences between groups:Adherence to diet & dialysisSleep qualitySymptom controlOverall health
29	Boult et al. (2011) United States	Coronary heart Disease patients (N= 850) I(n)= 425 C(n)=425 Transferred primary care settings to home	RCT	 20-months program Multidisciplinary team Protocol-derived transitional care program 	 Healthcare utilisation: Readmission Emergency department visit Home health services 	Reduction of using home health care
30	Wong et al. (2011) Hong Kong	Medical (N = 555) I(n=283) C(n=272) From hospital to home	RCT	 NCM & trained volunteers (TV), home visits, telephone follow-ups, the Omaha System, referral system Interventions: Health assessment Social support (TV) Promote safety environment Reinforce health self-management behaviour 	 Readmission rate QOL: SF-36 Self-efficacy: CDSES Patient satisfaction 	The intervention group has:Improved QOLImproved self-efficacyLower readmissionImproved satisfaction rate

Notes: RCT = randomised controlled trial; I= intervention group; C= control group; AED = Accident and Emergency Department; ADL= activities of daily living; CDSES = Career Decision Self-efficacy Scale; IADL=independent activities of daily living; SF= short form; QOL= quality of life; TV= trained volunteers

No.	Study Author(s)(year) Place	Subjects	Design of study	Types of interventions	Outcome measurements	Key findings
31	Saleh et al. (2012) United States	Medical, elderly patients (N= 333) I(n= 173) C(n=160) Discharged from hospital to home	RCT	 Protocol-derived Transitional Care program (1 year) Structured documentation: Pre-discharge planning Education of patient 	 Readmission rate QO: SF-36 Self-efficacy: CDSES Patient satisfaction Health assessment Level of understanding and adherence Healthcare utilisation Satisfaction with care 	 The intervention group had a low readmission rate A reduced healthcare cost in reduced readmission Self-management skill
32	Zwar, et al (2012) Australia	COPD patients N-451 C(n=226) I(c=225) Discharged from hospital to home	RCT	 RN-led program Protocol-driven guidelines Home visit by RN (specialty) Multidisciplinary team approach 	 QOL Lung function Smoking status Immunisation status COPD knowledge Health service usage 	 No differences between the group in: QOL Lung function Smoking status The intervention group presented better COPD knowledge
33	Wong et al. (2014) Hong Kong	Mixed diagnosis patients (N = 610) I: Home visit + telephone(n=196) I: Telephone (n=204) C(n=210) Discharged from hospital to home	RCT	 Program structure: Use of Nurse Care Manager & trained volunteers (TV), home visits telephone follow-ups: the Omaha System referral system Interventions: Health assessment Social support (TV) Promote safety environment Reinforce health self-management behaviour Referral for health and community resources 	 Readmission rate QOL Self-efficacy: CDSES Patient satisfaction 	In the study group: • Significant reduction of readmission • improvement in QOL, self- efficacy and satisfaction with care
34	Blakeman et al. (2014) United Kingdom	CKD stage 3 patients (N = 436) I:(n=215) C(n=221) Discharged from general practices care to home		 Protocol-driven intervention Nurse-led program Telephone follow-up Education Self-management 	QOLBlood pressure controlEngagement in lifeHealthcare cost	 Differences between groups with intervention groups: Control of BP Improved QOL Non-significant engagement in life Reduction in healthcare cost

Notes: RCT = randomised controlled trial; I= intervention group; C= control group; AED = Accident and Emergency Department; ADL= activities of daily living; CDSES = Career Decision Self-efficacy Scale; IADL=independent activities of daily living; SF= short form; QOL= quality of life; TV= trained volunteers

No	Study	Pa	tient group	Intervent	ion delivery mode		Intervention strategies		Intervention Effectiveness
Author (s) (Year)		A=Carchac disease B=Stroke C=CKD D=Chronic lung disease E=Organ failure /critically ill F=Mixed medical disease G=Cancer O=Others c=control group i=intervention group		Dose: a=duration (weeks) b=initiation of follow-up (hours) c=weekly d=monthly e=occasionally	Way: A=pre-discharge plan/assessment/educatio n B=home visit C=telephone follow-up D=patient-initiated call E=care coordination E1=social services E2=physician or healthcare professionals	Provider & <u>Coordinator</u> : a=APN/CNS/N P b=RN c=CN/PN/HC d=physician e=allied health professional f=social worker g=caregiver/relat ive h=others * coordinator	Care categories: A= assessment B= goal setting/care plan C= surveillance D= medication adjustment E= education /guidance/counselling F= lifestyle modification G= psychosocial support H= referral I= self-management O= others	Quality assurance: A=evidence-based B=protocol guided C=structured documentation (*used The Omaha System) D=education tool E=case conference F=training of providers G=family/caregiver involvement H=multidisciplinary approach/support O=others	Clinical & Functional outcomes: A=symptoms, B= biomarker changes, C= functional status, D= daily living ability, E= QOL <u>Psychosocial outcomes:</u> F= anxiety/ depression, G= coping /self-efficacy, H= compliance, I= knowledge/skills, <u>Health utilisation & Cost outcomes:</u> J=readmission, K=1 LOS L=use of health services, M=medical /direct cost <u>Satisfaction outcomes</u> N=patients, O=providers P=caregivers, Q=others
1	Naylor et al. (1999)	А	c=186 i=177	a: 24 b:48	A, B, C, E1, E2	a*, d, f, g	A,B, E, F, H	A, B, D, F, G, H	$^{0}C, {}^{0}F, \downarrow J, \downarrow K, {}^{0}L, {}^{0}M, {}^{0}N$
2	Stewart et al (1999)	А	c=100 i=100	a: 26 b:<168-336	В	a*	A, B, C, E, H, O	A, B, C, F, O	$\uparrow E, \downarrow J, \downarrow Q$ (mortality)
3	Blue et al. (2001)	А	c-83 i=82	a: 52 d	A, B, C, E1, E2	a*, c, d	A, B, C, E, G	B, D, F, H	$\downarrow J, \downarrow K, \downarrow M$
4	Andersen et al. (2002)	В	c-78 i(Dr)=54; i(Physio)=53	a: 26 b:<72 d	В	d, e	A, B, C	G, H, O	↓A
5	Hermiz et al. (2002)	D	C=84 i=93	a: 24 b:<48	В	c, h	A, B, C, F, G	A, B, E, F	†I,†N
6	Egan et al. (2002)	D	C=33 i=33	a: 6 b:<168 e	A, C, E, E1, E2	a*, b, d, e, g	A, B, C, E, G, O	A, F, G, H	⁰ F,↑I, ⁰ J
7	Laramee et al. (2003)	А	c=143 i=144	a: 12 b: <72 c	C, D	a*, g	A, E	A, F, G, H	↑N
8	Lim et al. (2003)	0	c=287 i=311	a: 24 d	С	a*	A, C, H	В	$\downarrow A, \uparrow E, \downarrow M$
9	Young et al. (2003)	A&D	c=85 i=71	a: 14 c	А	a*	A, C, E	B, D, E, O	$\downarrow J, \downarrow L$
10	Naylor et al. (2004)	А	c=368 i=368	a: 52 b: 24	A, B, E1, E2	a*, d	A, C	A, C, D, H	$\uparrow C, \uparrow E, \downarrow J, \downarrow L, \downarrow M, \uparrow N,$
11	Caplan et al (2004)	0	c=370 i=369	a: 4 b: 24	B, E, E2	a*, b, d, e	A, B, C, H	B, C, E, H	↑C, ↓F, ⁰ J, ↓L

Table 2.3 Summary of the features of study interventions of transitional care

Note: APN = Advanced Practice Nurse; CNS=Clinical nurse specialist; CNC = Nurse Consultant; NP = Nurse Practitioner; RN = Registered Nurse; CN= Community Nurse; HCN = Home Care Nurse; QOL= Quality of life; LOS = length of stay \uparrow = increase, \downarrow = decrease, 0 = no significant difference

No	Study	Patien	t group	Intervention	n delivery mode		Intervention strategies		Intervention Effectiveness
	Author (s) (Year)	A=Cardiac B=Stroke C=CKD D=Chronic E=Organ fa /critically ill F=Mixed nr disease G=Cancer O=Others c=control gr i=interventi	disease lung disease ilure nedical roup on group	Dose: a=duration (weeks) b=initiation of follow-up (hours) c=weekly d=monthly e=occasionally	Way: A=pre-discharge plan/assessment/educa tion B=home visit C=telephone follow- up D=patient initial call E=care coordination E1=social services E2=physician or healthcare professionals	Provider & Coordinator a=APN/CNS/NP b=RN c=CN/PN/HC d=physician e=allied health professional f=social worker g=caregiver/relative h=others * Coordinator	Care categories: A= assessment B= goal setting/care plan C= surveillance D= medication adjustment E= education /guidance/counselling F= lifestyle modification G= psychosocial support H= referral I= self-management O= others	Quality assurance: A=evidence-based B=protocol guided C=structured documentation (*used the OS) D=education tool E=case conference F=training of providers G=family/caregiver involvement H=multidisciplinary approach/support O=others	Clinical & Functional outcomes: A=symptoms, B= biomarker changes, C= functional status, D= daily living ability, E=QOL Psychosocial outcomes: F= anxiety/ depression, G= coping /self-efficacy, H= compliance, I= knowledge/skills, Health utilisation & Cost outcomes: J=readmission, K= LOS L=use of health services, M=medical /direct cost Satisfaction outcomes N=patients, O=providers, P=caregivers, Q=others
12	Kwok et al. (2004)	D	c=80 i=77	a: 24 b: <168 d	A, B, C, D, E1, E2	b, c, d	A, C	A, G, H (caregiver burden)	↑C,↓F, ↑J
13	Wong et al. (2004)	0	c=400 i=395	a: 4 b: 24 c	С	b*, d	A, C, E, G, H, I	A, B, D, F, H	$\uparrow A, \downarrow L$
14	Daly et al. (2005)	D	c=231 i=103	a: 8 b:<48 c	C, E1, E2	b	A, C, E	A, B, D, H	$\downarrow J, \downarrow K, \downarrow M, \downarrow Q \ (mortality)$
15	Forster et al. (2005)	0	c=307 i=313	a: 24 c	С	c*	A, C	В	↑C, ↑N
16	Sinclair et al. (2005)	А	c=161 i=163	a: 14 d	В	b	A, C, F, G, O	B, D	\downarrow J
17	Thomson et al. (2005)	А	c=48 i=58	a: 24 d	В	c*	A, B, C, E, F, G	A, B, E	$\uparrow 1$
18	Wong et al. (2005a)	F	c=60 i=60	a: 4 b: <168	A, C, E	a*, d	A, C, D, E, H	A, B, C, D, G, H	\downarrow B(HbA1c), \uparrow H, \downarrow J, \downarrow M, ⁰ N
19	Coleman et al. (2006)	Е	c=371 i=379	a: 24 b:<72	A, C, E	a, g	A, C	A, B, C, D	$\downarrow J, \downarrow M$
20	Brumley et al. (2007)	A, D, G	c=149 i=149	a: 24 b:<72	В	a, g	C, G	A, B, F, G, H	$\downarrow J, \downarrow L, \uparrow N$
21	Hassen et al. (2007)	А	c=132 i=156	a: 12 b:<72	В	a	A, C, G	B, D	$\uparrow C, \uparrow D, \uparrow E$
22	Bouman et al. (2008)	F (frail elderly)	c=170 i=160	a: 24 d	B, C, E2	a	A, B, C, E, F	A, B, D	⁰ C, ⁰ E
23	Wong et al. (2008)	F	c=166 i=166	a: 4 b: <168	A, B, C, E2	c*, d, f, g	A, B, C, E, H	A, B, C*, D, E, F, G	⁰ J, ↑N

Table 2.3 Summary of the features of study intervention of transitional care (continued)

Note: APN = Advanced Practice Nurse; CNS=Clinical nurse specialist; CNC = Nurse Consultant; NP = Nurse Practitioner; RN = Registered Nurse; CN= Community Nurse; HCN = Home Care Nurse; QOL= Quality of life; LOS = length of stay

 \uparrow = increase, \downarrow = decrease, ⁰ = no significant difference

No	Study	Study Patient group		Interventio	n delivery mode	Intervention strategies			Intervention Effective
	Author (s) (Year)	Author (s) A=Cardiac disease (Year) B=Stroke C=CKD D=Chronic lung disease E=Organ failure /critically ill F=Mixed medical disease G=Cancer O=Others c=control group i=intervention group Carer Carer		Dose: a=duration (weeks) b=initiation of follow- up (hours) c=weekly d=biweekly e=monthly	Way: A=pre-discharge plan/assessment/educatio n B=home visit C=telephone follow-up D=patient initiate call E=care coordination	Provider & Coordinator: a=APN/CNS/NP b=RN c=CN/PN/HC d=physician e=allied health professional f=social worker g=caregiver/relative h=others * Coordinator	Care categories: A= assessment B= goal setting/care plan C= surveillance D= medication adjustment E= education /guidance/counselling F= lifestyle modification G= psychosocial support H= referral I= self-management O= others	Quality assurance: A=evidence-based B=protocol guided C=structured documentation (*used the OS) D=education tool E=case conference F=training of providers G=family/caregiver involvement H=multidisciplinary approach/support O=others	Clinical & Functional outcomes: A=symptoms, B= biomarker changes, C= functional status, D= daily living ability, E= QOL Psychosocial outcomes: F= anxiety/ depression, G= coping /self-efficacy, H= compliance, I= knowledge/skills, Health utilisation & Cost outcomes: J=readmission, K= LOS L=use of health services, M=medical /direct cost Satisfaction outcomes N=patients, O=providers, P=caregivers,
24	Varial at 1	A	- 40	24	A T-1	-*	C		Q=others
24	Kwok et al., (2008)	А	c=49 i=56	a: 24, b: <168 c: 4 times	A, EI	a*,	C	A, B, D,	J, M, Q (walking exercise)
25	Jack et al. (2009)	G	c=375 i=374	a: 4 b: 48; c	C, D	a*	A, C, E, F, G, O,	А	E, J, L
26	Buurman et al. (2010)	O (elderly)	c=337 i=337	a: 52 b:<72 e:	В	a *	Α, Β	A, B, G	C, D, E, H, J, L, N, P, Q (survival)
27	Zhao & Wong (2009)	А	c=100 i=100	a: 12 b:168	A, B, C	a, e	A, C, E, G, O,	A, C*, D	Е, Н, І
28	Wong et al., (2010)	С	c=47 i=47	a: 12 b:168	A, B, C, E1	a*,	A, C, E, G	A, B, C*, D	A, E, H, L, N
29	Boult et al. (2011)	А	c=425 i=425	a: 80, e	A, B, E	a*, d	A, C, E, G	A, C, D, H,	J, L,
30	Wong et al. (2011)	F	c=283 i=272	a: 12 b:72	A, B, C, E1	a*, d,	A, B, C, E, F, G	A, B, C*, D, F	E. G., J., N
31	Saleh, et al. (2012)	F (elderly)	c=160 i=173	a: 52 b:168	А	a*, d	A, B, C, E, I	A, B, C, D	E, G, J, M
32	Zwar, et al. (2012)	D	c=226 i=225	a: 52 b:72	В,,	b*,	A, B, C, E, F, G	B, D,	C, D, E, I,
33	Wong et al. (2014)	F	c=210 i=196 +204	a: 12 b:<72 e:	B, C, E1, E2	b,*	C, D	A, B, C*, E, H	G, J
34	Blakeman et al. (2014).	С	c=221 i=215	a: 24 b: <72	С,	a*,	А, Е,	В,	Е,
Sum of	f frequency A B C D E E E	=13 G=2 =1 O=5 =2 i=6657 patien =6 c=6525 patien =1 =7	nts	a:4 weeks (wk) =3 a:6-8 wk = 2 a:12 wk=6 a:24-26 wk= 19 a:80 wk=1 b: 72-168 hours =26 a: $24-7$:a=5	A=15 B=21 C=17 D=3 E=5 E1=10: E2 = 10	a=23; *= 24 b=8 c=6 d=13 e=4 f= 2: s=6	A=31 F=8 B=14 G=14 C=28 H=7 D=2 I=2 E=20 O=5	A=24 F=9 B=25 G=8 C=10; C*5 H=13 D=13 O=3 E=6	A=4 F=4 J=22 N=11 B=1 G=3 K=3 O=0 C=9 H=4 L=10 P=1 D=3 I=4 M=9 Q=4 E=13

Table 2.3 Summary of the features of study intervention of transitional care (continued)

Note: APN = Advanced Practice Nurse; CNS=Clinical nurse specialist; CNC = Nurse Consultant; NP = Nurse Practitioner; RN = Registered Nurse; CN= Community Nurse; HCN = Home Care Nurse; QOL= Quality of life; LOS = length of stay \uparrow = increase, \downarrow = decrease, 0 = no significant difference

2.3.3 Results: Characteristics of included transitional care studies

2.3.3.1 Study description

Table 2.3 above summarizes the details of the studies to be explored. All of the 34 included studies were longitudinal in design. Places of study included Australia (n=8), Canada (n=2), Demark (n=1), China (n=1), Hong Kong, China SAR (n=8), Norway (n=1), The Netherlands (n=3), United Kingdom (n=3), and United States (n=8). Transitional care was characterized by a plan for a patient/client to move from one care setting to another such as a hospital, institution home, or assisted living facility. The majority of participants were discharged from the hospital (including inpatient, emergency department and clinical centre) to home (13/34 studies). Seven studies contained a health and community referral system to mobilize effective resources (Lim et al., 2003; Stewart et al., 1999; Wong et al., 2004; Wong et al., 2005; Wong et al., 2008; Wong et al., 2010; Wong et al., 2014). The sample size varied in different studies, ranging from 66 to 850, involving 13,182 participants in total. The study population of the 34 studies included a copious group of chronic diseases such as cardiac disease, chronic lung disease, CKD, DM, stroke, cancer, organ failure or chronically critically ill, and elderly with medical diseases. Six studies targeted elderly populations (Andersen et al., 2002; Bouman et al., 2008; Buurman et al., 2010; Caplan et al., 2004; Coleman et al., 2006; Saleh et al., 2012) and eight studies focused on organ failure (Blakeman et al., 2014; Brumley et al., 2007; Kwok et al., 2008; Laramee et al., 2003; Naylor et al., 2004; Stewart et al., 1999; Wong et al., 2010; Young et al., 2003). Only one study examined transitional care for non-dialytic CKD patients in stage 3 (Blakeman et al., 2014).

All studies applied an RCT design to test their interventions. The TRPP emphasized the recognition of health goals, development and implementation of a streamlined care plan and implementation of a streamlined plan of care; and continuity of care across settings and between providers throughout the transition from hospital to home as described by Naylor

(2004). The structure of TRPP commonly included discharge planning, telephone follow-up, home visit, and referral for maximising health resources allocation, patient-initiated telephone calls, standardised documentation, patient education and self-management of disease. Details of interventions of the reviewed studies will be further reported in the next section with the information from Table 2.3.

Six categories of outcome measures were characterised. They were (1) health service utilisation, including readmission, length of hospital stays, emergency room visits, cost etc.; (2) symptom intensity and physical function; (3) psychological distress, such as anxiety, depression; (4) QOL; (5) adherence to diet, exercise, medication, non-smoking etc.; and (6) satisfaction with care.

2.3.3.2 Key findings of outcome measures

From the reviewed studies, key findings of positive and non-significant results of each category were summarised. For healthcare services utilisation, a reduction in non-scheduled readmission was shown in 8 studies (Blue et al., 2001; Naylor et al., 2004; Naylor et al., 1999; Sinclair et al., 2005; Stewart et al., 1999; Thomson et al., 2005; Wong et al., 2005a; Young et al., 2003). In contrast, Kwok et al. (2004) reported increased readmission in the intervention group. Eight studies evidenced non-significant differences in unplanned readmission (Caplan et al., 2004; Daly et al., 2005; Egan et al., 2002; Laramee et al., 2003; Lim et al., 2003; Wong et al., 2005a; Zhao & Wong, 2010). Four studies reported reduced LOS during hospitalization (Daly et al., 2005; Wong et al., 2005a). Findings of 4 studies reported reduced emergency department visits with transitional care intervention (Brumley et al., 2007; Caplan et al., 2004; Wong et al., 2004;).

In addition, better symptom management was reported in 3 studies (Blakeman et al., 2014; Wong et al., 2005a; Wong et al., 2010). Improvement in psychological well-being was evidenced in Caplan et al. (2004), while non-significant psychological improvement was shown in Naylor et al. (1999) and Sinclair et al. (2005). Likewise, four studies showed improvement in QOL (Lim et al., 2003; Stewart et al., 1999; Wong et al., 2011; Wong et al., 2014), and a non-significant improvement in QOL was shown in Hassen et al., 2007 and Zwar et al., 2012. Furthermore, eight articles reported improvement in satisfaction with care (Forster et al., 2005; Hassen et al., 2007; Hermiz et al., 2002; Laramee et al., 2003; Naylor et al., 2004; Wong et al., 2008; Wong et al., 2011; Wong et al., 2014). Two studies reported non-significant improvement in satisfaction with care (Naylor et al., 1999; Wong et al., 2005a). Improved adherence to treatment, diet, medication and exercise were reported as reflected in 4 studies among the intervention subjects (Blue et al., 2001; Buuman et al., 2010; Wong et al., 2012).

Besides, other positive results included decreased healthcare costs in 9 studies (Brumley et al., 2007; Forster et al., 2005; Hermiz et al., 2002; Laramee et al., 2003; Naylor et al., 2004; Wong et al., 2008; Wong et al., 2011; Wong et al;, 2014), improvement of physical function (Andersen et al., 2002 and Caplan et al., 2004), decreased mortality (Daly et al., 2005), improvement of patient safety (Forster et al., 2005), a decrease in the utilisation of home care services (Boult et al., 2011) was reported in the intervention groups.

2.3.4 Results: Features of the transitional care model

The features of the TRPP, intervention strategies and outcomes of interventions are further summarised in Table 2.3.

2.3.4.1 Mode of delivery of transitional care

The structure of transitional care programs varied in the 34 studies afore-cited, although commonly involving: pre-discharge planning (n=15), home visit (n=23), telephone follow-up (n=18), patient-initiated telephone call (n=3), and care coordination (n=17). Sixteen trials included an in-hospital pre-discharge visit with follow-up care (Blue et al., 2001; Boult et al., 2011; Buurman et al., 2010; Coleman et al., 2006; Egan et al., 2002; Kwok et al., 2004; Kwok et al., 2008; Naylor, et al., 1999; Naylor et al., 2004; Saleh et al., 2012; Wong et al., 2011; Wong et al., 2008; Wong et al., 2010; Wong et al., 2014; Wong et al., 2005a; Zhao & Wong, 2009). Pre-discharge planning was aimed at facilitating a safe and smooth transition from hospital to home. Pre-discharge hospital visits, discharge assessment, and arrangement of resources in a home-based setting were all included in the reported studies.

The duration of intervention in 34 studies was $23.33 \pm 18.13 (4 - 80)$ weeks. Initiation followups, mainly using home visits, were usually arranged within 72 hours after discharge (n=15/22, 68.18%). Subsequent home visits were delivered at two-monthly intervals in between telephone follow-ups. Each visit lasted for 40 to 50 minutes with the first visit lasting for a longer time for comprehensive assessment and planning.

Five studies employed alternate telephone follow-ups and home visits in the first month after the patient had been discharged from the hospital (Bouman et al., 2008; Coleman et al., 2006; Wong et al., 2005a; Wong et al., 2008; Wong et al., 2014). The telephone calls were conducted weekly (n= 18). Telephone follow-up calls normally lasted for 30 minutes in the first follow up and around 15 to 20 minutes in subsequent calls (Wong et al., 2005a; Wong et al., 2008, Wong et al., 2005a; Wong et al., 2010; Wong et al., 2014).

The care providers of transitional care included physicians, nurses, allied health professionals (e.g. physiotherapists, occupational therapists, and dietitians), social workers, caregivers, and volunteers. Seven studies (20.59%) involved a multi-disciplinary intervention or multi-disciplinary support. Except for one study in which intervention was provided by a physician and physiotherapist (Anderson et al., 2001), all other studies engaged nurses as the key provider. The rank of nurse included advanced practice nurse (APN), clinical nurse specialist (CNS), nurse practitioner (NP) or nurse consultant (NC) in 70.59% of the studies (n =24); seven (20.59%) studies used registered nurses (RNs), and community nurses or home visit nurses provided care in five (14.71%) studies. Informal caregivers (family members or caretakers) were involved in the care process in 14.71% (n = 5) of the aforecited studies

It was noted that there was a nurse coordinator in the studies reviewed. In 33 (97.06%) of the studies, the nurse coordinator assisted in coordinating the related healthcare service. In 10 (29.41%) of the studies, nurses also helped to arrange social services, and in 10 (29.41%) of the studies, nurses referred the patients to physicians or allied health professionals for expertise management. Although different transitional care models were adopted in various studies, 22 programs evidenced the effectiveness of employing an NCM in delivering patient care and services (Blakeman et al., 2014; Boult et al., 2011; Buurnan et al., 2010; Egan et al., 2002; Frosten et al., 2005; Jack et al., 2008; Kwok et al., 2008; Laramee et al., 2003; Lim et al., 2003; Naylor et al., 1999; Naylor et al., 2004; Saleh et al., 2012; Stewart et al., 1999; Thompson et al., 2001; Wong et al., 2004; Wong et al., 2005; Wong et al., 2012).

2.3.4.2 Intervention strategies

Thirty-four reviewed studies provided at least one care intervention and one care quality assurance strategy. According to Table 2.3, the common care intervention strategies were

assessment (n=33, 97.05%), surveillance (n=30, 88.24%), education /guidance /counselling (n=19, 55.88%), goal setting/care planning (n=17, 50.00%) and psychological support (n=13, 38.24%). The common care quality assurance strategies applied in the studies included evidence-based intervention (n= 24, 70.59%), protocol guided (n=24, 70.59%) with five studies using the OS, use of education tools (n=18) and multidisciplinary approach/support (n=17).

Fifteen studies applied the two most common strategies of care and quality assurance, which were assessment and surveillance, and evidence-based and protocol guided intervention (Blakeman et al., 2014; Blue et al., 2001; Bouman et al., 2008; Brumley et al., 2007; Buuman et al., 2010; Coleman et al., 2005; Caplan et al., 2004; Daly et al., 2005; Egan et al., 2002; Forster et al., 2005; Hassen et al., 2007; Hermiz et al., 2002; Kwok et al., 2008; Lim et al., 2003; Naylor et al., 1999; Saleh et al., 2012; Sinclair et al., 2005; Stewart et al., 1999; Thompson et al., 2005; Wong et al., 2004; Wong et al., 2005a; Wong et al., 2008; Wong et al., 2009; Zwar et al., 2011; Wong et al., 2014; Young et al., 2003; Zhao & Wong, 2009; Zwar et al., 2012). A multidisciplinary approach was adopted in many TRPPs aiming at effective clinical outcomes with a high quality of care (n=17). A multidisciplinary team was formed with health professionals, allied health professionals, and social care providers who acted in various roles in the progress of transitional care. Patients and caregivers were actively involved in self-management (n=6).

2.3.4.3 Intervention effectiveness

Effects of transitional interventions were measured by a variety of categorised variables such as symptom management (n=5), psychosocial status (n=12), physical functions (n=5), health cost status (n=8), satisfaction with care (n=8), QOL (n=9), length of hospital stay (n=3), and

readmission (n=22). However, outcome variables of a burden on caregivers were noted in only one study (Kwok et al., 2004). Reductions in the re-hospitalisation rate were found in 73.53% (25/34) of the studies. Some studies found insufficient evidence to support the effectiveness of the proposed transitional care interventions in reducing hospital readmission in different chronic disease groups (Bouman et al., 2008; Hermiz et al., 2002; Kwok et al., 2004; Wong et al., 2008; Zhao & Wong, 2009).

2.3.5 Discussion

2.3.5.1 Post-discharge follow-up

ESRF patients are at high risk of progressive deterioration and acute exacerbations of renal function after their discharge from the hospital in between medical follow-ups. In referring to the study by Wong et al. (2011), the overall readmission rate at 28 days after inception of discharge was 16.7% for chronic disease in Hong Kong. To closely monitor and follow up on the effect, the continuity of care for the community-dwelling patient was highlighted by a home visit and telephone follow-up after the discharge of the patient. In the aforementioned studies, post-discharge follow-ups were commonly delivered through both home visits and telephone outreach. The components of follow-up had a crucial impact on the outcomes of the care model, which consisted of ongoing identification and surveillance of changes in clinical condition, treatment strategies, patient education, psychosocial support for patients and caregivers, as well as referral when medically indicated. Continuous follow-up is crucial to fill the gap between discharge from the hospital and the next medical consultation.

The first month is the optimal period to provide continuity of care to link up the hospital and community care (Coleman et al., 2006; Kwok et al., 2004; Naylor et al., 2004; Wong et al., 2014). The advantages of a series of follow-ups were to enable the ongoing surveillance of

progress in the disease trajectory, change of treatment pattern, coping skills, reinforcement of knowledge and self-care skills or self-management of symptoms, psychosocial support for patients and caregivers and referrals for expert care indicated. The high-quality care was ensured by adequate communication between patients and healthcare providers and the healthcare system was backed up by a wall structure system. Telephone communication was a commonly adopted tool for exchanging information, identifying problems, managing symptoms and counselling. To maintain the continuity of care, telephone follow-up between scheduled medical consultations was provided for the sake of early identification of patient problems, which guided the support as indicated. More than 50% of studies adopted telephone follow-up as the main post-discharge care component.

Apart from the visits and telephone follow-ups, patient-initiated telephone calls to acquire timely advice or assistance were accessible in three studies (Kwok et al., 2004; Jack et al., 2009; Laramee et al., 2003). The objective of patient-initiated telephone calls was for astute consultation and advice. Potential or actual problems were verified with the NCM for appropriate treatment or advice in the phone consultation to ensure sustainable and validated intervention.

Several active ingredients were also identified in the evidence-based review. Goal-oriented follow-up and review are important in each telephone call (Coleman et al., 2006; Hanssen et al., 2007; Wong et al., 2010). The content of the telephone follow-ups should comprise a health progress review (Andersen et al., 2003; Blue et al., 2001; Caplan et al., 2004; Coleman et al., 2006; Hanssen et al., 2007; Kwok et al., 2004; Lim et al., 2003; Stewart et al., 1999; Wong et al., 2004; Wong et al., 2005a; Wong et al., 2010), and monitoring of health adherence (Coleman et al., 2006; Hanssen et al., 2007; Wong et al., 2007; Wong et al., 2007; Wong et al., 2003; Jong et al., 2008; Wong et al., 2008; Wong et al., 2008; Wong et al., 2009; Wong et al., 2009;

2.3.5.2 Protocol-driven care strategies

From the above-mentioned research, the majority of studies (n=24) were protocol-driven programmes. The sustainable standardised practice was governed by protocol-driven practice to ensure consistency of care provision (Bouman et al., 2008; Coleman et al., 2004; Naylor et al., 2004; Wong et al., 2005; Wong et al., 2014). The care planning and effects of the protocol-driven practice are better communicated among the multidisciplinary care team in enhancing the clinical outcomes, which is one of the key components of quality assurance in transitional care.

The application of a standardised documentation system to facilitate effective communication across multidisciplinary settings was also noted in the TRPP. Approximately one-third of the studies adopted a standardised patient-centred documentation system to facilitate continuity of care delivery across different settings. Given the quality assurance of the program, five local studies (Wong et al., 2008; Wong et al., 2010; Wong et al., 2011; Wong et al., 2014; Zhao & Wong, 2009) adopted the OS documentation system and tested its effectiveness in guiding problem assessment. The OS was commonly adopted in the Chinese ethnicity with its multifunctions such as a framework for guiding interventions, surveillance, treatment and procedure, health assessment and systematic records between the multidisciplinary team.

2.3.5.3 Nurse-led programme

The provision of transitional care mainly involved the contribution of nursing professionals such as APNs, NCs/NPs, NCMs, or community nurses (33/34 studies). Studies especially addressed that the APNs played a critical role in positive outcomes in the mode of transitional care in the reviewed studies (Naylor et al., 1999; Naylor et al., 2004; Wong et al., 2011; Wong et al., 2014; Zwar et al., 2012). Nurses acted as case managers, patient advocates or

coordinators in transitional care. Hirschman et al. (2015) asserted that case management encompasses coordination, implementation and evaluation of care in the process of care. This ensures the consistency and competence of the care provider. The attributes of NCM include advanced knowledge, competent clinical experiences, specialised training and experience (Wong et al., 2014) which serve the purpose of offering continuous and quality transitional care. The characteristics of the TRPP were a nurse-led program with a case managementdriven, patient advocate, with the nurse acting as a patient advocate, collaborator of care, and coordinator of holistic care.

2.3.5.4 Approaches/models of the transitional care program

Transitional care covers the plan and logistics of care, coordination, and collaboration of care among healthcare providers and patients. Patient and family caregivers are also involved in the self-management of symptoms for improved care. In the process of care delivery, patient education relating to self-management of symptoms is reinforced for early identification of symptoms, better time management and promising outcomes. Patient empowerment is emphasised aiming at meeting their own needs and reducing the complications of illness. However, there are no process analyses and related findings to deduce the effects of interventions on patient-related outcomes including QOL, physical function, satisfaction with care and the burden of caregivers.

While using the multidisciplinary team approach in transitional care, the provision of a referral system was indicated in numerous articles to ensure better coordination of health resources during the transition period (Lim et al., 2003; Stewart et al., 1999; Wong et al., 2004; Wong et al., 2005; Wong et al., 2008; Wong et al., 2010; Wong et al., 2014). Bouman et al. (2008) developed a standard procedure for effective referral to hospital and community resources. Wong et al. (2014) established a referral protocol to standardise the scope and the

level of appropriate referral. The arrangement of referral for consultation of expertise for better clinical outcomes was reinforced.

Naylor and colleagues (1999; 2004) were the leading researchers for the transitional care model which involved pre-discharge assessment and planning, post-discharge follow-up and support to ensure the continuity of care. The key features attributed to the positive effects of the studies were comprehensive assessment and planning of care, continuous and regular follow-up (Wong et al., 2005; Wong et al., 2008; Wong et al., 2011; Zhao & Wong, 2009), empowerment of self-management of symptoms through patient education (Wong et al., 2008; Zhao & Wong, 2009), well coordination of care among the healthcare providers (Wong et al., 2005; Wong et al., 2005; Wong et al., 2014). These features were summarised to form the 4Cs (continuity, comprehensiveness, coordination and collaboration) as key approaches to the TRPP and the programme was tested by Wong et al. (2005a; 2011). This model has been applied in different populations locally with positive effects (Wong et al., 2005a; Wong et al., 2008; Wong et al., 2011; Wong et al., 2014). Recently, there have been a few transitional care studies conducted on the elderly population of organ failure individuals in Hong Kong, but no study has been conducted on the ESRF population using a palliative care approach (Wong et al., 2005a; Wong et al., 2010; Wong et al., 2014).

2.3.5.5 The effectiveness of transitional care

Transitional care provides promising clinical outcomes. Inconclusive results were found in 6 studies (Buuman et al., 2010; Caplan et al., 2004; Egan et al., 2002; Laramee et al., 2003; Lim et al., 2003; Wong et al., 2005a; Zhao & Wong, 2009) regarding the non-scheduled readmission rate. Wong et.al. (2014) were able to yield positive outcomes of the TC model on mixed medical diagnosis patients with a significant reduction of non-scheduled readmission, improvement in QOL, enhanced self-efficacy and satisfaction with care. The

quality assurance initiatives adopted by Wong and her colleague studies were associated with the use of the OS, patient education and self-management of symptoms. The component of health behavioural change coupled with continuous support exemplifies the characteristic of patient-centred care for a patient with chronic disease. The quality assurance measures may have contributed to the positive outcomes of the studies.

Despite the heterogeneous mixture of negative and positive studies in various transitional care programmes, a well-designed study with appropriately targeted interventions performed by well-trained advanced practice professionals proved crucial for positive outcomes (Wong et al., 2014). In reviewing these inconsistent results for patient and health outcomes, considerable knowledge was acquired from previous trials to improve the effects of the intervention (treatment), such as the specific needs of the study population, the type of interventions designed to meet clients' needs, and the length and intensity of the interventions to optimise patient or clinical outcomes. Multi-component interventions are warranted for optimal patient outcomes.

2.3.6 Conclusion

In accordance with the inclusion criteria, 34 RCTs were selected in this review to understand the important elements informing the development of the transitional care programme and protocols of this study. Characteristically, a successful TRPP was a nurse-led program which was protocol-driven, the patient was advocated with the nurse acting as a patient advocate, and collaborator of holistic care. Effective transitional care has been evidenced for various chronic disease groups, however, none of the reviewed studies has concentrated on ESRF. The effectiveness of the interventions on outcomes such as readmission, symptom control, QOL etc. is still inconclusive too. This is the reason for launching this trial, to fill the knowledge and practice gap in transitional renal palliative care for non-dialytic patients with ESRF.

2.3.7 The development trend in transitional care

The review of the current studies on transitional care tends to suggest that the reviews done, including studies in 2014 or before, are still consistent in terms of the approaches and processes. There are additional studies on using the palliative approach on end-stage organ failure patients.

Transitional care management of the chronic disease has been evidenced as favourable in its association with lower healthcare expenditure, mortality and readmission rates (Agarwal et al., 2018; Bindman & Cox, 2018). Recognising that transitional care from hospital to home holds a key opportunity to improve health care, Medicare implemented transitional care management codes to increase reimbursement to an ambulatory physician treating patients discharged from the hospital in 2013 (Marcotte et al, 2020). Transitional care management services were increasingly delivered from 260899 in 2013 to 1024366 in 2018. The trends and tendencies of transitional care development have also been explored in various studies. A home visit is the most effective patient service in reducing all-cause readmission of a discharged patient with heart failure (Van Spell et al., 2017). In addition, among 38 RCTs, transitional care interventions (no decisive category of intervention) effectively reduced allcause readmission for hospitalised heart failure patients (Qiu et al., 2021). Meanwhile, in the process of care delivery, the features of transitional care including collaboration and communications emerged from the qualitative studies as important strategies (Hirschman et al., 2017). Transitional care was enhanced with effective, optimal quality outcomes and costeffectiveness.

In caring for patients with advanced chronic disease, palliative care demonstrated a high quality of clinical outcomes in relieving symptoms of distress and improvement in the QOL in the last phase of life (Chan, 2018) in the local setting. There has been an increase in care transition associated with overwhelming hospital bed utilisation (Tsang & Ge, 2016) and the health strategies of the Hospital Authority in Hong Kong (2011) have shifted to community-based care. The challenge imposed by transitional care has been treated in different chronic disease populations (Wong et al., 2011; Wong et al., 2015; Wong et al., 2020). Various protocol-driven models of transitional care for end-stage organ failure populations aiming at clinical effects and patient safety have been considered by health service researchers (Ng et al., 2016) in Hong Kong. In recent decades, there has been an escalating trend of adopting specialist palliative services for organ failure patients. Professional-led transitional care, supported by volunteers, can minimize the unplanned readmissions, advance the QOL and attain improvement in symptom management among patients with end-stage heart failure patients (Wong et al., 2016).

In addition, transitional care involves deliberately designed programmes with protocol-driven and evidence-based practice support, to render proactive and sustained support to patients discharged from the hospital (Wong et al., 2016). Likewise, cost-effectiveness is another crucial concern from the administrative perspective. TPC for non-cancer organ failure patients has proved effective in terms of reduced healthcare expenditure as well as improved clinical outcomes (Wong et al., 2018).

2.3.8 Research gap identified from literature review

The health problems encountered by patients are symptom distress, psycho-emotional stress, physical immobility, compromised QOL, and caregiver burden. Non-dialysis palliative care has been commonly provided in a clinical setting with the approach of in-hospital and home-

based palliative care, especially for older patients with ESRF (Teruel et al., 2015), better outcomes of fewer AED visits in the last month of life for dialysis patients with home palliative care (Nesrallah et al., 2018). Transitional care interventions advocate an intersection of seamless hospital and community care to ensure an effective transition. High-quality transitional care is designed to support individuals in coping with complex chronic conditions by providing better service coordination and continuity of care (Naylor et al., 2017). However, only one study from the review articles focused on non-dialytic CKD patients in stage 3 (Blakeman et al., 2014) before the current study commenced. There are limited empirical studies on the effects of home-based palliative care for reference.

In summarising the structural development of transitional care programmes across 34 reviewed RCTs, the common components included well-structured protocol, case management, comprehensive discharge assessment and planning, standardised documentation, telephone follow-up and home visit, active health referral system and patientinitiated telephone consultation. The above-highlighted features of the transitional care programmes were taken into consideration in designing the transitional care programme for this pilot. Overall, the majority of the summarised transitional care studies were designed using multiple components of interventions, while focusing mainly on the patients. In the essence of multidisciplinary effects in transitional care, the care recipients are not limited to patients; the family caregivers are key team members in transitional care programmes. However, the outcome measures on informal caregivers are limited in transitional care interventions. This pilot RCT will address the burden of caregivers to bridge the knowledge and practice gap.

2.4. Summary of Literature Review

This chapter has reviewed the impacts of palliative care on non-dialytic ESRF patients. The clinical conditions of ESRF patients needed to be kept under control within an acceptable therapeutic range. TPC interfaces the positive effects of palliative care in organ failure patients and sustains support for post-discharge needs to reduce re-hospitalisation for whatever reasons raised. The NCM organises seamless care and renders support to meet the needs of patients and caregivers. The review of effective strategies for the management of ESRF patients was referred to for the development of a programme with well-evidenced protocols to ensure the consistency and effectiveness of practice.

CHAPTER THREE: METHODOLOGY

3. Introduction

This chapter centres on the methodological issues involved in this study. The first section describes the research questions, aim and objectives. The following ten sections detail the study methods, including the study's design, setting and participants, randomization and allocation concealment, interventions, outcomes, data analysis, intervention fidelity and ethical consideration. The final section provides a summary of this chapter.

3.1 Research Questions, Aim and Objectives

Non-dialytic patients with ESRF will experience a decline in general conditions with complex symptoms of distress. The sophisticated symptoms management of irreversible and life-threatening kidney disease is conventionally managed in the hospital. This study attempted to assess the feasibility of recruiting participants for planned RCT in testing out the effects of a transitional palliative program on non-dialytic patients with ESRF with minimal or no side effects or no side effects or unwanted reactions from a protocol-driven program.

This study aimed to explore the feasibility of the study approach and preliminary effects of the TPC program among patients with ESRF with concrete objectives stated as follows:

- (1) To assess the feasibility of conducting a TPC program for patients with ESRF, in terms of the following parameters:
 - Feasibility of participant recruitment: time used for subject recruitment, eligibility rate and recruitment rate

- Acceptability of the interventions: prospective acceptability, concurrent acceptability, and retrospective acceptability
- Feasibility of the measurement tools: the response rate of the self-reported questionnaires, and proportions of missing values of the items of each measurement tool
- (2) To assess the preliminary effects of the TRPP on the following outcomes among patients with ESRF:
 - Primary outcomes (unplanned readmission rate, length of hospitalisation and AED attendance)
 - Secondary outcomes (health-related QOL, symptom intensity, physical function, satisfaction, anxiety and depression)
- (3) To assess the preliminary effects of the TPC program on the burden of care among caregivers of patients with ESRF; and
- (4) To explore the experience of patients with ESRF and their caregivers regarding the TRPP.

3.2 Study Design

This pilot study was a prospective, two-arm parallel, single-blinded pilot RCT, supplemented with qualitative interviews to address the research objectives.

Leon et al. (2011) stated that a pilot study can be applied to examine the feasibility of subject recruitment, group randomization, retention of subjects, the procedure of assessment and implementation of novel strategies. The primary aim of this study was to develop and preliminarily test a home-based transitional palliative care program for ERSF patients with complex symptoms and health-related issues. Guidance of the Medical Research Council on developing and evaluating complex interventions (Craig et al., 2008) pointed out that

understanding processes is significant, but is not a replacement for the evaluation of outcomes. As pilot studies test out several methodological components and clinical outcomes simultaneously, it is suggested that the results of well-conducted pilot studies are important for research, irrespective of outcome (Arain et al., 2010). Hence, a pilot RCT was utilized as the main study methodology of this trial for addressing the study objectives carefully designed according to MRC guidance.

The study consisted of two stages (Figure 3.1). Stage one involved the preparation of protocol, measurement tools, structured documentation, and submitting them for validation. Stage two involved the pilot RCT process. Participants were randomly allocated to either the control or intervention group. The outcome measures were examined at five-time points: baseline (T0), first month (T1), third month (T3), sixth month (T6) and twelfth month (T12). A face-to-face interview was carried out alongside the pilot RCT to collect qualitative data from patients and caregivers of the intervention group, supplemented with a quantitative study in explaining the findings (Dos Santos et al., 2017; Hennink, 2007).



Figure 3.1 Flow of the study

3.3 Setting and Participants

This study was conducted among the ESRF patients discharged home for customary hospital-based care in a Renal Unit of a local regional hospital in Hong Kong from August 2014 to September 2017. A sampling strategy was a convenient approach in which the research team readily find target subjects in the study hospital. All in-patients with ESRF discharged from the study hospital and referred for renal palliative care were screened for study eligibility. Participants had to go through two steps of pre-recruitment assessment. The first assessment was used to determine whether the patient met the clinical criteria for

palliative care. A potential subject was further considered for eligibility for the pilot RCT. The informal caregivers of the recruited patient participants were invited to participate in the study.

Face-to-face interviews employed purposeful sampling because the targeted participants in the intervention group receiving the TRPP should be able to provide the research team with the most and best information about their experiences with TRPP. Through the interview, participants must be willing to share their experiences with TRPP, the research team collects the most relevant information about the phenomena of the TRPP.

3.3.1 Assessment of clinical criteria for non-cancer palliative care

Patients referred to palliative care have to meet the following clinical criteria: (a) patient's CKD and DM with serum creatinine <350 mmol/L or those without DM with serum creatinine <450 mmol/L who have refused RRT; and (b) patients were assessed by a renal team whether they were suitable for long term RRT with conditions such as multiple comorbidities, poor functional status, and social support (Hospital Authority, 2008).

3.3.2 Eligibility for pilot RCT

Patients with CKD who met the above clinical criteria for non-cancer palliative care were referred to the palliative care team by the physician in the Renal Unit. They were eligible for this pilot RCT when they also fulfilled the following inclusion and exclusion criteria.

Inclusion criteria

The patients were (i) Cantonese speaking, (ii) with the Chinese version of Mini-Mental State Examination (C-MMSE) scored > 20, (iii) communicable, (iv) able to be contacted by

telephone after discharge, and (v) residing in the geographic hospital service area. The potential participants were assessed for their cognitive ability because being able to comprehend the information provided and communicate in Cantonese was the primary requisite. For cognitive screening, the Mini-Mental State Examination - Chinese version (C-MMSE) was adopted because it is the most cited cognitive screening instrument in clinical settings (Lou et al., 2007) and the cut-off point for cognitive competence with C-MMSE > 20 referenced a transitional care study conducted by Wong et al. (2011). The subjects were required to be reachable by phone because the continuous follow-ups were conducted mainly through telephone communications in addition to home visits.

Exclusion criteria

Patients were excluded from enrollment if they were unable to communicate, old age home residents, or had medical diagnoses of severe psychiatric disorder or severe active malignancy.

3.3.3 Eligibility of caregiver-participants

The primary caregivers of the patient participants who provided care to the patients in the home environment were invited to participate in the study. In this pilot RCT, the primary caregivers were mainly the spouses or offspring of the patients. They actively provided care for daily activities and accompanied the patients for healthcare follow-up or admission into the hospital. The inclusion criteria of caregivers were adults >18 years and being the primary caregivers. The exclusion criteria of caregivers were those unable to communicate in either English or Cantonese.

3.4 Randomization and Allocation Concealment

Eligible participants, recruited and meeting the specified criteria between August 2014 and October 2016, were randomly assigned to either the intervention group (TRPP) or control group (customary hospital-based program).

3.4.1 Randomization and sequence generation

One set of randomization via block approach was prepared by a project coordinator from www.randomizatioon.com with a block size of 2 in the 1:1 allocation ratio. Each sequence set (1,2 or 2,1) was generated with a random block size of two. The sequences generated were prepared and the list of sequences was printed out on a sheet of paper for use as described below.

3.4.2 Allocation concealment

The sequence list was printed out on A4 paper which was cut sequentially. The cut numbered sheet was then folded once to hide the appearance of words before being placed into an opaque sealed envelope. The envelopes were stored in a folder that was stored in a locked room accessible only to the individual involved in the allocation.

3.4.3 Implementation of randomised allocation

The doctoral student investigator would assess the potential clients for the fulfilment of the research eligibility criteria. A thorough explanation of the study would be given to the patients and their caregivers. Once the patients and caregivers agreed to join the study with the consent form signed, the doctoral student investigator would collect the baseline data. Afterwards, the subject would be referred to the clinic nurse in charge (project coordinator) who would open the sequenced sealed envelope with a randomised number and assign the

recruited subject with the computer number '1'= customary hospital-based group, '2' = TRPP group. The participants and caregivers were then randomly assigned to either a control group (1) or an intervention group (2). Both project coordinators (one for generation of sequence of randomization and concealment of envelopes, and one responsible for allocation of groups) were not involved in this study.

3.4.4 Sample size

The sample size justification of a pilot study should provide the minimum number of participants required to meet the objectives of the study (Billingham et al., 2013; Polit & Beck, 2010; Whitehead et al., 2015). If a problem exists with a 5% (π =0.05) probability in a potential study, the intervention effect will almost certainly be identified with 95% confidence (γ =0.95) in a pilot study (Viechtbauer et al., 2015). Hence, not fewer than 60 participants were recruited in this pilot study so that the effect could be detected with a confidence level of 95%.

 $n = \underline{n(1-\gamma)}$ $n(1-\pi)$ n = number of participants $\gamma = confident level$ $\pi = effects exist$

(http://www.pilotsamplesize.com)

According to our best knowledge, non-dialytic patients with ESRF have a high mortality rate. Based on the anticipated high level of attrition due to mortality, we set the attrition rate at 20%. Adjustment for attrition: N1 = N / (1-q), where N1 is the adjusted sample size, N is the unadjusted sample size and q is the attrition rate (Hazra & Gogtay, 2016).

Adjusted sample size (N1) = unadjusted sample size (N) / 1 – attrition rate (q)

$$= 60 / 1 - 0.2 = 75$$

3.5 Transitional Interventions

As shown in Table 3.1, participants of both the control group and intervention group received customary palliative care, and those in the intervention group underwent a structured home-based TPC program in addition to routine care.

3.5.1 Customary palliative care (Control group)

The control group was assigned to the usual non-cancer palliative program (NCPP) which was a program funded by the Hospital Authority. The NCPP, which targets chronic illnesses such as renal, respiratory and neurological patients, was delivered by a team coordinated by a physician with the support of an APN, a social worker, a physiotherapist and an occupational therapist. When the patient's general condition became stable and they were fit for discharge the renal patients would be referred to the renal physician for the initial consultation of palliative care usually 2-3 days before the discharge. The renal physician would explain the palliative care approach and discuss with the patient and family caregiver the patient's health status and concerns. The physician referred the patient to the social worker for financial or psychological support and the occupational therapist if home readjustment was required. There could be a home visit performed by the social worker or occupational therapist after referral but there was no particular protocol to guide the content or frequency of the home visits. There was a patient-initiated hotline available to the patients. The ward nurses were responsible for responding to patients' calls. The patients with ESRF were followed up at the Renal Palliative Outpatient Clinic, an average of every 8 weeks. Table 3.1 below summarizes the customary care provided to patients.

3.5.2 Transitional renal palliative care (Interventional group)

In addition to the hospital-based palliative care, the intervention group received additional pre-discharge assessment and planning, post-discharge support with telephone follow-up and home visits. The discharge assessment and care planning enabled the healthcare provider to have an insight into the updated condition including physical, psychosocial and spiritual needs. Related planning and support were planned and arranged in a home-based setting. NCM coordinated and arranged the necessary support to the patient in a home-based environment accordingly. Telephone follow-up was another intervention in the post-discharge period in a home-based environment. Education, counselling, health-related communication and assessment through patient interviewing would be conducted through telephone follow-up. Moreover, the bi-monthly home visits enabled on-site assessment (especially for refractory symptom distress), education, and skill transfer to the patients and caregivers.

3.5.3 Justification for integrating the transitional care into the customary palliative program

Evidence revealed that readmissions of CKD patients were likely related to a high disease burden and driven by treatment noncompliance (Cameron et al., 2010); poor dietary and medication compliance (Christensen et al., 2002), and inadequate discharge planning (Hakim, & Collin, 2014). There is no formal discharge assessment for ESRF patients in the current clinical setting. Some patients may have unresolved problems and need for physical and psychosocial support in a home-setting environment as well as potential problems of ESRF upon discharge. After discharge, ESRF patients with the irreversible and advancing disease may have newly developed symptom distress or declined clinical condition. All these potential risk factors may contribute to unplanned readmission after discharge from
the hospital (Paratha et al., 2012; Matthew et al., 2015). Frequent readmission may pose a negative effect on rehabilitation as well as QOL (Cancan et al., 2014; Chippers et al., 2004). The study interventions were designed deliberately to fill the gap in services for patients with CKD immediately discharged from the hospital.

3.5.4 The TRPP

The intervention involved an innovative TRPP which will be further elaborated on in the next chapter. Briefly, it was a program backed up by a core multidisciplinary palliative renal (ESRF) team, which consisted of a renal physician with palliative care training, three NCMs, a physiotherapist, an occupational therapist and a social worker. As shown in Table 3.1, All patients were looked after by the renal physician at referral and followed up as described in customary care. In this study, the transitional care approach was integrated into the customary program. After the initial physician consultation, the NCM would initiate TRPP with the patients in the intervention group before they were discharged home.

	Customary Program	Transitional Renal Palliative Program (TRPP)									
	Before discharge interventions										
		*	Pre-discharge assessment: carried out by NCM: after the first medical consultation Pre-discharge planning								
Post-discharge interventions											
•	Medical consultation at 8 weekly intervals	•	Medical consultation at 8 weekly intervals								
٠	Patient initiated telephone consultation/call Regular case review conference EOL care for in-patient A home visit by an occupational therapist (home setting modification / social worker assistant (psychosocial counselling) on- demand cases Physiotherapy consultation Case review conference Advanced care planning	• • •	Patient initiated telephone consultation/call								
٠			Regular case review conference								
٠			EOL care for in-patient								
•			A home visit by an occupational therapist (home setting modification / social worker assistant (psychosocial counselling) on-demand cases								
		•	Physiotherapy consultation								
•		• • *	Case review conference								
٠			Advance care planning								
•			NCM Telephone follow up: weekly from 2nd week onward								
		*	A home visit by NCM within the first three days of discharge from the hospital and followed by a bi- monthly home visit.								

Table 3.1 Summary of the pilot randomised controlled trial intervention

Notes: *additional interventions by NCM, NCM = nurse case manager, EOL = end-of-life

3.6 Outcomes of the Study

The outcomes of this study were addressed according to the research objectives, including the feasibility and acceptability of transitional renal palliative care, as well as the effects of transitional interventions. The details of the study outcomes are described below.

3.6.1 Feasibility outcomes

According to the aspects of feasibility that can be examined with a pilot study suggested by

Leon et al. (2011) and the theoretical framework of acceptability (Sekhon et al., 2017), the

feasibility and acceptability of the evidence-based transitional renal palliative care for ESRF participants refer to the results of feasibility on enrollment and randomization allocation, and assessment processes, and acceptability of interventions.

3.6.1.1 Feasibility of subject enrollment and randomisation allocation

The following outcomes were assessed to measure the measurement of the feasibility of subject enrollment and the randomization allocation process: The time used for subject recruitment; the eligibility rate (the number of participants eligible for this study/number of potential participants screened prior to eligibility assessment), the recruitment rate (number of participants recruited in the study/number of eligible participants), and the retention rate (the number of participants completing the study/number of participants recruited into the study), the attrition rate (number of participants without observed outcome data in analysis per number of participants randomised in this RCT) (Institute of Education Sciences, n.d.; McKinstry et al., 2007).

3.6.1.2 Feasibility of the measurement tools

The feasibility of the measurement tools was assessed using the response rate of questionnaires and the proportions of missing values on the items of each questionnaire (Bouwmans et al., 2013).

3.6.1.3 Acceptability of the interventions

The theoretical framework of acceptability (Sekhon et al., 2017; Woo et al., 2009) suggests that the acceptability of the intervention is a multi-factorial construct, and included three major constructs, namely, prospective acceptability (before participating in the

Prospective acceptability refers to the participants' acceptability before participating in the intervention, i.e., how the individual perceives the intervention before participation (Sekhon et al., 2017; Woo et al., 2009), which is reflected by the affective attitude which can be interpreted by the recruitment rate, and burden which can be measured by the rejection of participation. The recruitment rate and the rejection rate were also elements used to the feasibility of subject enrollment and randomization allocation.

Concurrent acceptability refers to the intervention coherence and adherence, which includes the degree to which the participant adheres to the program and the level of engagement with the intervention. The health problems of participants are unique, and different interventions are planned for individual participants. In this study, concurrent acceptability was reflected by the extent of treatment compliance rate, involvement in the interventions, dropout rate, and reasons for dropping out of the study.

Retrospective acceptability mainly refers to the participant's perceived experience after participating in the intervention, including their perceptions (affective attitude after the intervention, perceived effectiveness), challenges, and level of satisfaction with interventions (Sekhon et al., 2017; Woo et al., 2009). In this study, individual interviews among participants and their caregivers in the intervention group were conducted during interventions. Their lived experiences with transitional renal palliative care were explored by the interviewers.

3.6.2 Trial outcomes

The primary outcome measures were healthcare utilisation. The secondary outcome measures constituted health-related QOL, symptom intensity, physical function,

satisfaction, anxiety and depression, and caregiver burden was included. Findings of experiences of participants and their caregivers were extracted from face-to-face interviews.

3.6.2.1 Health services utilisation

Healthcare utilisation, which included readmission rate, length of hospital stays and attendance in emergency rooms was referred from the hospital information systems.

3.6.2.2 Symptom intensity

Symptom manifestation guidelines were developed by the research team to assess the patient's symptom intensity. The initial symptom list had 24 items, which were typical symptoms reported by ESRF patients (Yong, et al., 2009). During the content validation process, the majority of experts (75%) remarked on seven items of SM guidelines as invalid. The expert comments were: (1) intolerance to cold was a symptom of coexistence and associated with anaemia, fatigue, and loss of energy; (2) declined skin texture was related to the accumulation of toxic and compromised secretary function; (3) impaired oral sensation was in coexistence with uraemia; (4) flatus related to the coexistence of gastrointestinal distress such as constipation; (5) dryness of mouth was associated with compromised salivary secretion; (6) impaired hearing, with irreversible degenerative changes; and (7) impaired interest in sex, which was a cultural issue. A panel meeting was then conducted to discuss the significance of the SM and a mutual agreement was made on the deletion of these seven items to produce a 17-item version.

The overall content validity index (CVI) of the SM was 0.78 when all the 24 items were included. After the deletion of the seven items, a scale level CVI of 1.00 was achieved. The final version of this assessment tool was tested among 15 patients over 7 days and the test-

retest reliability coefficient was 0.91. This 17-item SM was utilised in the present study for the measurement of symptom intensity of ESRF patients. The severity of symptoms was expressed by a 4-point scale (0-3) with a score of 3 showing the most serious status. A symptom rated with a score of 2 or higher would indicate symptom distress.

3.6.2.3 Physical function

The Palliative Performance Scale (PPS) was used to assess the patient's physical function. The PPS developed based on the Karnofsky Performance Scale (Anderson et al. 1996; Ho et al., 2008) is an instrument specially designed for palliative patients reporting their physical condition in the end phase of life. The scopes of PPS covered five, including ambulation, activity and extent of the disease, self-care ability, oral intake, and consciousness level. The status of physical function was divided into 11 PPS levels measured in 10% decrements, from 100% (normal) to 0 % (death). The construct validity of PPS has been supported by its high-level prognostic magnitude of declined condition (Anderson et al., 1996; Harrold et al., 2005; Lau et al., 2006; Virik & Glare, 2002). The scale had been validated and the inter-rater reliability between doctors and nurses was maintained at 0.85 with strong kappa values of 0.97 (Myers et al., 2010).

Anderson et al. (1996) suggested that in finding an overall best-fit term for the description of the physical function of the patient, among five aspects of function, it is warranted to read and assess across the table at each 10% decrement (Appendix 6a & 6b). Below is a description of the 5 aspects of PPS.

(1) Ambulation: The reduction of ambulation is referred to as the ability of the client to perform normal daily self-care such as eating, clothing, and face cleansing. The 'reduced ambulation' was marked at the level of PPS 70% and PPS 60%. For a client who was able to walk and transfer on his or her own but at PPS 60% referred to occasional help needs.

- (2) Activity & Extent of the disease: The extent of the disease was assessed by the ability to manage one's work and self-care. The type and severity of the disease were referred to as the level of physical function and self-care observed. The extent of illness was also evaluated in accordance with the ability to maintain daily activities.
- (3) Self-care: The clients were assessed on the extent they could move, walk independently, toilet, personal hygiene, and eating. Clients who needed support once daily or a few times weekly were regarded as needing 'occasional help'. 'Considerable assistance' meant that the client needed regular daily help. 'Total care' referred to those who were unable to perform total care including eating, toileting, and general hygiene.
- (4) Oral intake: This measure referred to the patient's usual eating habits while they were clinically stable, and if changed or reduced oral intake occurred with clinical manifestation. The rating involved a change in the quantity and texture of foods.
- (5) Consciousness Level: 'Full consciousness' implies full alertness and orientation with good cognitive abilities in various domains of thinking and memory. 'Confusion' was a reduced level of consciousness which was characterised by delirium, dementia with a reduced level of consciousness and drowsiness. 'Drowsiness' implied either fatigue, drug side effects, delirium, or closeness to death and is sometimes included in the term stupor. 'Coma' was the absence of response to verbal or physical stimuli with some reflexes that might or might not remain.

3.6.2.4 Health-related QOL

The Kidney Disease QOL (KDQOLTM) was a self-administered questionnaire to assess the QOL of patients with kidney disease. The abbreviated form of the KDQOLTM (Hays et al.,

1994) consisted of the short form-12 Health Survey instrument and 24 disease-specific items assessing QOL related to kidney disease. The results of the SF-12 instrument were grouped into the subscale of the Physical Composite Score (PCS) and the subscale of the Mental Composite Score (MCS). The 24 disease-specific items consisted of three subscales: Symptoms Problems List (SPL, 12 items), Burden of Kidney Disease (BKD, 4 items), and Effects of Kidney Disease (EKD, 8 items) (shown in Appendix 7a and 7b). The questionnaire was rated on a three to five points Likert scale. The raw scores could be transformed linearly from a range of 0 to 100, with higher scores showing better health-related QOL. Items on the same scale were averaged to create the subscale score.

The Cantonese version of KDQOL-36 (Hong Kong), which was translated by RAND Corporation (see: <u>http://www.rand.org/health/surveys_tools/about_translations.html</u>), and validated by our research team (Chow & Tam 2014), was adopted in this pilot RCT. The validation study results showed high validity with an overall ICC value of 0.98 in all subscales. For test-retest reliability, an ICC of 0.71 - 0.86 indicated the stability of the scale. The Cronbach's alpha values advised that the scale was internally reliable. The internal reliability of all subscales exceeded 0.65, with the exclusion of the PCS and MCS (Chow & Tam, 2014).

3.6.2.5 Anxiety and depression

The Hospital Anxiety and Depression Scale (HADS) was designed as a simple instrument to assess patients at risk for anxiety and depression (Zigmond & Snaith, 1983). It is a widely adopted questionnaire for depression and anxiety in primary care and hospital settings (Bjaelland et al., 2002). It has high validity evidence with the good internal consistency of $\alpha = 0.77 - 0.83$; and the test-retest reliability with coefficient correlation >0.8 achieved

(Johnston et al., 2000). The Cronbach's alpha for the total instrument anxiety subscale and the depression subscale was 0.78 and 0.81 respectively (Kring & Crane, 2009). The scores on both HADS sub-scores for anxiety (HADS-Anxiety) and depression (HADS-Depression) ranged from 0 to 21. As recommended by Bjelland et al. (2002), the cut-off score for the existence of anxiety and depression was eight. The ICC index of the Chinese version of HADS was 0.87 for both factors of Anxiety and Depression (Leung et al., 1999).

3.6.2.6 Satisfaction

The Patient Satisfaction, a self-administered 15-item questionnaire in Chinese which was applied in Wong et al.'s study (2011), was used to assess the patient's views on palliative care services in this pilot study. A 5-point Likert scale (1-strongly disagree to 5-strongly agree) was used for rating the items on the questionnaire of satisfaction surveys. The validity was evidenced by an expert panel and a test-retest reliability of 0.87 was achieved.

3.6.2.7 Caregiver burden

The Zarit Burden Index (ZBI) has been validated in many culturally diverse populations (Chan et al., 2010; Taub et al., 2004; Yeung & Chiu, 2004; Zarit et al., 1980). The Chinese version of ZBI was validated with the intra-class coefficient correlation of 0.99 and the split-half condition coefficient of 0.81. It attained high inter-rater reliability and internal consistency (Chan et al., 2005).

The ZBI (shown in Appendix 11a & 11b) was used to assess the caregiver burden. It had 22 questionnaire items measuring the extent to which caregivers perceived the changes in physical, psycho-social and financial stress as a result of caring for their family members with irreversible chronic diseases (Zarit, et al., 1980). The self-reported questionnaire items

were rated on a 5-point Likert scale from 'not at all (0)', to 'extremely' distressing (4). A total burden score was obtained by adding the responses to the individual items. The possible score ranged from 0 to 88, and a higher score indicated greater caregiver distress (Baumgartner et al., 1992).

3.6.3 Experiences towards the TRPP

Qualitative data on participants' and caregivers' experiences with palliative care were collected through face-face interviews. An interview guide was developed (Figure 3.2) which was related to the experiences and behaviours connected with TRPP. It addressed a wide variety of experiences encountered in real life. The developed interview guide was reviewed by the expert panel for relevancy and validity.

Research question one: What is the experience of transitional renal palliative program?

• Could you please tell me about your perceptions of Transitional Renal Palliative Program?

Research question two: How do the effects of transitional interventions affect patients' clinical condition?

- What are your experiences with the control of symptoms of the disease?
- What are your experiences in the prevention of complications of disease?
- What are your experiences in health education?
- What are your experiences with the referral system?
- How would you assess the nursing care provided by the NCM?
- What are your recommendations for better services and care after discharged from the hospital?

Figure 3.2 Semi-structured interview guide

3.6.4 Expert panel agreement on the trial outcomes

Alongside the intervention protocol validation to be presented in the next chapter, content validity on the relevance of using these instruments for measuring outcomes of intervention in this trial was performed by a panel of clinical experts with a content validity index (CVI) >0.75. The psychometric property of the measurement tools was summarised in Table 3.2.

Measures/variables	Instruments/tools	Items	ICC	CVI (%) (N=4)
Readmission rate	Hospital information system	1	NA	100
LOS during hospitalisation	Hospital information system	1	NA	100
AED visit	Hospital information system	1	NA	100
	Secondary Outcomes			
Symptom intensity	Symptom manifestation	17	0.91	100
Physical function	Palliative Performance Scale	5	0.86	100
Health-related QOL	KDQOL-36 (Hong Kong)	36		100
Symptom problems	Symptom Problem List	12	0.997	
Effect of kidney	Effect of Kidney Disease	8	0.993	
Burden of kidney disease	Burden of Kidney Disease	4	1.00	
Physical component	Physical Component Score	6	0.993	
Mental component	Mental Component Score	6	0.996	
Anxiety	C-Hospital Anxiety and Depression	7	0.87	100
Depression	Scale	7	0.87	
Satisfaction with care	C-Patient Satisfaction	15	0.87	100
Caregiver burden	C-Zarit Burden Index	22	0.99	100

Table 3.2 Overview of outcome variables and measures

LOD = length of stay in the hospital; AED = Accident and Emergency Department

ICC = Intraclass Correlation Coefficient, CVI= content validity index ICC data is obtained from the result of validation studies presented in 3.6.3.2 – 3.6.3.7 for each measurement tool, and CVI data is the result of an expert panel review in this study.

3.7 Data Collection

Both quantitative and qualitative data were collected for this study. Demographic data, clinical data and self-reported data were collected through a set of questionnaires. The procedure of data collection and management involved five stages: (1) preparation, (2) trial feasibility assessment, (3) baseline assessment, (4) post-intervention assessment, and (5) data management strategies.

3.7.1 Preparation of data collection

A trained data collector was responsible for the collection of quantitative data in this singlecentre study. Prior to the commencement of data collection, the doctoral student investigator provided training to the data collector. The content of data collection included the demographic variables, clinical characteristics, and primary and secondary outcome measures. The data collector was instructed to check if there was missing data in the collected questionnaire and asked the participant to fill up the blank data or clarify the missing data with participants. The techniques of collecting the data from the hospital information system, patient health records and questionnaires were demonstrated by the doctoral student investigator and practised by the research assistant satisfactorily.

3.7.2 Trial feasibility assessment

The eligibility assessment results could be retrieved from the hospital records. The records include the number of patients referred for consultation of palliative care, the number of patients eligible for recruitment to this trial, the number of potential patients willing to participate in this trial, reasons and number of non-eligibility, number of patients who were refused for the randomised group. All these data were collected for the feasibility test.

3.7.3 Baseline assessment

Demographics of patient participants included age, gender, marital status, education, occupation, accommodation, financial support, and care-taking support. Clinical characteristics assessed were co-morbidities, duration of hospitalisation at last discharge from the hospital, and episodes of AED visit. These baseline assessment data were retrieved from the Hospital Information System, and patient records and collected using self-reported questionnaires (Appendix 2). Demographic variables of caregivers were collected with a demographic questionnaire including caregiver's gender, employment status, leave applied for caring for the participants, healthcare products for sustained health status for the role of informal caregivers (Appendix 3). These measures have been validated and adopted in the study of Wong et al. (2011).

3.7.4 Post-intervention assessment

Post-intervention data were collected when the participants and caregivers attended the medical consultation at the palliative care clinic at four-time points (T1, T3, T6, and T12) in the first month, third month, sixth month and twelve months after the interventions. The same set of questionnaires was used for data collection. The primary outcome data, including readmission rate, length of hospitalisation and AED visit were recorded in the Hospital Information System. Secondary outcome variables involving health-related data (SM and PPS) were assessed by the nurses and recorded in patients' health records. The self-perceived data (QOL, anxiety and depression, satisfaction and caregiver burden) were reported by participants and caregivers and collected through self-administered questionnaires.

The qualitative data were collected by inviting participants and their family caregivers to participate in four face-to-face semi-structured interviews at the first (T1), third (T3), sixth (T6) and twelfth (T12) months. All interviews were conducted by the same doctoral student investigator with experience in quantitative and qualitative studies, either in interviewees' homes or in a single room of the out-patient clinic based on interviewees' preference. All interviews were audiotaped.

3.7.5 Data management strategies

A study number was assigned to each participant with his/her name removed from the data to ensure anonymity. The names of participants were kept in a separate record. The paper questionnaire was kept in a locked file storing room. Electronic data were stored in an encrypted file on a hard disk. The password was kept by the doctoral student investigator. Data management strategies were in place to ensure the confidentiality and security of data.

3.8 Quantitative Data Analysis

3.8.1 Data entry and screening

Before the process of data analysis, data screening and cleaning were carried out to ensure the validity of data analysis (Van den Broeck et al., 2005). Descriptive data of means, standard deviations for continuous variables, and frequency counts for the categorical variable were reviewed for the input of correct data (Portney & Watkins, 2009; Tabachnick & Fidell, 2001). The data sheets were prepared and screened manually for correctness against the original records. Box plot graphs or Q-Q plots were applied to identify data related to incorrect or irregular data entry (Polit & Beck 2012). Values that appeared beyond the reasonable range for each variable were highlighted for potential errors and were verified accordingly.

3.8.2 Missing data management

Missing data for any reason can bias findings and decrease the power limit and generalizability. The ultimate consequence of missing data in violation of the result of a study is that it compromises the external and internal validity of the results (Hardy et al., 2009; Little et al., 2002). However, missing data is a common and challenging issue in palliative care research due to the advanced and complex symptoms of distress of organ failure disease (Fielding et al., 2006). Munro (2005) stressed that three tasks should be performed before managing missing data, which included the recognition of the pattern and calculation of the amount of missing data, verification of the potential reasons for missing data, and the method of handling the missing data.

3.8.2.1 Recognition of the pattern and calculation of the amount of missing data When missing data is less than 5% in a large sample, the observed missing data resulting in only small biases in the effect estimates can be removed (Abu-Bader, 2010; Duffy, 2006; Tabachnick & Fidell, 2013). However, a substantial bias can result from a significant amount of missing data or if the missing data are dissimilar to those with complete data (Litter & Rubin, 2002).

When considering the missing data, the reasons for missing data should be examined. The frequency of missing data was compared by demographic characteristics such as gender, age, and clinical status, and the dropout was compared with the participants who completed the study to determine the correlation of the missing data with other known factors (Hardy, et al., 2009). There are three types of missing data. Firstly, data missing completely at random (MCAR) only if there is no relationship between the missingness of the data and any observed values. Those missing data points are a random subset of the data. There is

nothing systematic going on showing that some data may be more liable to be missing than others (Hardy, et al., 2009). There are no measured or unmeasured differences in the characteristics of those missing data and those collected. Secondly, data missing at random (MAR) is assumed when we can predict the value of missing data based on the other data collected (Hardy, et al., 2009). Lastly, missing not at random is the missing data that differ from those collected after adjusting for other measured factors (Hardy, et al., 2009; Manski, 1995)

3.8.2.2 Verification of the potential reasons for missing data

There are three kinds of non-response, namely unit, item and wave non-response (Hardy, et al., 2009). Non-response unit refers to no data collected on individual participants and there is no means to include the participants in the analysis. Non-response item refers to missing data for individual items due to the inability or unwillingness of the participant to respond to the item. Wave non-response is characterised by all data missing for a given assessment point in a longitudinal study (Hardy & Allore, 2009; Hussain et al., 2016; van Buuren, 2007). Given the nature of the study population, the missing data in this trial were wave non-response. For instance, if the patient died in the sixth month (T6), data to be collected beyond T6 would be missed.

Two possible types of missing data were anticipated in this study. One was due to the patient's failure to address it. The second anticipated reason for missing data was due to the participants leaving the study due to death, being transferred to another hospital, shifting to dialysis therapy, or change of residence to a nursing home.

3.8.2.3 Handling the missing data

People in palliative care die or withdraw as a direct result of disease progression not related to the intervention. Approximately 25% of data are missing in the palliative intervention studies in participants with advanced disease (Hussain et al., 2016) which reduces the statistical power, trial results precision, generalizability and validity of RCT findings (Li et al., 2014; Akl et al., 2015). To address the two possible types of missing data described above, two approaches to handle the missing data were utilised in this study accordingly. The first one was most commonly utilised by recovering the values by contacting the participants and asking them to fill out the missing values. The missing data were updated after verification. The second approach to handling missing data was the substitution of missing data with means of subsets through multiple imputations (MIs) (Graham, 2012) for data MCAR.

The MI method is one of the longitudinal imputation methods for replacing missing data in longitudinal studies (De Goeij et al., 2013; Jakobsen et al., 2017; Rubin, 1996; Schafer, 1999). When the variables are MAR or MCAR, the multiple imputation method directs the under-estimation of variables which are normally distributed and shown by a linear function of all variables.

The variance of the summarised statistics is illustrated from two components. The components of within-imputation variance involves the average of variances of the summarised statistics of the multiple imputations while the other components of imputation variance include the difference between the summarized statistic of each imputation and the

average of the summarized statistics of the multiple imputations (de Goeij et al., 2013; Jakobsen et al., 2017; Rubin, 1996; Schafer, 1999).

The MIs involve the substitution of each missing value with a set of credible values, leading to different sets of complete data (Allison, 2002; Little & Rubin, 2002). The MIs involve substituting each missing value with a set of plausible values, resulting in multiple different complete data sets. Each set is then analysed, and the combined results yield the correct variance (Allison, 2002; Gramham, 2012). The basic method of replacement of missing data with a set of logical values results in the synthesis of different complete sets of data. Each complete set of data is then interpreted using the standard procedures and the results are combined (Allison, 2002; Hardy et al., 2009; Little & Rubin, 2002). Studies comparing MIs with other imputation methods reveal that estimations generated format of the dataset with missing data are less biased (Graham, 2012; Houck et al., 2004; Liu & Gould, 2002; Sauro, 2015; Tang et al., 2005).

MIs were adopted to replace missing data in this trial in which missing data were categorised as missing completely at random (MCAR) when more than 10% of missing data were observed (Wood et al., 2004). The advantages are to take the data analysis with a complete data set for analysis. This method can test the sensitivity of different sets of mutations for a different mode of analysis. The disadvantages of MI are that the method of development, storage, and analysis is rather complicated as compared with simple or mean imputation (Gramhan, 2012).

With the confirmation of the extent and pattern of missing values, the multiple imputation method with subgroups means substitution in terms of linear regression was then applied. No definite episode of imputations was concluded for the missing dataset. In general, five datasets are adequate iterations to obtain sound results (Osborne, 2013). The fifth episode of the imputation of data was practically validated as effective (Polit, 2010; Portney & Watkins, 2009). In this trial, the fifth episode of the imputation of data was utilised for analysis (Osborne, 2013; Schafer, 1997) with considerable adequate iterations to attain sound analysis.

Reasons for missing data include unit, item and wave non-response (Hardy & Allore, 2009). In this trial, there were two types of reasons for missing data. In item no-response associated with the missing data for individual items due to participant's inability or a participant's reluctance to address the item due to privacy issues or other factors. Another reason for missing data was wave non-response. All data for a given assessment point in a longitudinal study are missing. For a patient out of the study in the sixth month, all data collection is truncated from the sixth month onwards (Hardy & Allore, 2009; Hussain et al., 2016; van Buuren, 2007).

The primary missing data in this trial was congruent with the average of 25% of primary endpoint data noted missing in RCT of palliative care of participants with advanced disease (Hussain et al., 2016). Usually, the reasons for missing data are related to the progression of the disease and the death of the participants. So, this type of missing data is associated with a systematic classification such as researcher control.

3.8.3 Statistical analysis

Statistics analyses were conducted using the computer-based statistical software package IBM Statistical Product and Service Solution (SPSS) Statistic 23 (IBM Corp., Armonk, NY, USA). Descriptive and comparison statistics were calculated for the sample population. All statistical tests performed were two-sided, and a p<0.05 was considered statistically significant unless specified.

3.8.3.1 Normality of data

Data distribution regarding normality was firstly assessed visually by using normal plots (Field, 2009) or by significance tests (Elliott & Woodward, 2007; Oztuna et al., 2006). Multivariate normality is the essential assumption for the repeated measure analysis of variance (RM-ANOVA) (Polit, 2010). Hence, Q-Q plots, normal probability plots, skewness, and kurtosis indices were commonly applied to define the normality of the outcome measures in different scales and subscales. Usually, normal indices of skewness and kurtosis closely approach 0 (Warner, 2008), yet a level of normality with a mean of zero and a standard deviation of +1 is still accepted as a normal level (Soares & Vaz Carneiro, 2002; Hair et al., 2010).

3.8.3.2 Analysis of baseline data

Descriptive and comparison statistics were calculated for the sample population. Descriptive statistics are presented as mean, standard deviation (SD) and range, or as median and quartile for continuous data according to the distribution characteristics of the data. Frequency and percentage were used to describe category data. The comparison of baseline categorical data was analysed by chi-square test for gender, marital status, education level and the like by Fisher's test for comorbidity. For the data of age, baseline continuous variable symptoms intensity, satisfaction with care, anxiety, depression, physical function, the burden of the caregiver, and KDQOL were compared between groups using an independent t-test.

3.8.3.3 Analysis of primary outcome measures

The independent t-test was performed to assess whether there was a statistically significant difference between the means of the LOS in the hospital, episodes of AED visit and days between the index discharge and the first readmission, in two unrelated groups (intervention group and control group) (Portney & Watkins, 2009). Pearson's chi-squared test was used to determine whether there was a statistically significant difference between the expected frequencies and the observed frequencies in one or more categories of contingency data such as the readmission rate between both groups (Portney & Watkis, 2009). Mann-Whitney U test and Friedman test were used to assess the difference in median of interceptive days of readmission which were not normally distributed between two independent groups.

3.8.3.4 Analysis of secondary outcome measures

The secondary outcome variables involved in this study were a longitudinal dataset of continuous outcome variables. For normally distributed data, an independent t-test was used to analyse the difference in outcome variables between two independent groups. In addition, RM-ANOVA tests were used to examine the differences between the study group and control group, within-group over five-time points and interaction effects (group x time) (Salkind & Green, 2011)

One-way RM-ANOVA was the principal statistical method used to analyse the secondary outcome measures over different time points in this trial. With the assumption of normally distributed data, the variances of datasets were assumed with sphericity. Each intervention effect in the study was then tested by the F ratio which showed the true risk of Type I error (Warner, 2008, p.907-908).

The principal analysis of the main effects of interventions produced significant differences in the outcome indicators. Repeated measures tests were conducted to identify the betweengroup, within-group, and interaction effects over time. Based on the mean difference (MD) of groups, post hoc tests were applied to identify which groups were significantly different from each other (Conover, 1980). The RM-ANOVA design was based on the homogeneity of variance assumption. With the application of Mauchly's test of sphericity, the compound symmetry (sphericity) in the homogeneity of variance assumption was checked. If Mauchly's test was not significant (p< 0.05), the assumption of compound symmetry of sphericity was violated, Greenhouse-Geyser with the epsilon correction was then adopted to adjust the degree of freedom for the F-ratio (Park et al., 2009).

Numerous comparisons between different time points on each clinical outcome were performed. When significant differences were identified, a post hoc test was applied to determine which periods (T0 vs T1, T0 vs T3, T0 vs T6, T0 vs T12, T1 vs T3, T1 vs T6, T1 vs T12, T3 vs T6, T3 vs T12, T6 vs T12) within the group indicated the within-group differences (time effect), as well as the occurrence of group effects over T0, T1, T3, T6, and T12 (group effect). To control Type-I errors within-group measures over five-time points, the alpha level was adjusted by 0.05/10 = 0.005. A p-value of < 0.005 was said to be significant unless specified. In an analysis of between-group measures, the alpha level was adjusted by 0.05/2 = 0.025. A *p*-value of < 0.025 was readjusted to be significant (Warner, 2008).

Multiple t-tests are not assumed for normally distributed parametric data because a chance of making a Type I error is anticipated for every attempt of the test. This error usually accounts for 5%. By running two t-tests on the same data, the chances of making a mistake are increased by 10%. These are unacceptable errors. An analysis of variance (ANOVA) controls these errors so that the Type I error remains at 5%. RM-ANOVA reduces the chance of making a type I error (Eddington, 2015; Macey et al., 2016). A summary of methods for data analysis is shown in Table 3.3.

In applying RM-ANOVA, several assumptions have to be made including (1) the normally distributed dependent variable in each group is being compared; (2) normality of the dependent variables in the population for each group, random sampling of the participant's population for achieving homogeneity of variance and no sampling bias and (3) independence of observations is maintained (Park et al., 2009). Significant statistical testing of variables is applied to confirm that the observed effect is realistic and not random and various tools are adopted to minimise the chance of insufficient analysis (Maher et al., 2013).

3.8.3.5 Intention-to-treat (ITT) and Per-protocol (PP) analysis

Attrition from the study is a common occurrence in clinical research which involves longitudinal observation for a longer and fixed period of follow up. The principle of ITT analysis is a conventional approach to managing missing data thus avoiding biased results (Armijo-Olivo et al., 2009; Matilde et al., 2006; Peduzzi et al., 2005). ITT analysis is usually preferred because time effects are observed in practice.

The ITT analysis mandates that all subjects randomised to a treatment arm should be included in the analysis by assuming that each participant received the intervention to which the participant was assigned (Portney & Watkins, 2009). Application of ITT analysis was the suggested and preferred approach to prevent bias in findings.

To provide a more valid assessment of the effects of the 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 the MIs were conducted for the outcome measures of QOL-36, symptom intensity, physical function, anxiety and depression, satisfaction with care, and burden of the caregiver.

PP analysis involved the participants who were recruited in the clinical study and complied with all study interventions stated clearly in the study protocol (Armijo-Olivo et al., 2009; Jakobsen et al., 2017; Mostazir et al., 2021; Shah et al., 2011). However, if PP analysis alone is applied, it tends to bias the result and shows the effects of treatment but at lower levels of useful evidence applied to analyse the adverse effects of treatment (Gupta, 2010; Jakobsen et al., 2017; Shah et al., 2011). The application of a single method of PP analysis tends to form attrition bias (Gupta, 2011). In addition to the intention-to-treat analysis, PP analysis was also carried out conducted to check the sensitivity of the results of secondary outcome variables (Jakobsen et al., 2017; Portney & Watkins, 2009; Schulz et al., 2010). The effectiveness of the intervention was further confirmed when the ITT and PP analysis resulted in similar conclusions (Brody, 2012).

Measures	Time			Analysis				Statistical test(s)
	TO	T1	T3	T6	T12	PP	ITT	-
Demographics	✓					√	√	Baseline (T0) group equivalence: Chi-square test or Fisher's exact test
								Independent t-test or Mann-Whitney U test
Readmission		\checkmark	\checkmark	\checkmark	\checkmark	\checkmark		Chi-square or Fisher's exact test
LOS		\checkmark	\checkmark	\checkmark	\checkmark	\checkmark		Independent t-test
AED services		\checkmark	\checkmark	\checkmark	\checkmark	\checkmark		Independent t-test
Healed related QOL	✓	√	✓	√	✓	~	✓	Baseline (T0) group equivalence: Independent t-test T0, T1, T3, T6 & T12 comparisons: Two-way RM-ANOVA One-way RM-ANOVA Bonferroni post hoc test A, B, C, D, E, F, G, H, I, J
Symptoms manifestations	✓	✓	✓	✓	✓	~	~	Baseline (T0) group equivalence: Independent t-test T0, T1, T3, T6 & T12 comparisons: Two-way RM-ANOVA One-way RM-ANOVA Bonferroni post hoc test A, B, C, D, E, F, G, H, I, J
Physical function	✓	✓	✓	✓	✓	•	~	Baseline (T0) group equivalence: Independent t-test T0, T1, T3, T6 & T12 comparisons: Two-way RM-ANOVA One-way RM-ANOVA Bonferroni post hoc test A, B, C, D, E, F, G, H, I, J
Anxiety and depression	•	~	•	•	~	~	✓	Baseline (T0) group equivalence: Independent t-test T0, T1, T3, T6 & T12 comparisons: Two-way RM-ANOVA One-way RM-ANOVA Bonferroni post hoc test A, B, C, D, E, F, G, H, I, J
Satisfaction with care	✓	~	~	•	~	~	✓	Baseline (T0) group equivalence: Independent t-test T0, T1, T3, T6 & T12 comparisons: Two-way RM-ANOVA One-way RM-ANOVA Bonferroni post hoc test E, F, G, H, I, J
Caregiver burden	~	~	•	~	~	~	~	Baseline (T0) group equivalence: Independent t-test T0, T1, T3, T6 & T12 comparisons: Two-way RM-ANOVA One-way RM-ANOVA Bonferroni post hoc test A, B, C, D, E, F, G, H, I, J
Qualitative data		\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	Thematic analysis

Table 3.3 Overall methods of data analysis at different timelines

Notes: LOS= length of stay, AED = Accident and Emergency Department, HRQOL= health-related QOL

T0 = baseline; T1 = first month; T3 = third month; T6 = sixth month; T12 = twelve month;

One-way RM-ANOVA = One-way repeated measures of analysis of variance;

Two-way RM-ANOVA= two-way repeated measures of analysis of variance;

Multiple comparisons (Bonferroni) [A: p-value for T0 vs T1, B: p-value for T0 vs T1, C: p-value for T0 vs. T6, D: p-value for T0 vs T12, E: p-value for T1 vs T3, F: p-value for T1 vs T6, G: p-value for T1 vs T12, H: p-value for T3 vs T6, I: p-value for T3 vs T12, J: p-value for T6 vs T12

3.9. Qualitative Data Analysis

In aiming to understand the subjective views of participants and caregivers, analysis of qualitative data was applied which was the series of actions in translating the written data into findings with verbatim transcription. Thematic analysis was adopted for analysing qualitative data in this pilot study. The thematic analysis enabled the description of influencing factors on the experiences of palliative care services (Braun & Clarke, 2012; Caufield, 2019) with the inductive approach characterised by a bottom-up synthesis of qualitative data.

3.9.1 Thematic analysis

In performing the thematic analysis, a six-step approach was conducted including familiarisation, identification of patterns, synthesis of themes, recognizing and defining themes, and writing up the results (Braun & Clarke, 2012). The first step was to become familiarised with the data. It was followed by the second step of coding the data. Phrases or sentences of the text were highlighted. Then the data were collated together in similar batches of codes which enabled the researcher to obtain a compacted overview of the data. The major ideas were repeatedly noted throughout the data. Turning codes into themes were carried out in the third step. By going through the codes created, patterns of codes were identified to come up with themes. Step four involved reviewing themes. Validation of the themes with an accurate representation of the data was essential in thematic analysis. Recognition and definition of themes were carried out in step five. Naming and defining themes were conducted with the final list of themes. The last step was writing up the results.

The research assistants who were fluent in Cantonese were responsible for the transcription of the audiotapes verbatim. The doctoral student investigator and a research assistant who had Master programme training and experience in qualitative data analysis performed the data analysis. They independently undertook line-by-line iterative thematic analysis by reading the interview transcripts (Liamputtong, 2009) in getting familiarised with the context. Coding was then performed and refined if a discrepancy was noted. The codes were then arranged into themes. The researchers identified specific experiences, perceptions and behaviours shared by the interviewees. Themes and subthemes were developed based on the frequency of shared perspectives identified during the analysis. The themes and subthemes were repeatedly compared. Each theme and sub-theme was reviewed for its appropriateness and relevance to the theme, which was considered by comparing and contrasting its interpretation. Discussion meetings were held frequently between the two researchers in managing the qualitative data. The themes were revised until consensus was attained. Re-reading the original transcripts was done to ensure that all categorised information approaches were considered appropriate in the context. The findings were reported through the entitlement of the Consolidated Criteria for Reporting Qualitative Research checklist (Tong et al., 2007).

3.9.2 Trustworthiness

In fulfilling the trustworthiness of the study, measures were taken to enhance credibility, confirmability, dependability and transferability (Amin et al., 2020; Lincoln & Guba, 1985; Sim et al., 1998).

Dependability of data involved the manner of conducting this study in terms of time and duration of the study, recruitment of subjects, data collection and analysis, and researchers (Amin et al., 2020). To ensure dependability, the research process was reviewed by an external observer who was qualified and familiar with qualitative studies, which included

recruitment of participants, data collection, data analysis and the identification of themes and subthemes. In addition, informants and family caregivers were interviewed by the same researcher who utilised the same interview guide to collect data on their experiences of receiving the transitional palliative program, in this way, data collection was conducted consistently across time and researcher. Moreover, an external auditor was involved in critical appraisal in verbatim transcription, data coding and analysis, and cross-over commentary. Furthermore, the collected data, after being transcribed verbatim, was confirmed with all informants through telephone or meeting in-home visits. The results were one hundred per cent provided to participants to determine the findings that revealed their experiences truthfully.

Confirmability was concerned with the degree to which the data was collected and analysed (Lincoln & Guba, 1985). The research processes were recorded and presented comprehensively. The research team was involved with the data coding and analysis process. The obtained data were reviewed by other research team members regarding the interpretation of the findings derived from the data extracted from the interviews. A Research Fellow outside the research team was invited to review the findings of this qualitative evaluation and appraise the themes and subthemes identified.

The aspect of credibility was addressed through various strategies (Lincoln and Guba, 1985, Sim et al., 1998). The researcher who conducted the interviews had more than 10 years of renal specialty experience, was competent in providing patient care with high efficiency and could communicate well with the participants in the native Cantonese. The credibility of the data would be ensured through the presentation of the extended clinical experiences of the researcher to increase patients' confidence as a recipient of palliative care who would be willing to broadly share their experiences. During the 12 months of the intervention, each participant would be interviewed four times. With the design of four-time interviews, each participant would have adequate time for interaction and exposure to the TRPP. Whilst, with a prolonged engagement whereby the researcher would continuously interact with the participants and work with the qualitative data, which would allow the researcher to achieve a better understanding of their experiences. Through the in-depth and repeated interviews, the research team focused on the extreme cases and provided a complete view derived from the advantages and disadvantages of merging. Those deviant data were incorporated into the analysis process until they could explain or account for many cases.

Data credibility was also warranted with different triangulation in terms of data, investigator and method employed. Data triangulation was revealed in the collection of data from all participants and caregivers in the intervention group four times throughout the study. Investigator triangulation was concerned with employing two researchers to conduct coding, analysis and interpretation of data. Face-to-face interviews and field notes to supplement more information about the environment, facial expressions and gestures of the interviewees were recorded to ensure method triangulation.

Transferability refers to the degree to which the findings of qualitative research can be transferred to other contexts or populations with other respondents (Lincoln & Guba, 1985; Sim et al., 1998). All patients and caregivers participants in the intervention group were invited to join the interview to ensure a diversity of participants in terms of various demographic variables, working experiences, history of illness and educational background were covered and described in detail. A clear and in-depth description of the entire process

of qualitative study, composite methodology, data analysis, and the trustworthiness of findings, facilitated the judgement of other researchers.

3.10 Intervention Fidelity

Intervention fidelity is interpreted as the extent of intervention adherence and the competent delivery of the intervention (Mowbray et al., 2003; Rixon et al., 2016). It is a critical methodological strategy to monitor and improve the reliable and valid screening of the design and implementation of the intervention (Bellg et al., 2004; Toomey et al., 2016). In light of the National Institutes of Health Behaviour Change Consortium treatment fidelity recommendations (Ory et al., 2002), five basic components should be taken into consideration in enhancing the intervention fidelity. They are the intervention design, training of care providers, intervention delivery, intervention recipient, and endorsement of treatment skills (Bellg et al., 2004; Rixon et al., 2016). The context of intervention fidelity constituted the followings:

- (1) Intervention design: the vital components of the interventions were prepared based on extensive systematic reviews and evidence-based practice. Strategies and dose of intervention (reference of dose) were ensured to be appropriate for the participants.
- (2) Training of care providers: TRPP was a nurse-led care program. The attribute and requisite of the NCM was having had at least five years of advanced renal practice and palliative care experiences. The NCM was competent in communication and related protocol-driven interventions. Most importantly, the NCM was well supported by the multidisciplinary palliative care team in coordination and collaboration of patient care.
- (3) Delivery of interventions: The NCM had experience in delivering post-discharge interventions. The process of intervention delivery was based on the specified protocols.

- (4) Intervention recipients: Adequate and appropriate communication between the participants and the care providers was crucial in the process of care delivery. High satisfaction with the care was closely related to the acceptance and maintenance of interventions.
- (5) Endorsement of intervention skills: Both advanced knowledge and clinical experiences of interventions were necessary for the interventionist (NCM). The telephone follow-up was recorded in the written record and audio-taped recording. The home visits were structurally recorded on paper according to the OS framework.

3.11 Ethical Considerations

The study proposal was submitted to the Research Committee of the Hong Kong Polytechnic University with ethical approval attained (Project ID: HSEARS20061221005). In addition, ethical and administrative approval was granted by the study hospital. All participants who joined the study received written information (Appendix 2a and Appendix 3a) on the nature and purpose of the study, a participant's right to confidentiality, privacy, and anonymity, assurance of voluntary-based participation and the right to withdraw from the study at any time. The formal written consent (Appendix 2b and 3b) was obtained from all participants and caregivers before their participation.

To ensure confidentiality, the research assistants and doctoral student investigators responsible for data collection, documentation and statistical analysis had kept all data and documents safe. Hard copies of the data were kept in a locked data room. The digital recorder was stored in a locked cabinet, and electronic data were stored on a computer with password-protected access or authorization. Every possible effort was made to ensure participants' anonymity. All participants were assigned with a study identification number

without any personal identifying information noted on any document of data analysis. Participants understood that they had an equal likelihood of being assigned to either intervention or usual care (control) group. They also had the right to withdraw at any time after participation in the study without any penalty, and normal healthcare services would not be affected.

3.12 Summary

This chapter has provided an overview of the preparation and methodology of the pilot RCT. Details of research questions, aims and objectives have been described. Different stages and contexts of this study including the design, setting and participants, randomization and allocation concealment, and the context of transitional interventions were elaborated. Outcomes of the trial were specified with the individual mode of data collection. Details of quantitative and qualitative data analysis were elaborated and followed by the involvement of the importance of ethical consideration. The next chapter will further detail the study protocol development, validation of protocol and instrument and the implementation of study interventions.

CHAPTER FOUR: THE DEVELOPMENT OF A TRANSITIONAL RENAL PALLIATIVE PROGRAMME (TRPP)

4. Introduction

The key to achieving the research aim and objective of this study is to develop and implement a transitional renal palliative program that satisfies the needs of the ESRF patient population at their end-stage of life. This chapter details the conceptual structure of transitional renal palliative care and the process of the development of the study protocols. The first section describes the conceptual framework formulation and the transitional care program. The second section describes the development of the intervention protocols for this pilot RCT. The significance and process of development are elaborated on in subsequent paragraphs.

4.1 Formulation of Transitional Renal Palliative Care Conceptual Framework

The conceptual framework was effected as a conceptual guide for program design. It was derived from the preceding literature review of two major sources. First are the recommendations of the ESRD Workgroup of Robert Wood Johnson Foundation on promoting excellence in EOL care (ESRD Workgroup of Robert Wood Johnson Foundation, 2002). Second is the structural framework of the OS (Martin, 2005) and features of 4C's transitional care model entitled by Wong et al. (2005; 2011). The rationale for adopting the above-mentioned pillars for developing the framework of this study is elaborated in the following paragraphs.

4.1.1 Recommendations of the workgroup for ESRF

The mission statement of renal palliative care is to improve supportive care and QOL for ESRF patients and their families. The TRPP is built on both recommended components of palliative ESRF care and transitional care.

The content of palliative care recommended by the ESRD Workgroup of Robert Wood Johnson Foundation (2002) includes palliation of pain and physical stress, advanced care planning, adequate communication among patients, families and healthcare professionals concerning treatment options and truthfulness in communicating clinical outcomes and the severity of illness. It also emphasises the importance of continuous and appropriate training of healthcare professionals aiming at the provision of quality assurance in the healthcare program.

4.1.2 Features of the 4Cs transitional care

Transitional care is a framework with a set of actions developed to secure the continuity of care as the patient is transferred from hospital-based management to home-based care (Coleman & Berenson, 2004). The guiding concept for the mode of service delivery is a transitional care model that is specifically designed for discharged patients with comprehensive preparation of discharge and ongoing home care with subsequent follow up. Transitional care has demonstrated considerable improvement in clinical outcomes and enhanced satisfaction with care resulting in a reduction in hospital readmission and healthcare costs among patients with advanced chronic disease (Brumley et al., 2007; Naylor, et al., 2004; Wong, et al., 2012; Wong et al., 2013; Wong & Yeung, 2015; Wong et al., 2016).

Wong et al. (2005, 2011) developed a transitional care programme with the application of features of the 4Cs which was implemented in an RCT with DM patients. This RCT was characterised by pre-discharge assessment and planning, and post-discharge follow-ups. The follow-up strategy was telephone follow up at specified intervals to reinforce the knowledge and skill of monitoring the blood sugar level, dietary compliance, and the sustainability of exercise. The positive outcomes of effective control of blood sugar level (HbA1c), good

monitoring adherence score, a higher exercise adherence score, shorter LOS in the hospital, and lower healthcare costs were shown in the patients of the intervention group. The study concluded that nurse-led transitional care facilitated the integration of treatment into daily life activities.

Since the development and application of the 4Cs transitional care model by Wong et al. (2005 & 2011), its concepts have been shared and evidenced in various patient groups with chronic diseases such as cardiovascular disease (Zhao & Wong, 2009), heart failure (Wong et al., 2016), ESRF patient on CAPD therapy (Chow & Wong, 2010; Wong, et al., 2010), gastro-intestinal carcinoma with a colostomy (Zhang, et al., 2013), hypertension (Zhu et al., 2014), stroke (Wong & Yeung, 2015) and elderly with different medical diagnoses (Wong et al., 2008; Wong et al., 2011; Wong et al., 2014). The 4Cs transitional care model has been proven to be practical and helpful for patients with chronic diseases. The conceptualised structure of the 4Cs of the TC model is a reference for developing similar services for other patient groups.

The 4Cs features of the transitional care model applied in the program refer to Comprehensiveness, Collaboration, Continuity, and Coordination. Wong et al., (2005; 2008; 2011; 2015 & 2016) gradually strengthened the features of the 4Cs in developing the framework of a transitional care model including continuity of care, a comprehensive care plan, coordination of care services, and collaboration with multidisciplinary team members including patients and their family involvement.

The 4Cs transitional framework proposed by Wong and her team (Wong et al, 2005; Wong et al., 2011) was applied in this study to achieve the goals of TPC for ESRF patients, to achieve the goals of symptom control, complication prevention and improvement of health-
related QOL as advocated by the Workgroup of Robert Wood Johnson Foundation (2002). A more elaborative account of the 4-C features is provided below.

Comprehensiveness involves the adoption of a holistic care model to address patients' concerns and needs upon discharge and after returning home (Yeung et al., 2011). It also takes into account patients' preferences for formulating goals setting (Wong et al., 2005; Wong et al., 2011).

Continuity of care emphasises the importance of care with regular, active, and sustainable follow-ups (Naylor et al., 2011; Wagner et al., 2002; Wong, et al., 2013). It is implemented through the delivery of discharge planning plus post-discharge home visits and telephone follow-up (Naylor et al., 2011; Wong et al., 2005; Wong et al., 2013, Wong et al., 2016). Continuous follow-up can ensure early identification of complications, address patient concerns, and reinforce treatment adherence behaviours (Wagner et al., 2002), which is crucial to sustaining the effects of a carefully designed care plan with the integration of appropriate interventions and strategies to meet patients' demands after being discharged home (Wong et al., 2005).

Collaboration is associated with the input of health issues from a multidisciplinary- team with agreed goals of patient care (Fearon & Langhorne 2012; Naylor et al., 2011; Wong et al., 2011). Collaboration is shown between patients and healthcare providers within which a collaborative process is equipped with an organised healthcare network supported by available resources (Wagner et al., 2002). Active involvement of patients and their families is encouraged during the process of care.

Coordination of complex patient care is undertaken by an NCM who facilitates communication among professional members of different disciplines, patients, and their families (Chow & Wong, 2010). Coordination of care involves a delivery system developed to enable the NCM to operate across a spectrum of care in collaboration with other healthcare team professionals in addressing patients' needs (Wong et al., 2008). With strong support from the multidisciplinary team, the NCM has access to expertise consultation whenever indicated to cope with the condition of the patient (Wagner et al., 2002; Wong et al., 2011).

The transitional care model has been adopted in other countries with a positive outcome and Wong and her colleagues proved their programs to be particularly effective in the Chinese population with chronic diseases (Chow & Wong, 2010; Wong et al., 2010; Wong et al., 2005, Wong et al., 2008; Wong et al., 2011; Wong & Yeung, 2015; Wong et al., 2016; Zhang, et al., 2013; Zhao & Wong, 2009). The abovementioned studies demonstrate the effects of transitional care in meeting patient care needs during their transition from hospital to home through the approach of comprehensive, continuity, coordinated and collaborative care, entitled the 4 Cs model of care by Wong et al. (2005).

Transitional care is characterised by a thorough assessment and well-planned care which is composed of coordination, continuity, and supportive care (Naylor, 2004; Wong et al., 2005; Wong et al, 2008; Parrish et al., 2009; Wong et al., 2011). Various studies on different issues of transitional care were explored. Naylor et al. (1999 & 2004) applied a seamless and comprehensive pre-discharge assessment, which supported patients and families with coordination of home-based services, continuous assessment through telephone outreach, and home visits to ensure smooth transitions at different levels of care setting. As a result of improved QOL and effective control of symptoms, patients showed improved satisfaction

with care (Cox et al., 2008; Hermiz et al., 2002; Rigel et al., 2002; Wong et al., 2011; Wong & Yeung, 2015).

4.1.3 The Omaha System

The OS, a systematic healthcare terminology, provides a framework to document client needs, describe interventions, and measure client outcomes in a simple yet comprehensive manner. It can be used across the spectrum of care for individuals, families, and communities (Martin, 2005). According to Finkelman (2001), OS backs up quality improvement, critical thinking, and communication. The OS is a middle-range theory that is rooted in the theory of Donabedian's structure, process, and outcome approach and the Neuman Systems Model (Neuman & Fawcett, 2011). Healthcare providers who have applied the OS include physicians, nurses, pharmacists, therapists, language pathologists, and chaplains. Other common users include nursing educators, researchers and post-graduate students (Chow et al., 2008; Erdogan & Esin, 2006; Vittorini et al., 2009; Yoo et al., 2008). Copious research involving the conceptual framework of OS has been conducted in different geographical regions such as China, South Korea, and Turkey (Chow et al., 2008; Erdogan & Esin, 2006; Vittorini et al., 2008; Erdogan & Esin, 2006; Neural Martin, 2005).

The OS has been widely utilised in nursing practice. In 2014, Minnesota was a pioneer in advocating that ANA-recognized point-of-care terminologies be adopted in all electronic health records. Around 96.5% of Minnesota countries applied the OS (Topaz et al., 2014). The OS is regarded as trustworthy nursing documentation meant for outcome measurement for mental illness patients (Barrer et al., 2003). In addition, OS is also an instrument that can be utilized as a strategy to introduce and incorporate evidence-based practice in undergraduate nursing training (Canham et al., 2014). Measures that can be applied in the OS include a

comprehensive list of health matters, nursing interventions, and an outcome evaluation scale for the assessment of information, behaviour and health condition to ensure nursing care standards and clinical outcomes (Cohen et al., 2000).

The OS has a high capacity for providing high-quality information concerning complex healthcare services (Topaz et al., 2014). Evidence suggested that with a bundle of care protocols and complex interventions implemented, the OS facilitates the structural documentation of patient's problems, multidisciplinary interventions, and evaluated outcomes of care in transitional care for various patient groups (Brooten et al., 2003; Wong et al., 2010; Wong et al., 2011; Wong et al., 2014; Wong & Yeung, 2015; Zhao & Wong, 2009).

The OS includes three components namely Problem Classification Scheme (assessment), Intervention Scheme (care plan) and Problem Rating Scale for Outcomes (evaluation). The process of utilising the OS consists of three steps.

The first step is the assessment employing the Problem Classification Scheme (PCS) which provides a structured and systematic guide that facilitates the user to conduct the assessment, sorting, and retrieving of collected data. The PCS consists of four levels of concepts. A comprehensive assessment of problems is executed through four levels of assessments. The first level includes four domains (environment, physiological, psychosocial, and healthrelated behaviour). Thirty-seven client problems or areas of concern were noted at the second level and five clients' problems (growth and development, sexuality, reproductive function, pregnancy and post-partum) were deleted because they were inappropriate for patients with ESRF. Two sets of problem modifiers are shown at the third level: health promotion, potential, and actual, including individual, family, and community. Actual problems with signs and symptoms are described at the fourth or most specific level (details shown in Figure 4.1).

The second step of the Intervention Scheme includes four categories: patient teaching, guidance and counselling, treatment and procedure, case management and surveillance (Figure 4.1) together with 76 targets and client-specific information, which were evaluated at the third level of the intervention scheme.

In the third step of the Problem Rating Scale for Outcomes, the provider evaluates the outcomes of interventions, which are rated on a Likert scale focusing on the area of knowledge gained by the patient, behaviour demonstrated by patients and clinical status of each problem identified (Martin, 2005).



Figure 4.1 Framework of the Omaha System

In this pilot RCT, nursing activities were organised based on the construct of the OS, the context of follow-up included ongoing assessment of patient problems, ESRF specific palliative care interventions offered in four categories and outcomes evaluation with the rating scale.

4.1.4 Case management: NCM and multidisciplinary care team

The abovementioned roles of a case manager were deliberately involved in implementing the main recommended components of the ESRD workgroup of Robert Wood Johnson (2002) and the 4Cs approach of Wong et al. (2005; 2011). In adopting OS as a structural framework for guiding assessment, interventions and evaluation of patient outcomes, the case manager was the key person in delivering the whole process of care. In fulfilling the multifarious intervention, the case manager was not working alone but was supported by the multidisciplinary teams in achieving optimal treatment outcomes. The nurse manager-led TPC and multidisciplinary team of TRPP are detailed in the following.

4.1.4.1 Case management

Case management is the process of assessing, planning, coordinating, implementing, and evaluating the care of an individual. It aims at developing cost-effective and efficient means of patient services to improve QOL (Hirschman, 2015). Case management is globally recognized as one of the most important models of social and health care coordination for vulnerable clients showing intense and multidimensional problems (Chen et al., 2000; Hébert et al., 2004). Thus, case management constitutes one of the most frequently prescribed professional coordination devices in advanced countries (Chen et al., 2000), and the key objective of case management is to sustain service integration aiming at a better continuity of services in the interests of both patients and healthcare teams (Hirschman, 2015).

Case management is a key element embedded in the features of 4Cs transitional care. An NCM, equipped with professional knowledge and clinical competency, was responsible for comprehensive assessment, anticipating patients' problems, and health concerns (Hickey et al., 2000; Wong, et al., 2008). Regarding clinical conditions, available and accessible resources, appropriate coordination of services and support were provided for home-based patients in maintaining the continuity of care to maintain their QOL.

One feature of case management involved service coordination in public services (day centres, day hospitals, intensive functional rehabilitation units, short-term geriatric units), the private sector (housekeeping services, pharmacists), and the community sector (meal delivery services such as Meals on Wheels, volunteer services) and service integration for individual clients being discharged from the hospital (Hirschman, 2015).

The practice guidelines for the management of CKD (Kidney Disease Initiative Global Outcomes, 2013) asserted the importance of multidisciplinary teamwork and shared care in the management of CKD. The NCM took the role of comprehensive assessment, planning according to anticipated needs and support of transitional care. As a coordinator, the NCM worked across the healthcare spectrum and collaborated with the healthcare team in addressing the needs of patients (Carrier, 2012; Wong et al., 2005).

4.1.4.2 Attributes of NCM

Stauffer (2011) suggested that nurses working at an advanced practice level are pivotal in contributing to the success of a transitional care program. A display of the intervention involved can be found in Table 4.3. Much empirical evidence of transitional care (Naylor et al., 2004; Wong et al., 2011) has reported the benefits of appointing a nurse manager to implement interventions and coordinate patient care.

To fulfil the roles and responsibilities of case management care, the NCM should be equipped with good communication skills, inter-professional practice, education skills, advanced interviewing, and advocacy skills in facilitating the client's self-determination and managing the termination of case management. All these skills are essential for enhancing the provision of appropriate services to the client (Guzys et al., 2017).

4.1.4.3 Multidisciplinary care team

The disease trajectory of ESRF is complex and the needs of patients and families are wideranging. A multi-disciplinary care team is indicated for ESRF patients and caregivers. In Hong Kong, the structure of the renal team is multi-disciplinary and is composed of nephrologists, renal nurses, social workers, physiotherapists, dietitians, and other healthcare providers. Expert consultation is available by referrals.

In chronic care, the findings of a significant improvement in dietary compliance, treatment compliance, improved QOL and increased satisfaction with care were revealed in an innovative model of skill mixed programs for chronic disease patients (Wong et al., 2010).

Concerning the continuity of care from hospital to home (Hand & Cunningham, 2014; Harrison et al., 2014; Wong and Yeung, 2015), not only does it require the collaboration of multi-disciplinary team members, but it also requires the involvement of patients and the active participation of the caregiver.

4.1.5 Summary of the conceptual framework

In conclusion, the recommendations of ESRD palliative care from the Robert Wood Johnson Foundation (2002) were reviewed for the development of the conceptual framework and integrated into the development of the interventions in this study. In addition, the constructive and systematic documentation and guided interventions depicted in the OS (Martin, 2005) have been widely adopted by various transitional studies and were used in developing the domain of strategic interventions. Communication among healthcare providers, patients, their relatives, and others is enhanced by the application of the OS, which is integrated into the process of care in this study. Furthermore, the application of the '4C' features of transitional care (Wong et al., 2005) captures key features of intervention that are described in the study's conceptual framework. This home-based TRPP also incorporates the concepts of self-management of symptoms, case management, evidence-based / research practice and holistic care defined by WHO (2002). Figure 4.2 shows a framework of TRPP for ESRF patients, which is composed of the key elements mentioned above.



C = decreased caregiver burden

Figure 4.2 Conceptual Framework of Transitional Renal Palliative Program

The TRPP in this study aimed to relieve symptoms with appropriate management at a homebased level through the four Cs approach of continuity, coordination, comprehension, and collaboration (Wong, et al, 2005) of renal palliative care. The OS (Martin, 2005) planned this study with a structured framework for nursing process management that constituted nursing assessment, implementation and evaluation of nursing interventions in client-central care. Both patients and caregivers were actively involved in the care process. The regular nurseinitiated telephone follow-ups and home visits provided by the NCM with support from the multidisciplinary team to ensure the application of timely and appropriate interventions for the relief of physical symptoms, psychosocial burdens, and spiritual problems.

4.2 Development of Evidence-based TRPP Intervention Protocols

Evidence-based protocols refer to structured manuals that are designed to assist practitioners to deliver interventions with structured guidelines (Asnaani et al., 2018). In this pilot RCT, evidence-based protocols constitute a series of written care plans specifying the procedures to be followed in providing patient care. They were developed to ensure that consistency of care was delivered across patients.

4.2.1 Evidence used in developing the TRPP protocols

Information obtained from clinical studies acted as a source of reference and offered a critical component for the development of the study protocol. In coupling with the recommendations of the clinical expertise. Integration of evidence-based practice and clinical expertise practice enhances the study's feasibility and applicability. The significance of clinical expertise was characterised by advanced knowledge, clinical competency and effective communications which are fully revealed in the validation of study protocols and patient outcomes. In addition, the groundwork for the development of research protocols and interventions was laid partly from the results of the qualitative study. Patient preferences indicated aspects of the care

approach which needed to be addressed. These findings increased the capability to meet the specific needs of ESRF patients in palliative care. There was no 'best solution' regarding treatment modality for patients with ESRF. Unless there are definite clinical contraindications the treatment modality choice should best serve patients' preferences according to their lifestyle. The sense of flexibility and factors in the choice of modality to maintain normalcy, while minimising limitations of physical function were emphasised.

Guided by the conceptual framework of the study, the best research evidence, the clinical expertise of healthcare providers and the preferences of patients provided the basis for the development of the evidence-based protocols of the TRPP in this pilot RCT (Marshall, 2006).

4.2.1.1 Research evidence

The component of research evidence includes researching, appraising and synthesising the best evidence from literature, studies, and practical guidelines and standards consistent with updated policies, procedures, and guidelines. The information obtained from clinical studies acted as a source of reference and provided a rationale for the justification of nurse dose applied in the OS-constructed TRPP intervention protocols.

Apart from the evidence obtained from the previous literature review on transitional care in the last chapter, the proposed nurse dose adopted in the OS-constructed TRPP intervention protocols for pre-discharge planning, telephone follow-ups, and home visits was supported by evidence found in numerous interventional studies. For instance, the dose-effect of APN was verified by different patient groups (Brooten et al., 2002) and used in the discharge program (Naylor, 2004) with dose components of extensive clinical experience, professional competence, home visits, and telephone follow-ups. Several nurse-led transitional care studies on chronic disease populations were driven by protocols incorporating nurse dose components (Wong et al., 2005a; 2005b; 2011; 2015; 2016), which provide evidence-based verification for the application of the nurse dose components in this trial.

Information obtained from clinical studies acted as a source of reference and offered some critical components for the development of the study protocol. In coupling with the recommendations of the clinical expertise, the integration of evidence-based practice and clinical expertise practice enhanced the study's feasibility and applicability. The significance of clinical expertise was characterised by advanced knowledge, clinical competency and effective communications which are fully revealed in the validation of study protocols and patient outcomes. In addition, the groundwork for the development of research protocols and interventions was laid partly from the results of the qualitative study investigating the preferences of the patients. Patient preferences indicated aspects of the care approach which needed to be addressed. These findings increased the capability to meet the specific needs of ESRF patients in palliative care. There was no 'best solution' regarding treatment modality for patients with ESRF.

4.2.1.2 Clinical expertise

Combining best evidence and clinical expertise practice makes the protocol scientific and applicable. Clinical expertise referred to informed opinion and recommendations from clinical experts of palliative care and renal specialty, individual expertise advice, and outcomes associated with transitional practice (Marshall, 2006). A panel of clinical experts with professional knowledge, experience, and skills relating to nephrology care were invited to provide a recommendation, information and informed opinions, and be involved in reviewing and validating the intervention protocols (also see section 4.6 below). The attributes of clinical experts were characterised by professional knowledge, experience, and skills relating to renal care, palliative care, or transitional care. For example, an item in the

questionnaire of SM for program outcome measure asks about a patient's interest in sex. Panel experts determined that it was inappropriate to assess the sexual problem in this group of elderly patients with ESRF, as they were vulnerable at this stage of advanced clinical condition and receiving palliative care. Experts also related their clinical experience that older patients and relatives considered this question as an impolite assessment. The contribution of clinical expertise was well demonstrated in the validation of intervention protocols and outcome measures, which will be further illustrated in section 4.4 of the current chapter.

4.2.1.3 Patient preference

Patient preference refers to the choices, concerns and needs those patients express. It is also related to demographic variables including ethnicity, religion, gender, age, and ethical impacts (Malloch et al., 2006; Marshall, 2006; Sanders et al., 2010). In devising the study strategies and the program structure, the preference of patients was one of the key considerations in the collection of relevant data. To obtain a better understanding of the experiences and expectations of patients in palliative care services, a face-to-face interview was conducted before the design of the intervention protocols in the preparation phase.

The objectives of the interview were to understand the meaning of the lived experience of palliative care treatment decision making for ESRF patients and to explore the factors influencing the treatment decision of ESRF. A total of 12 Chinese ESRF patients were recruited, of whom five were male and seven were female. The age of the twelve informants ranged from 61 - 87 years with a mean age of 72.3 ± 15.3 years. Eleven of them received education at primary or below level and one received university-level education. Five of them were retirees, and seven of them were housewives. They were undergoing the care provided by the Renal Palliative Care Team of the study hospital. Eleven of them received support from family caregivers and the remaining one was self-financed. All informants had a history

of hypertension, and nine had diabetes mellitus and hyperlipidemia. Three informants experienced the symptoms of gout. Three of them said that they had no religious belief while nine of them were Buddhists.

The experiences recollected by the informants were identified as situated structures. The situated structure is created from the analysis of transcribed verbatim which is outlined to address the guiding question of the objectives of the interview (Guilbeau, 2014). Four major themes emerged after the data analysis. These were: (1) predisposing factors for making treatment decisions, (2) enabling factors for making a treatment decision, (3) perceived medical needs factors, and (4) QOL. Illustrative descriptions showing the themes and sub-themes are highlighted in Table 4.1

Themes	Sub-themes		
Predisposing factors for making a treatment decision	 The key person of decision–making (role) Social environment Health-related information 		
	Health attitudeCommunicationFamily members		
Enabling factors for making a treatment decisions	 Person/family Accessibility of treatment Treatment available Professional referral Sharing with patient peers 		
Perceived medical need factors	 Evaluated health status Perception of health		
Quality of life	 Sustain the current style of living Free from pain and disease symptoms stress 		

 Table 4.1 Themes and sub-themes of the lived experiences of decision making of palliative care service

The lived experiences of ESRF patients in decision making for palliative care revealed some patient-centred preferences and concerns. All the information provided the cues for the development of the protocol and strategies in the trial.

In addressing the need for the development of protocols concerning patients' preferences, the identified themes of perceived medical need factors and QOL were highlighted and described. The significant insights of perceived medical need factors with sub-themes including evaluated health status and perception of health were closely related to the acceptance and compliance of treatment. Likewise, the theme of QOL with sub-theme includes maintaining the original status and freedom from disease symptoms. These analysed themes were associated with the planned intervention protocol and will be discussed in the following.

Patients suffering from ESRF were confronting different issues and problems, namely choice of treatment modality, being dependent, compromised QOL, and uncertainties (Mahon et al., 2013). Whatever treatment modality they had, still they would encounter stress, either originating from the disease pattern or secondary to the treatment undergone.

When participants were asked to relate their level of physical symptoms, they included poor sleep quality, anorexia, and bone ache. These symptoms, identified by participants, provided essential information for providing effective interventions in the main study. ESRF patients had expectations to be free from signs and symptoms, particularly generalized pain caused by renal disease. In the discussion, major complaints of participants were fatigue, insomnia, and breathing difficulties which interrupted their daily activities. They wished to avoid hospital readmission and experience a minimum burden in the disease trajectory.

Regarding communication between informants and healthcare providers, the informants preferred to receive early notification of clinical status to facilitate planning and care more effectively. Arrangement of personal affairs and social support issues could also be dealt with more effectively with good communication.

These findings showed that patients without dialysis therapy would benefit from palliative care to facilitate good self-management of the disease. Both caregivers and patients required adequate and accessible support. A valued interchange between healthcare providers, patients and family was also required to minimise uncertainty regarding the clinical status and disease progression.

When patients were more engaged and involved in their health care decisions there was a greater feeling of satisfaction and better outcomes. The choice of renal palliative care proved satisfactory for all patients. Their main concerns were predictably the effectiveness of treatment and freedom from pain and other symptoms. QOL had more value to them than life expectancy.

4.2.2 Context of TPC intervention

In the transition from hospital-based to home-setting care, the context /interventions characterised in this pilot RCT included the pre-discharge assessment and planning, post-discharge follow-ups through telephone calls and regular home visits, referral for expertise management and patient-initiated telephone consultation. Four evidence-based strategic protocols for the implementation of the TRPP were developed, including the surveillance protocol, patient education protocol, treatment and procedure protocol and case management protocol. The rationale, objectives, and nurse dose (including active ingredient/purity, amount, frequency and duration) of the four evidence-based intervention protocols are described

below. An NCM who had more than five year's clinical experience in renal palliative care was the key interventionist for the implementation of the four protocols.

4.2.2.1 Protocol of pre-discharge assessment and care planning

The pre-discharge assessment was the initial care of TRRP provided to the patient. Once the patient was confirmed to be discharged home, the pre-discharge assessment and planning phase was initiated to prepare the patients and their caregivers for home care. The objectives of pre-discharge assessment and planning are as follows:

- To appraise patients' needs in the context of physical, psychosocial, environmental and health-related behaviour;
- To educate and reinforce patients with the information and technique engaged in selfmanagement;
- To instil the patients with an active approach toward ESRF and coping with health issues;
- To strengthen patients' and family members' knowledge of the significance of family support in enhancing patient's health status; and
- To discuss with the patient and his/her primary caregiver a plan for home care.

About one to two days before the discharge from the hospital, the doctor in charge of the hospital conveyed the message of patient discharge via the nurse in the renal palliative team. The NCM was informed about the pre-discharge assessment which was carried out in the presence of the patient and their family members. The patient was assessed for renal disease-related health problems in the ward. Upon the completion of the assessment, a care plan was developed according to the problem identified and discussed with both the patients and their family members. If special home-based supportive equipment was needed, the request would

be forwarded to the healthcare provider in the hospital for specified arrangements before the patient was discharged home. The verbal and written information on self-management of symptoms of the ESRF were explained and clarified for any uncertainty raised. Before the end of the pre-discharge session, the NCM would arrange a mutually agreed date and time for the first home visit with the patient. The process of pre-discharge assessment and planning lasted for approximately one hour. The context of the assessment was guided by the structured items listed in the home-visit record which would be followed up in the subsequent home visits.

4.2.2.2 Protocol of post-discharge follow-up

ESRF patients with no dialysis therapy are at risk of advanced deterioration and acute exacerbations of renal impairment after their discharge from the hospital. The duration of intervention after discharge from the hospital is one of the factors needed to be considered in ESRF patients with palliative care. By adopting the Golden Standard Frameworks (GSF) 'surprise question', age and other comorbidities are used to predict the death within one year with ESRF (Feyi et al., 2015). ESRF patients who are identified with one year of life expectancy are put on palliative care which can facilitate the process of advanced care planning, provision of care at the EOL and support for their families.

Medical follow up is routinely recommended at 8 weeks if the clinical condition is stable. In this study, subjects were primarily followed up at 4 weeks after discharge, then subsequently followed up at 8-week intervals provided that there was a stable clinical condition. An increased frequency of follow-ups was indicated for declined clinical status patients. The post-discharge home-visit follow-up aimed to provide continuous supportive care from hospital to home-based settings by employing the provision of transitional strategies. The follow-up intervention lasted for 12 months and involved weekly telephone follow-up, bimonthly home visits, and a 24-hour patient-initiated telephone call option. The overall goal of the home follow-up was to provide continuous support to patients and their families so that they could actively implement home-based rehabilitation and self-management of the disease. Specific objectives are described for each of its strategic components in the following paragraphs.

4.2.2.2.1 Telephone follow-ups

The telephone follow-up intervention was considered a valuable means of exchanging information, health consultation, problem identification, health education, and symptom management. The objectives of telephone follow up were to (1) identify the problem; (2) follow up on the implemented strategies; (3) express encouragement and reinforcement to the patient; (4) ensure the compliance of treatment; (5) provide psychosocial and emotional support; and (6) readjust the goals and care plan if needed.

Frequency of telephone follow-up: In the present study, nurse-initiated weekly telephone calls were provided for 12 months in alignment with the duration of intervention. The telephone calls were made weekly between home visits and medical follow-ups to monitor progress, identify problems, deliver health advice, strengthen self-care behaviour, appraise the need for referral, and review the health goals with the participant. Each telephone follow-up call normally lasted for 15 to 20 minutes.

Care activities: During the telephone follow up at the scheduled /appointed time, the NCM assessed the patient following the framework of the OS. The issues to be assessed were (1) blood pressure reading, (2) blood sugar level for diabetic patients, (3) hydration status, (4) respiratory distress, (5) chest pain, (6) oral intake, (7) elimination, (8) skin condition, (9) physical mobility and (10) mental stage. Besides, medication compliance and dietary

compliance were evaluated with follow up advice. Then the NCM monitored the consequences of previously identified problems with follow-up action according to the protocol. Knowledge and skills of care were reinforced during the process. Mutual goals were revised as appropriate. Encouragement and arrangement for the next telephone appointment were offered at the end of the call.

Telephone Follow-up Record Forms were designed for documentation as shown in Appendix 12a and Appendix 12b. The Intervention Scheme of the OS continued to be used as the framework to guide the practice and documentation.

4.2.2.2.2 Home visits

Home visits were arranged after patients were discharged from the hospital to sustain the continuity of care and support across the spectrum of hospital-based and home-based care. The objectives of the home visits were: (1) to identify problems encountered by the patient after discharge home; (2) to implement interventions according to the specification of problems such as direct patient care, health education, counselling and referral for expertise management, (3) to appropriate the goal of the care plan according to an individual real situation, and (4) to observe the physical and the emotional well-being.

The intensity of home visits: According to a number of the reviewed studies, the first month is the optimal period to provide continuity of care to link up a hospital and community care and thus home visits within the first month after being discharged from the hospital were designed. There was a total of seven home visits to address the holistic care interventions. In this RCT, the first visit was arranged within 72 hours after discharge. Subsequent home visits were delivered at two-months intervals in between telephone follow-ups alternating with medical follow-ups. Regular on-site follow-ups at 8-week intervals were necessary for ESRF

with no dialysis therapy. The visits lasted for 45 to 90 minutes with the first visit lasting for a longer time to build a nurse-client relationship, conduct a comprehensive holistic health assessment, identify health problems, implement nursing procedures and provide patient education.

Care activities: Comprehensive holistic health assessment, multidisciplinary interventions and evaluation of the outcomes were the three core interventions. Blood pressure, body weight, hydration status, oral intake, physical mobility, the general condition of the gastrointestinal tract with the status of bowel movement, and blood glucose level (haemastix) for diabetic patients were common assessments performed during home visits. In referring to the problems identified, surveillance of the clinical status, related knowledge of the problem, and behaviour towards individual problems were reinforced and followed up. In addition to the newly identified health problems, the NCM would follow up on the outcomes of previously identified problems.

Self-management of symptoms is highly recommended for patients with ESRF. All taught information and skills were reinforced during each home visit to ensure the sustained quality of care and effective outcomes. Leaflets with details of self-management of symptoms were offered for reference (Appendix 24). Preventive measures for complications of the disease were also emphasised for better clinical outcomes.

4.2.2.2.3 Patient-initiated telephone call

Patient initiated telephone consultation was arranged to ensure the continuity of communication between the telephone follow-ups and home visits. The design of patient-initiated telephone calls was mainly for urgent consultation and advice.

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The objectives of patient-initiated telephone consultation were to enable patients to seek timely consultation and to discuss their condition or concerns with their NCMs as needed. Patient-initiated telephone calls were available during working hours (from 09:00 to 21:00) from Monday to Saturday. The calls from the patients were followed up by the NCM. The record of patient-initiated telephone consultation is referred to in Appendix 13. The patient-initiated telephone consultation could be considered as alternative support for the management of symptoms, with concise low-literacy printed instructions already provided to each patient for reminding them how to manage the symptoms.

4.2.2.2.4 Referral system

Provision of a referral system was indicated in numerous articles (Boult et al., 2008; Bouman et al. 2008; Wong et al. 2014) which showed the significance of networking of health or social resources. A standard procedure for effective referral to hospital and community resources was developed (Bouman et.al. 2008).

The objectives of a referral protocol were to enable the consultation of expertise to meet the needs of patients and their families whenever indicated. The TPC team including physicians, physiotherapists, social workers, and occupational therapists worked closely with the NCM. With the support of hospital clinical team members, the NCM carried out the care program for each participant.

A referral system (shown in Appendix 15) was established for patients who required further support from the relevant departments and professionals, including dietetic consultation, occupational therapy services, physiotherapy services, psychosocial services, medical consultation services, nurse clinic for complex health assessment and symptom management, and pastoral services. Moreover, referral for social care and counselling to social workers included the need for financial assistance and home meal service. Furthermore, health referrals including community nursing service and medical consultation for clinical admission would be provided if indicated.

4.2.2.3 Protocol of assessment and surveillance

According to Kidney Diseases Initiative Global Outcomes (2013), it was significant to assess the signs and symptoms of the disease or the complication, which reflected the level of severity of the illness. The surveillance represented assessment and surveillance, which were interrelated with each other with the aid of the OS. The objectives of surveillance were to monitor the updated clinical status, the related interventions and the evaluation of outcomes.

4.2.2.3.1 Part one: Assessment

The assessment was based on the PCS of the OS. It covered thirty-seven renal dysfunction related problems. Physical signs and symptoms were assessed through reporting, observation, physical examination, physical mobility and function assessment, laboratory findings and other investigation reports. The sequence and components of the assessment were described as follows:

- A comprehensive assessment of four domains of environmental, physical, psychosocial, and health-related behaviour was carried out in the pre-discharge consultation and postdischarge home visits.
- Telephone follow-up assessments, which included the problems identified in the predischarge consultation or the previous follow-ups (by telephone follow-up or home visit), newly identified problems including physical abnormality, emotional distress, and social relationship issues. The mutually agreed goal would be adjusted according to the updated clinical status. Encouragement and reinforcement were highlighted to support the patient and their caregivers in being active participants in the self-management of the distress of

the disease. A follow-up appointment would be arranged with the participant (details referred to Appendix 14 Record of home visit).

• Patient initiated telephone consultation, in which the telephone number for consultation and the aims of patient-initiated telephone consultation were given to patients and their families to facilitate a timely consultation or discussion of their condition or concerns.

4.2.2.3.2 Part two: Surveillance

The surveillance took place during telephone follow-up, home visits and patient-initiated calls. It was mainly targeted at the current clinical conditions and the progress of the problems identified in the previous contact. The focused components of surveillance included the following:

- Vital signs include blood pressure, pulse rate, body temperature, and blood sugar for DM patients.
- Environmental problems: residence (handrails in the bathroom or bedside rail for fall prevention).
- Psychosocial problems: social contact (attending activities organised by senior citizen centres), interpersonal relationship, spirituality, mental health (emotional distress)
- Physiological problems: skin (itchiness), pain, neuro-musculoskeletal function (intolerance of cold, fatigue, generalised weakness, numbness limb(s), physical mobility: chair bound, fully ambulatory), respiration (difficulty in breathing), circulation (oedema of peripheral limbs), digestion-hydration (nausea, anorexia, fluid intake and output balance), bowel function (constipation), urinary function (anuria).
- Health-related behaviours: nutrition (body weight, oral intake, diet adherence, fluid adherence), sleep and rest patterns (sleep and rest quality), health care supervision (participant's response to advice), prescribed medication regimen (drug compliance).

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The records served as a guide for the NCM in ongoing follow-up care and reference by the healthcare team. Whilst the patient's logbook provided the fundamental vital signs continuously for assessment and appraisal.

4.2.2.4 Overview of the intervention protocols of the TRPP

In alignment with the development of the study protocol for TRPP, three sets of protocols were developed for the provision of care capitalising on the approaches of comprehensiveness, coordination, collaboration and continuous home-based palliative care (referred to Figure 4.3).



Figure 4.3 Overview of the intervention protocols of the TRPP

4.2.3 Validation of intervention protocols and outcome measures

After the construction of evidence-based protocols, content validation is a strategy adopted to determine the relevance and validity of the interventions (Sidani & Braden, 2011). An independent panel of experts, representing clinical and administrative experts in renal and palliative care from the study hospital in Hong Kong were invited to perform the content validation of the protocols, and the measurement tools of the outcome measures of this study. A content validity index rated more than 0.75 is considered satisfactory (Polit & Beck, 2008). Their rating of the content validity, suggestions, opinions on the relevancy and other comments were collected and considered for the development of the final version of protocols.

4.2.3.1 Procedures of validation

In the present study, an independent expert panel, composed of one associate consultant of renal specialty with palliative care training, one palliative care nurse consultant and two APNs were invited to assess the content validity of the intervention protocols. A letter of invitation and an information sheet on the validation procedure was distributed to individual experts (Appendix 23). In section one of the information sheet, a 4-point rating scale was designed with 1 =not relevant, 2 =somewhat relevant, 3 =quite relevant, 4 =highly relevant. For each part, the CVI was calculated as the number of experts providing a rating of 3 or 4 and was divided by the total number of experts (Polit & Beck, 2008). The percentage of expert rating as relevant and highly relevant was computed on each form.

The items were considered valid if they were rated as relevant or highly relevant by at least 75% of experts (Polit & Beck, 2008). Experts were also invited to make descriptive comments in the second section (Appendix 23). The experts' comments were reviewed to identify which

parts should be considered for modification as appropriate. Subsequently, respective panel discussions were arranged to endorse the adoption of the modified versions.

4.2.3.2 Results of the validation of intervention protocols

For validating the study protocols, all panel members agreed that the protocols developed could guide the NCM to implement nursing strategies to achieve the goals of transitional care support for the renal patients returning home. Table 4.2 below summarises the content validity of the protocol developed.

Content Validation	Content Validity Index (CVI)	Expert Comment (n=4)
Protocol of pre-discharge assessment form (39 items)	1.0	N = 4
Protocol of telephone follow-up (23 items)		N = 4
Protocol of home visit (39 items)	1.0	N = 4
Protocol of patient-initiated telephone call (23 items)	1.0	N = 4
Protocol of referral system (31 items)	0.98	N=3 M=1 addition of referral for emergency department

 Table 4.2 Summary of the content rating and comments on the assessment form and study protocols

Notes: Options of comments for experts rating: N = no change, M = modification

In preparing the intervention protocol, best evidence practice, extensive clinical experience, and the expectations of clients were considered and referred to.

4.2.3.3 Results of the validation of measurement tools

The endpoint of the intervention was to achieve the program outcomes. All measurement tools used in this trial were also validated for the relevancy of their application as outcome assessments in the TRPP. All experts rated the assessment tools and the forms as relevant documentation and implementation plans. The CVI results have been reported in the previous chapter (see Table 3.3 Overview on outcome variables and measures, p 106). Specifically, three experts provided the recommendations for the assessment of SM (chapter 3, 3.6.2.2 Symptom intensity).

4.3 Summary

The first part of this chapter details the conceptual framework which consists of two pillars including a recommendation by the Robert Wood Johnson Foundation (2002) and the 4Cs approach of the transitional care model by Wong et al. (2011). The OS serves as a guide for assessment, interventions and evaluation of outcomes. The second part has provided an overview of the development of treatment protocol and the validation of measuring tools in this study. The strategies adopted to ensure intervention fidelity has also been elaborated. The next chapter describes the implementation of the pilot RCT.

CHAPTER FIVE: RESULTS

5. Introduction

This chapter presents the results of the study, regarding the feasibility and preliminary effects of the intervention program and the experiences of the patients and caregivers with the TPC program. The flow of the study is shown in Section 5.1. Section 5.2 reports the feasibility outcomes of this trial and the preliminary effects of TRPP are described in Section 5.3. Section 5.4 summarises the preliminary quantitative effects of the TRPP. A summary of this chapter will be concluded in section 5.5.

5.1 Flow of the Study

Study data were collected from August 2014 to September 2017. According to the Consolidated Standard of Reporting Trial (CONSORT) guideline (Eldridge et al., 2016), Figure 5.1 shows the whole process of participant enrollment, randomization, and trial-related activities of the pilot study.



Figure 5.1 Flow of participants' enrollment, randomization, and trial-related activities

Among those ESRF patients who opted for no dialysis, 156 patients who met the clinical criteria were referred by their physician in charge for palliative care consultation. These 156 potential participants were screened for eligibility. There were 76 who met the enrollment criteria and consented to participate in the present study. The doctoral research student then performed the demographic and clinical assessment including baseline variables, QOL, symptom intensity, anxiety and depression assessment, physical function, and burden of caregivers. All of these 76 participants were randomly assigned to either the intervention group or control group after baseline assessment, with 38 participants in each group. Participants underwent a 12-month intervention and followed up for 12 months. The preliminary effects of the intervention were assessed at four-time points first (T1), third (T3), sixth (T6) and twelfth (T12) months after baseline (T0) assessment. During the followup phase, in the control group, 19 patients died, one patient shifted to peritoneal dialysis treatment, three patients were admitted to nursing homes and two patients changed to other cluster service hospitals for their continued care. Thirteen participants completed the study in the twelfth month. In the intervention group, 11 patients died, one patient shifted to peritoneal dialysis treatment, two patients moved to elderly homes and one patient shifted to another hospital services region. Twenty-three participants completed the study in the twelfth month. Both the PP analysis and ITT analysis were conducted for the study's primary and secondary outcomes. The coming sections detail the feasibility of the study methodology.

5.2 Feasibility and Acceptance of the Study

The evaluation of the feasibility of the study methodology is reflected in the viability outcomes of this trial which include the feasibility of subject recruitment, the feasibility of the measurement tools, and the acceptability of interventions.

5.2.1 Feasibility of subject recruitment and enrollment

The viability of recruitment of participants included the time required for subject recruitment, eligibility rate and the recruitment rate.

Time used for subject recruitment: In this pilot study, sequential recruitment of subjects lasted for 26 months. On average, approximately 5 potential participants were screened for eligibility each month, and approximately 3 eligible patients participated in this single-centre study.

Eligibility rate and recruitment rate: A total of 156 in-patients were referred for consultation of palliative care by the physician in charge. There was 76 out of 156 (48.72%) subjects were identified to be eligible to participate in the study. All of the 76 participants and their informal caregivers agreed to join the study and signed the written consent form. One hundred per cent recruitment rate of both the participants (76/76) and the informal caregivers (70/70) was achieved.

5.2.2 Feasibility of the measurement tools

The measurement tools for the collection of data involved three approaches. Firstly, the clinical history, primary health outcomes of health services utilisation, symptom intensity and physical function were retrieved from the Hospital Information System or patient's health record. Secondly, the general demographic data, KDQOL, anxiety and depression score, satisfaction with care and the burden of caregivers were obtained from the questionnaires. Lastly, the interview guide designed for the qualitative data collection was applied to guide the face-to-face interviews to explore the experiences of the patients and their caregivers.

5.2.2.1 Response rate

All participants completed the questionnaires by themselves or with aid from their informal caregivers or research assistant at four-time points after recruitment. Response rates at T0 were 76/76 (100%) and 70/70 (100%) from the participants and the caregivers respectively. The time required for the participants and the caregivers to complete the questionnaire was 31.74 ± 5.96 minutes and 6.81 ± 2.95 minutes respectively.

5.2.2.2 Missing data

According to Hardy & Allore (2009), the non-response of data collection will end up with missing data. There are unit, item and wave levels of non-response of data. Missing data in the present study was identified as unit non-response, in which no data were collected from an individual participant who dropped out of the study because of death, transfer to another hospital or change of residency from home to an institution, and there were no alternative means to collect the replacement data for analysis.

5.2.2.2.1 Amount and pattern of missing data

The dataset was processed using SPSS software version 23. Besides the 26-baseline demography and clinical variables, there were three variables for healthcare utilisation and 64 scale variables from six sets of questionnaires for secondary outcomes, which amounted to 5062 units in the data fields for the longitudinal data collection. Missing values at follow-up the healthcare service utilisation (10.63%) and secondary outcomes (20.25%) were noted. The overall missing data rate of healthcare services consumption and the health-related variables were 18.63% (930/5062) as counted at the unit level for outcome measure variables (Table 5.1)

Participants lost to follow-up	Outcome variables (n=67)*	Unit missingness, n (%)	
(n=40)			
T0 (Baseline, n=0)	830	0 (0.00)	
T1 (1 month, n=2)	1058	22 (2.08)	
T3 (3 months, n=8)	1058	94 (8.88)	
T6 (6 months, n=25)	1058	299 (28.26)	
T12 (12 months, n=40)	1058	515 (48.68)	
Total	5062	930 (18.63)	

 Table 5.1 Data missing at unit level and distribution of missing at five timepoints

Notes:* The sum of 11 outcome variables assessed at five-time points plus 3 outcome variables assessed at four-time points (n=11*5+3*4=67), where the calculation was based on the data of 76 patients for 14 outcome variables, including 1) LOS, 2) Non-scheduled hospital readmission, 3) AED visit, 4) KDQOL-36 (HK)-PCS, 5) KDQOL-36 (HK)-MCS, 6) KDQOL-36 (HK)-SPL, 7) KDQOL-36 (HK)-BKD, 8) KDQOL-36 (HK)-EKD, 9) SM, 10) PPS; 11) PS; 12) HADS-A, and 13) HADS-D, and the data of 70 caregivers for the variable of 14) ZBI.

5.2.2.2 Distribution of missing data

The distribution of missing data at the five-time points was also shown in Table 5.1. No missing values were noted in the baseline assessment. Data missingness at the four followup time-points accounted for 2.08% at T1, 8.88% at T3, 28.26% at T6 and 48.68% at T12, respectively.

5.2.2.2.3 Reasons for missing data

There were 36 (47.37%) participants who completed the study in the 12^{th} month after the intervention. The missing data (52.63%) mainly related to the participants' failure to follow up because of death (n=30, 39.47%), being transferred to other hospitals (n=3, 3.95%), shifting to dialysis therapy (n=2, 2.63%), change of residence to a nursing home (n=5, 6.58%) as shown in Table 5.2.

Time-points	Number of dropouts	*Cumulative dropouts (%)	Reasons* Number (%)
T1	2	2 (2.63)	Died: 2 (2.63%)
T3	6	8 (10.53)	Died: 6 (7.89%) Elderly institution residents: 2 (2.63%)
Τ6	17	25 (32.89)	Died: 17 (22.37%) FU at other hospitals: 2 (2.63%) Elderly institution residents: 4 (5.26%) On dialysis therapy: 2 (2.63%)
T12	15	40 (52.63)	Died 30 (39.47%) FU at other hospitals: 3 (3.95%) Elderly institution residents: 5 (6.58%) On dialysis therapy: 2 (2.63%)

 Table 5.2 Reasons for failure to follow up data on outcome variables

*As stipulated by the intervention protocol.

5.2.3 Acceptability of the interventions

The components of acceptability of the study interventions include prospective acceptability, concurrent acceptability, and retrospective acceptability (Sekhon et al., 2017).

5.2.3.1 Prospective acceptability

Prospective acceptability was assessed by the recruitment rate and the refusal to participate rate. The recruitment rate was 78/78 (100%) for the screened eligible participants. No subjects refused to join the study.

5.2.3.2 Concurrent acceptability

Concurrent acceptability was evaluated by the extent of implementation and completion of intervention which also involved the retention rate and dropout rate with rationales. In this

trial, the study protocol included weekly telephone calls and bi-monthly home visits between telephone out-reaches were carried out for the intervention group. All (100%) participants adhered to the specified interventions. Telephone follow-ups were implemented according to the schedule. The NCM conducted a home visit for the participant at a specific period. No refusal of the interventions was noted.

5.2.3.2.1 Frequency of telephone follow-up

The frequency of telephone calls was once per week between the home visits. The total number of telephone calls was 1291, and each call lasted for around 20.64 ± 2.4 minutes (Table 5.3). No participant refused the telephone follow-up or expressed reluctance. The telephone follow-up adherence rate reached 98.03% (1291/1317). The reason for the missing nurse's initial calls was that the patient was readmitted to the hospital.

Months	Participants	Telephone follow-ups	Home visits	Patient- initiated calls	Referrals
1	38	114	38	0	3
2	38	114	0	1	0
3	35	140	35	5	0
4	35	105	0	2	0
5	35	140	35	5	0
6	29	87	0	2	2
7	29	116	29	5	0
8	29	87	0	1	0
9	29	116	29	6	0
10	29	87	0	1	0
11	29	116	29	3	0
12	23	69	0	2	0
Total		1291	195	33	5

Table 5.3 Frequency of post-discharge follow-ups

Notes: During the 12-month follow-up, 41 telephone follow-ups and 7 home visits were planned for each case. The number of follow-ups was counted on the actual number of participants who continued the study at each time point.
5.2.3.2.2 Frequency of home visits

A total of 195 home visits were conducted with an average of 5.5 ± 1.91 visits for each participant. In the first home visit, less than 72 hours immediately after discharge from the hospital, physical, psychosocial and spiritual assessments were further conducted to identify new developments and evaluate the progress. The actual time consumed on home visits was 65.20 ± 15.30 minutes for the first visit. The subsequent regular bi-monthly home visits were arranged with a mean duration of 43.98 ± 9.76 minutes (Table 5.3). No participant refused or objected to the arrangement of a home visit.

5.2.3.2.3 Feasibility of patient-initiated calls and referrals

A total of 33 patient-initiated calls were received for urgent consultation. The reasons for the consultation were mainly symptom management. Referrals were arranged with three referrals to social workers and two referrals to an occupational therapist for home safety assessment.

5.2.3.2.4 Feasibility of self-care management

The student investigator performed all the interventions for the participants in the intervention group in this study. The interventions included treatment, procedure, teaching, and surveillance. The target of patient education involved patients and their family members/caregivers. The simple self-care included monitoring and interpretation of vital signs and simple strategies for minor symptoms of distress. Generally, the participants expressed that patient teaching was appropriate with the approach of teaching as 'simple to complex' and accumulation from 'small to moderate' being adopted. Throughout the pilot study, no participant requested to change the treatment arm after randomization. There was also no adverse event that occurred related to the treatment protocols. No participant

dropped out as a result of strategic interventions. No participant-initiated dropout from the study.

5.2.3.3 Retrospective acceptability

Retrospective acceptability of intervention was reflected by the experience of the intervention recipients in the intervention group. It included their perceptions and challenges encountered during the intervention.

5.2.3.3.1 Characteristics of the participants and caregivers

There were 14 participants (P), 24 participants and the caregiver dyad (P & C dyad) and 13 caregivers (C) who attended the face-to-face interview with audio-taped records during the 12 months of interventions. A total of 177 sequential face-to-face interviews were conducted (Table 5.4). Their lived experiences towards the TRPP could explicitly reflect their acceptability of the study intervention from 177 transcribed verbatim. The demographic characteristics of participants and caregivers were described in Section 5.2.1 and section 5.2.2. The interviews took place in participants' homes where a non-disturbed and familiar environment was available with a duration lasting 39.7 ± 7.2 minutes (T1), 27.12 ± 9.2 minutes (T3), 6.7 ± 2.4 minutes (T6) and 7.5 ± 2.1 minutes (T12).

Months	Patient- participants	Patient interviews	Caregiver interviews	Patient- caregiver dyads interviews	Total
1 st month (T1)	38	14	13	24	51
3 rd month (T3)	35	14	13	21	48
6 th month (T6)	29	14	13	15	42
$12^{\text{th}} \text{ month} (T12)$	23	14	13	9	37
Total		56	52	61	177

Table 5.4 Frequencies of face-to-face interviews

5.2.3.3.2 Themes and subthemes

The major aims of the qualitative data were to analyse the experiences of the participants with transitional renal palliative care. The lived experiences of palliative care services were explored. All of the interviewed participants and caregivers expressed positive feedback on the post-discharge care they received, which will be further described below with quotations to illustrate the generated themes or subthemes. The interview notes were depicted with different timelines for the first month (T1), third month (T3), sixth month (T6) and twelfth month (T12). Thematic analysis of the experiences identified by the participants and caregivers was employed for data analysis. After comparing the initial codes, similar codes were collapsed to form the constituent subthemes. Fourteen subthemes were then further grouped and combined into four themes: (1) positive value of the TRPP (2) preparation of self-management of ESRF, (3) support of the NCM, and (4) scope of services. The themes and subthemes extracted from the interview are shown in Table 5.5 with the abbreviation of patients [P], caregivers [C], patient-caregiver dyads [P-C dyads] throughout four interviews at first (T1), third (T3), sixth (T6) and twelfth (T12) months.

Themes	Subthemes
The positive value of the TRPP	 New patient services Worthwhile patient services Useful interventive strategies
Preparation of self- management of ESRF	 Control of symptoms of ESRF Prevention of complications of ESRF Physical, psychological, social and emotional support Enhancement of self-care Patient empowerment
Support of the NCM	 Professional knowledge and skill Caring attitude Communications Referral arrangement
Scopes of service	Peer support groupExtension of consultation hours

Table 5.5 Themes and subthemes extracted from interviews

NCM = Nurse case manager, ESRF = End-stage renal failure, TRPP = Transitional Renal Palliative Programme

Theme one: The positive value of the TRPP

TRPP is an interdisciplinary model of whole-person care which involves optimising QOL and maintaining human dignity through effective communication with patients and families. Advanced healthcare planning and management of biopsychosocial and spiritual problems are involved. One participant expressed that he was respected and well treated by the healthcare professional as he regularly received a thorough assessment by the NCM via home visits and telephone follow-ups. Patients with ESKF facing terminal illness continue to focus on living and the contexts of their lives, even if their functional status declines. Health-related services are the care provided to patients. As long as the objectives, scope and logistics of health-related services provided are fully matched with patients' preferences and meet their needs, they are regarded as useful and worthwhile services under normal circumstances.

Subtheme 1.1 New patient services

The renal palliative care services were launched a few years before this qualitative evaluation was conducted in the study hospital. The accessibility, mission of services, and extent and type of services provided are not well known to the patients. Access to palliative care services is only available through referrals from doctors. The participants of this program had positive comments on these new services.

"....... I have been diagnosed with kidney disease for a year. It is too late for me to attend such a well-arranged renal follow-up." [P8, T1]

"I like these new services. I will not change to another mode of treatment." [P6, T6]

Subtheme 1.2 Worthwhile patient services

Patients and relatives appreciated that TRRP were provided as a worthwhile rescue service that alleviates the symptoms of the disease. All informants appreciated the interventions and support provided such as regular nurse-initiated telephone follow-ups which enabled them to have full confidence to be care recipients with appropriate and accessible interventions and support. "I can receive wonderful care from her (the nurse) and I don't need to incur extra costs for the excellent services and care provided. She (the nurse) convinced me to follow her instructions such as medication compliance and ...with clear explanation and followups" [P38, T3]

Patients considered the services worthwhile as evidenced by several aspects of healthcare services delivery that related to patients' high value and concern when they receive care with timely appointments, good access to information and effective communication with care providers. A positive perception of this innovative patient care was shared in the quotes.

"I need to spend a morning in the clinic for routine blood tests; nursing assessment and medical consultation. This program is different from the ones in the outpatient department. The nurse will tell me the laboratory reports, and the strategies for addressing the signs and symptoms of kidney disease. ... She (the nurse) is kind enough to call me weekly to ask if I have any discomfort? She also gives me very useful instruction to solve my problems..." [P & C dyad 42, T3]

"The TRPP is excellent, the logistics of TRPP enable me to access the services at ease. I understand my updated clinical condition, the advanced care planning, it's my preferred option of therapy." [P12, T3]

The doctors, nurses, and all staff are very nice and helpful. I cannot afford private practitioners and this palliative care helps me in different ways....it is fine with me. [P33, T3]

Subtheme 1.3 Useful interventive strategies

Strategies to prevent complications of ESRF and relieve physical or psychological distress were common concerns of the participants. Participants perceived the effectiveness of the strategies of telephone follow-ups which are associated with better control of symptoms of distress and improved QOL as quoted.

"She (the nurse) proactively teaches me not to take too much water and salt to reduce the swelling of my legs and to maintain physical activity to ensure good health (through the phone). All the information is very useful and within my understanding." [P & Cdyad 55, T1]

"I can receive wonderful care from her (the nurse) and I don't need to incur extra costs for the excellent services and care provided. [P38, T3]

"You see, I'm still alive! With the aid of this service, I did not require dialysis at home." [P38, T12]

The participants confirmed that the form of care services was a good fit and appropriate.

Theme two: Preparation of self-management of ESRF

In the realm of palliative care, self-management demonstrates that both the patients and caregivers have acquired knowledge and skill in managing the disease and adapted to the progression of the illness (Davidson, 2007). In addressing the need for effective preparation of care experience in facing the day-to-day care of ESRF, self-management care was integrated into the TRPP.

Subtheme.2.1 Control of symptoms of ESRF

Primarily, both patients and their caregivers were encouraged to manage the signs and symptoms of the disease. With the acquired knowledge of the disease trajectories, its treatment and related signs and symptoms through patient education, participants and caregivers positively expressed that they could manage the common signs and symptoms of CKD during their course of disease development.

"I'm proud of myself for being able to prevent swelling of lower limbs.... and I can put on my shoes. [P12, T1]

"I can read my blood pressure and know how to interpret it. She (the nurse) told me about the drugs and foods I can eat (diet compliance), which are very useful for controlling my blood pressure." [P22, T1]

Subtheme 2.2 Prevention of complications of ESRF

Kidney disease usually worsens slowly. In the late stages of kidney failure, signs and symptoms are complex due to the accumulation of wastes and extra fluid. Preventive measures and appropriate dietary habits may slow down the progression of disease symptoms. Sometimes, the patient may be not attentive enough to note and report the signs and symptoms. It is essential to teach the patient and their caregivers the causes and related interventions and preventive measures.

"I have had a very poor appetite (shaking of the head) since I was diagnosed with kidney disease. I like salty fish which is delicious and appetising, however, my blood pressure shifts upward and my legs get swollen right after eating salty food. I have to follow her (the nurse) advice to avoid the swelling and the high blood pressure." [P34, T3]

"Prevention is better than cure. It is my long cherishing hope to know the strategies for the prevention of complications of kidney disease. I have had diabetes mellitus for 20 years. It is not uncommon to have multi-organs involvement resulting from the poor control of my sugar level." [P10, T1]

Uraemic-related or any other reason for itchiness of the skin is a typical and challenging symptom encountered by patients with poor renal function. Uncontrolled pruritus not only affects appearance and physical comfort but also negatively influences sleep quality, appetite as well as QOL.

"Itchiness of skin makes me suffer a lot such as insomnia, skin erosion, poor appetite, and generally not feeling well. ...Now I understand the causes and some alternative strategies for overcoming the itchiness of the skin. The ointments and ways of skin cleaning are very useful. Thank you." [P34, T1]

A good understanding of the risk factors of complications and related treatment may facilitate the treatment compliance of the patient.

Subtheme 2.3 Physical, psychological, social and emotional support

With the progression of physical symptoms over time, role and emotional issues are intensified as well. Fluctuation of condition, the uncertainty of prognosis, and medical needs, can also produce a feeling of being alone and dependent. Consistent with the favourable effects of multidisciplinary transitional care evidenced in a self-management of chronic disease program. The TRPP should cover multifaceted physical, psychosocial and emotional support to meet the needs of patients.

In providing physical support for the participants, nurses may help patients and caregivers overcome the knowledge deficit and ensure feasible strategies to meet participants' needs.

".....I learned how to monitor and interpret the reading of vital signs, and how to cope with minor abnormalities..... All this helps me tremendously to solve problems and build up my confidence in caring for my father-in-law." [C3, T1] In addition to physical care, psychological and emotional support also plays an important role in palliative care. With the relief of psychological stress or emotional distress, the patient may cope more easily with the symptoms of the disease and adapt to the changes in lifestyle induced by the advancement of the illness. However, there was an unmet need for emotional care which was expressed by one caregiver.

"My mom is lonely and she has no friends to communicate with her in daily living. I hope she can join some patient groups (for psychological or emotional sharing)?" [C5, T3]

Spiritual support for informal caregivers is, therefore, an essential aspect of care. Healthcare providers can help caregivers by promoting communication between family members and the patient, facilitating the expression and understanding of their emotional issues, assisting caregivers to identify and meet patients' needs, and promoting the understanding of their clinical condition. Being a good listener is a form of spiritual support as quoted by the participants as well as other sources of emotional support being sought.

"I was very down after the death of my husband. I could talk to my caregiver However, she could not understand my feelings. I felt great gratitude towards the nurse who spent a lot of time listening...." [P27, T3]

The provision of psychological support to meet participants' needs through various means is critical and necessary in the process of care delivery.

Subtheme 2.4 Enhancement of self-care

A partnership of care between the patient and healthcare provider plays an important role in the self-care of chronic disease. Nursing tasks of self-care involve promoting positive behaviour changes, encouraging the recognition of treatment compliance, promoting appropriate use of resources and reporting better symptom management.

"I (exclamation) really can't tolerate the limitation of drinking water, thirst is the hardest thing to overcome.... She (NCM) provides some hints to overcome my discomfort. She also encourages me with some diversional activities to sidetrack my feeling of thirst." [P58, T1]

ESRF patients need to modify their lifestyle and behaviour to adapt to the decline in renal function and its related complications through a self-management approach. The key elements of self-care can be enhanced by patient education and collaboration between patients and healthcare providers. The competence of participants in self-management of the signs and symptoms of ESRF was shown in the interview text as:

"I used to talk with her (the nurse) over the phone, chatting about my favourite food. She (the) always encourages me to avoid food rich in sugar, but to have a few mouthfuls of this restricted food when the clinical condition is kept stable. She is the only one who encourages me to be cautious of food rich in sugar. I don't want to get sick because I want to see my son get married...I have 20 years of experience suffering from DM, I like the nurse who supports me to keep a normal blood sugar level and teaches me how to cook delicious food without adding salt." [P60, T1]

Subtheme 2.5 Patient empowerment

Providing patient education was one of the key roles of NCM in this study. The NCM taught the patients and caregivers about the disease trajectory and the potential treatment regimen and honestly communicated their updated clinical conditions. The learned knowledge enabled the patients and their families to understand the patient's situation and demands. There was a tremendous improvement regarding the knowledge deficit and the uncertainty of the process of therapy.

"I used to attend the AED strictly once I had swelling of lower limbs with mild difficulty breathing, ... However, I'm now learning to observe my vital signs and anticipate the health condition to plan my care." [P 27, T3]

"Before I joined this program, I would attend the emergency department when I had no bowel movement for a few days. Now, it is not necessary to attend the emergency department for my bowel problems. I can do the local abdominal massage....." [P42, T3]

Facilitating the patient's engagement in the education and treatment process gives patients the perception that they are enabled in managing their condition. In this study, patients and family caregivers commented that they needed more education related to their disease trajectory and treatment, however, the ongoing and continuous support for patients and their family members is lacking in the current healthcare system. Patient empowerment was motivating the patient to take an active role and participate in self-management as revealed in the quote.

"I knew nothing about ESRF. Many questions were in my mind. There is a remarkable change in my attitude in handling the problems encountered.... such as monitoring blood pressure...." [P57, T3]

Focusing on patient empowerment, the NCM aimed to improve the patient's independence and self-management in grasping his/her health problem.

Theme three: Support of the NCM

The NCM managed the cases with the consideration of individualised needs and a welldesigned care plan to ensure that the client received the best possible treatment. She also supported the client through the identification of individual needs, recognition of problems, and tailor-made strategies for care implementation and follow up evaluation. In addition to the role of an interventionist, the role of the NCM as a coordinator and patient advocate was positively appraised by the participants and their caregivers.

Subtheme 3.1 Professional knowledge and skill

In fulfilling the role of NCM in palliative care, a complementary approach to patient care that is coupled with advanced knowledge and clinical competence is critical. For instance, the identification of symptoms and timely interventions are the fundamental and essential domains of care. A symptom is sometimes not reported by ESRD patients as he/she may perceive the symptom as a normal presentation of the disease.

"I thought my father was very sick but I failed in persuading him to attend the Emergency Department (shaking her head and sighing). She (the nurse) successfully convinced my father-in-law to seek medical consultation in due course. Thank you very much for her big hand." [C3, T6]

Patient education should be provided according to an individual patient's needs. Professionalism and knowledge are key components of an NCM who can independently work with the patient and exercise critical clinical judgment.

"The nurse was very smart and she precisely anticipated the progress of my illness. I am confident in her care." [P26, T3]

Subtheme 3.2 Caring attitude

The set of caring attitudes includes caring, appropriate communication, responsibility, accountability, and compassion. A caring attitude is an essential attribute that affects the building of a good rapport between patients and healthcare professionals.

"My husband's blood pressure shot up immediately before the injection of anti-anaemia drugs (Erythropoietin stimulating agents) at the clinic. ...She (the nurse) was very considerate in trying all possible measures for the injection of medication for him (patient) ... She gave the injection during the home visit. His symptoms of anaemia improved"[C11, T3]

"She (the nurse) tried various means to relieve my fear of putting the needle into my mum's arm. The most important was her sustaining encouragement and support in overcoming my fear of injection for my mother at home." [C6, T3]

"Without the support, coordination, and special arrangements, my husband could not have received the periodic injections of medication as we have encountered many obstacles..." [C12, T3]

The caring attitude positions the professional as a peer and expert in supporting the patient to go through the experience of the health and illness process, which builds up trust and confidence in the patient and family members.

"My severe skin problem was annoying and made me feel down. She (the nurse) made extraordinary efforts in repeated assessments, searching for every possible means to overcome my skin itchiness... She was very keen and concerned about my poor quality of sleep as the consequence of severe pruritus." [P30, T6]

The trust gained by patients related to a good nurse-patient relationship can improve the quality of care and achieve higher care satisfaction.

Subtheme 3.3 Communications

Adequate communication with ongoing emotional support affects the general well-being of the informants. Frank communication enables the updates of the clinical condition. Appropriate communication minimises the uncertainty and relieves stress concerning the progress of the disease.

"She (the nurse) encouraged me to keep my present dietary pattern along with medication as my blood result is acceptable..." [P16, T3]

"I like her (the nurse) proactive information about my progress, I like her telling me about my progress and my updated laboratory readings..." [P45, T3]

Subtheme 3.4 Referral arrangement

Initiation of the referral system is indicated when problems of participants cannot be solved or whenever indicated. Further expert management would be made available for the patients.

"My husband suddenly lost the ability to urinate and complained of tremendous pain coupled with sweating. His face became pale. I did not know if I should take him to the AED or stay at home and keep waiting? Under such a critical situation, I recall getting help from her (the nurse). She (the nurse) calmed me down and asked me questions. She then arranged for my husband back to the hospital for emergency relief of urine in due course." [P & C10, T3]

Referral for an occupational therapist was provided for patient safety and environment adjustment in the TRPP.

"I have double vision and weakness of both lower limbs. I'm afraid I would fall easily. ...She (the nurse) referred my case to the expert. I was lucky enough, the occupational therapist settled my problem...." [P22, T1]

Besides, it is common to encounter issues not directly manageable by healthcare professionals such as home environment readjustment, financial cost incurred, health services support, and so on. Making an appropriate referral is deemed necessary in meeting the needs of patients.

Theme four: Scope of services

Palliative care underpins high-quality clinical care with better symptom management and improved QOL of patients and their families. Home-based palliative care services extend very great value to patients and families and hospitals, including comprehensive management and supportive care of symptom control, psychosocial and emotional distress. However, emotional support can be strengthened and sourced from another perspective such as peer support groups or patient self-help groups.

Subtheme 4.1 Peer support group

As care recipients of TRPP, the caregivers presented a willingness to express their worries and concern. They treasured the spiritual support from the healthcare providers, and a few participants and caregivers expressed their recommendations to have a peer support meeting for psychosocial sharing and mutual support among the caregivers.

"I have come across many challenges. Is there any access for me to vent my difficulties and stress with other peers" [P10, T6] "My friends had joined the diabetic patient group. The group members share their experiences as well as the effective measures. Is there any patient support group that I can join?" [P26, T6]

Peer group support and sharing play an essential part in the disease trajectory of ESRD with palliative care. Emotion sharing can bolster motivation to meet the challenge during the journey of caring for the patients, especially when the clinical condition declines.

"My mum feels bored and she prefers to communicate with other patients who are in the same boat." [C56, T6]

Knowledge exchange among peers is also important in ESRF patients with palliative care. These support groups can offer a variety of services and resources to assist individuals to cope and adapt to the lifestyle dictated by their illness.

Subtheme 4.2 Extension of consultation hours

There was no coverage of palliative consultation services out of hours in the TRPP. The need for support beyond official hours was repeatedly reflected by the participants and caregivers. Patients and family caregivers expect to have continuous service hours.

"I wanted to call (consult) you (the nurse) about my worry..... last Sunday, but there were no services available..." [P26, T3].

"What happens if I encounter a problem during the weekend? most probably I will call the ambulance services" [P-48, T3]

The continuity of services enables the participants to get support whenever necessary.

In summary, the participants in the intervention group reported an improved sense of selfmanagement of symptoms with reinforced health-related knowledge, information, and a greater appreciation of resources available to help with their illness. They reported better preparedness for daily experiences in the intervention group.

5.2.4 Summary of feasibility and acceptability of the pilot study

The second part of this chapter evidenced the high acceptability of the study protocols and interventions. No participants initiated withdrawal from the study. The high attrition rate was mainly due to the characteristics of advanced disease with declining renal function which leads to a high mortality rate. Also, the caregivers expressed their difficult considerations before shifting patients to be cared for by the elderly institution. There are no standard protocols or guidelines for supporting the social and emotional needs for reference.

The results on the feasibility of the study protocol and the acceptability of interventions are presented. The summary of the results on the feasibility and acceptability, which need improvement in the future main study, are highlighted as follows:

- The eligibility rate is 48.72% during a recruitment period of 26 months.
- The mortality rate is 39.47%, and 6.58% of participants shift to be the resident of the institution and on dialysis therapy.

5.3 Preliminary Effects of the TRPP on Primary and Secondary Outcome Variables

The preliminary effects of the interventions focused on all of the dependent variables of primary outcomes and secondary outcomes mentioned in chapter three are shown in the following sections.

5.3.1 Baseline demographic and clinical characteristics of participants

Table 5.6 shows the cognitive function of the participants who were screened with the C-MMSE with a median score of 24.5 (interquartile range, 20-28).

	Total	Grou		
C-MMSE	(n =76)	Control (n=38)	Intervention (n=38)	<i>p</i> value ^a
Mean (SD)	24.14	24.45(1.37)	23.84 (1.46)	0.61
Median score	24.50	24.20	23.80	
Range	20.00 - 28.00	22.00 - 28.00	20.00 - 28.00	

Table 5.6 Frequency distribution of the C-MMSE in the eligibility assessment

Abbreviations: C-MMSE = Chinese Mini-Mental State Examination, SD = standard deviation Statistical analysis:^a Mann-Whitney U test

5.3.1.1 Demographic and clinical variables of patients

The demographic and clinical characteristics of all participants are displayed and compared in Table 5.7. Comparisons were conducted through copious approaches including (a) intervention group versus the control group (ITT population), (b) Intervention group versus the control group (PP population), (c) PP population versus dropouts in the control group, and (d) PP population versus dropouts in the intervention group.

There were 42 males (55.26%) and 34 were females (44.74%), with a mean age of 80.47 (SD = 8.76; range: 48 - 94) years. The majority (88.00%) were married and had education at the primary level or above (70.00%). Most of the participants were homemakers in both control and intervention groups (75.00 % vs 55.26%), with 2.77% (n=1) employed. Ninety-four per cent (intervention group) vs 91.9% (control group) of the participants reported that their incomes were supported by family members. Only 4 (5.4%) participants lived alone

while others lived with one family member. About 50.00% of participants lived in either public or private accommodation. Concerning clinical characteristics, all participants had at least one or more comorbidities including hypertension, DM, respiratory distress disease, stroke, cerebrovascular disease, musculoskeletal pain, long-term pain, and cancer. The baseline characteristics of the participants in both groups were comparable. No statistically significant differences between groups were shown in the majority of the demographic and clinical data, except for comorbidities and chronic respiratory disease between the perprotocol population and dropouts in the control group (p=0.02 and p=0.04) respectively.

		ITT population		РР рорь	ulation	Drop	outs	<i>p</i> -value			
Variables	Total n=76 (%)	Intervention n=38 (%)	Control n=38 (%)	Intervention n=23 (%)	Control n=13 (%)	Intervention n=15 (%)	Control n=25 (%)	А	В	С	D
Age (years), Mean \pm SD	80.67 <u>+</u> 9.13	81.81 <u>+</u> 7.81	79.52 <u>+</u> 9.50	82.14 <u>+</u> 7.82	79.54 <u>+</u> 7.75	81.27 <u>+</u> 7.75	79.23 <u>+</u> 10.27	0.27 ^c	0.348 ^c	1.0 °	0.99
Sex n (%)											
Male	42 (55.26)	19 (50.00)	23(60.53)	13(56.52)	9(69.23)	9(60.00)	14(56.00)	0.25^{a}	0.38^{a}	0.39 ^a	0.29
Female	34 (44.74)	19 (50.00)	15 (39.47)	10(43.48)	4(30.77)	6(40.00)	11(44.00)				
Marital Status								0.52^{a}	0.64^{a}	0.53 ^a	0.39
Single	4 (5.26)	1 (2.63)	3 (7.89)	1(4.35)	1(7.69)	0	2 (8.00)				
Married	47 (61.84)	25(65.78)	22(57.89)	15 (65.22)	9(69.23)	10 (66.67)	13 (52.00)				
Divorced/ widowed	25 (32.89)	12(31.59)	13 (34.22)	7 (30.43)	3(23.08)	5(33.33)	10 (40.00)				
Education level, n (%)								0.55^{a}	0.49^{a}	0.96 ^a	0.63
Illiterate	19 (25.00)	9 (23.68)	10 (26.32)	7(30.43)	2(15.38)	2(13.33)	8(32.00)				
Primary or below	37 (48.68)	18 (47.37)	19 (50.00)	9 (39.13)	9(69.24)	9(60.01)	10 (40.00)				
Secondary and above	20 (26.32)	11 (28.95)	9 (23.68)	7(30.43)	2(15.38)	4(26.66)	7 (28.00)	0	0	0	
Employment, n (%)								0.12^{a}	0.91 ^a	0.83 ^a	0.69 '
Employed	1 (1.32)	0	1 (2.63)	0	0	0	1(4.00)				
Retired	53 (69.74)	25 (65.79)	28 (73.68)	15 (65.22)	12 (92.31)	10 (66.67)	16(64.00)				
Homemaker	22 (28.95)	15(54.21)	9 (23.09)	8 (34.78)	1 (7.09)	5 (55.55)	8 (32.00)	o cod	o d	o c d	o o
Household, II (%)	4 (5.20)	1 (2 (2)	2 (7.80)	1(4.25)	1(7(0)	0	4(16.00)	0.63	0.75	0.66	0.72
Living alone	4 (5.20)	1(2.03)	3 (7.89) 25 (02.11)	1(4.33)	1(7.09) 12(02.21)	0 15 (100 00)	4(10.00) 21(84.00)				
Occupation $n(\%)$	12 (94.73)	37 (97.37)	33 (92.11)	22(95.05)	12(92.31)	15 (100.00)	21(84.00)	0.048	0.008	0.70 ^a	0.218
Employed	1 (1 32)	0	1 (2.63)	0	0	0	1(4.00)	0.94	0.89	0. 78	0.31
Self-employed	1(1.32) 1(1.32)	1 (2 63)	1 (2.03)	1(4 35)	0	0	1(4.00)				
Retired	74 (97 37)	37 (97 37)	37 (97 37)	22(95.65)	13(100.00)	15(100.00)	24(96.00)				
Accommodation, n (%)	, (), (37)	57 (57.57)	37 (77.37)	22(99.09)	15(100.00)	15(100.00)	21(90.00)	0.82^{b}	0 35 ^b	0.36 ^b	0.59
Public	38 (50.00)	19 (50.00)	19 (50.00)	10(43.48)	6(46,15)	8(53,33)	12(48.00)	0.02	0.55	0.50	0.57
Private	38 (50.00)	19 (50.00)	19 (50.00)	13(56.52)	7(53.85)	7(46.67)	13(52.00)				
Area of accommodation, r	n (%)			· · · ·				0.62^{a}	0.59^{a}	0.49^{a}	0.35^{a}
Public	5 (6.58)	3 (7.90)	2 (5.26)	2(18.70)	1(7.69)	1(6.67)	1 (4.00)				
Room	31 (40.79)	14(36.85)	17 (44.74)	7(30.43)	5(38.46)	7(46.67)	12(48.00)				
Flat	40 (52.63)	21 (55.26)	19 (50.00)	14 (59.87)	7(53.85)	7(46.67)	12(48.00)				
Financial status, n (%)								0.85^{a}	0.12 ^a	0.09 ^a	0.08^{a}
Self-financed	1 (1.32)	0	1 (2.63)	0	0	0	1 (4.00)				
Family support	72 (94.74)	37 (97.37)	35 (92.11)	22 (95.65)	11 (84.62)	15 (100.00)	24 (96.00)				
Government support	3 (3.95)	1 (2.63)	2 (5.26)	1 (4.35)	2 (15.38)	0	0				

Table 5.7 Baseline demographic and clinical variables of patient

ІТТ рор		ITT population		PP popu	lation	Drope	<i>p</i> -value				
Variables	Total	Intervention	Control	Intervention	Control	Intervention	Control	Δ	B	C	Л
	(N=76)	n=38 (%)	n=38 (%)	n=23 (%)	n=13 (%)	n=15 (%)	n=25 (%)	71	Ъ	C	D
Comorbidities n (%)								0.21^{a}	0.89^{a}	0.02^{a}	0.943 ^a
Zero	6(7.89)	1 (2.63)	5 (13.16)	1 (4.35)	1 (7.69)	0	4 (16.00)				
1	24(31.58)	21 (55.26)	16 (42.11)	10 (43.48)	2 (15.38)	11 (73.33)	14 (56.00)				
<u>></u> 2	23(30.26)	16 (42.11)	17 (44.73)	12 (52.17)	10 (76.93)	4 (26.67)	7 (36.00)				
Hypertension								0.87^{a}	0.79^{a}	0.69^{a}	0.77^{a}
Yes	71 (93.42)	36 (94.74)	35 (92.11)	22 (95.65)	12 (92.31)	14 (93.33)	23 (92.00)	0.07	0.77	0.07	0.77
No	5 (6.58)	2 (5.26)	3(7.89)	1 (4.35)	1 (7.69)	1 (6.67)	2 (8.00)				
Diabetic mellitus								1.00^{a}	0.31 ^a	0.23 ^a	0.32 ^a
Yes	36 (45.37)	18 (47.37)	18 (47.37)	11(47.83)	6 (46.15)	7 (46.67)	12(48.00)				
No	40 (52.63)	20 (52.63)	20 (52.63)	12(52.17)	7 (53.85)	8 (53.33)	13(52.00)				
Cerebral vascular disease								0.16^{a}	0.74^{a}	0.14^{a}	0.17^{a}
Yes	20 (26.32)	9 (23.68)	11 (28.95)	5 (21.74)	3 (23.08)	4 (26.67)	8 (32.00)				
No	56 (73.68)	29 (76.32)	27 (71.05)	18 (78.26)	10 (76.92)	11 (73.33)	17 (68.00)				
Stroke								0.71 ^b	0.98 ^b	0.62 ^b	0.72 ^b
Yes	7 (9.21)	3 (7.90)	4(10.53)	3(13.16)	1 (7.69)	0	3 (11.50)				
No	69 (90.79)	35 (92.10)	34 (89.47)	20 (86.84)	12(92.31)	15 (100.00)	22 (88.50)				a
Chronic respiratory disease	10 (00 (0))	10 (47.07)	0	2 (12.16)	0	15 (100.00)	0	0.08	0.24	0.04	0.08
Yes	18 (23.68)	18(4/.3/)	0	3(13.16)	12 (100.00)	15 (100.00)	0 25 (100 00)				
INO Laint nain	38 (70.52)	20 (32.03)	38 (100.00)	20 (80.84)	15 (100.00)	0	23 (100.00)	0.04 h	0.70 h	0.04 h	0.64 h
Joint pain	5 (6 58)	3 (7.00)	2 (5 26)	1(4.35)	1(7.60)	2(13.35)	1(4,00)	0.84 °	0.78°	0.84 °	0.64 °
No	71 (93 42)	35 (92.10)	36 (94 74)	22(95.65)	12(92.31)	13(86.65)	24 (96 00)				
Chronic pain	/1 (/0112)	00 ()2110)	00()	==(>0.00)	12()2:01)	10(00100)	- () 0.00)	0.09 ^b	0.60^{b}	0.10 ^b	0.10 ^b
Yes	22 (28.95)	11 (28.95)	11 (28.95)	5 (21.74)	5 (38.46)	6 (40.00)	6 (24.00)	,			
No	54 (71.05)	27 (71.05)	27 (71.05)	18 (78.26)	8 (61.54)	9 (60.00)	19 (76.00)				
Cancer								0.91 ^a	0.84^{a}	0.69 ^a	0.42^{a}
Yes	14 (18.42)	8 (21.05)	6 (15.79)	5 (21.74)	2 (15.38)	3 (20.00)	4 (16.00)				
No	62 (81.58)	30 (78.95)	32 (84.21)	18(78.26)	11 (84.62)	12 (80.00)	21 (84.00)				

Table 5.7 Baseline demographic and clinical variables of patients (Continued)

M = mean, SD = Standard deviation, *P<0.05

^a Pearson chi-square test, ^b Fisher's exact test, ^c independent t-test; A: intervention group vs control group (ITT population: 38 vs. 38), B: intervention group vs control group (PP population: 23 vs. 13), C: PP population vs. dropouts (control group: 15 vs. 25), D: PP population vs. dropouts (intervention group: 23 vs. 15). [#] More than one option in this parameter

5.3.1.2 Demographic characteristics of family caregivers

As shown in Table 5.8, the gender of the family caregiver of the patients was 22 (31.43%) males and 48 (68.57%) females. Within this group of caregivers, 15 (21.43%) of them had full-time and 14 (20.00%) had part-time employment. Thirteen caregivers had retired (18.57%) or were housemakers (35.71%). In fulfilling the caring role for the patient, 22 (31.43%) caregivers were not employed while 48 (68.57%) could manage to work. In caring for their family member who was the patient, 64 (91.43%) did not take any leave and 6 (8.57%) of the caregivers took leave from work for one week as they acted as the primary caregiver. Fifteen (21.43%) caregivers had to take health products to sustain their health status for performing the caring role for their family patients. The cost of health products taken by the caregivers ranged from HK\$500 to HK\$3000 per month. Caregivers could be significant others, spouses, friends as well as relatives in this study.

Characteristics	Total (n=70) n (%)	Intervention (n=37) n (%)	Control (n=33) n (%)	$\chi^2/z/t$ score	<i>p</i> -value
Sex				12.13	0.78 ^a
Male	22 (31.43)	12 (32.43)	10 (30.30)		
Female	48 (68.57)	25 (67.57)	23 (69.70)		
Employment				21.95	0.86^{a}
Employed: full time	15 (21.43)	8 (21.62)	7 (21.21)		
Employed: part-time	14 (20.00)	7 (18.92)	7 (21.21)		
Unemployed	3 (4.29)	1 (2.70)	2 (6.06)		
House maker	25 (35.71)	14 (37.84)	11 (33.33)		
Retired	13 (18.57)	7 (18.92)	6 (18.18)		
Managed to work				0.51	0.74^{a}
No	22 (31.43)	13 (35.14)	9 (27.27)		
Yes	48 (68.57)	24 (64.86)	24 (72.73)		
Need to take time off				0.65	0.65^{a}
No need to take time off	39 (55.65)	21 (56.75)	18 (54.55)		
≥1 week	31 (44.35)	16 (43.25)	15 (45.45)		
Taking health products				2.27	0.06^{a}
Yes	15 (21.43)	5 (13.51)	10 (30.30)		
No	55 (78.57)	32 (86.49)	23 (69.70)		
Health product cost (HK\$), n=15				1.48	0.12 ^b
<u><</u> 500	2 (13.33)	1 (20.00)	1 (10.00)		
501-1000	7 (46.67)	2 (40.00)	5 (50.0)		
1001-1500	1 (6.67)	0	1 (10.00)		
1501-2000	3 (20.00)	1 (20.00)	2 (20.00)		
>2000	2 (13.33)	1 (20.00)	1 (10.00)		

Table 5.8 Demographic characteristics of informal caregivers

^a Person chi-square test, ^b Fish's Exact test

* Significance p < 0.05

5.3.1.3 Comparison of baseline outcome measurement

Table 5.9 displays the group comparisons at baseline with regards to the QOL, symptom intensity, anxiety and depression, palliative performance, the burden of the caregiver and LOS of the index hospitalisation. There was no significant difference identified in any of the outcome variables between both groups at baseline.

Outcome variables	Intervention (n=38) Mean (SD)	Control (n=38) Mean (SD)	t value	<i>p</i> -value ^a
KDQOL-36 (HK)				
Symptom Problem List	86.66 (10.37)	80.66 (13.87)	2.13	0.08
Effects of Kidney Disease	69.24 (27.59)	61.84 (30.51)	1.11	0.06
Burden of Kidney Disease	94.64 (7.60)	90.88 (8.78)	2.00	0.07
Physical Composite Score	44.17(5.31)	39.79 (10.14)	2.36	0.08
Mental Composite Score	53.24 (6.05)	51.59 (8.67)	0.96	0.34
Symptom Manifestation	7.79 (5.06)	9.29 (6.54)	1.12	0.27
HADS-Anxiety	3.63 (3.77)	3.50 (3.73)	0.15	0.88
HADS-Depression	4.65 (4.60)	4.53 (3.95)	0.13	0.89
Palliative Performance Scale	79.21 (11.48)	75.79 (12.22)	1.26	0.21
Zarit Burden Index	26.45 (8.54)	29.39 (12.21)	0.20	0.23
Length of stay (index hospitalisation)	37.80 (4.67)	37.18 (4.32)	0.13	0.76

Table 5.9 Comparison of outcome variables at baseline assessment

Abbreviations: KDQOL-36 (HK) = Kidney Disease Quality of Life- 36^{TM} (Cantonese), HADS = Hospital Anxiety and Depression Scale Statistical analysis: ^a Independent t-test, *significance < 0.05

5.3.2 Normality of outcome variables

Graphical assessment of outcome variables was done by quantile-quantile (Q-Q) plot. Plots of parametric scales and subscales were evidenced for checking for normality of the data set before statistical analysis with RM-ANOVA. The indices of normality of nine outcome variables in both groups are displayed in Table 5.10. Most of the skewness and kurtosis indices were calculated with values of means of 0 and a standard deviation of ± 1 except for the primary outcomes (Soares & Vaz Carneiro, 2002). Three kurtosis indices and one skewness indices noted in the control group had a difference beyond the normal range which reflected that the abnormally distributed data should be managed by the non-parametric data analysis.

Outcome variables	Skew	ness	Kurtosis		
	Intervention	Control	Intervention	Control	
Non-scheduled readmission	-0.11	0.00	-2.10	7.62	
Length of stay	1.07	1.28	0.01	2.42	
AED visit	0.00	3.25	-2.11	9.06	
KDQOL-36 (HK)					
Symptom problem list	0.80	0.72	-0.35	-0.45	
Effects of kidney disease	0.39	0.25	-0.82	-0.83	
Burden of kidney disease	-0.78	-0.34	-0.04	-0.62	
Physical composite score	0.35	0.81	0.06	0.36	
Mental composite score	-0.12	-0.14	-0.50	-0.45	
Symptom manifestation	0.45	0.76	0.27	0.38	
Palliative performance scale	0.66	0.76	0.62	0.48	
Patient satisfaction	0.72	0.53	0.20	0.12	
HADS-Anxiety	0.33	0.28	0.14	0.22	
HADS-Depression	0.37	0.32	0.11	0.20	
Zarit burden index	0.05	0.32	0.70	0.98	

Table 5.10 Normality of the outcome variables

Abbreviations: AED = Accident and Emergency Department, KDQOL-36 (HK) = Kidney Disease Quality of Life-36 (Hong Kong), HADS = Hospital Anxiety and Depression Scale

5.3.3 Preliminary effects of the intervention on primary outcome variables

Chi-square tests were carried out for testing the relationships between the groups and nonscheduled readmission. Mann-Whitney U tests were conducted for not normally distributed data of LOS during hospitalisation and AED visits were reported.

5.3.3.1 Effects of intervention on unscheduled readmissions

Unscheduled readmissions ITT analysis results: Regarding the unplanned readmission since recruitment, the episodes of unscheduled readmission into the hospital were 37 and 20 for the control group and intervention group respectively in 12 months. A chi-square test of independence performed by the ITT analysis did show significant differences between the two groups in non-scheduled readmission at T6 and T12 (T6: $\chi^2 = 7.67$, d.f.= 2, p=0.02), and

(T12: χ^2 =12.22, d.f.=2, *p* =0.01), but not at T1 (T1: χ^2 =5.35, d.f.=1, *p*=0.05). The control group had shown a higher readmission rate than the intervention group (Table 5.11).

A chi-square test performed by the PP analysis also evidenced significant differences between the two groups in non-scheduled readmission at (T1: χ^2 2=4.46, d.f.=1, p=0.04), (T6: χ^2 =7.67, d.f.=2, p=0.02), and (T12: χ^2 =12.22, d.f.=2, p=0.01). The control group showed a high readmission rate than the intervention group (Table 5.12). The control group had more non-scheduled readmission than the intervention group.

5.3.3.2 Effects of intervention on LOS in hospital

LOS in hospital ITT analysis results: In adopting the Mann-Whitney U test, participants in the control group had a longer mean LOS in hospital than those in the interventional group at T6, which accounted for (median = 0.00, n=38) and the control group accounted for (median = 7.28, n=38), U= 461, Z=-2.85, p=0.004 and at T12 (intervention: median = 2.33, n=38) and (control: median = 12.95, n=38), U=487.00, Z=-2.46, p=0.01 as shown in Table 5.11.

LOS *in hospital PP analysis results*: The Mann-Whitney U test (Table 5.12) showed that patients in the control group had a longer hospital stay than patients in the intervention group. There was a significant difference of LOS at T6 between the control group (median=26.50, n=22) and intervention group (median = 0.00, n= 29), U=216.00, Z=-2.38, p<0.02 and at T12, the control group (median = 37.00, n=13) and the intervention group (median = 0.00, n=23), U=61.00, Z=3.08, p=0.01. The control group had longer hospitalisations than the intervention group.

5.3.3.3 Effects of intervention on utilisation of AED

Utilisation of AED ITT analysis results: The median episodes of the utilisation of AED at T1 for the control group (control: median=0.00, n=38) were higher than the intervention group (intervention: median = 0.00, n=38), U= 433.00, Z =-3.84, p<0.001; at T3 (control: median = 1.00, n=38), (intervention: median = 0.00, n= 38), U=310.00, Z= -4.71, p<0.001; at T6 (intervention: median = 0.00, n=38), U=228.00, Z=-4.73, p<0.001; at T6 (control: median =1.00, n=38), (intervention: median = 0.00, n=38), U=413.00, Z= -3.35, p<0.001; and at T12 with the control group (median = 1.00, n=38) compared to the intervention group (median = 1.00, n=38), U=500.00, Z= -2.34, p=0.02 as shown in Table 5.11.

Utilisation of AED PP analysis results: The median episodes of the utilisation of AED in T1 for the control group (control: median = 0.00, n=36) were higher than the intervention group (intervention: median = 0.00, n=38), *U*=395.00, *Z*=-4.11, *p*<0.001, at T3 (control: median = 1.00, n=33), (intervention: median = 0.00, n = 35), *U*=228.00, *Z*= -4.73, *p*<0.001; at T6 (control: median = 1.00, n=22), (intervention: median = 0.00, n=29), *U*=93.00, *Z*=-4.7, *p*<0.001; at T12 (control: median = 1.00, *n*=13), (intervention: median = 1.00, n=23), *U*= 93.00, *Z*=-4.75, *p*<0.001; and at T12 with the control group (median = 1.00, n=13) compared to the intervention group (median = 0.00, n=23), *U*=88.00, *Z*=-2.32, *p*=0.02 as shown in Table 5.12. The control group attended AED more frequently than the intervention group.

		T1		Т3		T6	T12	
	n	Episodes (%)/ Median (25 th – 75 th quartile)	n	Episodes (%) / Median (25 th – 75 th quartile)	n	Episodes (%)/ Median (25 th – 75 th quartile)	n	Episodes (%) / Median (25 th – 75 th quartile)
Readmission								
Control	38		38		38		38	
Yes		5 (13.16)		7 (18.42)		15 (39.47)		12 (31.58)
No		33 (86.84)		31 (81.58)		23 (60.53)		26 (68.42)
Intervention	38		38		38		38	
Yes		0 (0.00)		3 (7.89)		7 (18.42)		10 (26.32)
No		38 (100.00)		35 (92.11)		31 (81.58)		28 (73.68)
χ^2 (<i>p</i> -value) ^a		5.35 (0.05)		2.64 (0.27)		7.67 (0.02*)		12.22 (0.002*)
LOS								
Control	38	0.00 (0.00-1.45)	38	0.00 (0.00-3.73)	38	7.28 (4.08-13.07)	38	12.95 (8.41-16.41)
Intervention	38	0.00 (0.00-1.45)	38	0.00 (0.00-3.73)	38	0.00 (4.08-13.07)	38	2.33.5 (8.41-16.41)
$Z(p-value)^{b}$		-1.18 (0.24)		-1.41 (0.16)		-2.85 (0.04*)		-2.46 (0.01*)
AED visit								
Control	38	0.00 (0.00-0.68)	38	1.00 (0.00-1.00)	38	1.00 (0.00-1.05)	38	1.00 (0.11-1.31)
Intervention	38	0.00 ((0.00-0.68)	38	0.00 (0.00-1.00)	38	0.00 (0.00-1.05)	38	1.00 (0.11-1.31)
$Z(p-value)^{b}$		-4.11 (<0.001**)		-4.73 (<0.001**)		-4.75 (<0.001**)		-2.32 (0.02*)

Table 5.11 Comparison of the primary outcomes by ITT analysis at T1, T3, T6 and T12

Notes: AED = Accident and Emergency Department, LOS = length of stay during hospitalisation

Statistical analysis: ^a Chi-square test; ^b Mann-Whitney U test *significant at p<0.05; ** significant at p<0.01

		T1		Т3		T6		T12
	n	Episodes (%)/ Median (25 th – 75 th quartile)	n	Episodes (%) / Median (25 th – 75 th quartile)	n	n Median (25 th – 75 th quartile)		Episodes (%)/ Median (25 th – 75 th quartile)
Readmission								
Control	36		33		22		13	
Yes		5 (16.13)		7 (21.21)		15 (68.18)		12 (92.31)
No		31 (83.87)		26 (78.79)		7 (31.82%)		1 (7.69)
Intervention	38		35		29		23	
Yes		0 (0.00)		8 (22.86)		7 (24.14)		10 (43.48)
No		38 (100.00)		27 (77.14)		22 (75.86)		13 (56.52)
$\chi^2 (p$ -value) ^a		4.46 (0.04*)		2.64 (0.27)		7.67 (0.02*)		12.22 (0.01*)
LOS Control Intervention	36 38	0.00(0.00 - 0.00) 0.00 (0.00 -0.00)	33 35	0.00 (0.00-0.00) 0.00 (0.00-0.00)	22 29	0.00 (0.00-9.00) 0.00 (0.00-9.00)	13 23	25.00 (3.50-20.00) 0.00 (3.50-20.00)
Z (p-value) ^b		-1.42 (0.16)		-1.23 (0.22)		-2.38 (0.02*)		-3.08 (0.01*)
AED visit								
Control	36	0.00 (0.00-1.00)	33	1.00 (0.00-1.00)	22	1.00 (0.00-1.00)	13	1.00 (0.00-1.00)
Intervention	38	0.00 (0.00 -1.00)	35	0.00 (0.00-1.00)	29	0.00 (0.00-1.00)	23	1.00 (0.00-1.00)
$Z(p-value)^{b}$		4.11 (<0.001**)		-4.73 (<0.001**)		-4.75 (<0.001**)		-2.32 (0.02*)

Table 5.12 Comparison of the primary outcomes by PP analysis at T1, T3, T6 and T12

Abbreviations: AED = Accident and Emergency Department, LOS = length of stay during hospitalization Statistical analysis: ^aChi-square test; ^bMann-Whitney U test ^{*}significant at p<0.05; ^{**} significant at p<0.01

5.3.3.4 Comparison of ITT analysis and PP analysis of the primary outcome variables Through the Chi-square test or Mann-Whitney U test, the ITT analysis and PP analysis revealed similar results (12/13= 92.31%) for the non-scheduled readmission, length of hospitalisation and attendance of AED between the control and intervention group (Table 5.13). The results of the study indicated that there was a significant difference in the effects of the intervention and usual care received by the control group in the non-scheduled readmission rate, length of hospital stay, and utilisation of AED services.

Table 5. 13 Comparison of the primary outcomes by PP analysis at T1, T3, T6 and T12

Measures	ТО		T1		Т3		T6		T12	
	ITT	PP								
Non-scheduled Readmission	NA	NA	NS	S	NS	NS	S	S	S	S
LOS	NS	NS	NS	NS	NS	NS	S	S	S	S
AED visit	NA	NA	S	S	S	S	S	S	S	S

Notes: AED = Accident and Emergency Department, LOS = length of stay, NA = not applicable, NS = not significant, S = significant

5.3.4 Effects of intervention on secondary outcome measures

This section shows the results for all of the secondary outcome variables outlined in chapter three, which demonstrate the effects of the interventions on health-related QOL, symptoms manifestation, functional status, psychological disorder, satisfaction with care and burden of the caregiver. Three statistical tests were performed for the data analysis. Firstly, a mixed RM-ANOVA was conducted to determine the between-group differences, within-group differences across the five-time points and the interaction effects between group and time with Greenhouse-Geisser Correction criteria employed. Secondly, if significant differences were noted, a post hoc pairwise comparison with Bonferroni correction for multiple comparison tests was conducted to identify which time points exhibited differences. Thirdly, the mean differences of the dependent variables between the two groups at each time point were determined by an independent t-test. The results of the secondary outcome measures were reported herewith in the sequence of (1) findings of ITT analysis, (2) findings of perprotocol (PP) analysis, and (3) comparison of the ITT and PP analysis.

5.3.4.1 Effects of intervention on QOL (KDQOL-36, Hong Kong)

Health-related QOL was measured by KDQOL-36, Hong Kong which is composed of five subscales namely, Symptom Problem List (SPL), Effect of Kidney Disease (EKD), Burden of Kidney Disease (BKD), Physical Composite Score (PCS) and Mental Composite Score (MCS).

5.3.4.1.1 Effects of interventions on Symptom Problem List (SPL)

Results of SPL by ITT analysis: A RM-ANOVA with a greenhouse-Geisser correction showed that there was a significant effect on SPL between the intervention group and the control group overtime points, F $_{(1,72)}$ = 4321.97, *p*<0.001. The intervention group attained higher SPL scores than participants in the control group at all time points except at the baseline, T1 (91.03 vs 72.43, p<0.001), T3 (93.36 vs 69.14, *p*<0.001), T6 (93.66 vs 65.07, *p*<0.001), T12 (93.42 vs 63.99, *p*<0.001) respectively (Table 5.14). The participants in the intervention group managed their kidney-related symptoms better than those in the control group after recruitment. The mean SPL scores increased gradually from T0 up to T12 in the intervention group while the SPL scores decreased consistently in the control group. Further, there was significant interaction between times and effects on SPL, F (2.133, 153.585) = 47.52, *p*<0.001. Intervention group participants showed an increase in SPL scores after recruitment, while control group participants showed a downward trend in SPL scores. The SPL level was minimised throughout the disease trajectory in the intervention group while there was no improvement noted in the control group. Whereas there was no time effect on SPL within-groups overtime points, F $_{(4, 296)} = 8.03$, *p*=0.002. The intervention group demonstrated improvement, but not significantly, on SPL and the control group presented slight deterioration in symptom management (see Table 5.14).

Results of SPL from PP analysis: In PP analysis, an independent t-test showed that participants in the intervention group experienced fewer symptoms than those in the control group at four time-points after recruitment at T1 (t=6.27, p<0.001), T3 (t=7.75, p<0.001), T6 (t=9.42, p<0.001), T12 (t=11.05, p<0.001) (Table 5.15). There was time effect of SPL within groups overtime points, F ($_{2.459, 162.587}$) = 8.86, p<0.001. The post hoc (pairwise) multiple comparison showed that there was a statistically significant differences of SPL at T0 vs T3 (MD) = 8.414, p=0.05), T0 vs T6 (MD = 15.45, p<0.01), T0 vs T12 (MD = 17.95, p<0.001), T1 vs T6 (MD = 11.59, p<0.001), T1 vs T12 (MD=14.09, p<0.01), T3 vs T6 (MD = 7.04, p=0.01), T3 vs T12 (MD = 9.54, p=0.01)] in the control group. Furthermore, a statistically significant difference of time effects was shown within the intervention group at [T0 vs T1 (MD=6.83, p<0.01), T0 vs T3 (MD = 10.33, p<0.01)] (Table 5.15 and Figure 5.4). Whereas there was no time group interception effect on SPL overtime points F ($_{2.459, 162.587}$) = 0.45, p=0.06.

Comparison of results of SPL by ITT and PP analysis: Table 5.16 summarises the significant results of the two methods of analysis (ITT vs PP). It can be seen that the two sets of results were similar except for the within-group effect, for which the results of both ITT analysis and PP analysis showed a significant time effect within the intervention group and control group. The two analyses revealed the same trends of SPL changes across four time periods

for both the intervention and control groups. The mean SPL increased substantially from T0 to T12 in the intervention group while the score of SPL decreased in the control group. Given the time effect on within-group difference, there were significant differences in SPL in the control group and the intervention group when applying both ITT and PP analysis.



Figure 5.2 Scores of Symptom Problem List (PP analysis)



Figure 5.3 Scores of Symptom Problem List (ITT analysis)

5.3.4.1.2 Effects of interventions on Effects of Kidney Disease (EKD)

Results of EKD by ITT analysis: In regard to the subscale of EKD, higher scores indicate less significant effects of kidney disease in this assessment. The results of RM- ANOVA with a Greenhouse-Geisser correction showed that there were significant differences in EKD between the groups F $_{(1, 74)}$ = 15926.47, *p*<0.01 and a significant interaction in EKD between times and group, F $_{(1.893, 140.08)}$ = 13.12, *p*<0.001, whereas there was no time effect of EKD within groups overtime points, F $_{(1.893, 140.08)}$ = 2.23, *p*<0.20 (Table 5.14). Independent t-tests revealed that there were significant differences of EKD between the intervention group and control group at T1 (*t*=4.79, *p*<0.001), T3 (*t*=5.31, *p*<0.001), T6 (t=6.35, p<0.001) and T12 (t=6.43, p<0.001) respectively (Table 5.14). The participants in the intervention group experienced fewer effects of kidney disease than those in the control group after recruitment. The intervention group demonstrated insignificant improvement in EKD and the control group presented slight deterioration of the effects of kidney disease (Table 5.14 and Figure 5.5).

EKD by PP analysis: Through PP analysis, an RM-ANOVA showed that there were significant between-group differences in EKD at all-time points except at the baseline (T0), F _(1, 34) =1572.8, p<0.01. The independent t-test showed that there were significant differences between both groups at T1 (t=4.7, p<0.001), at T3 (t=5.25, p<0.001), at T6 (t=6.23, p<0.001) and T12 (t=6.45, p<0.001). There were significant differences in EKD between both groups with the intervention group revealing higher EKD scores than those in the control group. RM-ANOVA with a Greenhouse-Geisser correction indicated there was no significant interaction of EKD over time and group, F_(2387, 71.612)=131.76, p<0.19. There were no time effects of EKD in both groups (Table 5.15).

Comparison of the effects of EKD by ITT and PP analysis results: The significant results of the two methods of analysis (ITT vs. PP) can be seen in Table 5.18 with the two sets of results being similar. The mean EKD increased substantially from T0 to T12 in the intervention group. However, there was a minimal decrease in EKD from T0 to T12 in the control group (see Figure 5.4 and Figure 5.5).



Figure 5.4 Scores of Effects of Kidney Disease (PP analysis)



Figure 5.5 Scores of Effects of Kidney Disease (ITT analysis)

5.3.4.1.3 Effects of interventions on the Burden of Kidney Disease (BKD)

Results of BKD from ITT analysis: The results of RM-ANOVA showed that there were significant differences in BKD between the groups $F_{(1, 74)}$ =615.88, *p*<0.01. Besides, the independent t-test further indicated that the burden of kidney disease was better managed in the intervention group than those in the control group with the between-group difference of BKD at T1 (*t*=3.80, *p*<0.001), T3 (*t*=5.58, *p*<0.001), T6 (*t*=5.99, *p*<0.001), T12 (*t*=5.73, *p*<0.001). There was no significant time effect noted within groups at F (1.981, 146.62) =0.32, *p*<0.03, but there was time group interaction of BKD, F (1.981, 146.62) =16.75, *p*<0.001 shown in Table 5.14. The trend of BKD in both groups being in the opposite direction indicated that the participants in the control group perceived a higher level of burden of kidney disease than those with a higher score in the intervention group. The higher score indicated less burden of kidney disease which was associated with a better QOL in this assessment. Participants in the intervention group experienced less burden of kidney disease as the burden of kidney disease was better managed in the intervention group than in the control group.

Results of BKD by PP analysis: In PP analysis, the results of RM-ANOVA measurements showed that there were significant differences between the groups at F (1, 34) =273.25, p<0.001). However, there were no significant within-group differences of BKD over time, F (2.791, 83.736) =2.02, p=0.19, and no interaction effect of BKD over groups and time F (2.791, 83.736) =2.65, p<0.58. The independent t-test further indicated that the burden of kidney disease was better managed in the intervention group than in the control group with the between-group difference of BKD at T1 (t=8.51, p<0.001), T3 (t=5.16, p<0.001), T6 (t=4.53, p<0.001), T12 (t=2.61, p<0.001). The higher score of the subscale of BKD indicates a better QOL in this assessment. The participants of the intervention group achieved no significant improvement across all time points (Table 5.15).

Comparison of BKD by ITT and PP analysis: The results of ITTA and PPA of BKD were similar (Table 5.18). Concerning the RM-ANOVA of the subscale of BKD findings, the BKD scores increased from baseline to T12 (Figure 5.7 in the control group from ITT analysis. In PP analysis, the post hoc test of pairwise comparison revealed that there was no significant difference in BKD within group members in the control group (p=0.15-1.00) and the intervention groups (p=0.07-1.00) (see Figure 5.6).


Figure 5.6 Scores of Burden of Kidney Disease (PPA)



Figure 5.7 Scores of Burden of Kidney Disease (ITTA)

5.3.4.1.4 Effects of interventions on Physical Composite Score (PCS)

All the physical components were grouped to the principal physical composite score (PCS). The higher score of PCS indicates a better physical context of QOL experience.

Results of PCS by ITT analysis: In Table 5.14, the RM-ANOVA of the PCS subscale results showed a significant difference between groups, F (1, 74) =1844.28, p<0.01, as well as an interaction of the PCS and groups over time, F (2.73, 201.99) =33.88, p<0.001). However, no significant differences in the main effects of PCS were observed within groups, F (2.73, 201.99) =0.07, p=0.03). The independent t-test further showed that there were significant effects of between-group differences from the time point of T1 (t=5.86, p<0.001), T3 (t=6.8, p<0.001), T6 (t=8.01, p<0.001) and T12 (t=8.30, p<0.001). Participants with interventions experienced a higher score of PCS which increased after recruitment for interventions while the participants in the control group presented PCS score in a decreasing trend. Hence, there was a trend in the opposite direction of the progress of PCS between the intervention group and the control group. The level of PCS was minimised throughout the disease trajectory

while there was no improvement in physical well-being in the control group. Participants expressed better physical well-being with higher scores in the intervention groups.

Results of PCS using PP analysis: In the PP population, an RM-ANOVA with a Greenhouse-Geisser correction indicated that there were significant between-groups differences of PCS overtime points $F_{(1, 34)} = 1984.96$, p<0.01. Likewise, there was an interaction of PCS over group and time effect, $F_{(2.741, 197.39)} = 28.12$, p<0.001. However, significant differences in the main effects of PCS were observed within groups, $F_{(2.741, 197.39)} = 1.98$, p=0.005) shown in Table 5.15. The independent t-test further revealed that there were significant effects of between-group differences from the timeline of T1 (t=5.20, p<0.001), T3 (t=5.57, p<0.001), T6 (t=4.51, p<0.01) and T12 (t=4.11, p<0.001). Participants with intervention experienced a higher PCS score which increased after recruitment for interventions while the participants in the control group presented PCS score in a decreasing trend. Consequently, there was a trend of the opposite direction of the progress of PCS between the intervention group and the control group. The level of PCS was minimised throughout the disease trajectory while there was no improvement in physical well-being in the control group (Table 5.15 and Figure 5.8).

Comparison of PCS by ITT and PP analysis: Table 5.18 summarises the significant results of the two methods of analysis (ITT vs PP). The two sets of results were similar in yielding the significant differences in PCS between groups at four-time points except for baseline (p<0.001) as well as significant differences in interaction over group and times (Table 5.14 and Figure 5.11). In ITT analysis (Figure 5.11), there was an improvement of PCS at all-time points (p<0.001) in the intervention group while there was a statistically significant difference within the intervention group at T0 vs T1 (p<0.001) and at T0 vs T3 (p<0.001).



Figure 5.8 Scores of Physical Composite Score (PPA)

Figure 5.9 Scores of Physical Composite Score (ITTA)

5.3.4.1.5 Effects of interventions on Mental Composite Score (MCS)

The higher score of MCS indicates less mental distress which was related to the better QOL in this assessment.

Results of MCS by ITT analysis: Table 5.14 shows the results of RM-ANOVA with a Greenhouse Geisser correction illustrated that there were significant differences in MCS between the groups, $F_{(1, 74)} = 5419.98$, p < 0.001, as well as an interaction of effects of MCS over time and group, $F_{(2.684, 189.63)} = 6.47$, p = 0.001. In contrast, there was no time effect of MCS overtime points, $F_{(2.684, 189.63)} = 3.78$, p = 0.02. Besides, the independent t-test further indicated that the mental composite scores experienced in the intervention group and those in the control group had a between-group difference of MCS at T1 (t=3.04, p < 0.03), T3 (t=4.94, p < 0.001), T6 (t=3.65, p < 0.001), T12 (t=4.09, p < 0.001). The participants in the intervention groups experienced a moderate level of MCS score while those in the control group and the

control group presented in the opposite direction indicated that the participants in the control group perceived a higher level of mental distress than those with a moderate score in the intervention group. The higher score indicated less mental distress which was associated with a better QOL in this assessment.

Results of MCS by PP analysis: From PP analysis of the subscale of MCS, the RM-ANOVA, there was no significant difference in MCS within-groups, F ($_{2.554, 76.62}$) = 0.98, p=0.17. Whereas there was the effect of time group interception noted, F ($_{2.554, 76.62}$) = 4.23, p<0.03. However, there was a significant difference in MCS between groups, F ($_{1, 34}$) = 3523.30, p<0.01 (Table 5.15). The independent t-test further assessed the differences between both groups overtime points, T1 (t=3.57, p<0.001), T3 (t=4.18, p<0.001), T6 (t=3.82, p<0.001), and T12 (t=3.42, p<0.001). Participants attained a moderate score of mental distress in the intervention group while those in the control group who attained a lower score of mental distress could be more mentally distressed (Table 5.15).

Comparison of the results of MCS by ITT and PP analysis: Comparatively, the result of ITT and PP analysis presented similar results to MCS (Table 5.18). In PP analysis (Figure 5.10), the differences in interaction effects of MCS were shown in both ITT analysis and PP analysis of MCS (Figure 5.11). Both ITT and PP analysis showed no significant time effect of MCS within-groups, but a statistical difference in MCS between groups. Participants in the intervention group presented a better mental health state.



Figure 5.10 Scores of Mental Composite Score (PP analysis)



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Figure 5.11 Scores of Mental Composite Score (ITT analysis)

		то		T1		T3		T6		T12	Between groups	Interaction effects	Within groups	Multiple comparisons within groups
KDQOL-36 (HK)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	F (p-value) ^b	F (p-value)	F (p-value) ^c	[A, B, C, D, E, F, G, H, I, J] ^e
SPL ^a											4321.97 (<0.01**)	47.52 (<0.001**)	8.03 (0.002*)	
Control	38	80.66 (13.87)	38	72.43 (15.89)	38	69.14 (16.90)	38	65.07 (15.08)	38	63.99 (14.81)			6.02 (0.005*)	[0.04*, 0.37, 0.23, 0.01*, 0.19, 0.81, 0.23, 0.02*, 0.01*, 0.20]
Intervention	38	86.66 (10.37)	38	91.03 (7.15)	38	93.36 (6.32)	38	93.66 (6.32)	38	93.42 (6.00)			0.58 (0.004*)	[0.57, 0.65, 0.17, 0.53, 0.90, 0.39, 0.25, 0.11, 0.21, 0.01*]
T (p-value) ^d		2.132 (0.08)		6.58 (<0.001**)		8.34 (0.001**)		10.77 (<0.001**)		11.35 (<0.001**)				
EKD ^a											15926.47 (<0.01**)	13.12 (<0.001**)	2.23 (0.20)	
Control	38	90.88 (8.78)	38	90.41 (8,43)	38	89.76 (9.58)	38	88.91 (9.01)	38	88.91 (9.09)			0.39 (0.58)	[0.53, 0.20, 0.04, 0.42, 0.24, 0.03, 0.04, 0.02, 0.05, 1.00]
Intervention	38	94.64 (7.60)	38	97.46 (3.31)	38	98.31 (2.59)	38	98.5 (2.29)	38	98.68 (2.26)			0.28 (0.83)	[1.00, 1.00, 1.00, 1.00, 0.13, 0.13, 0.09, 0.60, 0.37, 0.16]
T (p-value) ^d		2.00 (0.06)		4.79 (<0.001**)		5.31 (<0.001**)		6.35 (<0.001**)		6.43 (<0.001**)				
BKD ^a											615.88 (<0.01**)	16.75 (<0.001**)	0.32 (0.03)	
Control	38	61.84 (30.51)	38	54.77 (30.63)	38	51.97 (28.18)	38	50.0 (26.63)	38	50.49 (26.11)			2.05 (0.28)	0.35, 0.03, 0.01, 0.01, 0.83, 0.21, 0.31, 1.00, 1.00, 1.00]
Intervention	38	69.24 (27.59)	38	77.96 (21.93)	38	82.07 (17.56)	38	80.92 (17.43)	38	80.59 (18.99)			0.88 (0.45)	$\begin{matrix} [0.1, \ 0.05, \ 0.06, \ 0.12, \ 1.00, \ 1.00, \\ 1.00, \ 1.00, \ 1.00 \end{matrix}$
T (p-value) ^d		1.11 (0.27)		3.80 (<0.001**)		5.58 (<0.001**)		5.99 (<0.001**)		5.73 (<0.001**)				
PCS ^a											1844.28 (<0.01**)	33.88 (<0.001**)	0.07 (0.03)	
Control	38	39.79 (10.14)	38	34.27 (11.98)	38	33.10 (11.94)	38	31.61 (12,17)	38	31.57 (12.14)			2.20 (0.06)	$\begin{matrix} [0.05, \ 0.06, \ 0.05, \ 0.05, \ 1.00, \ 0.09, \\ 0.11, \ 0.49, \ 0.35, \ 1.00 \end{matrix}$
Intervention	38	44.17 (5.31)	38	46.36 (4.26)	38	47.40 (5.08)	38	48.91 (5.37)	38	49.48 (5.44)			0.89 (0.07)	[0.21, 0.05 0.05, 1.00, 0.12, 0.03, 0.47, 0.05, 1.00, 1.00]
T (p-value) ^d		2.36 (0.06)		5.86 (<0.001**)		6.80 (<0.001**)		8.01 (<0.001**)		8.30 (<0.001**)				
MCS ^a											5419.98 (<0.001**)	6.47 (0.001**)	3.78 (0.02)	
Control	38	51.59 (8.67)	38	50.2 (8.29)	38	49.77 (9.21)	38	48.04 (437)	38	47.65 (9.46)			2.23 (0.07)	[1.00, 0.73, 0.06, 0.05, 1.00, 0.48, 0.28, 0.44, 0.19, 1.00]
Intervention	38	53.24 (6.05)	38	54.72 (3.92)	38	57.68 (3.54)	38	54.42 (4.37)	38	55.31 (6.58)			0.92 (0.06)	[0.89, 0.07, 1.00, 1.00, 0.06, 1.00, 1.00, 0.002, 0.09, 1.00]
T (p-value) ^d		9.96 (0.34)		3.04 (0.03*)		4.94 (<0.001**)		3.65 (<0.001**)		4.09 (<0.001**)				

Table 5.14 Comparison of the utilisation of healthcare services and KDQOL by groups over five time points by ITT analysis (T0, T1, T3, T6 and T12)

Abbreviations: SPL= Symptom Problem List, EKD = Effects of Kidney Disease, BKD = Burden of Kidney Disease, PCS = Physical Composite Score, MCS = Mental Composite Score, Data collection time-points: T0 = baseline, T1 = first month, T3 = third month, T6 = sixth month, T12 = twelve month

Statistical analysis: "2-way Repeated measures ANOVA, b Adjusted between-group repeated measures significant at p < 0.025; Adjusted within-group repeated measures significant at p < 0.005. *, Independent t-test

⁶Multiple comparison (Bonferroni) [A: p value for T0 vs T1, B: p value for T0 vs T1, C: p value for T0 vs. T6, D: p value for T1 vs T3, F: p value for T1 vs T3, F: p value for T1 vs T6, G: p value for T3 vs T12, H: p value for T3 vs T6, I: p value for T3 vs T12, J: p value for T0 vs T12, E: p value for T1 vs T3, F: p value for T1 vs T4, G: p value for T1 vs T12, H: p value for T3 vs T6, I: p value for T3 vs T12, J: p value for T0 vs T12, E: p value for T1 vs T3, F: p value for T1 vs T4, G: p value for T1 vs T12, H: p value for T3 vs T6, I: p value for T3 vs T12, J: p value for T0 vs T12, E: p value for T1 vs T3, F: p value for T1 vs T4, G: p value for T3 vs T6, I: p value for T3 vs T12, J: p value for T0 vs T12, E: p value for T1 vs T3, F: p value for T1 vs T4, G: p value for T3 vs T6, I: p value for T3 vs T12, J: p value for T0 vs T12, E: p value for T1 vs T3, F: p value for T1 vs T4, G: p value for T3 vs T6, I: p value for T3 vs T12, J: p value for T0 vs T12, E: p value for T1 vs T4, E: p value for T1 vs T4, E: p value for T4 vs T12

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

KDQOL-36 (Hong Kong)	-	T0	-		T1	-		T3	-	T6	-		T12	Between groups	Interaction effects	Within groups	Multiple comparisons within groups
KDQOL-36 (HK)	n	Mean (SD)		n	Mean (SD)	n	1	Mean (SD)	n	Mean (SD)		n	Mean (SD)	F (p-value) ^b	F (p-value)	F (p-value) ^c	[A,B,C,D,E,F,G,H,I,J] ^e
SPL ^a	•		-			•	•		-		-			3013.06 (<0.01*)	0.45 (0.06)	8.86 (0.001*)	
Control	38	80.66 (13.87)	4	36	73.36 (15.752)	3	33	70.74 (16.607)	22	70.56 (12.75)		13	66.14 (10.25)			5.07 (0.01*)	$ \begin{array}{l} [0.63, \ 0.05, \ < 0.01^*, \ < 0.001^*, \ 0.47, \\ < 0.001^*, \ < \ 0.01^*, \ < 0.01^*, \ < 0.01^*, \ < 0.01^*, \\ 1.00] \end{array} $
Intervention	38	86.66 (10.37)	1	38	91.03 (7.147)	3	35	93.43 (6.01)	29	95.29 (4.87)		23	94.83 (4.61)			1.34 (0.05*)	$\begin{matrix} [<\!0.01^*, \ <\!0.01^*, \ <\!0.01^*, \ <\!0.01^*, \ <\!0.01^*, \ \\ 0.25, \ 0.06, \ 0.63, \ 1.00, \ 1.00, \ 1.00 \end{matrix} \end{matrix}$
T (p-value) ^d		2.132 (0.08)			-6.27 (<0.001**)			-7.75 (<0.001**)		-9.42 (<0.001**)			-11.05 (<0.001**)				
EKD ^a														1572.28 (<0.01*)	131.76 (0.19)	1.23 (0.32)	
Control	38	90.88 (8,78)	3	36	90.38 (8.66)	3	33	89.29 (10.50)	22	88.26 (8.69)		13	87.50 (6.36)			0.48 (0.68)	[1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00]
Intervention	38	94.64 (7.60)	1	38	97.46 (3.31)	3	35	98.55 (2.14)	29	98.72 (1.743)		23	98.38 (3.19)			1.03 (0.83)	[0.20, 0.09, 0.07, 0.17, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00]
T (p-value) ^d		2.00 (0.06)			-4.70 (<0.001**)			-5.25 (<0.001**)		-6.23 (<0.001**)			-6.45 (<0.001**)				
BKD ^a														273.25 (<0.01**)	2.65 (0.58)	2.02 (0.19)	
Control	38	61.84 (30.51)	1	36	56.25 <u>(</u> 30.73)	3	33	53.71 (28.04)	22	54.45 (26.08)		13	60.63 (22.25)			2.18 (0.24)	[1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 0.15, 0.26]
Intervention	38	69.24 (27.59)	1	38	77.96 <u>(</u> 21.93)	3	85	82.43 (17.67)	29	81.92 (16.26)		23	80.68 (19.18)			0.68 (0.49)	[1.00, 0.07, 0.20, 0.26, 0.15, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00]
T (p-value) ^d		1.11 (0.27)			-8.51 (<0.001**)			-5.16 (<0.001**)		-4.53 (<0.001**)			-2.61 (0.014*)				
PCS ^a														1984.97 (<0.01**)	28.12 (<0.001**)	1.98 (0.005*)	
Control	38	39.79 (10.14)	1	36	35.15 (11.67)	3	33	34.29 (11.34)	22	34.65 (2.267)		13	31.99 (7.80)			2.2 (0.05*)	[0.12, 0.01*, 0.00*, 0.06, 1.00, 1.00, 0.09, 0.26, 0.47, 1.00]
Intervention	38	44.17 (5.31)	3	38	49.25 (5.09)	3	85	50.10 (5.54)	29	51.26 (5.86)		23	51.33 (6.54)			0.89 (0.05*)	[0.01*, 0.01*, 0.04*, 0.01*, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00]
T (p-value) ^d		2.36 (0.06)			-5.20 (<0.001**)			-5.57 (<0.001**)		-4.51 (<0.001**)			-4.11 (<0.001**)				
MCS ^a														3523.30 (<0.01*)	4.23 (0.03*)	0.98 (0.17)	
Control	38	51.59 (8.67)	1	36	50.05 (8.50)	3	33	48.73 (9.62)	22	47.23 (10.69)		13	46.15 (9.21)			2.18 (0.006)	[1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00]
Intervention	38	53.24 (6.05)		38	56.30 (4.08)	3	85	57.73 (3.58)	29	57.63 (3.60)		23	56.00 (7.85)			0.88 (0.005)	[0.49, 0.11, 0.43, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00]
T (p-value) ^d		9.96 (0.34)			-3.57 (<0.001**)			-4.18 (<0.001**)		-3.82 (<0.001**)			-3.42 (<0.001**)				

Table 5.15 Comparison of the KDQOL by groups over five-time points by PP analysis (T0, T1, T3, T6 and T12)

Abbreviations: SPL= Symptom Problem List, EKD = Effects of Kidney Disease, BKD = Burden of Kidney Disease, PCS = Physical Composite Score, MCS = Mental Composite Score, Data collection time-points: T0 = baseline, T1 = first month, T3 = third month, T6 = sixth month, T12 = twelve month Statistical analysis: ^a 2-way Repeated measures ANOVA, ^bAdjusted between-group repeated measures significant at p < 0.025; ^cAdjusted within-group repeated measures significant at p < 0.005. *, ^d Independent t-test

^e Multiple comparison (Bonferroni) [A: p value for T0 vs T1, B: p value for T0 vs T1, C: p value for T0 vs. T6, D: p value for T0 vs T12, E: p value for T1 vs T3, F: p value for T1 vs T6, G: p value for T1 vs T12, H: p value for T3 vs T6, I: p value for T3 vs T12, J: p value for T0 vs T12, E: p value for T1 vs T3, F: p value for T1 vs T6, G: p value for T3 vs T6, I: p value for T3 vs T6, D: p value for T0 vs T12, E: p value for T1 vs T3, F: p value for T1 vs T6, G: p value for T3 vs T6, I: p value for T3 vs T12, J: p value for T0 vs T12, E: p value for T0 vs T12, E: p value for T1 vs T3, F: p value for T1 vs T6, G: p value for T3 vs T6, I: p value for T3 vs T12, D: p value for T0 vs T12, E: p value for T1 vs T3, F: p value for T1 vs T4, F: p value for T0 vs T12, D: p value for T0 vs T12, D: p value for T0 vs T12, D: p value for T0 vs T12, E: p value for T1 vs T3, F: p value for T1 vs T4, F: p value for T0 vs T12, D: p value for T0 vs T12, *significant at p < 0.05; ** significant at p < 0.01

5.3.4.2 Effects of intervention on Symptoms Manifestation (SM)

A symptom list of 17 items was adopted for the assessment of symptoms experienced by the participants (Figure 5.14). It is ranked by the 5 points Likert scale with a score at or above 2 regarded as a complained symptom. The top 5 symptoms commonly reported by participants in this study included: (1) fatigue; (2) itchiness of skin; (3) weakness; (4) oedema and (5) feeling cold. Figure 5.12 and Figure 5.13 show the prevalence of symptom intensity in this trial.



Figure 5.12 Prevalence of symptom manifestation



Figure 5.13 Comparison of prevalence of symptom manifestation between the control group and intervention group

Results of SM *by ITT analysis*: In this assessment, a lower score means less symptom manifestation experienced by the participants. In ITT analysis, through the RM-ANOVA of SM, it was shown that there were significant between-group differences in the main effects of SM at four-time points F (1, 74) = 258.32, p=0.001 (Table 5.16). The independent t-test results revealed that there was a significant between-group difference of symptom intensity at T1 (*t*=2.42, p<0.02), T3 (*t*=2.45, p<0.02) and T6 (*t*=3.51, p<0.001) and T12 (*t*=2.67, p<0.01). Participants in the intervention group demonstrated less SM than those in the control group. The symptom intensity increased at the time point of T6 and T12 which was the late phase of life before death in the intervention and control group (Table 5.16). In addition, there were significant time effects of SM overtime point, F (2, 2.96) = 3.56, p=0.01. There was no significant change in the SM within the group over time (Table 5.16). Besides, there was no interaction of symptoms intensity over time and group, F (2, 2.96) = 2.12, p=0.08

(Table 5.16). The trend of development of symptom distress was in a similar direction in the intervention group and control group. The symptom intensity increased from baseline until 1 year after recruitment with an insignificant change in the control group. The intensity of symptoms increased at the time points of T6 and T12 which were in the late period before death in the intervention group.

Results of SM *by PP analysis*: In PP analysis, there was a significant between-group difference in symptom distress at all-time points except for the baseline. As shown in Table 5.17, RM-ANOVA showed that there was a between-group difference $F_{(1, 34)} = 154.955$, *p*<0.001. The independent t-test further displayed that there was a significant difference in symptom intensity within groups in four time points, T1 (*t*=1.84, *p*<0.05), T3 (*t*=1.44, *p*<0.05), T6 (*t*=1.44, *p*<0.02) and T12 (*t*=1.04, *p*=0.296). Participants with study interventions presented less symptom distress than those in the control group. Further, there was no significant time effect of symptom distress over group and time effect at F (3.181, 98.622) =1.73, *p*<0.16 (Table 5.17). There was a kick decrease in symptom intensity at T3 in the control group in the ITT analysis without any conclusive reason. Otherwise, there was a trend of increasing SM from T0 to T12 which was consistent with the progression of ESRF.

Comparison of SM by ITT and PP analysis: From Tables 5.18 and 5.19, similar results were observed in both ITT analysis and PP analysis. No significant group difference between the main effects of symptoms intensity was noted and no within-group difference was noted. Both ITT and PP analysis yielded similar trends. Participants in the intervention group presented less symptom distress than those in the control group (Figure 5.14 and Figure 5.15).



Figure 5.14 Scores of symptom manifestation (PP analysis)

Figure 5.15 Scores of symptom manifestation (ITT analysis)

5.3.4.3 Effects of interventions on Palliative Performance Scale (PPS)

As one of the secondary outcome measures, a PPS was adopted for assessing the physical functions of the participants. A higher scale of PPS means better physical function perceived in this assessment.

Effects of interventions on PPS by ITT analysis: In ITT analysis, the RM-ANOVA with Greenhouse-Geyser correction determined a significant between-group difference of PPS at $F_{(1, 74)} = 4057.02$, p=0.001, as well as a significant difference of PPS within groups, $F_{(2.637, 135.114)} = 9.59$, p=0.001. Furthermore, there was an interaction of PPS over groups and time, $F_{(2.637, 135.114)} = 5.84$, p=0.01 as shown in Table 5.16. The independent t-test was conducted and revealed that there were significant differences in PPS between both groups at T3 (t=2.54, p<0.01), T6 (t=3.60, p<0.001) and T12 (t=4.93, p<0.001). Physical ability

significantly improved in the intervention group with a significant between-group difference at three-time points (Table 5.16). Participants in the intervention group presented better physical function than those in the control group. The participants in the control group expressed declined physical function during the last few months of their lives. In the analysis of the within-group difference of PSS, the physical function deteriorated from T0 to T6 (MD = 6.403, p<0.001); T0 to T12 (MD = 9.67, p<0.01); T1 to T12 (MD = 7.72, p<0.01) and T3 to T12 (MD = 6.50, p<0.01) in the control group, whereas there was no significant improvement was shown within the intervention group (Table 5.16).

Results of PPS by PP analysis: As shown in Table 5.17 the RM-ANOVA of PPS analysis determined that there was a significant between-group difference of PPS at $F_{(1, 34)}$ =1850.78, p<0.001, as well as the significant difference of PPS within groups $F_{(2.588, 80.235)}$ =11.913, p<0.001. Furthermore, there was an interaction of PPS and groups effect at $F_{(2.588, 80.235)}$ =9.98, p<0.001. The independent t-test further indicated that there were significant differences of PPS between both groups at T1 (t = 1.46, p<0.05), T3 (t= 2.27, p<0.02), T6 (t=2.17, p<0.03) and T12 (t=3.10, p<0.002). As the intervention group experienced physical function improvement whereas the control group demonstrated deterioration of physical function between groups. In view of the within-group difference of PPS, there was deterioration of physical function in the control group from T0 to T12 (MD = -15.46, p>0.001), from T1 to T6 (MD = -10.919, p<0.001), from T1 to T12 (MD = -16.34, p<0.001), from T3 to T6 (MD = -8.82, p=0.01) and from T3 to T12 (MD = -13.636, p<0.001).

Comparison of PPS by ITT analysis and PP analysis:

There was a trend of decline in PPS in the control group by the ITT analysis and PP analysis (Figure 5.18 and Figure 5.19) while the intervention group experienced better physical function in both ITT and PP analysis. Likewise, similar between-group differences in PPS were noted in both PP analysis and ITT analysis (Table 5.19). Participants in the intervention group presented better physical function than the control group (Figure 5.16 and Figure 5.17).



Figure 5.16 Scores of Palliative Performance Scale (PP analysis)



5.3.4.4. Effects of interventions on anxiety

Anxiety is a reaction to stress, physical ability, illness, and perceived experience. A low level of anxiety is assumed normal as assessed by HADS-Anxiety.

Results of Anxiety by ITT analysis: In a RM-ANOVA of anxiety showed that there were significant between-groups differences over time point $F_{(1,74)} = 131.12$, *p*<0.001, as well as

an interaction of the effects of anxiety of groups over time effects, $F_{(2.413, 178.55)} = 4.96$, p = 0.01. The independent t-test further showed group differences of anxiety noted at T1 (t=1.16, p<0.24), T3 (t=4.53, p<0.98), T6 (t=3.70, p<0.001), T12 (t=0.86, p<0.39) (Table 5.16). The participants experience mild levels of anxiety in this study. There was an improvement in anxiety levels in the intervention group while there was a deterioration of anxiety levels in the control group which contributed to the opposite trend of development of anxiety during the disease trajectory. Whereas there was no significant time effect of anxiety within-group overtime point, $F_{(2.413, 178.55)} = 4.96$, p=0.11 (see Table 5.16).

Results of Anxiety by PP Analysis: The RM-ANOVA of anxiety showed that there was no significant difference in depression within-group at F (2.36, 170.362) =2.82, p<0.06) While the anxiety subscale results showed a significant difference between groups at F (1, 34) = 47.82, p=0.02, as well as the interaction of anxiety of group over time effect at F (2.36, 170.362) =2.88, p=0.04). The independent t-test further indicated that there was a significant difference between both groups at T6 (t=0.46, p=0.05). Participants in the control group expressed higher levels of anxiety than those in the intervention group (Table 5.17). The participants experienced a mild degree of anxiety in the intervention group while those in the control group presented a moderate degree of anxiety. Hence, there was a contrasting trend in the development of anxiety.

Comparisons of the effects of interventions on anxiety between ITT analysis and PP analysis:

Table 5.19 showed that similar results of anxiety from both ITT analysis and PP analysis were noted. Overall, there was a difference in anxiety levels between both control and intervention groups at T6. Also, there was no significant difference in anxiety within the

control group and intervention group by PP analysis (Figure 5.18) or by ITT analysis (Figure 5.19).



5.3.4.5 Effects of intervention on depression

Depression was assessed by the HADS-Depression with a low score indicating patients experienced a lower level of depression.

Results of Depression from ITT analysis: As shown in Table 5.16 the independent t-test indicated that there was significant difference between groups at T1 (t=2.05, p=0.04), T3 (t=3.98, p<0.001), T6 (t=2.94, p=0.01) and T12 (t=2.18, p<0.03). The RM-ANOVA of depression showed that there were significant differences between groups in depression, F (1, 74) =219.62, p<0.001 (Table 5.16). Further, the RM-ANOVA showed that there was no significant difference in depression within-group at F (2.537, 187.76) =1.44, p<0.02, as well as no interaction of depression over group and time effect at F (2.537, 187.76) =2.87, p<0.05). Participants in the control group expressed higher levels of depression than those in the intervention group.

Effects of intervention on Depression by PP analysis: As shown in Table 5.17, the RM-ANOVA showed that there were significant between-group differences in depression mood over time, F (1, 34) =129.54, p=0.01. The independent t-test indicated that there were significant differences between groups at T3(t=1.95, p=0.05). Participants in the control group expressed higher levels of depressive emotion than those in the intervention group. The one-way ANOVA of Depression showed that there was no significant difference in depressive mood within-group at F (2.36, 170.362) = 0.46, p=0.66 and no interaction of depressive mood over group and time effect at F (2.36, 170.362) = 3.48, p=0.37) (Table 5.17).

Comparisons of the results of Depression of ITT and PP analysis: Both PPA and ITTA demonstrated similar results of depression. In ITT analysis, there were significant between-group differences in the depressive mood at T1, T3, T6 and T12 (see Figure 5.21) while there was a significant between-group difference in depressive mood noted only at T3 in the PP analysis (see Figure 5.20).



Figure 5.20 Scores of Depression (PP analysis)



Figure 5.21 Scores of Depression (ITT analysis)

5.3.4.6 Effects of intervention on Patient Satisfaction

Patient satisfaction with palliative care was assessed at T1 when patients had experienced transitional renal palliative care for one month after recruitment.

Effects of intervention on the Patient Satisfaction from *ITT analysis*: the RM-ANOVA with a Greenhouse-Geisser correction determined that mean satisfaction with care presented a statistically significant within-group difference over time F (1.314, 141.629) = 3.88, p<0.01. There was an interaction of satisfaction with care over groups and time effect, F (1.314, 141.629) = 7.96, p=0.001 but the analysed results revealed a significant between-group effect, F (1, 74) = 7715.35, p<0.001 (Table 5.16). The independent t-test revealed a significant difference of satisfaction with care observed between both groups at T1 (t=7.68, p<0.001), T3 (t=3.7, p<0.001), T6 (t=6.96, p<0.001) and T12 (t=6.69, p<0.001). Levels of satisfaction with care were remarkably higher in the intervention group than those in the control group.

Effects of intervention on the Patient Satisfaction from PP analysis: The results of the independent t-test revealed that there were significant between-group differences in satisfaction with care at time points of T1 (t=7.42, p<0.001), T3 (\underline{t} =7.21, p<0.001), T6 (t=6.21, p<0.001) and T12 (t=4.98, p<0.001). Participants in the intervention group expressed more satisfaction with the care than those in the control group. The RM-ANOVA showed that there was a between-group difference in satisfaction with care over time, F (1, 34) = 4430.81, p<0.001 (Table 5.17). There was no significant difference in satisfaction with care within the control group, F (1.467, 60.146) = 0.59, p=0.50, and no effect of group and time interception of satisfaction with care F (1.467, 60.146) = 2.05, p=0.15.

Comparison of results of Patient Satisfaction from ITT and PP analysis: In ITT analysis, there existed a similar trend of satisfaction with care for the intervention group and the control group along the course of care (Figure 5.22). In PP analysis, participants in the intervention group depicted higher levels of satisfaction with care than those in the control group (Figure 5.23).



60 50 40 30 20 10 0 T1 T3 T6 T12 Control Intervention

Figure 5.22 Scores of Patient Satisfaction (PP analysis)

Figure 5.23 Scores of Patient Satisfaction (ITT analysis)

5.3.4.7 Effects of interventions on Zarit Burden Index (ZBI)

The caregiver burden was assessed using the short version of the ZBI. Higher scores of ZBI indicate a greater burden and a score of 17 or more was considered a high burden.

Results of the caregiver burden by ITT analysis: In ITT analysis, RM-ANOVA showed that there was a significant between-group difference in the caregiver burden, $F_{(1, 74)} = 581.43$, *p*=0.001, as well as an interaction of burden with the group over time effect $F_{(1.768, 130.80)}$

=17.76, p=0.01 (see Table 5.16). The independent t-test test was conducted and illustrated that there were significant between-group differences at T1 (*t*=4.15, *p*<0.001), T3 (*t*= 5.73, *p*<0.001), T6 (*t*=6.01, *p*<0.001) and T12 (*t*=6.09, *p*<0.001). Control group participants expressed a higher level of caregiver burden than those in the intervention group. The results of multiple comparisons showed that the level of caregiver burden decreased from the baseline to T1 (*p*=0.04), T3 (*p*<0.001), T6 (*p*=0.01) and T12 (*p*=0.01) in the intervention group. However, there was no significant difference in the within-group of burden as evidenced by overtime points, $F_{(1.768, 130.80)} = 2.65$, *p*=0.004 (see Table 5.16).

Results of caregiver burden by PP analysis: The RM-ANOVA of the burden of caregiver burden showed that there was a significant between-group difference overtime points, $F_{(1)}$ $_{34)}$ =132.13, p<0.001. The independent t-test further revealed a significant difference between both groups at all four time points: T1 (t=6.24, p<0.001), T3 (t= 6.6, p<0.001), T6 (t=5.14, p<0.001) and T12 (t=4.45, p<0.001). Caregivers in the intervention experienced less burden than those in the control group (see Table 5.17). It was also noted that there was an interaction of burden and time effect over time points, $F_{(1.467, 60.15)} = 2.53$, p=0.01. Those in the intervention group perceived less burden than those in the control group who encountered a relatively higher level of burden during the period of data collection. The trend of the development of burden was noted in an opposite direction. However, there was no significant difference within-group as evidenced by overtime points $F_{(1.467, 60.146)} = 3.98$, p=0.05. Caregivers in the control group presented a burden increase from T0 to T12 without any statistically significant difference, especially as the burden level increased steeply in approaching the end phase of the life of their relatives. The caregiver burden in the intervention group had a significant improvement in burden level after recruitment into the intervention group from T0 (baseline) to T6 (Table 5.17). A drastic increase in caregiver burden was noted from T6 to T12 when patients in the control group had declined health conditions in the late stage of life.

Comparison of the caregiver burden from ITT analysis and PP analysis: The results of caregiver burden of the intervention group were similar in ITT analysis (Table 5.18) and PP analysis (Table 5.19). Different burden levels of caregivers of the control group were noted between the ITT analysis and the PP analysis, a consistent level of burden did exist in the control group. In ITT analysis, there was a trend of increase in the caregiver burden from T0 to T12 in the control group. In the intervention group, caregivers experienced less burden from baseline to T6, yet there was a rebound of the burden from T6 to T12 in approaching the late phase of the life of the patient (Figure 5.25). In PP analysis, the caregiver burden in the control groups was increased from T0 to T12 without any statistically significant difference. Yet the burden level shot up in approaching the EOL phase of their relatives in the control group. The participants in the Intervention group expressed a statistically significant improvement in burden level from T0 (baseline) to T6 and recoil of burden in caring for the patient in the last phase of life (Figure 5.24).





Figure 5.24 Scores of Burden (PP analysis)

Figure 5.25 Scores of Burden (ITT analysis)

		T0		T1		T3		T6			T12	В	Setween Groups	Interaction Effects	Within Groups	Repeated comparisons within groups
	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	1	n	Mean (SD)		F (p-value) b	F (p-value)	F (p-value) ^c	[A, B, C, D, E, F, G, H, I, J] ^e
SM		•											258.32 (<0.001**)	2.117 (0.08)	3.56 (0.01)	
Control	38	9.29 (6.54)	38	10.63 (6.96)	38	9.87 (6.55)	38	10.79 (6,03)	3	38	11.50 (6.53)				2.16 (0.051)	[0.04, 0.37, 0.03, 0.01, 0.19, 0.81, 0.23, 0.02, 0.01, 0.20]
Intervention	38	7.79 (5.06)	38	7.42 (4.28)	38	7.42 (4.28)	38	6.94 (3.32)	3	38	8.26 (3.64)				2.56 (0.06)	[0.59, 0.65, 0.17, 0.53, 0.89, 0.39, 0.24, 0.11, 0.21, 0.02]
T(p-value) ^d		1.12 (0.27)		2.42 (0.02*)		2.45 (0.02*)		3.51 (0.001**)			2.67 (0.01*)					
PPS ^a													4057.02 (0.001**)	5.84 (<0.01*)	9.59 (0.001**)	
Control	38	75.79 (12.22)	38	73.94 (14.62)	38	72.63 (13.29)	38	69.73 (11.27)	3	38	66.05 (11.03)				8.5 (0.01*)	[1.00, 0.18, 0.001**, 0.01*, 1.00, 0.31, 0.01*, 0.15, 0.01*, 1.00]
Intervention	38	79.21 (11.48)	38	78.95 (10.60)	38	79.73 (11.02)	38	78.42 (9.73)	3	38	78.16 (19.36)				3.9 (0.01*)	[1.00, 1.00, 0.04*, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00]
T (p-value) ^d		1.26 (0.21)		1.71 (0.09)		2.54 (0.01*)		3.60 (0.001**)			4.93 (<0.001**)					
HADS-A ^a													131.12 (<0.001**)	4.96 (0.01*)	2.10 (0.11)	
Control	38	3.5 (3.73)	38	3.03 (3.05)	38	3.32 (3.38)	38	4.08 (3.50)	3	38	3.92 (3.34)				2.91 (0.03)	[1.00, 1.00, 1.00, 1.00, 1.00, 0.22, 0.61, 0.03, 1.00, 1.00]
Intervention	38	3.63 (3.77)	38	3.89 (3.38)	38	2.08 (1.49)	38	1.76 (1.69)	3	38	3.16 (3.29)				3.2 (0.06)	1.00, 0.22, 0.11, 1.00, 0.01, 0.01, 1.00, 1.00, 0.3, 1.00]
T (p-value) ^d		0.153 (0.88)		1.16 (0.24)		4.53 (3.98)		3.70 (<0.001**)			0.86 (0.39)					
HADS-D ^a												:	219.62 (<0.001**)	2.87 (0.05)	1.44 (0.22)	
Control	38	4.53 (3.95)	38	5.89 (4.84)	36	5.89 (4.84)	38	5.95 (4.75)	3	38	5.92 (5.06)				0.49 (0.59)	[1.00, 1.00, 1.00, 0.57, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00]
Intervention	38	4.65 (4.6)	38	3.92 (3.42)	38	2.55 (1.86)	38	3.37 (2.56)	3	38	3.74 (3.55)				(0.28 (0.83)	[1.00, 0.77, 0.1, 1.00, 1.00, 0.13, 0.85, 0.31, 1.00, 1.00].
T (p-value) ^d		0.13 (0.89)		2.05 (0.04*)		3.98 (<0.001**)		2.94 (0.01*)			2.18 (0.03*)					
PS ^a												7	715.35 (<0.001**)	7.96 (0.001*)	3.88 (0.004*)	[E to J] ^f
Control			38	38.97 (5.44)	38	43.81 (5.67)	38	41.71 (5.78)	3	38	43.42 (6.57)				0.42 (0.52)	[0.22, 0.06, 1.00, 1.00, 1.00, 1.00]
Intervention			38	48.29 (5.14)	38	48.87 (6.22)	38	53.63 (6.60)	3	38	53.50 (6.20)				0.19 (0.01*)	[0.04*, 0.05*, 1.00, 1.00, 0.59, 0.39]
T (p-value) ^d				7.68 (<0.001**)		3.7 (<0.001**)		6.96 (<0.001**)			6.69 (<0.001**)					
ZBI ^a													581.43 (<0.001**)	17.76 (0.01*)	2.65 (0.004*)	
Control	38	29.39 (12.21)	38	31.61 (12.64)	38	32.5 (13.97)	38	33.47 (14.32)	3	38	33.55 (14.3)				2.92 (0.09)	[1.00, 0.77, 0.26, 0.26,1.00, 1.00, 0.95, 0.97, 1.00, 1.00]
Intervention	38	26.45 (8.54)	38	22.05 (6.42)	38	18.21 (6.40)	38	18.16 (6.40)	3	38	17.95 (6.72)				0.88 (0.05*)	[0.04*, <0.001*, 0.01*, 0.01*, 0.10*, 0.01*, 0.0*1, 1.00, 1.00, 1.00]
T (p-value) ^d		0.20 (0.23)		4.15 (<0.001**)		5.73 (<0.001**)		6.01 (<0.001**)			6.09 (<0.001**)					

Table 5.16 Comparison of SM, PPS, HADS-A, HADS-D, PS and ZBI of caregivers by groups over five time-points by ITT analysis (T0, T1, T3, T6 and T12)

Abbreviations: SM = Symptom manifestation, PPS = Palliative Performance Scale, HADS-A = Hospital Anxiety and Depression Scale - Anxiety, HADS-D = Hospital Anxiety and Depression scale - Depression, PS = Palient Satisfaction, ZBI = Zarit Burden Index Data collection time-pints: <math>T0 = baseline, T1 = first month, T3 = third month, T6 = sixth month, T12 = twelfth month

Statistical analysis: ¹2-way Repeated measures ANOVA, ^b Adjusted between-group repeated measures significant at p < 0.025, ^c Adjusted within-group repeated measures significant at p < 0.005*; ^d Independent t-test; ^b Multiple comparisons (Bonferroni) [A: p-value for T0 vs T1, B: p-value for T0 vs T1, C: p-value for T0 vs. T6, D: p-value for T0 vs. T6, D: p-value for T1 vs. T6, G: p-value for T1 vs. T12, H: p-value for T3 vs. T6, I: p-value for T3 vs. T6, I: p-value for T0 vs. T12, J: p-value for T0 vs. T12]; ^f Adjusted within-group repeated measures significant of satisfaction at p < 0.0083

		Т0	-	T1	-	T3	T6		T12		Between Groups	Interaction Effects	Within Groups	Repeated comparisons within groups
	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	F (p-value) ^b	F (p-value)	F (p-value) ^c	[A, B, C, D, E, F, G, H, I, J] ^e
SM ^a						- · ·		· ·			154.95 (<0.001**)	1.73 (0.16)	2.64 (0.02)	
Control	38	9.29 (6.54)	36	10.08 (6.229)	33	9.69 (6.018)	22	10.01 (4.925)	13	11.31 (7.002)			1.24 (0.03)	[0.29, 1.00, 1.00, 0.19, 1.00, 1.00, 1.00, 1.00, 0.88, 0.28],
Intervention	38	7.79 (5.06)	38	7.605 (4.532)	35	7.77 (3.902)	29	7.55 (4.473)	23	8.81 (5.556)			2.04 (0.06)	1.00, 100, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00]
T(p-value) ^d		1.12 (0.267)		-1.84 (0.05*)		-1.44 (0.05*)		-1.44 (0.02*)		-1.04 (0.296)				
PPS ^a											1850.78 (<0.001**)	9.79 (<0.001**)	11.93 (0.001*)	
Control	38	75.79 (12.22)	36	73.89 (14.42)	33	72.38 (13.3)	22	69.44 (10.29)	13	64.65 (11.97)			7.32 (0.01*)	[1.00, 1.00, 0.04*, 0.001*, 1.00, <0.001*, <0.001*, <0.001*, <0.001*, 0.06]
Intervention	38	79.21 (11,48)	38	79.21 (10.63)	35	79.95 (11.17)	29	78.32 (10.62)	38	76.78 (12.35)			2.54 (0.06)	[1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00]
T (p-value) ^d		1.26 (0.21)		-1.46 (0.05*)		-2.27 (0.02*)		-2.17 (0.03*)		-3.104 (0.002*)				
HADS-A ^a											47.82(<0.02*)	2.88 (0.04*)	2.82 (0.06)	
Control	38	3.50 (3.73)	36	3.06 <u>(</u> 3.14)	33	3.66 (4.14)	22	3.95 (4.90)	13	6.38 (6.19)			2.91 (0.03)	[0.39, 0.87, 0.21, 0.05, 1.00, 1.00, 0.60, 1.00, 0.82, 1.00]
Intervention	38	3.63 (377)	38	3.89 (3.38)	35	3.03 (2.77)	29	3.93 (3.4)3	38	3.13 (3.53)			3.20 (0.06)	[1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00]
T (p-value) ^d		0.153 (0.88)		-0.15 (0.27)		-0.17 (0.46)		-0.46 (0.05*)		-1.03 (0.21)				
HADS-D ^a											129.54 (<0.01*)	3.48 (0.37)	0.46 (0.66)	
Control	38	4.53 (3.95)	36	5.50 (5.385)	33	6.19 (5.03)	22	6.55 (4.69)	13	7.77 (5.86)			0.49 (0.59)	[0.26, 0.29, 0.06, 1.00, 1.00, 1.00, 0.60, 1.00, 0.00]
Intervention	38	4.65 (4.60)	38	4.45 (4.310)	35	3.65 (3.02)	29	4.69 (4.36)	23	3.83 (4.13)			0.28 (0.83)	[1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00]
T (p-value) ^d		0.133 (0.89)		-0.68 (0.51)		-1.95 (0.05*)		-1.34 (0.28)		-1.33 (0.19)				
PS ^a											4430.81 (<0.001**)	2.05 (0.15)	0.59 (0.50)	[E to J] ^f
Control			36	37.69 (3.632)	33	37.22 (3.72)	22	38.27 (3.269)	13	38.77 (4.166)			0.42 (0.54)	[1.00, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00,
Intervention			38	56.61 (3.673)	35	58.11 (2.81)	29	58.76 (2.12)	23	58.26 (4.15)			0.22 (0.06)	[0.07, 0.11, 1.00, 1.00, 1.00, 1.00, 1.00]
T (p-value) ^d				-7.42 (<0.001**)		-7.21 (<0.001**)		-6.21 (<0.001**)		-4.979 (<0.001**)				
ZBI ^a											132.13 (<0.001**)	2.53 (0.01*)	3.98 (0.05)	
Control	38	29.39 (12.21)	36	34.56 (14.10)	33	35.34 (13.423)	22	34.86 (13.49)	13	43.63 (29.25)			2.67 (0.11)	[0.01, 0.15, 0.72, 0.09, 0.32, 1.00, 0.22, 1.00, 0.47, 0.33]
Intervention	38	26.45 (8.54)	38	12.39 (8.52)	35	9.84 (7.39)	29	10.59 (12.66)	23	13.44 (25.31)			0.98 (0.08)	[0.09, 0.06, 0.07, 0.28, 0.07, 1.00, 1.00, 1.00, 1.00, 1.00, 1.00]
T (p-value) ^d		0.198 (0.23)		6.24 (<0.001**)		6.6 (<0.001**)		5.14 (<0.001**)		4.45 (<0.001**)				

Table 5.17 Comparison of SM, PPS, HADS-A, HADS-D, PS and ZBI of caregivers by groups over five time-points by PP analysis (T0, T1, T3, T6 and T12)

Abbreviations: SM = Symptom manifestation, PPS = Palliative Performance Scale, HADS-A = Hospital Anxiety and Depression Scale - Anxiety, HADS-D = Hospital Anxiety and Depression Scale - Depression, PS = Patient Satisfaction, ZBI = Zarit Burden Index Data collection time-pints: T0 = baseline, T1 = first month, T3 = third month, T6 = sixth month, T12 = twelfth month

Statistical analysis: ¹2-way Repeated measures ANOVA, ^b Adjusted between-group repeated measures significant at p < 0.025, ^c Adjusted within-group repeated measures significant at p < 0.005*; ^d Independent t-test; ^e Multiple comparisons (Bonferroni) [A: p-value for T0 vs T1, B: p-value for T0 vs T1, C: p-value for T0 vs. T6, D: p-value for T0 vs T12, E: p-value for T1 vs T3, F: p-value for T1 vs T6, G: p-value for T1 vs T12, H: p-value for T3 vs T6, I: p-value for T6 vs T12]; ^f Adjusted within-group repeated measures significant at p < 0.0083

5.3.5 Summary of ITT analysis and PP analysis

The significant data analysis results of the primary and secondary outcome variables in ITT analysis were compared with those in PP analysis. There were 299 comparisons of the ITT analysis with PP analysis in Tables 5.18 and 5.19. Among them, 42 comparisons show different results. The two approaches of data analysis produced similar results for most of the comparisons (257/299 = 85.95%). There were no other remarkable differences between the ITT and PP analyses. Hence, the main conclusions of this pilot trial can be drawn from ITT analysis as it has been shown to have preserved the strength of randomization.

Table 5.18 Comparison of ITT analysis and PP analysis of KDQOL-36 (Hong Kong)

Measures	Between-group comparison ^a										Between- Ir group effects			Interaction Within- effects group effects		thin- oup ects									Mult	iple co	mpari	sons								
	Т	0a	Т	1a	Т	'3a	т	ба	Т	12a							Т0 у	rs T1	T0 v	rs T3	T0 v	/s T6	T0 vs	s T12	T1 v	/s T3	T1 v	rs T6	T1 v	s T12	T3 v	s T6	T3 vs	s T12	T6 vs	T12
	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP
SPL ^b	NS	NS	S	s	S	s	s	S	s	s	s	S	s	NS	S	s	-		-			-	_			-	-		-	_						
Control ^c																	S	NS	NS	NS	NS	S	S	S	NS	NS	NS	s	NS	S	S	S	S	S	NS	NS
Intervention ^c																	NS	S	NS	S	NS	S	NS	S	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	S	NS
EKD ^b	NS	NS	S	s	S	s	s	S	S	s	s	S	S	NS	NS	NS																				
Control ^c																	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Intervention ^c																	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
BKD ^b	NS	NS	NS	NS	S	S	s	S	S	s	S	s	s	NS	NS	NS																				
Control ^c																	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Intervention ^c																	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
PCS ^b	NS	NS	S	s	S	s	s	S	S	s	s	S	S	s	NS	s																				
Control ^c																	NS	NS	NS	S	NS	S	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Intervention ^c																	NS	S	NS	S	S	s	NS	S	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
MCS ^b	NS	NS	S	s	S	s	S	S	S	s	s	S	S	s	NS	NS																				
Control ^c																	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Intervention ^c																	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS

ITT = Intention-to-treat analysis, PP = Per protocol analysis, SPL= Symptom Problem List, EKD = Effects of Kidney Disease, BKD = Burden of Kidney Disease, PCS = Physical Composite Score; MCS = Mental Composite Score

 $^{\rm a}$ Independent t-test, $^{\rm b}$ two-way RM-ANOVA, $^{\rm c}$ one-way RM-ANOVA NS=non-significant difference, S = significant difference

Measures	Between-group comparison ^a										Betw gro effe	een- up cts	Intera effe	ction ects	ion Within- s group effects		1-) S								Mult	iple co	ompari	sons								
	Т	0a	Т	1a	T.	3a	Т	ба	T1	2a							T0 v	vs T1	T0 v	's T3	TO	vs T6	T0 v	s T12	T1 v	vs T3	T1 v	vs T6	T1 v	s T12	T3 v	s T6	T3 vs	T12	T6 vs	T12
	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP	ITT	PP
SM ^b	NS	NS	S	S	S	S	s	S	s	NS	s	s	NS	NS	NS	NS	_	-	_	-	_	-	-	-		_	-	-	_	-	-					
Control ^c																	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Intervention ^c																	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
PPS ^b	NS	NS	NS	s	NS	S	s	S	s	s	s	S	s	s	s	s																				
Control ^c																	NS	NS	NS	NS	S	S	S	S	NS	NS	S	S	S	S	S	S	S	S	NS	NS
Intervention ^c																	NS	NS	NS	NS	S	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
HADS-A ^b	NS	NS	NS	NS	NS	NS	s	S	NS	NS	s	S	s	s	NS	NS																				
Control ^c																	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Intervention ^c																	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
HADS-D ^b	NS	NS	S	NS	S	NS	S	NS	S	S	S	S	NS	NS	NS	NS																				
Control ^c																	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Intervention ^c																	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
PS ^b			S	S	S	S	S	S	S	S	S	S	S	S	S	NS																				
Control ^c																									NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Intervention ^c																									S	NS	S	NS	NS	NS	NS	NS	NS	NS	NS	NS
ZBI ^b	NS	NS	S	S	s	S	s	S	s	S	s	S	s	s	NS	NS																				
Control ^c																	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Intervention ^c																	s	NS	s	NS	s	NS	S	NS	S	NS	S	NS	s	NS	NS	NS	NS	NS	NS	NS

Table 5.19 Comparison of ITT analysis and PP analysis of SM, PPS, HADS-A, HADS-D, PS and ZBI

SM = Symptom manifestation, PPS = Palliative performance scale, PS = Patient Satisfaction, HADS-A = Hospital Anxiety and Depression Scale – Anxiety, HADS-D = Hospital Anxiety and Depression Scale – Depression, ZBI = Zarit Burden Index

^a Independent t-test, ^b two-way RM-ANOVA, ^c one-way RM-ANOVA

NS=non-significant difference, S = significant difference

5.4 Summary of Preliminary Quantitative Effects of the TRPP

The third section of this chapter has presented the results of data analysis of a series of dependent variables, showing that the patients in the intervention group, who received transitional care through regular telephone follow-up and periodical home visits, had a significantly lower readmission rate, shortened LOS, less attendance of AED, better management of symptoms, improved QOL, improved physical function, less anxiety and depression, increased satisfaction with care and less burden of the caregiver.

5.5 Summary

This chapter covered five aspects of the outcomes of this trial, namely the feasibility of study methodology, the feasibility of interventions, the acceptance of intervention, the preliminary effects of the transitional renal palliative care and the fidelity of the study. This chapter presents validation studies on the three questionnaires that were adopted as a measurement to collect data for evaluating the effects of interventions, including health-related QOL, selfefficacy and patient satisfaction. The background section explains the importance and overall aims of these validation studies. Following this section, an overview of the study design is depicted before giving a detailed delineation of the specific background and objectives, validation procedures and results of each of these three validation studies. At the end is the conclusion section.

CHAPTER SIX: DISCUSSION

6. Introduction

This chapter contains three major sections discussing the results presented in Chapter five in light of the previous literature and the features of the TRPP. The first section focuses on the feasibility and acceptability issues of the pilot study, including the feasibility of the recruitment process, acceptability of intervention and follow-up, and feasibility of outcome measures. The second section of this chapter discusses the preliminary effects of interventions on health services utilisation, QOL, symptom intensity, physical function, psychological stress, satisfaction and burden of the caregiver. The features that make the intervention work will be discussed in the third section.

6.1 Feasibility and Acceptability of the Pilot Study

Palliative care is regarded as an important component of treating a life-limiting disease. Rigorous clinical trials in palliative care are needed to build up the palliative care evidence base. To our knowledge, the present study is the first in Hong Kong to investigate the feasibility of a TPC program to support patients with ESRF discharged from hospital to home. The findings of this pilot RCT achieved one of the proposed goals in identifying the feasibility of conducting a TPC program among patients with ESRF which will be discussed below.

6.1.1 Feasibility of the recruitment process

6.1.1.1 Referral/ screening for eligibility

This study adopted the original referral system of the study hospital. The sampling was mainly from doctor initiated referrals of their ESRF patients to the palliative care team. The referral

rate of approximately six patients per month was similar to that of the pre-study period, but the eligibility rate was low. The recruitment period lasted for 26 months.

The eligibility screening rate was 48.71%, which was compared with Blue et al. (2001) with 54.29%, yet it was lower than Wong et al. (2011) with an 84.69% eligibility rate. On the other hand, the exclusion rate of 51.28% in this trial was lower than various RCTs including Saleh et al. (2012), Ng et al. (2018), and Ahmed et al. (2015) with an exclusion rate of 90.37%, 78.14% and 73.53% respectively. The subjects excluded from this study accounted for 18.59% with cognitive impairment, 32.05% being elderly home residents and 0.64% because of the language barrier.

Among the 80 participants excluded from this trial, 29 patients (36.25%) had cognitive impairment and were incapable of communication. This is a commonly anticipated problem for ESRF patients, given that renal impairment is associated with cognitive deterioration (Da Silva et al., 2014; Kurella et al., 2006; Kurella Tamura et al., 2011; Yaffe et al., 2010). Fifty patients (62.50%) were elderly home residents. Informal caregivers of patients with ESRF play an important role in providing prolonged substantial care for their sick relatives, often with unsatisfactory support or very limited resources, making it a difficult situation. The impacts of palliative care are not well known to the public. Another rationale behind this is the perception of the severity of the illness of the interceptive admission. Family members were not competent to be the informal carer. They found no other access to support from their family members or the healthcare system. Given that the living environment with a nuclear family was not favourable for a few generations living in the same house, many of the patients were placed in an institution for continued care. One patient (1.25%) was a foreigner who could not communicate in Cantonese. The eligibility rate was low in this pilot study because of the issues of cognitive impairment and elderly home residents, which were taken into

consideration in the study design, but their proportion in the eligible population that could be included was overestimated.

For the referral and screening process, it is crucial to have physicians cooperate in facilitating the recruitment of patients for palliative care study. Hence, eligibility criteria must be clear, unbiased and easily grasped by recruiters and referring clinicians. To determine the eligibility criteria for the patients, appropriate training of healthcare professionals is helpful to avoid the low referral rate. In addition, staff promotion is deemed to increase understanding of palliative care and encourage earlier and wider engagement (Yip et al., 2021). It is suggested that pocket cards, leaflets, posters or flyers with eligibility criteria translated into lay language are helpful for recruiters to recognize eligible subjects.

6.1.1.2 Recruitment

Randomised controlled trials (RCTs) in palliative care often encounter challenges in participant recruitment. This study demonstrated a recruitment rate of 100%, which was higher than other studies. For example, insufficient recruitment of participants has been identified as a challenge in the majority of palliative care studies (Rinck et al., 1997) because of the additional vulnerability of participants with progressive advanced clinical conditions (Hsu et al., 2013). The challenge is even greater for Chinese participants because of cultural constraints such as death and dying being taboo subjects (Hsu et al., 2013). Palliative care research faces significant problems in patient identification and enrollment in clinical trials. Difficulties in the recruitment of patients are locating trial-eligible patients and those with advanced conditions (Hansn et al., 2014). Nearly half (47%) of the patients with ESRD in a multi-site RCT had refused participation due to the declining condition and severity of their disease (Brickey et al., 2020). Similarly, a palliative care clinical trial (LeBlanc et al., 2013) reported that the patient feeling too sick was the most commonly cited answer for refusal of

study participation. Some patients often view randomization as a loss of control and prefer their doctors to prescribe their treatment (Jenkins & Fallowfield, 2000; Sheridan et al., 2020). The above-quoted findings were commonly encountered during the process of recruitment in this trial. Effective strategies are crucial in the successful recruitment of participants and were well planned in terms of face-to-face recruitment and a clear explanation of the aims and objectives of the trial.

Research is necessary to build an evidence-based bank in guiding high-quality palliative care and the adoption of appropriate interventions to maximise the health outcomes for the patients and their families with a sufficient number of participants to increase the scientific validity (Aoun & Nekolaichuk, 2014). In palliative care, enrollment of participants in RCTs is challenged by the serious clinical conditions of the patients who have irreversible and advanced illnesses that are life-limiting (Hussainy & Marriott, 2009). Patients and caregivers become physically and emotionally vulnerable in facing the declined condition. Hence, palliative care-related studies are seldom performed with less than 1% of clinical trials and seriously sick patients are excluded from other studies (Gibbin et al., 2012). This study contributes to filling the knowledge gap because of the few studies conducted.

As the TRPP is integrated into routine palliative care, patients might benefit from the innovative health measures. However, potential unremarkable effects are anticipated from customary palliative care which is the basic care for all the patients even if they are not participating in the study all patients who were approached agreed to participate in this study (excluding patients who did not meet the inclusion criteria which may have resulted from several reasons). Before the agreement to participate in the study, a face-to-face recruitment procedure with a clear explanation of the study was provided to each potential patient and family caregiver by the research student investigator.

In this trial, participants anticipated the benefits of interventions of transitional care, yet, they still participated in the study because there was no deprivation of health care even if they were randomised to the control group and received the customary care. The most important motivation for the participation of the RCT in TRPP was their long cherishing hope that other patients could benefit from the interventions. Some participants expressed that research participation provided them with a "sense of purpose" and "meaning to life" which is consistent with Bloomer et al.'s (2018) study findings. Such evidence would be valuable when educating healthcare professionals and patient families to overcome the barrier of palliative research in subject recruitment.

In addressing the difficulties of recruitment of participants for palliative care studies, various approaches have suggested some success. For example, Ngune et al. (2012) and Kinney et al. (1998) have suggested that physician involvement and recruitment of participants in their clinics are the most important and effective recruitment strategies. Furthermore, physician recommendations and referrals to research studies have also had a strong and positive effect on participation (Avis et al., 2006). This RCT adopted face-to-face recruitment with a clear explanation to attain the remarkably high recruitment rate. The approach of physician engagement and referral was adopted in this study.

6.1.1.3 Attrition rate

Attrition is common in palliative clinical studies. No participant initiated withdrawal from the study but the attrition rate was high (52.6%). The main reason for withdrawal from the study was the high mortality rate of the participants, at 39.5%, higher than the general mortality rate of approximately 30.0% in non-dialysis CKD patients. Comorbid cancer was reported in 7 of 30 deaths (9.2%), which may have contributed to high mortality. Furthermore, there was a

significant difference in mortality between the control and intervention groups (50.0% vs. 28.9%), which may relate to the effects of the TRPP. In projecting the sample size of the palliative care study, the high mortality rate of this pilot trial provides reference data for the estimation of the attrition rate of non-dialytic CKD patients.

The second most common reason for attrition from the study was that the participants moved to elderly homes (9.21%) as their family caregivers were no longer able to take on the caring role either physically or psychologically in facing the patients' fluctuating clinical progress.

Family caregivers were primarily responsible for caring for a community-residing family member with ESRF and providing help with activities of daily living (ADLs). Same-generation caregivers (spouses or siblings) are prone to perceive that caregiving is their duty. Schulz et al. (2012) found that 60% of spousal caregivers and 51% of adult children respectively reported that they had no alternative to taking on the caregiving role. Among the informal caregivers, same generation caregivers felt that they were more responsible for caregivingance for caregiving than next-generation caregivers. These same-generation caregivers are at a higher risk of age-related physical and cognitive declination, and some level of disability (Schulz & Sherwood, 2008).

Numerous evidence-based studies have further documented the psychological and physical health effects of caregiving, appraised caregivers are at risk for unfavourable outcomes, and developed a scope of strategies to meet the needs of caregivers and assist them to stay healthy and delivering quality care to their patients (Roth et al., 2015; Schulz et al., 2020). Informal caregivers are expected to embrace a high level of stress when they lack sufficient internal (e.g. information, skills and coping strategies) and external (e.g. finance, assistance from another family member, formal care) resources to cope with caregiving situations (Gibbons

et al., 2014) resulting in them giving up the role of caregiver. In facing the fluctuating condition and complex symptom distress of the patient, and unmet needs of psychosocial support of family, caregivers found themselves incapable of being the primary carer of patients who were alternatively cared for by the staff of an elderly institution home. This might explain why 9.21% of the subjects were moved to elderly homes during the process of the study.

Another 3.95% of participants shifted to dialysis therapy in this trial. They were comparatively younger (51 - 65 years of age) among the population of ESRF and received acute dialytic therapy in embracing acute episodes of pulmonary oedema with the prevalence of acute fluid accumulation. Their decision to shift to dialysis therapy tended to be influenced by the encouragement of their family members. There is no study concerning ESRF patients with palliative care shifted to dialysis therapy for reference. Instead, as patient-centred care aimed at alleviating dialysis distress, the study by Grubb et al. (2014) emphasised a palliative approach to dialysis patients with limited life expectancy.

The challenges of recruitment and retention of participants in research on palliative care patients with advanced disease do exist. Potential high attrition rates need to be considered in any palliative care research when determining the sample size (Preston et al., 2013). Sometimes, oversampling is warranted (Mazzocato et al., 2001) because of the anticipated large number of withdrawals, which is a common and particular problem in longitudinal palliative care studies. In this trial, we aimed to recruit at least 60 patients and caregiver couples for the power of data generalisation. Given a high probability of attrition, we finally recruited an additional 20% for such anticipated attrition (Hulbert-Williams et al., 2019) to balance the high attrition rate observed during the study.

6.1.1.4 Summary of the feasibility of the recruitment process

The features of the engagement of physicians, face-to-face recruitment, and clear explanation to the patients attributed to the success of the feasibility of the recruitment process. Several ideas on the recruitment process in this pilot study were noted. The low eligibility rate for palliative care services may be related to the indication and targets of renal palliative services that may not be familiar to some patients. Education of palliative care for the patients as an alternative treatment plan is deemed necessary for patients with end-stage organ failure.

6.1.2 Acceptability of interventions: prospective, concurrent and retrospective

During the process of interventions, participants accepted the interventions provided with good treatment compliance. Sometimes, some participants would be proactive to clarify some of their queries related to health problems. The process of implementation of interventions was uneventful according to the planned study protocols and guidelines. No participant refused the assigned interventions. Participants were satisfied with the protocol-driven interventions. No adverse clinical conditions were reported in the pilot study. As for the retrospective perspective of acceptability of interventions, the participants revealed positive feedback towards the TRPP with a high satisfaction rate. They related the TRPP as a worthwhile service from which they benefited. A more detailed discourse of acceptability is provided below.

6.1.2.1 Frequency and duration of the post-discharge follow-up

In this pilot study, the first post-discharge medical follow-up was arranged in the first four weeks and subsequent follow-ups were arranged at bi-monthly intervals unless specified for some patients. All participants followed the schedule of follow-ups without the indication of a need for increasing follow-up frequency or earlier appointments. The frequency of telephone calls was once per week between the home visits. The duration and frequency of

telephone calls were appropriate and was able to math with nursing follow-up, patient education, and provision of advice. Patients welcomed this mode of follow-up and no participant refused the telephone follow-ups.

A home visit was arranged for each participant within 72 hours after discharge from the hospital for early identification of problems and provision of support. In the first home visit immediately after discharge from the hospital, a comprehensive assessment including physical, psychological, and spiritual assessment was further conducted to identify newly developed symptoms and evaluate progress. The duration of the first home visit was about 1.5 hours. The subsequent home visit was about 45 minutes to one hour. Again no participant refused or objected to the home visit arrangement.

6.1.2.2 The acceptability of self-management of disease

One of the features of transitional care is the involvement of self-management in the context of palliative care, which aims at equipping patients and caregivers to manage symptoms of disease, fulfilling life roles and facilitate adaptation to the changing condition brought about by the progress of illness (Davidson et al., 2012; Ng et al., 2016).

TPC services favour patients to stay at home as long as possible (Kwok et al., 2008; Saleh et al., 2012). Effective symptoms self-management could decelerate disease progression (Shah et al., 2021). Disease-specific knowledge is critical for health literacy which is indispensable for effective self-management of CKD. In this pilot RCT, less text health literacy was designed and developed with eye-catching diagrams because 18.5% of the participants were illiterate and might find difficulty in reading.
Patient education is recommended as a key component of the concept of self-management for chronic disease patients (Giddens, 2015; Glasglow, 2003) with the attainment of knowledge and skills for the enhancement of treatment compliance and clinical outcomes (Glasglow, 2006). As a result of good patient empowerment, participants managed their symptoms effectively which was linked with reduced utilisation of AED services (Gustafsson et al., 2016) as shown in this study.

The NCM enabled the patient to optimise his/her self-management so that his/her health, as well as the QOL, was improved in this study. The level of compliance to interventions necessitated close monitoring and frequent follow-up by the NCM who knew the participants well and solved problems through continuous communication.

Patient education in this trial was aimed at promoting self-management of ESRF. The informal caregivers were also encouraged to participate in a training program that covered the knowledge and skills of care.

The content of educational information (Appendix 23) was prepared and distributed to each patient before discharge or in the first outpatient clinic consultation. The main focus of the educational information was to facilitate the self-management of common signs and symptoms of renal failure. In this trial, all support services were individualised and tailored to each patient's motivation and readiness. The basic low-intensity interventions were taught to all participants to master commonly anticipated symptom distress.

6.1.2.3 The feasibility of compliance with interventions

Adherence is a continuous and dynamic behavioural process in which the effects of any intervention are greatly influenced by a preference to change (Sabate, 2003). Rosen et al. (2007) show that non-adherence to medication leads to negative health effects, resulting in hospitalisation. Patient compliance is difficult to achieve especially if the patient has a chronic health problem that needs sustainable compliance with the treatment prescribed, especially for patients with a life-limiting disease, the treatment is complex and far-ranging (Jin et al., 2008). Uncontrolled symptoms usually end up with emergency remedial care or management in the hospital. Long-term behavioural adaptation will consequently be attributed to treatment adherence. Hence, patient-centred education and training in self-management will facilitate symptom control and improvement of clinical effects. The non-adherence to treatment was noted in a few patients related to the self-adjusted dosage of antihypertensive drugs. Overall treatment compliance was noted as high in the intervention group. Through counselling with the NCM, their difficulties were solved and non-compliance was limited.

6.1.2.4 Summary of the feasibility of interventions

To sum up this section, the protocol-driven interventions provided encouraging results which could be applied to optimise the care path for transitional renal palliative care for the ESRF patient population. The results showed that the participants readily accepted the transitional interventions.

6.1.3. Feasibility of outcome measures

The measurement tools were generally feasible. Both quantitative and qualitative data were collected. Mode of data collection, application of instruments, data management, and data analysis were carried out according to the study plan. These measurement tools could be adopted for further study on the population of ESRF patients with palliative care.

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6.1.4 Summary of the feasibility and acceptability of the pilot study

There is strong evidence supporting the feasibility of the design of this pilot study. The high attrition rate was noted due to the high mortality rate which is congruent with the characteristics of ACKD. In conclusion, the summary of the results on the feasibility and acceptability reflected that further improvement or readjustment in the future main study is needed such as the shortening of the intervention period to 6 months, adjusted estimation of the proportion of non-eligible patients with cognitive dysfunction and residents of elderly homes.

6.2 The Preliminary Effects of the TRPP

Transitional care consists of a set of activities or services planned to ensure the appropriate coordination and continuity of health care as patients transfer between different locations with optimal communication (Hirschman et al., 2015). Despite the availability of validated treatment protocols, the appropriate approach to care delivery is also critical and was tailor-made for patients with ESRF in this trial. In the provision of sophisticated and comprehensive patient care, the care coordination approach, and collaboration between different healthcare providers are well demonstrated by the NCM in the process of continuous care delivery. Nelson & Pulley (2015) asserted that the content of optimal transitional care includes coordination and arrangement of post-discharge care support in a home setting, facilitation of communication among healthcare professionals, patients and their families as well as providing education to patients and caregivers.

Participants in the intervention group gained remarkable benefits from the continuous follow-ups after discharge via telephone calls and home visits. The second characteristic of the design of this pilot study was the adoption of a nurse-led transitional program that efficiently maximised the therapeutic effects of telephone calls and home visits. Our study

results have shown positive evidence and provided significant implications for palliative care services, which can lead to a better QOL for elderly ESRF patients with multi-comorbidities.

With the involvement of self-management and the feasibility of compliance with interventions, the enabling factors including improved QOL, decreased symptom intensity, improved physical functions and satisfaction with care, decreased anxiety and depression and less caregiver burden, were strengthened, which may have contributed to the positive outcomes. Here below is a more detailed discussion of the findings with reference to studies in similar areas.

6.2.1 Demographic characteristics of the participants

In Hong Kong, the mean age for RRT patients was 60 years with 56% (more than 60 years) and 44% (more than 70 years) (Central Renal Committee, 2020). There was an increase in new incidents of 1,293 patients. A retrospective study (Xu et al., 2020) on the subjects with non-dialysis conservative care in the specialty out-patient department of the study hospital revealed that the mean age of CKD patients was 68.9 ± 10.9 years and the male gender accounted for 50.8%. With reference to comorbidities, 100% had hypertension, 44.1% had diabetics, 10.1% had a history of stroke, 9.4% had cardiovascular disease, and 2.1% had COPD. In this trial, the male gender accounted for 55.26% and the mean age of ESRF patients was 80.67 (\pm 9.13) which was higher than the general CKD population. The comorbidities of TRPP patients included hypertension (93.42%), diabetics (45.37%), stroke (9.21%), cardiovascular disease (26.32%), and chronic respiratory disease (23.68%), which were similar to Xu et als' study (2020). The demographic characteristics and clinical variables, except age, were comparable with the participants in this study and those follow-ups at the outpatient department in Hong Kong.

The demographic characteristics of the study subjects also share some similarities with the prospective study of Teruel et al. (2015) conducted among non-dialysis patients with advanced CKD from 2012 to 2014 in Spain. The mean age of participants was 80 ± 7 years, 48 male (63.16%) and 28 female (36.84%), and the median patient follow-up time was 165 days (168.5 days in this trial).

6.2.2 Effects on health services utilisation

Unplanned readmission in ESRF is a prime issue of concern for hospital administrators for its association with rehabilitation and healthcare expenditure. Whilst avoidable, readmission is costly and does not benefit the physical and psychological condition of the patients (Landrm & Weinric, 2006; Upadhyay et al., 2019).

6.2.2.1 Non-scheduled readmission

Readmission in patients with advanced kidney disease is common because of inadequate assessment with insufficient home-based support, declined clinical condition, and inadequate community support (Miller & Scbaper, 2015). This phenomenon commonly occurs among patients with ESRF as highlighted in the interviews that patients tended to attend AED once symptoms appeared. There were various possible reasons for non-scheduled readmission.

The high readmission rate among ESRF patients in Hong Kong imposes a substantial burden on the healthcare system and the issue of readmission was even apparent in patients with a first-year diagnosis of renal impairment (Wong et al., 2011). In addition, comorbidities such as cardiovascular disease, DM or cancer are associated with an increased rate of readmission. Rymer et al (2019) asserted that their patients with cardiovascular problems had a higher probability of being admitted to the hospital as compared with the general population with no cardiovascular disease. Our study showed that 93.42% of participants in this study (92.11% and 94.7% in the intervention group and the control group respectively) had the comorbidity of hypertension and they had a high tendency of readmission due to cardiac problems. In this trial, unplanned readmission was evidenced in the intervention group with fewer readmissions than the control group, 20 vs 37, p<0.01. The between-group differences in readmission were noted at T6 (p=0.02) and T12 (p=0.01). The effects of unplanned readmission were incongruent with the findings of Wong et al. (2016) with a reduced readmission rate of the group of heart failure patients. The promising results of fewer unplanned readmissions in the intervention group at 4-time points of this study were determined from the United States Renal Data System of 2013 (Collins et al., 2014) that 34% of ESRF patients were readmitted within 30 days of a hospital discharge without a transitional approach of pre-discharge assessment.

Frequent re-hospitalisations may result from poor management of problems due to preventable chronic illnesses (Kirby, 2010). A significant causative factor of re-hospitalisation is the insufficient pre-discharge preparation of patients and their families, especially for elderly patients who have multi-comorbidities and are discharged to their residence (Coleman, 2003; Lundereng et al., 2020). Other related factors of repeated hospital readmission are mainly due to unresolved symptom control, provision of fragmented home care services, lack of support for caregivers and complex needs related to EOL care (Thomas et al., 2020). A low readmission rate is attributed to appropriate pre-discharge assessment, good symptom control, appropriate self-management of symptom/health, less cause for emotional burden, improved QOL as well as improved satisfaction with care services, which are supported by the post-discharge backups and follow-ups.

As with various TC programs designed with multifarious characteristics, (Kirby et al., 2010; Jasinski et al., 2018; McCusker & Verdon, 2006; Naylor et al., 2017; Yu et al., 2015), this pilot trial was comprehensively developed and well-designed care plans which advocated low

complexity of self-care techniques and knowledge with the collaboration of patient empowerment and proper continuous guidance for patients in follow-ups. In accordance with the study of Jasinski et al. (2018), interventions of this study included assessment, interventive management, patient education, evaluation, and referral and demonstrated positive effects in minimising unplanned readmission. This study adopted heterogenic interventive strategies and various qualitative assurances were applied in the studies previously reviewed.

Non-scheduled readmission could potentially be avoided with a favourable approach to care such as better clinical coordination, a secured stable condition before discharge, adequate outpatient support after discharge, appropriate discharge planning, and provision of support at home that meets patient's demands (Landrum & Weinrich, 2006, Voss et al., 2011; Yam et al., 2010). It is an important goal to be able to identify the factors leading to avoidable readmission and to consider these factors when formulating relevant policy and planning patient care. The encouraging results of this trial can meet these service needs and demonstrate the practical validity of the implementation of the components of this TRPP.

6.2.2.2 LOS in the hospital

In the analysis of the primary outcome measures, the intervention group presented a shortened LOS during hospitalisation than the control group at 4-time points. Decreased length of hospitalisation brings benefits to the patients as well as to the hospital. The findings yielded from the study of Trtchounian et al. (2017) showed that a decrease in LOS would facilitate the achievement of the following outcome measures in (1) patient's satisfaction with palliative care, (2) prevention of suffering through aggressive symptom management, (3) avoidance of unnecessary re-hospitalisation and (4) decrease in healthcare cost, all of which were correlated with earlier initiation of palliative care consultation.

Numerous studies have demonstrated the merits of a transitional care system that included cost savings by the relief of symptoms, and reduced utilisation of expensive healthcare services such as in-patient consultation, and admission (Jack et al., 2009; Daly et al., 2005; Stamp et al., 2014; Wong et al., 2018); social partnership and patient empowerment (Wong et al., 2011); QOL and health behaviour improvement (Hannsen et al., 2007); emergency room visits (Blickem et al., 2013). Yet other benefits include an increased level of satisfaction (Lee et al., 2016) and improved living conditions with improved QOL for those with chronic illness coupled with progressive life-limiting disease (Brumley et al., 2007; Wong, et al., 2016).

6.2.2.3 Accident and Emergency Department (AED) attendance

In this pilot study, there was a significant difference in AED utilisation between the intervention group and control group during the intervention period (p=0.02 - p<0.001). Participants of the control group attended AED more frequently than those in the intervention group.

There has been an ever-increasing utilisation of AED for emergency services worldwide. The elderly more than 65 years old are the major increased population for AED services because older patients present with complex clinical conditions and multiple comorbidities (Lowthian et al., 2012). The mean age of the participants in this study was 80.67. \pm 9.13 years. Hence, training patients and family members as a way to enhance their knowledge of the early warning signs for relapse (Patel et al., 2020; Yam et al., 2010) is essential. Nursing and social services support, and good management of medication (Wong et al., 2011; Wong et al., 2020) was also asserted.

In conclusion, the TRPP showed promising effects on health services utilisation in this preliminary study. The strategies of telephone follow-ups and home visits, an alternative postdischarge care bundle aimed at high-risk elderly inpatients' decreased unplanned readmission within 30 days following discharge (Baecker et al., 2020; Stamp et al., 2014). The effects of interventions also lasted for a year in this study. The intervention group has had fewer unplanned readmissions as compared with the control group. The results of reduced readmission in this study echoed the pilot results of Chan et al. (2015) that suggested that intensifying post-discharge renal palliative care clinic follow-up reduced the utilisation of acute medical services. Collaboratively, decreased utilisation of healthcare services was illustrated in the intervention group in this study in terms of low readmission rate, shortened LOS in the hospital, and reduced visits to the AED.

6.2.3 Effects on health-related QOL

ESRF is an irreversible and advanced chronic disease. Patients with ESRF having a negative association with their physical and psychological well-being were evidenced in various studies. One of the objectives was to evaluate the improvement of QOL concerning the TRPP.

QOL can be applied as a measurement of the difference between the expectations of individuals and the reality of their lives (Bragazzi & Puente, 2013), as a predictor of hospital readmission and death among patients with organ failure (Rodríguez-Artalejo et al., 2005). Patients and families have to adapt to the changes and challenges encountered and change their expectations over time through the journey of facing the illness. Since personal experiences, expectations, and levels of clinical illness will alter over time, Malindretos (2012) and Ng et al. (2020b) recommended that continuous assessment of these health-related domains in the QOL is warranted. Continuous monitoring of QOL status assists in

anticipating clinical conditions. Hence, the periodic assessment of HR-QOL was utilised in the trial.

The QOL of the intervention group was substantially higher than that of the control group over the 5 domains of the KDQOL-36, HK. The KDQOL-36 measures the effects of TRPP in maintaining the optimal QOL of patients in the transitional phase of care.

The domains of perception of Symptoms Problems List were well demonstrated in the intervention group through post-discharge follow-ups and support. The intervention group demonstrated a sustainable improvement of better perception of symptoms and problems with the timely identification and treatment of symptoms with continuous support from the NCM, whereas, the control group evidenced a sustainable deterioration of perception of symptoms and problems at 4 time-points.

The domain of effects of kidney disease includes the perception of discomfort brought about by kidney disease including restriction in fluid intake and dietary intake, challenges in travelling, role function, and symptoms of kidney disease, dependent on healthcare providers, physical appearance, and self-efficacy (Schatell & Witten, 2012). In this study, both groups experienced remarkably mild effects of kidney disease which were sustained throughout the intervention period while the intervention group even experienced fewer effects of kidney disease in comparison with the control group at 4 time-points after recruitment into the study.

The improvement of the level of burden of kidney disease in the intervention group could be attributable to the success of transitional interventions to control symptoms and psychosocial support. The promising results were evidenced in the intervention group with a sustainable better perception of the burden of kidney disease at 4-time points.

The general domains of QOL of ESRF patients were assessed by the KDQOL-36 health survey. The results were consistent with Wong et al. (2010) that the KDQOL-36 survey demonstrated that the statistically significant effects included physical role functioning, pain and symptoms of kidney disease, social functioning and emotional well-being. The measurement tool was feasible in showing the efficacy in improving patients' emotional well-being after recruitment and was sustained throughout the 12 months. The results conferred the accomplishment of TRPP in improving the physical and psychosocial well-being of the participants. The QOL measures can provide meaningful results that can be incorporated and interpreted as an indicator for an assessment of patient care.

TRPP interventions affect QOL, which in turn can be affected by several variables including symptom controls, physical functions, psychological well-being and satisfaction with services. In addition, other variables may affect QOL, for instance, well-managed symptoms may relieve physical distress as well as a psychological burden in embracing the management of symptom distress. A normal physical functional status enabled the participants to have an independent lifestyle associated with fewer readmissions and a shorter length of hospitalisation. The results of KDQOL-36 were consistent with other studies (Chow et al., 2010; Tao et al., 2017) which were applied in the NCM approach to provide transitional interventions for the patient with ESRF.

In conclusion, there were statistically significant group differences in the five domains of the KDQOL-36 at 4-time points. The improved domains of QOL showed sustainable improvement during the intervention period.

6.2.4 Effects on Symptom Manifestation

ESRF patients with advanced illness are at risk of pain and suffering from multiple sources of symptom burden. The top five most prevalent symptoms reported in this trial are discussed in the following paragraphs. Symptom management is an essential aspect of self–care for CKD patients because engaging in the effective management techniques leads to improved clinical or patient-centred outcomes (Curtin et al., 2002; Fishbone & Spinowitz, 2018). Findings of this pilot trial demonstrated that participants in the intervention group had less symptom distress than those in the control group. The possible contributing factors are discussed in the following paragraphs with a focus on the management of the five top symptoms.

Fatigue was the top symptom prevalence in the pilot study, which is a subjective, unpleasant experience that extends from being tired at one end to being exhausted at the other. It is further persistent and affects people's abilities to function normally (Ahlberg et al., 2005; Joshwa & Campbell, 2017).

Self-management of fatigue is also significant for improving the QOL of ESRF patients. Patients learning and practising self-management of fatigue is essential to enhance the development of strategies and innovations that will facilitate the control of fatigue for patients with palliative care. In addition to the prescribed pharmacological treatment of anaemia, nursing input for control of fatigue is mainly and commonly focused on the reduction of energy consumption. Many causes of fatigue can be managed and QOL can be improved by appropriate coping mechanisms and modification of lifestyles. In this trial, participants were taught to organise activities in similar groups to be carried out within a short duration, without causing exhaustion. Intermittent rest was emphasised. On the other hand, initiation of pharmacological therapy was indicated with the evidence of an abnormally low level of haemoglobin. Anaemia can be managed with pharmacologic agents such as iron and Erythropoietin stimulating agents (Biggar & Kim, 2017). The nursing intervention focused on the self-injection of ESA, pre-injection monitoring, and the ongoing monitoring of side effects such as hyperkalemia, convulsion, and high blood pressure. Not only were both knowledge and skill of injection taught according to individual needs such as uncontrolled blood pressure, which is contra-indicated for injection of ESA, but ongoing monitoring of haemoglobin and the potential side effects of ESA injection were emphasised and maintained. Also, training of patients and family caregivers was provided with close monitoring in the transitional care services with effective clinical improvement (Biggar & Kim, 2017).

General weakness was the second most common complaint made by the ESRF patients in this trial. ESRF patients often have significant muscle weakness and lack of endurance. General weakness usually results in a sedentary lifestyle (Miller, 2019). Perception of weakness can overlap with anaemia, malnutrition, lack of exercise, and adverse effects of high uremia. Poor oral intake may contribute to poor nutritional intake with subsequent poor physical strength and activities.

Palliative strategies were stressed to improve appetite such as mouth rinsing before meals, preparing a favourable diet, providing an environment favourable for eating, and trying to calm irritated moods. The majority of the participants in this study were elderly and lacked exercise. All participants in both groups were assessed and supervised for physical activities by a physiotherapist after recruitment. To improve physical strength, gentle exercise and physical movement were encouraged and the extent of the exercise was increased gradually to enable the patients to achieve increased physical strength. Those with high morbidity or declined physical function were referred to a physiotherapist for the recommendation of appropriate exercise. Patients and family caregivers were taught about, not only different

ways of exercise but also how to sustain strength and energy in alignment with their deteriorating physical condition.

Pruritus is the third common symptom reported by the participants in this study. Uncontrolled pruritus may disrupt patients' QOL in terms of daily activity, social life, insomnia, loss of appetite, skin erosion, infection, and mental well-being. Both pharmacologic and nonpharmacologic measures are offered for optimal outcomes. Severe pruritus is psychologically associated with anxiety and emotional irritability. Common pharmacological treatments include hydroxyzine (Chater, 2000) and antidepressant, namely Sertraline (Shakiba et al., 2012). A patient may experience extreme itchiness of the skin at sleeping time. Nursing interventions include bathing the patient with no or minimal amount of soap, using moisturising oils in bath water or lotions, and avoiding products that contain alcohol or perfumes that may promote dryness and increase pruritus. In this study, participants who complained of pruritus were well managed with non-pharmacologic agents (Huizen, 2017 and appendix 20).

Oedema/fluid retention is the fourth commonly noted sign related to renal impairment. Impaired urinary excretion and continuous fluid intake result in oedema. Fluid retention may lead to swelling that occurs when too much fluid becomes trapped in the interstitial tissues of the body, particularly the skin. Oedema usually starts slowly, but the onset can be sudden. It is a common problem, but it can become a critical condition, especially in four limbs. However, it can also affect the muscles, hearts, lungs, eyes, and brain. There are many types of oedema in CKD. Each one can indicate a range of further health conditions. The most common types of oedema are peripheral oedema and pulmonary oedema. Peripheral oedema affects the peripheral limbs, and puffiness of the face and induces difficulty in moving parts of the body. Pulmonary oedema results when excessive fluid collects in the lungs which make respiration difficult. It usually results from either CHF or kidney impairment. Oedema can occur in other locations as well, but those mentioned above are the most common (Arumugham & Shahin, 2021).

For the management of oedema, the most common pharmacological treatment is the prescription of an anti-diuretic with or without electrolyte supplements (Arumugham & Shahin, 2021). Non-pharmacological remedies, such as compression stockings can help reduce swelling and discomfort of oedema of peripheral limbs. Likewise, some non-pharmacological measures (Mayo Clinic staff, 2014) (appendix 20) are adopted for fluid retention resulting from kidney dysfunction of ESRF. Furthermore, in attempting to remove the excess fluid in the pulmonary tissue, oxygen may be used to treat an individual with cardiogenic pulmonary oedema who may need additional oxygen if they have difficulty in taking enough oxygen. Several incidents of early recognition of oedema were noted by the NCM with the adoption of timely management to solve the problems. The non-invasive management of oedema can be generally fulfilled by meticulous self-management. Participants were instructed on how to identify, prevent, and manage a mild degree of oedema. Hence, the participants with telephone follow-ups and home visits were more competent in mastering the issue of oedema.

Intolerance to cold is the fifth most commonly reported symptom in this pilot. With the apprehension of anaemia, malnutrition and lack of physical activity, patients frequently complain of intolerance to cold. The correction of anaemia usually improves the symptoms. Body temperature is regulated by several physiological systems. Cold intolerance can be the result of inadequate heat intake due to problems with heat regulation by the hypothalamus and thyroid gland or poor health status (Olsson, n.d.). Cold intolerance is a symptom of an underlying condition. The treatment will depend entirely on the diagnosis and the causes of

cold intolerance. The top symptoms identified in this study were consistent with Yong et al. (2009).

The intervention group presented fewer symptoms than the control group throughout the intervention period with effective symptom management, which was congruent with Brown et al. (2015) in that the transitional care programme effectively managed symptoms for non-dialytic ESRF patients. It was the rationale of the study intervention involving the component of self-management aiming at better control and management of physical symptoms. Adherence to the treatment regimen in the attempt to prevent symptom distress through self-management behaviour will contribute to the control of symptoms in chronic disease.

In a study by Murtagh et al. (2011), there was a phenomenon where a sharp increase in symptom distress and health-related concerns were reported by the older ESRF patients in their last two months before death with conservative treatment. Although this study didn't investigate the symptom intensity at the late phase of life before death, participants in both groups reported the highest scores in SM at T12, the end of 12 months of follow-up after recruitment. Hence, healthcare professionals should sensitively anticipate their increased symptom distress and provide related care and support to patients who are clinically indicated as approaching death (Murtagh et al., 2011). Regular assessment of both symptoms and QOL is warranted particularly if clinical experience indicates that the person is likely to be in their last year of life, whereas integrated palliative care programs could assist with easing the symptom burden during this critical period (Bonner, 2018).

6.2.5 Effects on physical function

In this trial, there was a significant group and time interaction effect on the physical functional status of non-dialytic patients with ESRF, and the intervention group generally remained

stable until the last month or week of life, while patients in the control group showed a trend of decline in physical function. With the impact of an individualised care plan and ongoing assessment, participants in the intervention group presented better physical function than the control group.

The requirement to meet individual needs is indicated because patients with ESRF have high rates of symptom distress such as fatigue, itchiness, weakness, oedema, intolerance to cold and chronic pain. Cultural issues with a significant impact on perceived distress should be considered in assessing physical function. In this study, culturally sensitive and individualised care plans were tailored to meet the needs of participants to relieve the physical, psychological, and existential suffering of CKD.

Participants in both control and intervention groups maintained a sustainable physical functional state until at T6 and T12 with the progression of clinical condition, the intervention group revealed better physical function as compared with the control group. Swidler (2012) conducted a retrospective study and concluded from the data that there was a phenomenon of abrupt functional decline in the last month of life of patients in a palliative care unit, which indicated the likelihood of a shorter life span in palliative care patients and this prediction was considered as reliable. The results of another study (Murtagh et al., 2011) indicated the phenomenon of a steep decline of functional status in the last month of life while it had remained stable for the last year of his life. This has important clinical implications for healthcare services which need to have a timely response to meet the changing needs of the ESRF population as their functional status declines in the last month or last week of their life (Murtagh et al., 2011).

It is common to note that patients' needs may alter over time. Hence, continuous assessment of physical function and QOL is crucial to identify their needs and implement appropriate and timely interventions. Participants in the intervention group attained a higher physical competence scale which might be related to better symptom control and improved QOL.

6.2.6 Effects on anxiety and depression

The characteristics of kidney dysfunction affect the multi-systems of a patient with ESRF. In aiming at better clinical and patient-centred outcomes, patients were requested to comply with treatment and the application of self-care management at a home-based level. The treatment adherence to ESRF added patient responsibilities which may negatively affect ESRF patients as reflected in numerous studies that patients have poor QOL and mental health distress in terms of anxiety and depression (Borglin, 2006; Demura, 2003; Nilsson, 2006). Apart from the benefits of fewer healthcare expenses, the physical and emotional well-being accompanying reduced readmission was the main focus of patient care provided to this group of ESRF patients. The most important was the initiation of less emotional burden as evidenced by the experiences of participants.

Depression is more prevalent in CKD (Goh & Griva, 2018; Ortiz et al., 2012), while cognitive dysfunction and depression are the common mental disturbance in elderly ESRF patients (Ortiz et al., 2012). Rodrigo et al. (2013) found that a large percentage of patients suffering from CKD had symptoms of moderate to severe anxiety regardless of demographic variables (gender, age, financial status, stage of CKD, and mode of treatment). In addressing the socio-demographic issue, the findings of Theofilou (2011) provided evidence that socio-demographic variables like being older, less educated, divorced/widowed, and female gender presented higher scores of anxiety and depression. The majority of participants being a mean

age of 80.67 ± 9.13 in this pilot, was postulated as one of the suspected causes of anxiety and depression. Yet, it was not the case in both groups of this trial.

The human body can deal with the regular day-to-day stress that most people endure. However, having CKD, especially ESRF, can add many serious stressors on top of the normal daily activities that our bodies are equipped to manage. These additional stressors include financial problems, social issues, treatment compliance, dietary constraints, and the disease itself. Depression in ESRF patients has become prevalent and correlated with lower QOL (Cukor et al., 2007), greater medical comorbidity and decreased survival (Rosenthal Asher et al., 2012; Shirazian et al., 2017).

A self-administered questionnaire (HADS) was adopted in the screening of anxiety and depressive symptoms in this pilot. Each subscale of anxiety and depression is summed up separately providing a sum of 0-21. A score of 7 or above is considered abnormal (Zigmond & Snaith, 1983). The participants in the intervention group encountered less anxiety (p<0.001) and depression (p<0.001) than those in the control group. The anxiety score of the control (3.03-4.08) and intervention (1.76 – 3.89) groups indicated both groups in the current study experienced a normal level of anxiety with a statistically significant difference in T6 between the two groups.

The depression score of the control (4.53-5.89) and intervention (2.55-4.63) groups reflected those participants in both groups experienced a normal level of depressive stress too. Yet, the intervention group revealed an extremely low level of depression as compared with the control group at 4 time-points after interventions (p<0.001 to p=0.04).

In the process of assessment, the participants were asked to recall their psychological status in the previous 4 weeks. It is a challenge for non-dialytic ESRF patients as their memory is compromised. Thus, the score of anxiety and depression may be under-estimated. However, this measurement tool is not a diagnostic tool, instead, it is used as a preliminary device to identify the apparent high level of anxiety and depression.

Uraemic patients are easily and mistakenly diagnosed with depression using a self-reported questionnaire. The study also indicated that the application of HADS for assessing a depressive disorder does not guarantee the most accurate cut-off score as there has always been a coincidence of somatic symptoms of depression and the ESRF related symptoms including fatigue, difficulty or inability to concentrate (Drayer et al., 2006). Hence, taking the suggested approach of Shirazian et al. (2017), the report could be verified by adopting a supplementary clinical interview which is recommended for diagnosing depression in ESRF patients. There is a significant concern for understanding the emotional experience of ESRF patients, which includes anxiety, worry, fear of progression of kidney disease, and physical trauma (Goh & Griva, 2018). Clarke et al. (2016) interpreted the results of some studies that CKD patients receiving palliative care have symptoms of depression and anxiety that are not true reflections of their health status but are a sense of perception of illness. Depressive symptoms are associated with the progress of the disease.

To a certain extent, a low level of anxiety is favourable for awareness and sensitivity for the competency of day-to-day self-management of the disease, yet too much stress resulting from uncertainty, knowledge deficit, expectation and challenges, contributes to depression. The anxiety level was assessed continuously at an eight-week interval during each out-patient follow-up. Interventions and referrals for expertise management were made when a higher anxiety score was noted in this trial. This may be one of the contributing factors that

participants in both groups presented a normal degree of anxiety and depression; while only one participant in the control group was referred to a psychologist who provided expert management and the conditions were well managed without further deterioration. The relationship between anxiety and depression was not included in this study, but it is a critical context that needs to be investigated in the future.

ESRF is an advanced irreversible chronic illness that leads to a persistent decline in organ function and impaired QOL. During the late phase of palliative care, the level of anxiety and depression will increase following the declined clinical condition in the late phase of the lifespan. Similar to Weissman et al. (2010), several domains of care in TRPP included leading to patient goals of care, physical, psychological and spiritual symptom management, and various types of support to patients and caregivers. Given the high prevalence of advanced age, comorbid conditions, and high mortality rates among the ESRF population, we attempted to optimise their QOL by anticipating, preventing, and treating psychological distress.

6.2.7 Effects on satisfaction with care

Patient satisfaction is an important and commonly adopted indicator for measuring quality in the healthcare setting. The response of patient satisfaction reflects the perception of the patient which affects clinical outcomes, and patient retention (Prakash, 2010). The key elements of patient satisfaction illustrated in the satisfaction questionnaire include mode of services, the attitude of the healthcare providers, explanation of instruction, written information (pamphlet), and quality of patient's services arrangements.

Satisfaction with patient care is multifactorial and sophisticated (Johansson et al., 2002). The findings of a qualitative study (Seccareccia et al., 2015) evidenced that communication was the most important theme regarding the quality and satisfaction of palliative care. Recently,

Wentlandt et al. (2016) expressed that the key elements of a patient's satisfaction with palliative care are related to the QOL. Firstly, an inter-professional team that comprises different disciplines functions as a whole team for patient care. Secondly, appropriate communication facilitates the development of rapport between healthcare providers, patients, and their families, assists the EOL discussions, and so on. Thirdly, Palliative care including physical and psychosocial contexts should be individualised, well-coordinated, and respect patient perspectives in terms of attentive follow-up reactions (Henderson et al., 2004). Fourthly, family-centred support should be available to patients, families, or caregivers. Fifthly, it is important to have adequate and accessible resources. Lastly, the clinical settings should be free from the institution with disclosure and resocialization (Wentlandt et al., 2016). All these attributes to the high satisfaction of patients towards the health-related QOL are warranted.

The transitional intervention care, which is closely related to fewer hospital readmissions and decreased emergency department attendance in this trial has demonstrated a considerable impact on clinical outcomes and enhanced patient satisfaction. The results were congruent with the studies among patients with chronic and advanced diseases (Brumley et al., 2007; Naylor et al., 2004; Wong et al., 2012; Wong et al., 2013; Wong & Yeung, 2015). Participants in the intervention group revealed significant satisfaction compared with those in the control group (p<0.001) at all-time points after recruitment. The design of palliative care services is consistent with key elements of patients' satisfaction. The higher satisfaction of care attained in the intervention group has reflected the significance of the interventions provided, which include the empowering experience of clear patient education and useful low-complexity skills gained by the participants.

Besides, the essential attributes of transitional home-based palliative care models were communication and coordination between providers, enhancement of skill, and response capacity to meet changing needs and preferences of individual patients (Luckett et al., 2016). The impact of communication is crucial in providing TRPP and its effectiveness is closely related to the extent of satisfaction of care of the participants. In this pilot study, the NCM acted as a patient advocate, counsellor, and health collaborator who communicated between patients and all healthcare providers. The qualitative data revealed the proficiency of NCM in both health information and practical skills.

The extent and the implications of communication have not been explored in this trial. Patient satisfaction is an attitude that is a strong motivating factor. Quality patient service does not stand still but is always enhanced. Hence, one should endeavour to provide better patient care and exceed patients' anticipations.

6.2.8 Effects on the burden of family caregivers

Caregivers embrace a considerable level of stress burden. The caregiver burden was great in this study sample as assessed by the ZBI [control group scored 29.39 (±12.21) and the study group scored 26.45 (±8.54)], a score of 17 or more being considered a high burden. However, there is no conclusive data from RCT studies for reference in assessing the caregiver burden in transitional care services for reference. Caregivers embrace a considerable stress burden in the process of their role. The caregiver burden increases significantly as functional and cognitive impairments imposed by CKD limit the ability of the patient to care for himself (Gayomali et al., 2008). Regardless of the type of the disease, caregiver burden is a multidimensional phenomenon affecting caregivers physically, emotionally, and socially (Verma et al., 2016). As Adelman et al. (2014) pointed out caregivers' health should be enhanced since the health of the patient depends on the quality of home-based caregiving.

Being the caregiver of CKD patients can be very stressful. Depressive and anxious feelings and burdens are often expressed in the population of ESRF and they are interrelated (Van Wijnen et al., 2017; McCullagh et al., 2005; Shaffer et al., 2016). There were significant and strong relationships between patient emotional HRQOL and caregiver mood state (Hodges, et al., 2005; Northouse et al., 2000; Shahi et al., 2014). This supports the need for interventions that address both patient and caregiver emotional status.

Caring for a dependent person is linked to a series of burdens that often lead to physical, psychological, and emotional difficulties for the caregivers. The emotional status of the caregiver will be modulated by the physical, psychological, and emotional stages of the patient. The participants in the control group had poor symptom control, a high level of depression, and anxiety with lower scores of QOL in this study. Simultaneously, informal caregivers have to embrace all these unfavourable clinical outcomes of their family patients.

Providing care by a family caregiver is described as attending to the needs of the patients, accompanying the patient to attend the doctor's appointments, helping with the administration of medication, coordinating with housework, cooking, feeding, general hygiene and ADL. Healthcare professionals should enable informal caregivers to support and make small tasks easier, thus capacitating their competency and reducing their exhaustion.

6.3 Features of TRPP

Palliative care is regarded as an important component of treating a life-limiting disease. The decision to choose palliative care over dialysis can be a positive option not only for ESRF patients but also for their health care system and community. The palliative care approach has proven to be beneficial for end-stage organ failure patients (Wong et al., 2016). This pilot

trial also provides evidence to confirm the beneficial effects of a TRPP as compared with routine care. What are the features that make the interventions work?

6.3.1 A comprehensive approach to TPC

The design of TRPP encompasses the integration of the approaches of the 4Cs transitional care model into palliative care, evidence-based protocol practice and the OS as the framework of communications among the multidisciplinary care team (details in Chapter 4 Development of the conceptual framework of this study). The findings of previous transitional care studies showed that successful interventions seem to incorporate the 4Cs approach of comprehensiveness, continuity, coordination, and collaboration. The NCM functions in multiple roles with the support of the multidisciplinary team in meeting the needs of patients in the process of delivery of care, which is fully exhibited in adopting the 4Cs approach in care delivery.

At the system level, the approach of NCM has been reported to contain health costs through different roles taken by NCM such as assessors, interventionists, educators, collaborators, facilitators, and patient advocators (Scott, 2017). The multifarious roles enacted by an NCM were pronouncedly reflected by the clinical outcomes and experiences of the participants. Nurse-led care has largely shown a positive impact on patient outcomes, patient satisfaction, access to care, and mixed results on cost-effectiveness (Randall et al., 2017). Fragmented care was diminished with the continuity of care approach and care coordination provision.

The professionalism, clinical competency, and nurse dose were well described in this trial, which added important insights to the current discussion on the possibility of implementing an NCM approach care program for chronic disease (Yip et al., 2021). The findings of this study can add to the knowledge base of a transitional care program. The dose of nursing is

greatly associated with the clinical outcomes as well as the confidence of the participants. For instance, the assessment and identification of symptoms play a pronounced role in the early identification of problems and subsequent interventions. The claim is grounded in the fact that the improvement of clinical outcomes exceeded the levels suggested in previous research as did the improved physical function and satisfaction with care. There was no adverse event reported throughout the program implementation period.

Besides, more successful outcomes were concluded by the adoption of an APN to carry out interventions with the evidence-based protocol for consistency of care practice. The NCM spent considerable time educating patients about the disease trajectory, the potential treatment regimen, and the significance of frank communication of updated clinical conditions. The knowledge acquired enabled the patients and families to understand the patient's situation and the required treatments. There was a tremendous improvement in the knowledge deficit and the uncertainty of the process of therapy. In addressing the context of self-care management, the NCM can execute the transfer of knowledge and skills to both patients and family caregivers which enables them to carry out day-to-day self-care.

6.3.2 High-quality care provided by specialty NCM

The challenges in caring for patients with ESRD are to deal with complex symptoms and complications, communicate with patients concerning the issue of updated information in the end-stage period of life, and provide timely emotional support to both patients and caregivers for their psychological distress. Intervention fidelity is the key to successful interventions and requires competent interventionists with knowledge and skills to maintain a helpful working relationship with patients and healthcare professionals. A study by Naylor et al. (2015) suggested that designating an NCM who was competent in the coordination of care with appropriate collaboration with other healthcare professionals, had evidenced successful

intervention programs with positive acceptance of the intervention by the participants. Rigours of treatment interventions were carried out by an NCM with the evidence-based protocol for guiding practice and maintenance of care consistency. Various studies also revealed that APN-led TPC services reduce the utilisation of healthcare services and improve the QOL for participants through high-quality interventions (Mora et al., 2017; Naylor et al., 2004; Wong et al., 2005a).

The NCM in this pilot had a solid knowledge base and extensive and advanced clinical experience in renal and palliative care. She independently integrated the advanced knowledge and clinical experience in providing protocol-driven TPC services. Through telephone outreach and a home visit, she directly identified the needs of patients and families, as well as authorised the development and implementation of an individual health care plan for the patient. Her performance and contribution to the pilot were well appreciated by the participants. This pilot study reflected that TRPP has the potential to decrease preventable readmission, but the level of evidence is insufficient to allow for generalisation, warranting further main studies and the adoption of more APNs with advanced knowledge and skills in delivering transitional care to the population with chronic diseases.

6.3.3 Multi-disciplinary team approach

Given the complexity of ESRF and the diversified needs of patients and families, a multidisciplinary care team with the active participation of ESRF patients and informal caregivers is warranted. A single group of care providers cannot yield effective or improved patient outcomes, but the collaboration of multidisciplinary team care will contribute to improved clinical effects with the good allocation of time and resources in caring for the patients.

The design of a nurse-led program in this trial attributed to the effective communication in the renal palliative care team with strong engagement of patients and caregivers with selfmanagement, including treatment compliance, adapting lifestyle, and modifying health behaviour through patient education. Through the interventions, the NCM was involved in the decision making and responsible for information and skill transfer to facilitate the patients and families in utilising self-care management.

6.3.4 Patient empowerment

In chronic disease management, patient empowerment is crucial in organ failure patients with palliative care, which enhances the patients' feelings of control, coping abilities and self-efficacy and so on. Self-management involves patient participation in the self-management programs and interaction with the healthcare providers resulting in the building up of knowledge and higher self-efficacy. It involves the change of behaviour contributing to better disease management, improved clinical outcomes, higher patient satisfaction and better healthcare services utilization (Battersby et al., 2010).

Self-management education enables the patient to manage their condition with appropriate knowledge and skills learned. The context of self-management includes problem-solving, retrieving and adopting community support, collaboration with the healthcare team, and acquiring and initiating new health behaviours.

In supporting patient self-management, patient brochures and leaflets were used with clipart presentations to enhance positive learning effects for the patient. Well-coordinated continued education provided by the NCM implemented patient education and promoted more systematic and efficient self-management, more closely following an efficient execution plan. In addressing the ever-changing situation in ESRF, self-management aimed to enhance the patients' capacity to gain maximal control of symptoms and improved QOL. The direct effects of self-management will lead to better control of symptoms and general well being. The indirect effects of self-management include patient satisfaction, improved self-regulatory behaviours, improved coping skills, reduced utilization of healthcare services and strengthening of support from a caregiver (Wallerstein, 2006). Both direct and indirect effects were reflected in the intervention groups of this pilot.

6.3.5 Continuous client-centred services

Seamless holistic patient care should be continuous-based care for ESRF patients in a homebased setting. Many participants expressed their opinions of appreciation for home-based renal palliative care, but the care services of peer support groups and patient-initiated consultation services still have room for improvement such as the week-day patient-initiated consultation service hours. Whenever nursing manpower support is feasible, continuous nonfragmented patient care is highly warranted to enable seamless patient services. For instance, a 24-hours patient hotline with continuous based patient-initiated consultation services should be feasible to increase patients' confidence in seeking help related to the illness.

Caring for a person at the EOL may be particularly stressful for the family and significant others and that caring may compromise the physical health and emotional well-being of caregivers (Vitaliano et al., 2003). Caregivers of ESRF patients embrace intangible stress associated with a clinical condition, disease progression, challenges encountered, and support perceived. A major part of psychosocial support involves having peer support networks for patients, where they can talk to and be understood by other patients with the same illness (Poppel et al., 2003). Through peer support and communication, a way of managing the

problems encountered by the patients was anticipated and implemented with the acquired knowledge.

Lessons learnt from this pilot study are that seamless holistic palliative care encompasses physical, psychological, social and spiritual care (WHO, 2020) and could be further enhanced by introducing a peer support group into the TRPP. Provision of physical care is the key role of the care providers, while psychosocial and emotional support can be facilitated by different parties concerned, such as medical, nursing, social workers, counsellor, chaplain, patients and family members. Sometimes, psychological and emotional support can be even better acknowledged from the support of the informal caregivers and peer groups of patients because they share the same common problems.

In summary, the intervention group reported having more information for self-management and a greater understanding of available resources for coping with the health problems. They reported that they were in a better position to prepare for their daily experiences. Persons with progressive life-limiting chronic diseases often require heavy utilisation of expensive health care services in terms of emergency room visits, and frequent, lengthy hospital stays (Mariotto et al., 2011). In referring to the results of the report of Paterick et al. (2017) which underscored the importance of patient education and surveillance after discharge, the strengthening of community-based care and support are critical in meeting patients' needs. The NCM assists the patient to identify early signs and symptoms of a deteriorating condition to precipitate prompt intervention and avoid preventable re-hospitalisation. It can be regarded that the model of TRPP for ESRF patients in this study was effective in the minimization of unscheduled readmission, shortened LOS in the hospital, less utilisation of AED, improved QOL in terms of physical symptoms of distress, better physical function, increased satisfaction with care and less caregiver burden.

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6.4 Summary

In addition to the appraisal of the methodology of this trial, this chapter offers an in-depth discussion of the quantitative and qualitative findings of the TRPP trial for ESRF patients. To satisfy the needs of ESRF patients with non-dialytic conservative therapy at an integrated level, the provision of TRPP services that aims at an improved QOL in the late phase of life should be encouraged. Regarding the advantages of reduction in healthcare expenditure, there was clinical and subjective evidence in this study that emphasized the improvement of QOL of ESRF patients as well as the reduction of burden stress of the caregivers. Various forms of support, adequately provided to meet the needs of the participants, were warranted. The outcomes of palliative care are greatly related to the multifarious component of the intervention and its dose (Manojlovich and Sidani, 2008). Intervention doses in this pilot RCT were designed with evidence-based support.

CHAPTER SEVEN: CONCLUSION

7. Introduction

This concluding chapter commences with a summary of the major outcomes of this study and its contributions to health service research, followed by a discussion of the challenges encountered, limitations of the trial and implications of the study from the perspective of clinical practice, healthcare services and research knowledge. It ends with suggestions for further study and the overall conclusions of the trial.

7.1 Challenges

Timely referral for palliative care is vital. High quality and effective palliative care should be available and accessible to more people earlier in the course of advanced illness and lifelimiting disease and the period of the final days aiming at the enhancement of the quality of both living and dying with the disease. With the declination of renal function, palliative care assumes increasing significance with time and is an indispensable part of "peaceful death."

One challenge for the palliative care program is the need for additional resources in providing education for other healthcare providers who are not team members of the palliative care unit but must deal with patients in need of EOL care. With the acquisition of knowledge, appropriate referrals for palliative care will be made accordingly. Another challenge is limited patient-initiated consultation hours. Palliative consultative services are currently available during weekdays and regular work hours due to resource constraints. Very few specialist palliative physicians and nurses are available after hours to provide services to patients who are staying at home on a 24-hours basis. The extended operating hours would enable the care providers to access consultation on a continuum basis.

7.2 Limitations

This being the first RCT to assess the effects of TPC for participants with ESRF in the local setting, several limitations were noted.

7.2.1 Fragility and compromised renal function

Patients with ESRF on palliative care are characterised with frailty, having compromised kidney function associated with multi-organs functional problems which may have interfered with data collection, contributing to the failure of follow up with an incomplete set of data. Besides, participants found it difficult to concentrate and recall some events during data collection. Consequently, the high attrition rate in terms of random attrition is relatively common due to high mortality. It will affect the power of generalisation.

7.2.2 Confounders influencing the intervention effects

It is challenging to care for the frail elderly with ESRF. It is particularly difficult in Hong Kong as there is a shortage of structured community support. Apart from this, physical strength is another concern in caring for the patient. These entire phenomena are the leading factors in moving patients to reside in elderly institutions. Consequently, random attrition of the study due to violation of inclusion criteria occurred.

In clinical research, the elderly have more health and functional problems that interfere with all aspects of data collection, which is attributed to the failure to follow up with a complete set of data. This is not surprising to note that in a palliative care setting only 36 (47.37%) patients with ESRF were alive at 52 weeks after recruitment to the palliative care program. It is advised to shorten the period of data collection to six months (the median life expectancy of TRPP participants was 168.3 days).

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7.2.3 Not all non-dialytic ESRF patients eligible for TRPP

This study was limited to the uptake of all ESRF patients living in elderly homes due to the aims of the study being focused on the evaluation of the effects of the TRPP in home-based care. In the long run, with the availability of resources and the positive effects of transitional care, patients with ESRF, home-based or in elderly-home care may benefit from transitional care.

7.3 Implications of the Study

There were important implications noted in this study, which will be discussed in the following paragraphs.

7.3.1 Implications for nursing

The deficits of conventional palliative care have been demonstrated in various studies. The encouraging results of this pilot study revealed that participants in the intervention group had reduced healthcare utilisation and improved clinical outcomes. Continuous post-discharge follow-up and support from NCM are associated with pronounced improvements in clinical outcomes and QOL. The impacts of the nurse-led approach care program may be associated with the positive effects of the TPC model in this trial. The nursing training curriculum should be diversified to strengthen nursing competency in fulfilling multi-functional roles including assessor, interventionist, educator, counsellor, and coordinator in the preparation of nurses as the emerging role in community-based service. Learned knowledge consolidated into daily practice enables the nursing roles to be effectively demonstrated in the process of care delivery.

Effective symptom control for patients with the advanced disease requires the coordinated efforts of a multidisciplinary team. For instance, excellent palliation can be achieved in

patients suffering from pain as well as fatigue or weakness in the lower limbs. Protocol driven interventions are developed to ensure the consistency of care provided by healthcare providers. The dose of nursing care is ensured with fidelity and credibility.

Nursing is the cornerstone of effective palliative care. Through accurate assessments and expertise in delivering interventive strategies, nurses ensure optimal palliation of symptom distress. According to Herman et al. (2016), nurses are the team members of the multidisciplinary care team who spend the greatest amount of time with patients and are in a key position to appraise the problems and symptoms. The patient may not report the symptoms because they are not experienced in recognizing the symptoms that can be managed. They may assume that their abnormal distress is expected and that their chronic disease is the inevitable outcome. Nurses have a dominant role in an interdisciplinary team and they should be responsible for communicating with patients and families concerning the aims of care and its prognosis. Moreover, nurses should also take the role of providing education through available resources. Hence, the training curriculum focused on the multifunction nursing role is warranted to meet the needs and to ensure highly competent output.

7.3.2 Implications for healthcare services

As the number of older patients with ESRF has been increasing, the adoption of conservative treatment instead of RRT has been increasingly considered as a suitable treatment option. The patient has not been abandoned and continues to receive nephrology care, whether or not a decision for RRT has been made (Dasgupta & Rayner, 2009). The life span is generally longer in patients with RRT than in conservative treatment (Lin et al., 2013) but the 'no dialysis' palliative care option might be suitable for those who either present with severe comorbidities or who cannot benefit from extended life expectancy from dialysis therapy. The pronounced

preliminary effects of this TRPP have informed administrators about the significance of the development and integration of TRPP into customary nephrology care services.

The roles of patients and families are indispensable in the process of TPC. Support for the caregiver is very important in the journey of caring for the ESRF patient with palliative care. The offering of services that might include home care, activities within social networks, or patient counselling have been explored in other countries (Nipp et al., 2016; Palliative Care Health Services for the Aged Delivery of Health Care, 2004). Attaining emotional support from peer groups is associated with better QOL and reduced anxiety and depression (Nipp et al., 2016). There was positive feedback from the participants who took up the opportunity to communicate with peers, yet formal evaluation of their benefits is still not conclusive (Harding & Higginson, 2003; Reblin & Uchino, 2008). Further evaluation and evidence are required to ascertain the effectiveness and priorities of supportive services for caregivers. This group of supportive services for caregivers is currently limited in the study hospital.

The integration of a palliative approach into the management of chronic illness offers advantages. With adequate communication between the healthcare provider, patients, and families, there is a greater awareness of the diagnosis of the illness and the available palliative services and their benefits. It enables timely discussion of the chronic illness trajectory and the issue of EOL, goals of care and advanced care planning. The patient can access palliative care services as needed without any referral. There is better pain and symptom management throughout the illness. Hence, there is a greater capacity to minimise suffering resulting in greater patient and caregiver satisfaction. The impact of palliative care implies less utilisation of invasive health services. This group of supportive services for caregivers is currently limited in the study hospital. Ways to integrate palliative care into normal routine care services have not been determined and should be a focus of further evaluation and research.
7.3.3 Implications for research

The role of palliative care in ESRF has been well developed in the United Kingdom, United States of America, Italy, and Canada (Collins et al., 2009; Murtagh et al., 2007; Greaves et al., 2009).

Few local hospitals under the Hospital Authority provide palliative care services with considerable variation in providing renal palliative care. Less evidence of developed standards of renal palliative care in ESRD is available. Palliative care is essential in the context of non-dialysis therapy or withdrawal of dialysis therapy with the aim of palliative treatment of symptoms.

The objective of palliative care which focuses on symptom assessment and management has facilitated the improvement of QOL for patients. The results and limitations of this study shape the further research agenda. It can be concluded from the results that there is a high attrition rate due to the high mortality rate of 39.47% (30/76) one year after recruitment. The proposed period of intervention should be readjusted to six months as the results of this study have evidenced that the median life expectancy after recruitment is 168.3 days. The study protocol can be adopted for further study as evidenced by the strong acceptance of participants in this pilot study.

To have a powerful generalisation of the result findings, the homogeneity of the data collection including demographic characteristics and clinical conditions is ensured by inferring the results from a sample and applying it to a population (Mills et al., 2018). More than one centre of recruitment of candidates is recommended for a larger-scale RCT.

Continuous post-discharge follow-up and support are associated with pronounced improvements in clinical outcomes, QOL, and less healthcare utilisation (Randall et al., 2017), but its implementation is intensively resourced. The cost-effectiveness of the care model was not analysed in this study, as the approach of case management was adopted in this study, which has been documented to contain health costs through effective care coordination (Joo & Huber, 2013; Wong et al., 2018). It is suggested to include the cost of resource utilisation for program implementation and the healthcare expenditure of the patients.

The current study shows that the NCM performed multi-roles as assessors, interventionists, educators, facilitators, and collaborators during the process of care delivery which contributed to improving clinical outcomes and decreased psychological stress. The approach to care delivery solved the issue of fragmented care in the process of patient care. The relationships between different interventions were underdetermined; even though higher levels of physical function were noted in the intervention group as compared to the control group. The effects of individual interventions leading to positive clinical outcomes are not determined in this pilot study.

The findings on the effects of the nurse-led approach (NCM) on self-management abilities, health-related QOL, patient satisfaction, and readmission among populations with chronic disease are encouraging and pronounced, yet the evidence cannot be generalised to the ESRF population with palliative care. Provision of continuous follow-up and support was pivotal to the patients and their family members, achieving positive clinical outcomes. Thus, home-based behavioural support strategies were incorporated into the intervention. Self-management is a kind of specific behavioural support strategy facilitated by the NCM which

includes patient education, continuous monitoring, a collaboration of care services, and patient advocacy.

Finally, the NCM approach for the transitional care model could be enhanced by incorporating a process evaluation into the design of a future study. Such evaluation assists in assessing intervention fidelity, showing how specific interventions contribute to program outcomes. Further studies of the transitional care model for chronic disease patients could be improved by examination of the relationship between the components of the program and the outcomes. Besides, the significance of individual components being explored through process evaluation is recommended.

Additional studies that aim at testing interdisciplinary approaches such as complex symptom management in palliative care teams are also warranted. The expected feedback on palliative care is to acquire a favourable QOL by minimizing suffering, controlling symptoms and restoring functional capacity together with maintaining sensitivity to personal cultural and spiritual beliefs and practices.

7.3.4 Implications for healthcare policy

The beneficial effects on the improved health-related QOL and reduction of health services utilisation achieved through the TRPP indicate that continuous follow-up with timely support can provide better symptom control and prevent complications. The treatment protocol was well-received with no patient-initiated dropout in this study. To facilitate the clinical implementation of transitional care, it is necessary to integrate transitional care into routine renal services for patients with ESRF. Continuous follow-up and support for palliative patients deserve high administrative priority.

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7.3.5 Implications for expansion or enhancement of TRPP

There is an ever-advancing technology in healthcare services nowadays. A variety of technologies enable a healthcare team to monitor a patient's health remotely. The significance of telehealth (e-health or mobile-health) is that it enables access to patients who stay at home and provides more convenient patient services for patients with limited mobility or transportation options. A post-discharge follow-up and support will be enhanced with telehealth or advanced technology which enable assessment, education and follow up evaluation in remote locations. The intervention program of this research project can be implemented through outreach services or advanced technology such as telehealth as possible ways to reach ESRF residents in an elderly nursing home.

7.4 Conclusion

In view of the inadequacy of conventional palliative care, the study evidenced herein was designed to examine the effects of a TRPP for ESRF patients with non-dialysis therapy. The primary outcomes were objective measures of non-scheduled readmission, LOS in the hospital, and episodes of AED visits. The participants in the intervention group presented less non-scheduled readmission, shortened LOS in the hospital, and fewer visits to AED. The improved health-related QOL, physical functions, satisfaction rate, decreased anxiety and depression, less symptom intensity and less burden on the family caregiver further support the positive effects of the rehabilitation of ESRF patients.

A well-conducted pilot study will facilitate methodological rigour, ensure the results are scientifically valid and will act as the groundwork of the main study with high feasibility and acceptability of the study protocol. According to the interpretation of the preliminary results, this pilot study concluded that a future main study with a similar design and instruments together with the involvement of more than one single study centre will attain an improved recruitment rate.

To ensure that patients have the best possible QOL, palliative care focuses on reducing disease-related symptoms, supporting and meeting patients and their family needs, and creating a mutual agreement on the care plan. The results of the analysis of the intervention demonstrate that it was successful in the reduction of readmissions rate, shortening the LOS during hospitalisation, maintenance of a good QOL, improved physical function, increased satisfaction with care and reducing family caregiver burden.

Many individuals with aggressive chronic diseases spend most of their time at home. Hence, it is important to have well planned and executed care with a holistic approach and appropriate community-based support. The supportive care during the last phase of life should be similar to the specific period of antenatal care for a pregnant female. Should this preemptive care planning not be well organised and provided, a period of crisis will result which does not meet the needs of the patients and the common clinical indicator is repeated hospitalization is noted. Reasons for readmission include symptoms not being well controlled, fragmented home care services and inadequate support for the family caregivers. In contrast, readmission into the hospital can be minimised with the provision of advanced care planning, support to the family caregiver and intensive palliative care.

Moreover, family caregivers should be involved as one the team members of palliative care. They should be enabled, forewarned, well informed, and trained, as well as empowered to care for the patient as desired. Caring for the patient can involve both physical and psychological aspects especially if the spouse of the elderly patient acts as a family caregiver. In particular, the caregiver's anxiety and depression may be influenced by the alteration of the patient's clinical status as the condition deteriorates. In embracing the sophisticated and complex care as required, it is important to equip the caregiver with care-related knowledge and skill. 'Teaching them to fish is better than feeding them with a fish'. Innovative family caregiver teaching includes adequate time for questions from a family caregiver, discussion of decision making, relief of anxiety and facilitates a better understanding of the clinical condition and judgement.

Palliative care services should address the needs of patients and family caregivers and approach their agenda. In general, patients prefer to have symptom free and well-supported care with adequate information and proactive planning. This allows and enhances the possibility of a trusted relationship and supportive role between the patient and care provider.

Besides, the qualitative information indicates the significant role of the NCM, which enhances care-giving magnitude and capacity by communicating with and supporting the patient and their family. Apart from physical support, the NCM provides consistent holistic care to address the psychosocial and emotional needs of ESRF patients.

This nurse-led TRPP was potentially effective in reducing healthcare utilisation, primarily by reducing readmissions and AED visits. In this clinical trial, the post-discharge transitional intervention described here was developed with the multipurpose of improving the quality of care, promoting health, assisting participants to adhere to their prescribed treatment, obtain appropriate standard care, and psychological support and engaging in self-management of their condition to reduce the likelihood of readmission.

The sustainability of good QOL is crucial in the trajectory of ESRF with palliative care. The key components of facilitation of such sustainability include physical care, psychosocial and emotional support with the involvement of multi-disciplinary effort. Patients and family caregiver involvement play an important role in the process of home-based palliative care.

The ways and approaches to the provision of psychosocial and emotional support are still inconclusive and it is highly recommended to have further exploration in the future. Meanwhile, consistency and basing interventions on existing evidence on symptoms, QOL, and experience will maximise holistic care.

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Appendix 1: 長者認知評估

參加者編號:_____

日期:_____

長者認知評估

Mini-Mental Status Examination (MMSE)

Assessor:

错误正確		不明			
0	1	9	1)	今年是那一年?	
			2)	現在是什麼季節?	
			3)	今天是幾號?	
			4)	今天是禮拜幾?	
			5)	現在是那一個月份?	
			6)	我們現在是在那一個省?	
			7)	我們現在是在那一個縣、市?	
			8)	這間醫院(診所)的名稱?	
			9)	現在我們是在幾樓?	
			10)	這裡是哪一科?	
			11)	藍色 請重複這三個名稱,按第一次複述結果計分,	
				蘋果最多只能重複練習三次;練習次數:	
				火車、藍色、蘋果	
			12)	請從 100 開始連續減 7,一直減 7 直到我說停為止。(每減對一次得一分)	
				93 ; 86 ; 79 ; 72 ; 65	
			13)	約五分鐘以後,請說出剛才請你記住的三樣東西,每對一項得一分,不論順 序 藍色、火車、蘋果	

0	1	9	14)	(拿出手錶)這是什麼?
			15)	(拿出鉛筆)這是什麼?
^	-	-	16)	請跟我唸一句話 『白紙真正寫黑字』
-	-	-	17)	請唸一遍並做做看 『請閉上眼睛』
^	-	^	18)	請用左/右手(非利手)拿這張紙(三步驟指令,每對一步驟得一分)
^	-	-	19)	把它折成對半
^	-	~	20)	然後置於大腿上面
^	-	^	21)	請在紙上寫一句語意完整的句子。(含主詞動詞且語意完整的句子)
-	-	-		

22) 這裡有一個圖形,請在旁邊畫出一個相同的圖形。(兩五邊形,交一四邊形,有兩交點,則給分)

摹倣繪圖



23) 請畫一個鐘指示三點鐘

總分:

Appendix 2a: 參加者資料

參加者編號:_____

日期:_____

參加者資料

請填妥以下資料或在適當之空格加上☑號

- 1. 參加者編號:
- 2. 年龄:
- 3. 性別: □ 男 □ 女
- 4. 婚姻狀況: 未婚 結婚 寡婦/鰥夫
- 5. 教育程度: 未有正統教育 小學 中學大學或以上
- 6. 職業:
- 7. 居住環境: □公屋 □私人住宅
- □ 房間 □ 全層 □小屋 □全座
- 8. 經濟程況: □ 受薪 □自僱 □退休 □主婦 □失業
- 9. 請問你的同住情況:總同住人數(包括你在內) 人

(可選多於一個答案)

- □1 與配偶同住 □2 與子女同住 □3 只與傭工同住
- □4 與其他家人同住,請例明關係
- 10. 照顧者支援: □ 有 □ 無
- 11. 請問上次入住醫院是多久之前? 年 月
- 12. 請問今次入住醫院共住了多少日? 日
- 13. 使用其它醫院服務(如急症室): 🗌 有 🗌 無

其它重要疾病(請註明):

	有	無
血壓高		1
糖尿		
心臟毛病		
中風		
哮喘/肺氣腫/慢性支氣管炎或其他慢性的胸肺病		
慢性的關節毛病		
慢性痛楚		

Appendix 2b: Particular of participant

Study number: Date: Particulars of participant Please fill in the space provided or tick in the \Box 1. Data code: 2. Age : 3. Gender : $\Box 1$ Male $\Box 2$ Female 4. Marital status: □ Single □ Married □Widow/Widower □ Divorced 5. Educational level: no formal education Primary Secondary University or above 6. Occupation: 7. Accommodation:
□ Public housing \Box Private housing: \Box room \Box flat \Box apartment \Box house \Box self-employed \Box housewife \Box retired \Box unemployed 8. Financial status: \Box employed 9. Household status: No. of cohabited (you are included) (Choose more than one answer) answer) \cdots \square with a spouse \Box with offspring \Box with maid \cdots \Box with other family members, please specify

10. Carer support \Box Yes \Box No

11. Last hospitalization:

12. Last hospitalization day;

13. Utilization of other hospital services (e.g. A&E Dept)

14. Other co-morbidities (please specify): Yes No Hypertension Diabetic mellitus Cardiovascular disease Stroke Asthma/emphysema/COPD Chronic joint problem Chronic pain Others

Appendix 3a: 參與研究資料及同意書(病人)

參加者編號:_____ 日期:____

伊利沙伯醫院、香港理工大學護理學院聯合主辦

腎臟舒緩治療護理

參與研究資料及同意書 (病人)

誠邀閣下參加由香港理工大學護理學院與伊利莎伯醫院負責執行的研究計劃,請閱讀 此研究資料和同意考慮參與這項研究。

研究資料

引言

末期腎衰竭患者須接受長期透析治療,以維持生命,透析治療紙能降低體內過多的水 份和新陳代謝的廢物,接受腹膜透透析治療的病人仍會患上非透析治療的臨床徵狀, 例如骨痛、皮膚痕癢、荷爾蒙失調、貧血、心臟病等,有些病人除了患上腎衰竭外, 亦同時患上其他嚴重的疾病,如癌症、嚴重心臟病等,未能從透析治療得益。有見及 此,腎臟舒緩治療可為末期腎衰竭患者提供支援和舒服的治療,提高病人的生活質素, 減少末期腎衰竭帶來的不適。此研究將會在醫院管理局九龍中聯網轄下的伊利沙伯醫 院進行,約一百七十六位末期腎衰竭患者被邀請參加此研究。

研究目的

這研究之目的是透過提升舒緩治療護理,支援和協助末期腎衰竭病人進行治療護理,並評估其成效。

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治療組別的抽簽安排,研究組和對照組各 35 標簽分別放入盒內撈亂,研究小組入員依 次序抽出標簽並放入有號碼的信封內,此抽簽程序共進行兩次,以平衡兩個組別的參 加人數各佔 70 人。

參加者閣下先進行評估,根據抽簽安排的信封號碼,合適參加者依據次序而被安排治 療組別。病人接受治療後的基本、第一、三、六個月和一年後,接受問卷調查和訪問; 此外,照顧者亦接受問卷調查。

在進行研究期間,我們會提供所有與此研究的最新資料給與閣下知悉,以便閣下取捨 是否繼續參與此研究。假如閣下不參與或者退出此研究,根據部門指引,您仍可繼續 如常接受正常醫療護理,如有任何有關此研究的問題,請聯絡研究小組查詢更多資料。

個人資料保障權聲明

依照香港特別行政區的法律,尤其是個人資料(私隱)條例(第486章),您享有個人資 料保密的保障權,例如有關在此研究中收集、持有、保存、處理、控制,或使用(包括 分析或比較),在香港以內或以外的傳送,不作披露、删除和/或使用任何途徑去處理 或棄置您的任何個人資料。

閣下提供的資料將會受到受到研究小組的絕對保密處理,資料紙用作研究分析,任何 個人資料將不會在研究報告中披露。如果願意參與這項研究,請您在這份同意書末端 簽署和寫上日期來表明您明白研究內容明白研究內容和自願參加。您亦可以聯絡研究 小組查詢更多的資料。

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您在此同意書簽署和寫上日期,表示您同意容許我們在此研究中收集、持有、保存、 處理、控制,或使用你的個人資料作為研究之用。如您有任何疑問,請資詢私隱專員 公署或其辨公室 (電話: 2827 2827)有關保障您個人資料的適當監管或指導,以確保 您完全知道

和明白遵守個人資料(私隱)條例的重要。

如您對此項研究有疑問,請聯絡:

伊利沙伯醫院腎科

電話:2958 6512 (譚美玲護士)

如您對個人資料保障權有疑問,請聯絡:

九龍中及九龍東聯網臨床研究倫理委員會

電話:2958 6623
Appendix 3a: 同意書

參加者編號:

同意書(病人)

以下句子是為了確定你是否明白及同意參與這項研究的各程序:

- 我肯定我已閱讀過和明白(或由他人讀出並解釋) 有關以上研究的資料,並得到一 份副本作保存。我有機會對這研究計劃提出疑問,並了解進行這研究的原因和所涉 及的風險。
- 2. 我明白我的參與純屬自願。
- 3. 我同意參與這項研究。
- 4. 我樂意讓研究小組向我自己和我的醫生詢問,並翻查我的病歷,以撮取與研究相關 的資料。
- 5. 我明白研究小組會向我提供與研究相關的最新資料。
- 我明白所有由我自己提供或是透過我的醫生遞交給研究小組的資料將會絕對保密, 只有研究小組能夠閱看。
- 7. 我明白通過簽訂書面同意書, 我授權臨床研究倫理委員會和監管機構直接核查此 研究數據。
- 我同意在這計劃中提供資料作研究,我明白收集資料的方法,並自願地為這研究提供此資料。我有權隨時拒絕或收回這資料的使用權,而不用提供任何理由。
- 9. 我明白我將需要在研究期間內接受問卷調查、電話跟進、探訪及訪問。
- 10. 我明白這個項目是不牽涉任何金錢交換。
- 11. 我明白我有權隨時退出這項研究,而不用提供任何理由。
- 12. 我明白研究小組在有合理解釋的原因下,有權隨時拒絕或終止參與此研究。

参加者姓名	(請用正楷寫上)	簽署	日期
研究員姓名	(請用正楷寫上)	 簽署	日期
見證人姓名	(請用正楷寫上)	 簽署	日期

Study number: _____

Date: _____

Queen Elizabeth Hospital and The Hong Kong Polytechnic University Transitional renal palliative care model for ESRD patients

Information sheet and consent form (Patient)

You are cordially invited to participate in the study co-organized by Queen Elizabeth Hospital and The Hong Kong Polytechnic University. Please read the following statement and agree to participate in this study.

Study information

Introduction

ESRD patients needed to sustain their lives through long term renal dialysis. However, dialysis only carries out the purpose of the removal of waste products and excessive fluid. Those ESRD patients with dialysis therapy still encounter the signs and symptoms of pain, pruritis, hormonal disturbance, anaemia, cardiovascular disease, and so on. In addition, some patients may also suffer from other co-morbidities such as cancer, and severe cardiac illness, and may not benefit from dialysis therapy. Hence, renal palliative care may provide supportive therapy and care for the ESRF patient, which aims at relieving the discomfort of the renal disease and promoting their quality of life. This study will be conducted in Queen Elizabeth Hospital in Kowloon Central Cluster. 174 patients will be invited the participation in this study

Objectives

This study aims to explore the effect of transitional palliative care for end-stage renal failure patients.

Procedure

The assignment of type of therapy group, either the control group (1) or interventional group (2), will be randomized by the computer software Research Randomize by a research team member. A preliminary assessment will be done for the recruitment of suitable candidates who will be allocated to the therapy group according to the sequence of randomization. At the time of baseline, 1st month, 3rd month, 6th month, and 1 year after receiving the palliative therapy, the participants have to answer the questionnaire, home visit, and interview. In addition, the carer will be invited to have a survey.

During the study period, in enhancing your option of withdrawal from the study or not, we will provide all data related to this study for your perusal and information. If you prefer to withdraw from this study, without giving any reason, you can continue to receive our care and therapy as usual according to the departmental policy. Please contact the study team for further details of the study.

Personal information protection statement

Under the Basic Law of Hong Kong S.A.R., in particular, the personal data (Privacy) Ordinance (chapter: 48th), you have the right to keep the confidentiality of personal information protection. In this study, management of data such as the collection, possession, preservation, processing, control, or utilization (including analysis or comparison); transmitted within or outside Hong Kong, against the disclosure, delete, and/or the use of any means to deal with or dispose of any of your personal information.

Data will be provided under the strict confidentiality of the study group. The data are used solely for research and analysis, and any personal information will not be disclosed in the report.

If you agree to participate in this study, your consent to this consent form with your sign and date indicating your understanding of the content of the study and participation in this study voluntarily. You can also contact the team for more information.

You hereby consent to sign and date, showing you agree to allow us to manage the data of study regarding collection, possession, preservation, processing, control, or use of your personal information for research purposes • If you have any questions, please inquiry Office of the Privacy Commissioner or the Office (Telephone: 28272827) Relating to the protection

of your personal information with the appropriate supervision or direction, to ensure that you fully understand the importance of compliance with the personal data (Privacy) Ordinance essential.

Should you have any questions related to this study, please contact:

Queen Elizabeth Hospital, Renal Unit, Tel. No. 29586512 (Bonnie TAM, Registered Nurse)

Should you have any questions related to the privacy ordinance and related rights, please contact:

Research Ethical Committee, KCC, KEC Tel No. :2958 6623

Appendix 3b: Consent form

Study number: _____

Consent form (Patient)

The following sentences are stated to ensure that you understand and agree to participate in

the study program:

- 1. I am sure that I have read and understood (or read by others and explain) the information research, save a copy and get a copy. I had the opportunity to question this research plan and understand the reasons for conducting the research and the risks involved.
- 2. I know my participation is voluntary.
- 3. I agree to participate in this study.
- 4. I do agree with the study team to ask for data from myself and my doctor, check my background and collect research-related information.
- 5. I appreciate that the study group will provide the latest information on the related study.
- 6. I understand that everything I possess or the information I submitted to the study group of doctors will be kept confidential. Only limited to be reviewed by the study panel.
- 7. I understand that by signing a written consent, I authorize the research ethics/ethical Committee and the regulatory institutions directly to verify the study data.
- 8. I agreed to provide information for this research, I understand the process of collecting information, and I am willing to provide the information for this study voluntarily. I also reserve the right to refuse or withdraw from this study, without providing any reasons.
- 9. I understand that I will need to receive surveys, telephone follow-ups, home visits and interviews during the study period
- 10. I understand that the project does not involve any conflict of interest.
- 11. I understand that I have the right to withdraw from the study at any time, without providing any reasons
- 12. I appreciate the study group, under reasonable conditions, reserves the right to reject or terminate my participation in the study.

Please sign and date at the end of this written consent:

Name of Participant (Block Letter):	Signature:	Date:
Name of team member (Block Letter):	_Signature:	Date:
Name of Witness (Block letter):	Signature :	Date:

Appendix 4a: 參與研究資料及同意書(照顧者)

參加者編號:

日期:_____

伊利沙伯醫院、香港理工大學護理學院聯合主辦

腎臟舒緩治療護理

參與研究資料及同意書(照顧者)

誠邀閣下參加由香港理工大學護理學院與伊利莎伯醫院負責執行的研究計劃,請閱讀 此研究資料和同意考慮參與這項研究。

研究資料

引言

末期腎衰竭患者須接受長期透析治療,以維持生命,透析治療紙能降低體內過多的水 份和新陳代謝的廢物,接受腹膜透透析治療的病人仍會患上非透析治療的臨床徵狀, 例如骨痛、皮膚痕癢、荷爾蒙失調、貧血、心臟病等,有些病人除了患上腎衰竭外, 亦同時患上其他嚴重的疾病,如癌症、嚴重心臟病等,未能從透析治療得益。有見及 此,腎臟舒緩治療可為末期腎衰竭患者提供支援和舒服的治療,提高病人的生活質素, 減少末期腎衰竭帶來的不適。此研究將會在醫院管理局九龍中聯網轄下的伊利沙伯醫 院進行,約一百七十六位末期腎衰竭患者被邀請參加此研究。

研究目的

這研究之目的是透過提升舒緩治療護理,支援和協助末期腎衰竭病人進行治療護理, 並評估其成效。 治療組別的抽簽安排,研究組和對照組各 35 標簽分別放入盒內撈亂,研究小組入員 依次序抽出標簽並放入有號碼的信封內,此抽簽程序共進行兩次,以平衡兩個組別的 參加人數各佔 70 人。

參加者閣下先進行評估,根據抽簽安排的信封號碼,合適參加者依據次序而被安排治 療組別。病人接受治療後的基本、第一、三、六個月和一年後,接受問卷調查和訪問; 此外,照顧者亦接受問卷調查。

在進行研究期間,我們會提供所有與此研究的最新資料給與閣下知悉,以便閣下取捨 是否繼續參與此研究。假如閣下不參與或者退出此研究,根據部門指引,您仍可繼續 如常接受正常醫療護理,如有任何有關此研究的問題,請聯絡研究小組查詢更多資料。

個人資料保障權聲明

依照香港特別行政區的法律,尤其是個人資料(私隱)條例(第486章),您享有個人 資料保密的保障權,例如有關在此研究中收集、持有、保存、處理、控制,或使用 (包括分析或比較),在香港以內或以外的傳送,不作披露、删除和/或使用任何途徑 去處理或棄置您的任何個人資料。

閣下提供的資料將會受到受到研究小組的絕對保密處理,資料衹用作研究分析,任何 個人資料將不會在研究報告中披露。

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如果願意參與這項研究,請您在這份同意書末端簽署和寫上日期來表明您明白研究內容明白研究內容明白研究內容和自願參加。您亦可以聯絡研究小組查詢更多的資料。

您在此同意書簽署和寫上日期,表示您同意容許我們在此研究中收集、持有、保存、 處理、控制,或使用你的個人資料作為研究之用。如您有任何疑問,請資詢私隱專員 公署

或其辨公室 (電話: 2827 2827)有關保障您個人資料的適當監管或指導,以確保您 完全知道和明白遵守個人資料(私隱)條例的重要。

如您對此項研究有疑問,請聯絡:

伊利沙伯醫院腎科

電話:2958 6512 (譚美玲護士)

如您對個人資料保障權有疑問,請聯絡:

九龍中及九龍東聯網臨床研究倫理委員會

電話:2958 6623

同意書 (照顧者)

以下句子是為了確定你是否明白及同意參與這項研究的各程序:

- 我肯定我已閱讀過和明白(或由他人讀出並解釋)有關以上研究的資料,並得到一份副本作保存。我有機會對這研究計劃提出疑問,並了解進行這研究的原因和所 涉及的風險。
- 2. 我明白我的參與純屬自願。
- 3. 我同意參與這項研究。
- 我樂意讓研究小組向我自己和我的醫生詢問,並翻查我的病歷,以攝取與研究相關的資料。
- 5. 我明白研究小組會向我提供與研究相關的最新資料。
- 我明白所有由我自己提供或是透過我的醫生遞交給研究小組的資料將會絕對保密, 只有研究小組能夠閱看。
- 我明白通過簽訂書面同意書, 我授權臨床研究倫理委員會和監管機構直接核查此 研究數據。
- 我同意在這計劃中提供資料作研究,我明白收集資料的方法,並自願地為這研究 提供此資料。我有權隨時拒絕或收回這資料的使用權,而不用提供任何理由。
- 9. 我明白我將需要在研究期間內接受問卷調查、電話跟進、探訪及訪問。
- 10. 我明白這個項目是不牽涉任何金錢交換。
- 11. 我明白我有權隨時退出這項研究,而不用提供任何理由。
- 12. 我明白研究小組在有合理解釋的原因下,有權隨時拒絕或終止參與此研究。

請在此同意書末端簽署和寫上日期:

參加者姓名	(請用正楷寫上):	簽署	日期
研究員姓名	(請用正楷寫上):	簽署	日期
見證人姓名	(請用正楷寫上):	簽署	日期

Appendix 4b: Study information

Study No.: _____

Date: _____

Queen Elizabeth Hospital and The Hong Kong Polytechnic University Transitional renal palliative care model for ESRD patients Information sheet and consent form (Carer)

You are cordially invited to participate in the study co-organized by Queen Elizabeth Hospital and The Hong Kong Polytechnic University. Please read the following statement and agree to participate in this study.

Study information

Introduction

ESRD patients needed to sustain their lives through long term renal dialysis. However, dialysis only carries out the purpose of the removal of waste products and excessive fluid. Those ESRD patients with dialysis therapy still encounter the signs and symptoms of pain, purities, hormonal disturbance, anaemia, cardiovascular disease, and so on. In addition, some patients may also suffer from other co-morbidities such as cancer, and severe cardiac illness, and may not benefit from dialysis therapy. Hence, renal palliative care may provide supportive therapy and care for the ESRF patient, which aims at relieving the discomfort of the renal disease and promoting their quality of life. This study will be conducted in Queen Elizabeth Hospital in Kowloon Central Cluster. 176 patients will be invited the participation in this study.

Objectives

This study aims to explore the effect of transitional palliative care for end-stage renal failure patients.

Procedure

The assignment of type of therapy group, either the control group (1) or interventional group (2), will be randomized by the computer software Research Randomize by a research team member. A preliminary assessment will be done for the recruitment of suitable candidates who will be allocated to the therapy group according to the sequence of randomization. At the time of baseline, 1st month, 3rd month, 6th month, and 1 year after receiving the palliative therapy, the participants have to answer the questionnaire, home visit, and interview. In addition, the carer will be invited to have a survey.

During the study period, in enhancing your option of withdrawal from the study or not, we will provide all data related to this study for your perusal and information. If you prefer to withdraw from this study, without giving any reason, you can continue to receive our care and therapy as usual according to the departmental policy. Please contact the study team for further details of the study.

Personal information protection statement

Under the Basic Law of Hong Kong S.A.R., in particular, the personal data (Privacy) Ordinance (chapter: 48th), you have the right to keep the confidentiality of personal information protection. In this study, management of data such as the collection, possession, preservation, processing, control, or utilization (including analysis or comparison); transmitted within or outside Hong Kong, against the disclosure, delete, and/or the use of any means to deal with or dispose of any of your personal information.

Data will be provided under the strict confidentiality of the study group. The data are used solely for research and analysis, and any personal information will not be disclosed in the report.

If you agree to participate in this study, your consent to this consent form with your sign and date on indicating your understanding of the content of the study and participate in this study voluntarily. You can also contact the team for more information.

You hereby consent to sign and date, showing you agree to allow us to manage the data of study regarding collection, possession, preservation, processing, control, or use of your personal information for research purposes. If you have any questions, please inquiry Office of the Privacy Commissioner or the Office (Telephone: 28272827) Relating to the protection of your personal information with the appropriate supervision or direction, to ensure that you fully understand the importance of compliance with the personal data (Privacy) Ordinance essential.

Should you have any questions related to this study, please contact:

Queen Elizabeth Hospital, Renal Unit, Tel. No. 29586512 (Bonnie TAM, Registered Nurse)

Should you have any questions related to the privacy ordinance and related rights, please contact:

Research Ethical Committee, KCC, KEC Tel No.:2958 6623

Study number: _____

Consent form (Caregiver)

The following sentences are stated to ensure that you understand and agree to participate in the study program:

- 1. I am sure that I have read and understood (or read by others and explain) the information research, save a copy and get a copy. I had the opportunity to question this research plan and understand the reasons for conducting the research and the risks involved.
- 2. I know my participation is voluntary.
- 3. I agree to participate in this study.
- 4. I do agree with the study team to ask for data from myself and my doctor, check my background and collect research-related information.
- 5. I appreciate that the study group will provide the latest information on the related study.
- 6. I understand that everything I possess or the information I submitted to the study group of doctors will be kept confidential. Only limited to be reviewed by the study panel.
- 7. I understand that by signing a written consent, I authorize the research ethics/ethical Committee and the regulatory institutions directly to verify the study data.
- 8. I agreed to provide information for this research, I understand the process of collecting information, and I am willing to provide the information for this study voluntarily. I also reserve the right to refuse or withdraw from this study, without providing any reasons.
- 9. I understand that I will need to receive surveys, telephone follow-ups, home visits and interviews during the study period
- 10. I understand that the project does not involve any conflict of interest.
- 11. I understand that I have the right to withdraw from the study at any time, without providing any reasons °
- 12. I appreciate the study group, under reasonable conditions, reserves the right to reject or terminate my participation in the study.

Please sign and date at the end of this written consent:

Name of Carer (Block Letter):	Signature:	Date:
Name of team member (Block Letter):	_Signature:	Date:
Name of Witness (Block letter):	Signature:	Date:

參加者編號:_____

日期:_____

徵狀評估

	徵狀			
	日期			
1	怕冷			
2	疲倦			
3	肢體無力			
4	手腳痲痺			
5	水腫			
6	肌肉抽搐/筋			
7	肢體不自主踢動			
8	癢痕			
9	胃口轉差			
10	胃脹			
11	作嘔			
12	便秘			
13	失眠			
14	身體疼痛			
15	頭暈			
16	氣促			
17	咳嗽			

Scale: 0 (No) - 3 (severe)

Appendix 5b: Assessment of symptom manifestation for ESRF

Study no.:

Date:

Assessment of symptom manifestation for ESRF

	Manifestation / Date			
1	Intolerance of cold			
2	Fatigue			
3	Generalized weakness			
4	Numbness of limb(s)			
5	Oedema			
6	Muscle cramps			
7	Involuntary movement			
8	Itchiness			
9	No appetite			
10	Gastric distension			
11	Nausea			
12	Constipation			
13	Insomnia			
14	Pain			
15	Dizziness			
16	Shortness of breath			
17	Cough			

Scale: 0 (No) - 3 (severe)

參加者編號:_____

```
日期:_____
```

%	行動	活動和病徵	自我照顧	飲食	清醒程度
100	完全活動	正学活動	宗令白我昭顧	正堂准金	宗令清醒
100	儿王伯勤	沒有病徵	儿王日祝灬炳	II	九王捐輯
90	完全活動	正常活動	完全自我照顧	正常進食	完全清醒
		少許病徵			
80	完全活動	需廢氣力進行正	完全自我照顧	正常或减少	完全清醒
		常活動		進食	
		少許病徵			
70	减少活動	不能正常工作	完全自我照顧	正常或减少	完全清醒
		少許病徵		進食	
60	减少活動	不能工作/娱樂	間中須要協助	正常或减少	完全清醒或混
		出現明顯嚴病徵		進食	亂
50	時常卧下	不能工作任何情	間中須要協助	正常或减少	完全清醒或混
		出現嚴重病徵		進食	亂
40	卧床休息	不能工作任何情	時常須要協助	正常或减少	完全清醒或混
		出現嚴重病徵		進食	亂或迷糊
30	完全卧床休	不能工作任何情	完全須要協助	减少進食	完全清醒或混
	息	出現嚴重病徵			亂或迷糊
20	完全卧床休	不能工作任何情	完全須要協助	少量水	完全清醒或混
	息	出現嚴重病徵			亂或迷糊
10	完全卧床休	不能工作任何情	完全須要協助	口腔護理	迷糊或昏迷
	息	出現嚴重病徵			
0	死亡				

進行紓緩治療程況級別

Appendix 6b: Palliative Performance Scale (PPS)

Study No.:

Date:

Palliative Performance Scale (PPS)

%	Ambulation	Activity & Evidence of Disease	Self Care	Intake	Conscious level
100	Full	Normal activity No evidence of S & S	Full	Normal	Full
90	Full	Normal activity Some evidence of S & S	Full	Normal	Full
80	Full	Normal activity with effort Some evidence of S & S	Full	Normal or reduced	Full
70	Reduced	Unable to normal job/work Some evidence of disease	Full	Normal or reduced	Full
60	Mainly sit/lie	Unable hobby/housework Significant S & S	Occasional assistance necessary	Normal or reduced	Full or confusion
50	Mainly in bed	Unable to do any work Extensive S & S	Occasional assistance required	Normal or reduced	Full or confusion
40	Totally bed- bound	Unable to do any work Extensive S & S	Mainly assistance	Normal or reduced	Full or confused or drowsy
30	Totally bed- bound	Unable to do any work Extensive S & S	Total care	Reduced	Full or confused or drowsy
20	Totally bed- bound	Unable to do any work Extensive S & S	Total care	Minimal sips	Full or confused or drowsy
10	Totally bed- bound	Unable to do any work Extensive S & S	Total care	Mouth care only	Drowsy or coma
0	Death	-	-	-	-

Appendix 7a: 腎病及生活質素(KDQOL[™]-36)香港廣東話

參加者編號:_____

日期:_____

腎病及生活質素(KDQOL[™]-36)香港廣東話

你的健康

這份問卷包括多項有關你的健康及生活的問題,我們希望知道你對每項問題的感受。 請在一個方格內填上¹²號來回答每個問題。如果您不肯定怎樣回答,請按照您的理解 選擇最合適的答案。

 一般來說,你會形容你的健康狀況為: 	極好	很好	好	一般	差
	□1	□2	□3	□4	□5

下列問題是您日常生活中可能進行的活動。以您目前的健康狀況,您在進行這些活動時,有沒有受到限制?如果有的話,程度如何?

	有很大限制	有少許限制	完全沒有限制
 中度活動,例如移動桌子、推吸塵器、打羽毛球或耍太極拳 	□1	□2	□3
3. 上幾層樓梯	□1	□2	□3

在過去四個星期裏,您在工作或其它日常活動中,有多少時間會因為身體健康狀況的 原因而遇到下列的問題?

4 完成得少於你想達到的..

5. 只限做某類工作或其他活 動....

常常	大部分	有時	偶爾	從來沒
□1	$\Box 2$	□3	□4	□5
□1	$\Box 2$	□3	□4	□5

在過去的四個星期裏,您在工作或其它日常活動中,有多少時間由於情緒方面的原因

(比如感到沮喪或焦慮)遇到下列的問題?

	常常如	大部分時	有時	偶爾	從來沒
	此	間			有
6. 完成得少於你想達到的	□1	□2	□3	□4	□5
7. 不如平常般小心地工作	□1	$\Box 2$	$\Box 3$	$\Box 4$	$\Box 5$

8. 在過去四星期,痛楚對你正 毫無影 有一些 極大影 有很少 有較大 常工作的妨礙(包括家務及 影響 影響 影響 蠁 響影 家居以外的工作)有多大影 蠁? $\Box 1$ $\Box 2$ $\Box 3$ $\Box 4$ $\Box 5$

這些問題是關於在過去 四 星期 你的感受及你的生活狀況。就每項問題選一個最接近你的感受的答案。在過去 四星期 ,有多少時候會......

	常常如	大部分時	有時	偶爾	從來沒有
	此	間			
9. 你感到平静和安詳?	□1	□2	□3	□4	□5
10 你是否精力充沛?	□1	□2	□3	□4	□5
11. 你感到悶悶不樂和沮喪	□1	□2	□3	□4	□5

12. 在過去四個星期裹,有多少	常常	大部分時	有時	偶爾	完全沒有
時間由於您的身體健康或情緒問	有妨礙	間有妨礙	有妨礙	有妨礙	妨礙
題妨礙了您的社交活動 (比如探					
親、訪友等)?	□1	□2	□3	$\Box 4$	□5

請在下列各項,選擇一個最能真實地形容你本身情況的 答案。

		肯定對	大致對	不知道	大致不對	肯定不對
13	腎病對我的生活有太大影響.	□1	□2	□3	□4	□5
14	處理腎病用了我太多時間.	□1	□2	□3	□4	□5
15	應付腎病使我感到挫敗	□1	□2	□3	□4	□5
16	我覺得自己是家人的負擔	□1		□3	□4	□5

在過去四星期,以下情況對你有多少困擾?

		毫無困擾	輕微困	中度困擾	很多困擾	極度困擾
17.	肌肉痛?	□1	□2	□3	□4	□5
18.	胸口痛?	□1	□2	□3	□4	□5
19.	抽筋?	□1	□2	□3	□4	□5
20.	皮膚痕癢?	□1	□2	□3	□4	□5
21.	皮膚乾燥?	□1	□2	□3	□4	□5
22.	氣促?	□1	□2	□3	□4	□5
23.	頭昏眼花?.	□1	□2	□3	□4	□5
24.	非常疲倦?	□1	□2	□3	□4	□5
25.	手腳麻痺?	□1	□2	□3	□4	□5
26.	無胃口?	□1	□2	□3	□4	□5
27.	作嘔或胃部不適?	□1	□2	□3	□4	□5

腎病對你日常生活的影

有些病人的日常生活因腎病而受困擾,而有些病人則不受影響,

腎病對你的日常生活有多少困擾呢?

		毫無困擾	輕微困擾	中度困擾	很多困擾	極度困擾
29.	限制飲水?	□1	□2	□3	□4	□5
30.	進食限制?	□1	□2	□3	□4	□5
31.	家務勞動能力?	□1	□2	□3	□4	□5
32.	旅行能力?	□1	□2	□3	□4	□5
33.	倚賴醫生及其他醫療人 員?	□1	□2	□3	□4	□5
34.	因腎病而感到有壓力及憂 慮	□1	□2	□3	□4	□5
35.	性生活?	□1	□2	□3	□4	□5
36.	個人外表?	□1	□2	□3	□4	□5
25.	手腳麻痺?	□1	□2	□3	□4	□5
26.	無胃口?	□1	□2	□3	□4	□5
27.	作嘔或胃部不適?	□1	□2	□3	□4	□5

多謝回答這些問題!



Kidney Disease and Quality of Life (KDQOL[™]-36)

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.



Thank you for completing these questions!

Study of Quality of Life For Patients on Dialysis

What is the purpose of the study?

This study is being carried out in cooperation with physicians and their patients. The purpose is to assess the quality of life of patients with kidney disease.

What will I be asked to do?

For this study, we want you to complete a survey today about your health, how you feel and your background.

Confidentiality of information?

We do not ask for your name. Your answers will be combined with those of other participants in reporting the findings of the study. Any information that would permit identification of you will be regarded as strictly confidential. In addition, all information collected will be used only for purposes of the study, and will not be disclosed or released for any other purpose without your prior consent.

How will participation benefit me?

The information you provide will tell us how you feel about your care and further understanding about the effects of medical care on the health of patients. This information will help to evaluate the care delivered.

Do I have to take part?

You do not have to fill out the survey and you can refuse to answer any question. Your decision to participate will not affect your opportunity to receive care.

Your Health

This survey includes a wide variety of questions about your health and your life. We are interested in how you feel about each of these issues.

1. In general, would you say your health is: [Mark an 🖂 in the one box that best describes your answer.]



	Yes No
4.	Accomplished less than you would like
5.	Were limited in the <u>kind</u> of work or other activities
Dur with	ing the past 4 weeks, have you had any of the following pro 1 your work or other regular daily activities as a result of an
emo	otional problems (such as feeling depressed or anxious)?
	$\bigvee Yes No$
6.	Accomplished less than you would like
	Didn't do work or other activities as carefully as
7.	usual

These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks ...



Your Kidney Disease How true or false is each of the following statements for you? Definitely Mostly Don't Mostly Definitely know false false true true **13.** My kidney disease interferes too much with my 1 2 3 4 life 5 14. Too much of my time is spent dealing with my ٦ ₂۲] ، [].....[۰..... s kidney disease **15.** I feel frustrated dealing with my kidney disease 1..... 3 5 **16.** I feel like a burden on my family] ₂] [] [5

	During the <u>past</u> of the following?	4 weeks, to what extent were you bothered by each
		Not at all Somewhat Moderately Very much Extremely bothered bothered bothered bothered
17.	Soreness in your muscles?	1 2 3 4 5
18.	Chest pain?	1 2 3 4
19.	Cramps?	1 2 3 4
20.	Itchy skin?	1 2 3
21.	Dry skin?	1 2 3
22.	Shortness of breath?	1 2 3 4 5
23.	Faintness or dizziness?	1 2 3 4 5
24.	Lack of appetite?	1 2 3 4 5
25.	Washed out or drained?	1 2 3 4 5
26.	Numbness in hands or feet?	1 2 3 4 5
27.	Nausea or upset stomach?	1 2 3 4 5
28 ^a .	(Hemodialysis patie	nt only)
	Problems with your access site?	1 2 3 4 5
28 ^b .	(Peritoneal dialysis	patient only)
	Problems with your catheter site?	1 2 3 4 5

Appendix 8a: 醫院焦慮抑鬱量表

參加者編號:	醫院焦慮	抑	鬱量表	日期:	
醫生都認識到情緒在多種下病疾	 中扮演重要角色,因此,	若果	你的醫生了解你的感受	一,他便能更加全面地	
暂 助你。這份問卷的設計就是為了幫助你的醫生去了解你的咸受,請閱讀下列每題,並屬出最近接你過去					
一星期的情緒狀況。請不要花太多	多時間考慮你的答案,你對	十問	題的立刻反應,往往比	反覆思量來得更準確	
1 我感到神經緊張:	8	3.手	戈感到缺乏衝勁,整	個人都慢下來	
A. 大部份時間感到	А	۱.	差不多全部時候		
B. 很多時間感到	В	8.	非常多時候		
C. 有時候、間中感到	C		有時候		
D. 完全不感到	D).	完全沒有		
2 我依然享受我以前享受的	事物 9).	我有一種忐忑不安	的驚恐(十五、十	
A. 肯定和以前一樣	7	六白	的感覺)		
B. 有點不及以前	А	۱.	完全沒有		
C. 只及以前小許	В	8.	間中有		
D. 和以前差得極遠	С		相當多時候有		
	D).	很常有		
3. 我有一種驚恐,好像有些	可怕的事情會發				
生	1	0.	我對自已的儀容失-	去興趣:	
A. 很肯定有,而且相當厲	害 A	۱.	肯定失去		
B. 有少許,但不太厲害	В	8.	比我應該關心的少		
C. 有,但不令我擔心			可能比我以前關心	的少	
D. 完全沒有	D).	我像以前一樣關心		

4. 我能看到事物有趣的一面並且會心微笑	11. 我感到不能安靜,像要不停地走動:
A. 和以前一樣	A. 很強烈
B. 有點不如以前	B. 相當強烈
C. 肯定不如以前	C. 不太強烈
D. 完全不能	D. 完全沒有
5. 煩惱的念頭在我腦海中浮現	12. 我對未來的事抱有熱切期望:
A. 絕大部份時候	A. 和以前一樣
B. 很多時候	B. 較為不如以前
C. 有時候,但不太常	C. 肯定不如以前
D. 只是間中	D. 絕無僅有
6. 我感到高興	13. 我突然感到驚惶失措
A. 完全不感到	A. 非常多時候
B. 不時常感到	B. 相當多時候
C. 有時候感到	C. 不太多時候
D. 大部份時候感到	D. 完全沒有
7 我能安坐並感到鬆弛	14. 我能夠享受喜歡的書,電台或電視節
A. 肯定能夠	目:
B. 通常能夠	A. 經常能夠
C. 不時常能夠	B. 有時候能夠
D. 完全不能	C. 不常能夠
	D. 絕少能夠
Appendix 8b: Hospital Anxiety and Depression Score (HADS) (English)

Study No.: _____

Date: _____

Hospital Anxiety and Depression Scale (HADS)

Emotion poses an important role in different kinds of diseases and is highly recognized. Therefore, your doctor may further assist you comprehensively upon he/she understands your feeling further. This questionnaire is designed solely to assist your doctor to perceive your feeling. Please read the following questions and circle the most appropriate feeling in the last week. It is not necessary to spend lots of time choosing your answer. Your prompt reaction is more appropriate than your repeated consideration.

- 1 I feel tense or 'wound up':
- A. Most of the time
- B. A lot of the time
- C. From time to time, occasionally
- D. Not at all
- 2 I still enjoy the things I used to enjoy:
- A. Definitely as much
- B. Not quite so much
- C. Only a little
- D. Hardly at all
- 3 I get a sort of frightened feeling as if something awful is about to happen:
- A. Very definitely and quite badly
- B. Yes, but not too badly
- C. A little, but it doesn't worry me
- D. Not at all

- 4 I can laugh and see the funny side of things:
- A. As much as I always could
- B. Not quite so much now
- C. Definitely not so much now
- D. Not at all
- 5 Worrying thoughts go through my mind:
- A. A great deal of the time
- B. A lot of the time
- C. From time to time, but not too often
- D. Only occasionally
- 6 I feel cheerful:
- A. Not at all
- B. Not often
- C. Sometimes
- D. Most of the time
- 7 I can sit at ease and feel relaxed:
- A. Definitely
- B. Usually
- C. Not Often
- D. Not at all
- 8 I feel as if I am slowed down:
- A. Nearly all the time
- B. Very often
- C. Sometimes
- D. Not at all

- 9 I get a sort of frightened feeling like butterflies in the stomach:
- A. Not at all
- B. Occasionally
- C. Quite Often
- D. Very Often
- 10 I have lost interest in my appearance:
- A. Definitely
- B. I don't take as much care as I should
- C. I may not take quite as much care
- D. I take just as much care as ever
- 11 I feel restless as I have to be on the move:
- A. Very much indeed
- B. Quite a lot
- C. Not very much
- D. Not at all
- 12 I look forward with enjoyment to things:
- A. Much as I ever did
- B. Rather less than I used to
- C. Definitely less than I used to
- D. Hardly at all
- 13 I get sudden feelings of panic:
- A. Very often indeed
- B. Quite often
- C. Not very often
- D. Not at all

- 14 I can enjoy a good book or radio or TV program:
- 1. Often
- 2. Sometimes
- 3. Not often
- 4. Very seldom

Scoring (add the as = Anxiety. Add the Ds = Depression). The	0-7 = Normal
norms below will give you an idea of the level of Anxiety and	8-10 = Borderline abnormal
Depression.	11-21 = Abnormal

Appendix 9: Protocol of common signs and symptoms

Collaborative study

Queen Elizabeth Hospital and The Hong Kong Polytechnic University

Transitional renal palliative care model for ESRD patients

The protocol of nursing interventions

Oedema:

- low salt intake
- limitation of fluid intake
- positioning/elevation of edematous peripheral limb
- adjustment of anti-diuretic medications according to prescription
- shortness of breath:
- ensure a well-ventilated environment
- no tight clothing around the collar
- prop up a position with a back well supported
- apply general massage for a soothing effect
- adjustment of anti-diuretic medications according to prescription

Hypertension:

- Ensure appropriate intake of anti-hypertensive medication
- Low salt diet
- Limitation of fluid intake
- Adequate rest
- Hypotension:
- Ensure appropriate intake of anti-hypertensive medication

Hypotension

- Rule out any severe diarrhoea or vomiting
- Encourage fluid and sodium intake temporary

Blood sugar level

- Hyperglycemia
- Ensure appropriate intake of anti-hyperglycemic medication
- Rule out any dietary non-compliance
- Reinforce the importance of dietary compliance
- Hypoglycemia
- Ensure appropriate intake of anti-hyperglycemic medication
- Rule out any nausea, vomit or anorexia
- Reinforce the importance of dietary compliance

Pruritus

- Maintain personal hygiene
- Use non-irritating soap/cleansing lotion
- Apply skin lotion or cream for dry skin
- Keep well-ventilated environment
- Administer prescribed sedative

Insomnia

- Maintain personal hygiene
- Put on comfortable clothing
- Avoid any intake of coffee or tea before bed
- Undergo relaxation activities e.g. enjoy music, read books
- Adopt meditative / relative exercise
- Avoid sleeping at day time
- Arrange comfort bed linen
- Arrange a quiet and comfortable sleeping environment
- Administer prescribed sedative

Constipation

- Encourage tolerated level of exercise
- Adopt a high roughage diet
- The general message of the abdominal wall
- Administer prescribed laxative

Muscle cramps / joint pain

- Maintain regular exercise
- Apply muscle relaxant ointment
- Apply warm /cold compass locally
- Keep the affected area warm/cool
- Administer prescribed analgesic

The protocol of nursing interventions

1. Imbalance of hydration:

I. Oedema:

- low salt intake
- limitation of fluid intake
- positioning/elevation of edematous peripheral limb
- adjustment of anti-diuretic medications according to prescription

ii. Shortness of breath:

- ensure a well-ventilated environment
- no tight clothing around the collar
- prop up a position with a back well supported
- apply general massage for a soothing effect
- adjustment of anti-diuretic medications according to prescription

2. Blood pressure

I. Hypertension:

- Ensure appropriate intake of anti-hypertensive medication
- Low salt diet
- Limitation of fluid intake
- Adequate rest

ii. Hypotension:

- Ensure appropriate intake of anti-hypertensive medication
- Rule out any severe diarrhoea or vomiting
- Encourage fluid and sodium intake temporary

3. Blood sugar level

i. Hyperglycemia

- Ensure appropriate intake of anti-hyperglycemic medication
- Rule out any dietary non-compliance
- Reinforce the importance of dietary compliance

ii. Hypoglycemia

- Ensure appropriate intake of anti-hyperglycemic medication
- Rule out any nausea, vomit or anorexia
- Reinforce the importance of dietary compliance

4. Pruritus

- Maintain personal hygiene
- Use non-irritating soap/cleansing lotion
- Apply skin lotion or cream for dry skin
- Keep well-ventilated environment
- Administer prescribed sedative

- 5. Insomnia
- Maintain personal hygiene
- Put on comfortable clothing
- Avoid any intake of coffee or tea before bed
- Undergo relaxation activities e.g. enjoy music, read books
- Adopt meditative / relative exercise
- Avoid sleeping at day time
- Arrange comfort bed linen
- Arrange a quiet and comfortable sleeping environment ix. Administer prescribed sedative
- 6. Constipation
- Encourage tolerated level of exercise
- Adopt a high roughage diet
- The general message of the abdominal wall
- Administer prescribed laxative
- 7. Muscle cramps / joint pain
- Maintain regular exercise
- Apply muscle relaxant ointment
- Apply warm /cold compass locally
- Keep the affected area warm/cool
- Administer prescribed analgesic

Appendix 10a: 滿意程度調查

參加者編號:_____

日期:_____

病人滿意程度(對照組)

圈上最合適的數字

	非	同	普	不	非	不
請你話俾我知你嘅意見,對今次醫院俾到你嘅安排及服務,你覺得點 呀?	常	意	通	同	常	適
	同		啦	意	不	用
1. 你滿意今次醫院俾到你嘅安排或者服務。	5	4	3	2	1	0
2. 整體嚟講,你滿意醫院內醫護人員嘅工作態度。	5	4	3	2	1	0
3. 醫院嘅安排或者服務,可以幫倒你解決疑難或者問題。	5	4	3	2	1	0
 醫院嘅安排或者服務,可以令你照顧病患者時不會覺得孤 獨無助 	5	4	3	2	1	0
 5. 醫院俾你嘅安排或者服務,可以令你多啲明白你嘅病情、多啲關心 自己。 	5	4	3	2	1	0
6. 醫院俾你嘅安排或者服務,可以令你返到屋企之後更加安心啲。	5	4	3	2	1	0
7. 醫院俾你嘅安排或者服務,可以令你更有效咁處理及服用葯物。	5	4	3	2	1	0
 醫院俾你嘅安排或者A服務,可以令你更有效咁控制你嘅病情。 	5	4	3	2	1	0
9. 醫院內嘅健康單張或資料指引可以幫到你。	5	4	3	2	1	0
10. 醫院俾你嘅安排或者服務,可以满足到你嘅需要,令你舒服啲。	5	4	3	2	1	0
11. 醫院俾你嘅安排或者服務可以令你多啲留意日常生活或飲食習慣等。	5	4	3	2	1	0
12. 整體嚟講,你满意醫院俾你嘅安排或者服務。	5	4	3	2	1	0

13. 你覺得醫院可以俾多啲咩服務俾你呢

14. 醫院有邊幾方面可以幫到你嘅呢?

15. 你對醫院俾你嘅安排或者服務重有咩嘢意見

Appendix 10b: Patient satisfaction (Control)

Study number:

Date:

Patient Satisfaction (Control group)

Circle the appropriate answer

Please provide your comments on the home visit, telephone follows up. How do you feel about the services? Any agreement with the statement?	Agree Strongly Agree	No comment	Disagree	Strongly	Not Applicable
1. You are satisfied with the hospital arrangement and services.	5 4	3	2	1	0
2. Overall, you satisfy with the attitude of the staff in the hospital.	5 4	3	2	1	0
3. The hospital services provided by the hospital can help you to solve the query or problems.	5 4	3	2	1	0
4. The hospital services make you feel that you are not alone in taking care of	5 4	3	2	1	0
5. The hospital services enhance your better understanding of your disease and concern for your self-care.	5 4	3	2	1	0
6. The hospital services enhance your competency in caring upon your discharge home	5 4	3	2	1	0
7. The hospital services enhance your competency in handling your medication.	5 4	3	2	1	0
8. The hospital services enhance your control of the disease effectively.	5 4	3	2	1	0
9. You can benefit from the health-related pamphlet provided by the hospital.	5 4	3	2	1	0
10. The hospital services entertain all your needs.	5 4	3	2	1	0
11. The hospital services enhance your focus on your daily living style and dietary habits.	5 4	3	2	1	0
12. On the whole, you satisfy with the hospital services or arrangement.	5 4	3	2	1	0

13. What other services the hospital can provide?

14. You can benefit from which category of hospital services.

15. Any comments on the hospital services?

參加者編號:_____

-	110		
ы	ŦН	•	
	ĿН		
-	7YJ	•	

病人滿意程度(實驗組)

圈上最合適數字

		非	同	普	不	非	不
請你 你學	< <p>話俾我知你嘅意見,對於我地嚟探你、同埋打電話 俾你, ·得點呀?你同唔同意我講嘅嘢呀?</p>	常	意	通	同	常	適
		同		啦	意	不	用
1.	你滿意我地用電話同你聯絡安排嘅探訪時間。	5	4	3	2	1	0
2.	整體嚟講,你滿意我地啲工作人員嚟探你或打電話俾你果陣 時嘅態度。	5	4	3	2	1	0
3.	我地嘅服務,例如電話跟進,可以幫倒你解決疑難或者問 題。	5	4	3	2	1	0
4.	我地嘅服務,可以令你照顧病患者時不會覺得孤獨 無助	5	4	3	2	1	0
5.	我地嘅服務可以令你多啲明白你嘅病情、多啲關心自己。	5	4	3	2	1	0
6.	我地嘅服務可以令你返到屋企之後更加安心啲。	5	4	3	2	1	0
7.	我地嘅服務,可以令你更有效咁處理葯物。	5	4	3	2	1	0
8.	我地嘅服務,可以令你更有效咁控制你嘅病情。	5	4	3	2	1	0
9.	我地俾你睇嗰啲健康單張可以幫到你。	5	4	3	2	1	0
10.	我地俾倒你嘅服務,可以滿足倒你嘅需要。	5	4	3	2	1	0
11.	我地嘅服務可以令你多啲留意日常生活或者飲食習慣等。	5	4	3	2	1	0
12.	整體嚟講,你滿意我地呢個嘅服務。	5	4	3	2	1	0
10	1 8 11 4 10 11 1-4 12 11	l	1	1	1	1	1

13. 你覺得我地嚟探你嘅時候,仲可以做啲乜嘢呢?

14. 呢個服務有邊幾方面可以幫到你嘅呢?

15. 你對我地嘅服務有咩嘢意見呢?

Appendix 10d: Patient Satisfaction

Patient Satisfaction (Interventional group)

Circle the appropriate

Please provide your comments on the home visit, telephone follows up.	Stro	Agr	No c	Disa	Stro	Not
How do you feel about the services? Any agreement with the statement?	ngly agree	ee	comment	gree	ngly	Applicable
Are you satisfied with the arrangement of a home visit through a telephone call	5	4	3	2	1	0
Overall, you satisfy with the attitude of the staff in the home visiting or phone calling?						
Our services, e.g. telephone follow up, can facilitate your problem solving or quiz answering.	5	4	3	2	1	0
Our services make you feel that you are not alone in taking care of	5	4	3	2	1	0
Our services enhance your understanding better of your disease and concern yourself care more.	5	4	3	2	1	0
Our services enhance your competency in caring upon your discharge home.	5	4	3	2	1	0
Our services enhance your competency in handling your medication.	5	4	3	2	1	0
Our services enhance your control of the disease effectively.	5	4	3	2	1	0
You can benefit from the health-related pamphlet we provided.	5	4	3	2	1	0
The services we provided can entertain all your needs.	5	4	3	2	1	0
Our services enhance your focus on your daily living style and dietary habit.	5	4	3	2	1	0
On the whole, you satisfy with this service.	5	4	3	2	1	0
13. What other issues we can provide when we home visit you?		1				1

14. You can benefit from which category of these services.

15. Any comment on the services we provided

Appendix 11a: 沙氏照顧者負擔訪問

參加者編號:_____

日期:_____

沙氏照顧者負擔

請用圈選擇你所感受的程度。

		没	甚	間	時	頻
		有	少	中	常	密
		出	出	出	出	出
		現	現	現	現	現
1	你有没有感到你這親人所要求的幫助過於他/她真正需要的	0	1	2	3	4
2	你有没有感到因花了時間在這親人身上,而使自己時間不足	0	1	2	3	4
3	你有没有因為要照料這親人,又同時要應付家庭和工作上的	0	1	2	3	4
	種種責任而感到有壓力呢?					
4	你有没有為你親人的行為而感到尷尬呢?	0	1	2	3	4
5	當你親人在你附近時,你有否感到忿怒呢?	0	1	2	3	4
6	你有否感到你親人在你與其他家人的關係上產生負面的影響	0	1	2	3	4
	呢?					
7	你有否為你親人的將來感到害怕呢?	0	1	2	3	4
8	你有否感到你親人正依賴著你呢?	0	1	2	3	4
9	當你親人在你左右時,你會否感到緊張呢?	0	1	2	3	4
10	你有否感到因為照顧這親人而使自己的健康受損呢?.	0	1	2	3	4
11	你有否感到你親人使你的私人空間不能如你希望有的多呢?	0	1	2	3	4
12	你有否感到你親人使你的社交生活受到限制呢?	0	1	2	3	4
13	你有没有因為你親人的原故,對於請朋友到訪而感到不安?	0	1	2	3	4
14	你有否感到你的親人正期望你照料他/她,好像就只有你是	0	1	2	3	4
	他/她所能依靠的?					
15	你有没有覺得没有足夠的金錢去應付你自己及照顧患者的開	0	1	2	3	4
	支呢?					
16	你有没有覺得没你將不能夠繼續照顧患者?	0	1	2	3	4
17	你有没有覺得自從患者病發之後,你失去支配自己的個人生	0	1	2	3	4
	活?					
18	你有没有希望別人能夠代你照顧患者?	0	1	2	3	4
19	你有没有感到不能肯定你能為你的親人做什麼事呢?	0	1	2	3	4
20	你有没有感到你該為你親人做更多的事情呢?	0	1	2	3	4
21	你有没有感到在照料你親人的事上,你其實可以做得更好	0	1	2	3	4
	呢?					
22	總括來說,在照料你親人上你感到有很大的負擔?	0	1	2	3	4

謝謝你回答這問卷!

Study number: _____

Date: _____

Zarit Burden Index

Please circle your feeling.

		Never	Rarely	Sometimes	Quiet frequently	Nearly always
1	How do you feel that your relatives ask for more help than he/she needs?	0	1	2	3	4
2	Do you feel that because of the time you spend with your relative that you don't have enough time for yourself?	0	1	2	3	4
3	Do you feel stressed between caring for your relative and trying to meet other responsibilities for your family or work?	0	1	2	3	4
4	Do you feel embarrassed about your relative's behaviour?	0	1	2	3	4
5	Do you feel angry when you are around your relative?	0	1	2	3	4
6	Do you feel that your relative currently affects your relationships with other family members or friends in a negative way?	0	1	2	3	4
7	Are you afraid of what the future holds for your relative?	0	1	2	3	4
8	Do you feel your relative is dependent on you?	0	1	2	3	4
9	Do you feel strained when you arc around your relative?	0	1	2	3	4
10	0 Do you feel your health has suffered because of your involvement with your relative?				3	4
11	Do you feel that you don't have much privacy as you would like because of your relative?	0	1	2	3	4
12	Do you feel that your social life has suffered because you are caring for your relative?	0	1	2	3	4
13	Do you feel uncomfortable about having friends over because of your relative?	0	1	2	3	4
14	Do you feel that your relative seems to expect you to take care of him/her as if you were the only one he/she could depend on!	0	1	2	3	4
15	Do you feel that you don't have enough money to care for your relatives in addition to the rest of your expenses?	0	1	2	3	4
16	Do you feel that you will be able to take care of your relative much longer!	0	1	2	3	4
17	Do you feel that you have lost control of your life since your relative's Illness?	0	1	2	3	4
18	Do you wish you could just leave the care of your relative to someone else!	0	1	2	3	4
19	Do you feel uncertain about what to do about your relative?	0	1	2	3	4
20	Do you feel you should be doing more for your relative?	0	1	2	3	4
21	Do you feel you could do a better job of caring for your relative?	0	1	2	3	4
22	Overall, how burdened do you feel in caring for your relative?	0	1	2	3	4

Thank you for your participation in this study

Appendix 12a: Checklist of telephone follow-up

Collaborative study

Queen Elizabeth Hospital and The Hong Kong Polytechnic University

Transitional renal palliative care model for ESRD patients

Checklist of telephone follow-up

Physiological assessment

- Vital signs:
- Blood pressure
- Temperature: fever
- Blood sugar level: hyper or hypoglycemia
- Respiration: any respiratory distress
- Hydration status: hydration balance
- Volume of intake
- Intake of salty food
- Volume of urine
- Symptoms of distress
- Shortness of breath
- Oedema
- Constipation
- Nausea/vomit
- Blood pressure
- Blood sugar level
- Pruritis / dry skin
- Insomnia
- Muscle cramps / joint pain

Health-related behaviour

- Drug compliance
- Dietary compliance

Psycho-social and spiritual assessment

- A feeling of the patient towards his/her general condition, the progress of the disease
- Relationship with carer/family

Progress of previously identified problems e.g., Home setting/safety measures

Set the mutual goal of a newly identified problem

Appendix 12b: 電話跟進記錄表

Telephone Follow-up	參加者編號:
第 電話跟進記錄表	
	Data of talambana EU.
	Date of telephone PO.
電話跟進開始時自我介紹:	
XXX,你好,我是 利沙伯醫院紓緩科家訪讀院後回 家生活的健康資訊(列出一個曾經講) 亞?	隻士 XXX,仲記得 X 日之前我嚟過你屋企探訪你,同你傾過一些出 過之內容:掂樣可以幫助自己處理症狀?),而加你個身體狀況怎樣
Health Assessment / Surveillance [健康評估及	監測]
Goals set in last home visit:	
1) 2) 3)	4)
 Physiological [生理]: signs & symptor 上一次家訪時你提到有 xx 症狀(例如: 頭暈, 了(例如: 胸口痛)以外, 仲有無,其他吾舒服? 並 建議提供:_ 	ns ,心口毅痛,胸口痛, 高血壓, 水腫,下肢腫脹), 你而家覺得點樣亞? 除 遇到這些症狀, 你會怎麼做?
2. Psycho-social-spiritual [心理/社交/心] 你而家嘅心情怎樣?對於你嘅身體狀況或 去?你同家人/照顧者啲關係怎樣?有無放 排? 建議提供:	臺] 者將來,你有咩嘢槑?有咩嘢元素(自己/別人/上天)比你力量撐落 唔低□事?有無親戚朋友想去見□?有無同屋企人商量身後事點樣安
3. Health related behavior [健康相關行為 你仲記得食緊幾多種藥?有方依時服藥?你 我們訂立啲計劃來做?或有無做運動/落樓行 建議提供:	[9] 仲記得有(例如: 減少食鹽同水份) 可以嘗試做阿?你有方跟 住 -□?
4. Environment [環境]: (if any) 上一次家訪時提出了一啲改善居家/環境危 善設施,你有冇安裝? 建議提供:	.險因素的建議,有冇落實執行阿?上一次家訪時提出的家居安全改

# = Rating ac	cording to the Problem I	Rating Scale [K-B-S]			
'K' =	1= No knowledge	2= Minimal knowledge	3= Basic knowledge	4= Adequate	5= Superior
'В' =	1= No appropriate	2= Rarely appropriate	3= Inconsistently	4= Usually appropriate	5=
'S' = Status	1= Extreme signs /	2= Severe signs /	3= Moderate signs /	4= Minimal signs /	5= No
結尾鼓勵說言	T 舌:慢性腎衰竭是慢性;	病,唔容易處理,我下;	文再打電話比你。你?	「 有冇一 D 嘢想做令自己	· 舒服
D?依家我地	一齊訂下目標,等我「	司你打打氣!			
Setting Goals	with the patient [我都想	息同你再訂立一些新目標	;]:		
1.					
2.					

Appendix 13: Patient-initiated telephone call

Record of the patient-initiated	Study number:
患者發起的電話記錄	Date of telephone call:
Health assessment:	Complaint(s):
• BP, P, Temperature, respiration	
Hydration	
• Appetite	
• BO	
• Sleep	
Emotion	
Pruritus	
Problems (KBS)	Strategies / interventions:
	Counseling / advice / education
	Treatment / therapeutic procedure

Patient initiated the telephone call

2. Mutual goals set up

Goal	Strategies

Goals set in last home visit:		

Remarks: (S & S stabilized, the incident of avoidance of hospitalization

日期:_____

訪問指引

伊利沙伯醫院暨香港理工大學護理學院聯合主辦

腎臟舒緩治療護理末期腎衰竭患者對腎臟舒緩治療護理

的個人感受(經驗)研究

自我介紹

(病人名稱), 你好, 我係香港理工大學護理學院學生,我地同伊利沙伯醫院合作做緊 一個調查研究,了解下病人嘅需要,想同你做個錄音訪問, 唔知有方問題呢?

面對面訪談的開放式問題

- 您能告訴我您對過渡舒緩護理的看法嗎?
- ·您在控制疾病症狀方面有哪些經驗?
- 您在預防疾病併發症方面有哪些經驗?
- ·您在病人健康教育方面有哪些經驗?
- ·您對轉介推薦服務有何經驗?
- •您如何評估護士個案經理提供的護理服務?
- ·您對改善舒緩護理服務和護理有何建議?

希望依家嘅治療方法可以幫到你,我地今日傾到呢度先,多謝你接受我地嘅訪問。

Appendix 14b: Interview guide

Interview Guide

Hong Kong Polytechnic University and Queen Elizabeth Hospital

Lived experience of renal palliative care

Date: _____

Study No.: _____

Part 1: Self-introduction

(Patient's name). How are you? I am a nursing student at Hong Kong Polytechnic University; in collaboration with Queen Elizabeth Hospital, we are now performing research to explore the experiences in palliative care through an interview. We are going to tape-record the interview, are you comfortable with this arrangement?

Open-ended questions for a face-to-face interview:

- Could you please tell me about your perceptions of TRPP?
- What are your experiences with the control of symptoms of the disease?
- What are your experiences in the prevention of complications of disease?
- What are your experiences in patient education?
- What are your experiences with the referral system?
- How would you assess the nursing care provided by the NCM?
- What are your recommendations for better services and care?

Hoping that the present treatment will keep you well, we finished the interview. Thank you for your participation.

Appendix 15: Protocol of referral

Protocol of referral

Renal Pallaiative Care

Category	Indication of referral	
Dietitian	• poor oral intake with a decreased BW of more than 3 Kg in 2 weeks	
	• BMI < 18	
	• serum albumin 25 gm /dL	
Occupational	• adjustment of home setting indicated e.g. anticipated risk of fall	
therapist	• anticipated risks of fall	
	facilitation of physical activities	
Physiotherapist	physical mobility encountered	
	• learning of exercise / physical activities	
Social worker	financial support	
	• psychological support	
	• social support	
	• emotional distress	
Physician	• surgical problem	
	• acute retention of urine	
	• imbalance hydration with respiratory distress, SOB	
	• hypertension with SBP > 160 OR DBP > 110	
	• hypotension with SBP <90 OR DBP < 50	
	• uncontrolled hyperglycemia: persistent blood sugar (haemstix) >14 gm%	
	• medication adjustment	
	• cardiac problems	
	• uncontrolled pain: secondary to poor quality of rest, oral intake and physical mobility	

	• anaemia: Hgb<8 with clinical manifestation e.g. dizziness, SOB on exertion
	 respiratory distress: prop up with> 2 pillows, cyanosis or SaO₂ < 92% at room air
	• hyperkalaemia / hypercalcaemia: Potassium > 5.2 mmol/L or with cardiac arrhythmia
	• infection: fever and other signs and symptoms of infection
APN / Nurse	• procedure e.g. dressing of the wound
consultant:	• sophisticated nursing problems
Nurse clinic	• complex nursing care indicated
Chaplain	• the pastoral or religious issue
	• spiritual support

Procedure of referral

- A full assessment of problems and documentation by the nurse case manager.
- NCM contacts the nurse coordinator of the renal palliative unit.
- The nurse coordinator arranges the referral for expertise management accordingly.
- The nurse coordinator informs the patient of the details of the consultation.

References for clinical practice and strategic planning

Hydration

Normal hydration: balance of fluid intake and output, no signs of fluid imbalance (fluid overload or dehydration), normal blood pressure

Over-hydration: high blood pressure SBP>160, DBP>95, shortness of breath, cough with blood-stained sputum, low SaO2 (< 92% with room air).

Dehydration: low blood pressure SBP < 90, DBP <50, symptoms of dizziness, the difficulty of breathing, low SaO2 (< 92% with room air).

Respiration

Normal: regular rate and rhythm; no difficulty of respiration unless engaged in vigorous exercise

Grade 1: shortness of breath in climbing a few stairs upwards

Grade 2: shortness of breath during walking on a plateau pathway with longer times compared with same-age people.

Grade 3: shortness of breath in walling for 100 meters on a plateau pathway

Grade 4: shortness of breath and intolerance to going outdoor

Nutritional assessment

3.1 Nutritional status:

	Normal	Mild	Medium	Severe
		malnutrition	malnutrition	malnutrition
Percentage of ideal body weight	90-110%	80-90%	60-80%	Below 60%
Body mass index (BMI)	21 > BMI < 23	18.5 - 20	16 - 18.5	Below 16
Serum albumin	35 g/L	30-34.9 g/L	25 – 29.9 g/L	Below 25 g/L

3.2 BMI measurement = Body weight (Kg) / body weight 2

Healthcare providers involved in the implementation of clinical intervention strategies

in the study

Researchers

- Responsible for the execution and coordinative management of the study in the study hospital
- Ensure the availability of resources.
- Communicate with the research team, the healthcare provider, the ethical committee of the study hospital and the Hong Kong Polytechnic University.
- Response to the enquire from the participants.
- Report the progress to the ethical committee of the study hospital.
- Refer to the consent

Coordinator of the study

- Communication between the study team and all multi-disciplinary members involved.
- Arrange and assist in the training of the multi-disciplinary team if indicated.
- Manage the inquiry from the participants of this trial
- Maintain communication between study team members with updated problems encountered and the progress of the study
- Attend the case conference
- Participate in the meeting with multi-disciplinary team members.

Data collector: renal nurse of the Renal Palliative Care Clinic

- Receive the training of the study focusing on the questionnaires
- Collection of data according to the schedule.
- Storage of the collected data in the study hospital.
- Maintain communication with the researcher, research coordinator, and the patient.

On-site study coordinator: APN of Renal Palliative Care Clinic

- Assignment of randomization to participants
- Coordinate the nursing and other health-related referrals.

Nurse case manager

- Acquires/attains the training and clinical experience in nurse case management of renal palliative care.
- Conducts pre-discharge assessment and care planning
- Provides continuous interventive nursing care, in addition to the basic care required, according to the protocol.
- Collects and documents the progress of the patients.
- Provides continuous and transitional care in terms of telephone follow up and home visits according to the study protocol.
- Provides an update on the progress of palliative care provision.
- Attends the case conferences.
- Conducts a face-to-face interview according to the study protocol.
- Communicate with the patient and family members, nurse coordinator, data collectors, physicians, and the research team.

Physician

- Assists in the verification of the eligibility of participants for the study.
- Provides support to the referral from the NCM
- Provides medical consultation to the NCM
- Attends case conferences and provides expert management.

Research assistant

- A research assistant, blinded to the randomization, retrieved the data from the questionnaire and the health information system of the hospital into the computer system.
- Report the progress of data retrieved.

Indications for consideration of referral:

- Uncontrolled hydration imbalance with respiratory distress, SOB
- Uncontrolled hypertension with SBP > 160 OR DBP > 110
- Uncontrolled hyperglycemia: persistent blood sugar level > 20
- Uncontrolled pain: secondary to poor quality of rest, oral intake and physical mobility
- Anaemia: Hgb<6 or Hgb<8 with clinical manifestation e.g. dizziness, SOB on exertion
- Respiratory distress: orthopnoea (prop up with.>2 pillows), cyanosis or SaO₂ < 92% at room air
- Hyperkalaemia/hypercalcaemia: $K^+ > 5.2$ or with cardiac arrhythmia
- Infection: fever and other signs and symptoms of local infection
- Social problem(s)
- Pastoral/religious issue
- Emotional distress

Conditions that require A&E referral

- The patient feels ill and lethargic
- Difficult or rapid breathing
- Fever
- Palpitation
- Severe hypertension / hypotension

Conditions that warrant medical advice

- An intolerable medications side effect
- Fainting/headache
- Infections did not resolve after completion of a course of antibiotic treatment
- Abnormal hydration: fluid overload or dehydration
- Persistent abnormal blood pressure

Conditions that require nurse consultation

- Inconsistent dietary / fluid management
- Presence of severe skin breakdown/bedsore
- Medication non-adherence
- Constipation
- Shoulder / back pain / joint pain
- Declined skin problems
- Severe ankle oedema
- Nausea and vomit
- Difficult breathing

Others:

- Financial issues: refer to medical social workers
- Spiritual support: pastoral experts
- Emotional distress: psychologist

Appendix 16a: 參加者家屬資料

參加者編號:_____

日期:_____

參加者家屬資料

請填妥以下資料或在適當之空格加上√・號

- 1. 性別: □1 男 □2 女
- 2. 職業: □全職 □兼職 □失業 □主婦 □退休 □義工
- 3. 在照顧病人期間,你能否擔任全職/兼職工作?

□否	□能夠
----	-----

- 4. 在過去三個月,為了照顧病者家人覆診,你是否需要向顧主請假
 - □否 □是 請說明
 - □一星期 □二星期 □一個月 □二個月 □半年

5. 在過去三個月,為了照顧病者家人,你是否需要健康食物品以增加體力

Appendix 16b: Particular caregivers

Study number: _	 Date:

Particulars of caregiver

1. Gender: \Box Male \Box Female

2. Occupation: □ Full-time job □ Part-time □ Unemployed □ Housewife □ Retired □ voluntary work

3. Did you manage yourself for a full-time/part-time job in caring for the patients?

 \Box No \Box Yes

4. Did you take time off from the work in accompanying your patient for follow up or treatment care?

 \square No

- □ Yes, please specify:
 □1 week □ 2 weeks □ 1 month □2 months □ 6 months
- 3. Did you take any health care product aiming at promoting your health status/ strength?
 - \Box No \Box Yes, please specify the cost\$

Appendix 17: Ethical Approval from the Research Ethical Committee of the study hospital



AUTHORITY

REC(KC/KE) Effective Date: Feb 2011 Revision No: 1.6 Title: REC Approval Form Document No: KCKE SOP001F6a Page 1 of 3 群 策 群 力 為 病 人 · 優 質 醫 護 滿 杏 林

Quality Patient-Centred Care Through Teamwork

Research Ethics Committee (Kowloon Central / Kowloon East)

c/o Queen Elizabeth Hospital 30 Gascoigne Road Kowloon

Dr CHAN Hoi Wong

Associate Consultant Renal Unit Department of Medicine Queen Elizabeth Hospital

3 March 2014

Ref: KC/KE-13-0248/FR-1

Dear Dr CHAN,

The REC(KC/KE) members are appointed by the Cluster Chief Executives to review and monitor clinical research independently according to the guidance of Declaration of Helsinki and ICH GCP Guidelines in order to safeguard the rights, safety and well-being of research subjects. It has the authority to approve, require modifications (to secure approval), or disapprove research. This committee has power to terminate/suspend a research at any time if there is evidence to indicate that the above principles and requirements have been violated.

The Committee has reviewed and approved your research application on 21 January 2014 at a review panel meeting. The approval decision was based on the documents submitted and the information presented by Ms TAM Mee Ling Bonnie at the meeting. You are required to adhere to the attached conditions:

Title of Study	Effects of a transitional palliative care model on patients with end- stage renal failure
Principal Investigator	Dr CHAN Hoi Wong, Associate Consultant, Renal Unit, Dept of Medicine, QEH
List of Co-investigators	Ms YEUNG Wai Fong Ellen, Nurse Consultant (Palliative Care), Dept of Clinical Oncology, RHTSK
	Ms LIU Chun Fong Faith, Nurse Consultant (Palliative care), Dept of Clinical Oncology, QEH
	Ms TAM Mee Ling Bonnie, Dept of Medicine, QEH
	Professor WONG Kam Yuet France, School of Nursing, HK PolyU
	Dr CHAU Ka Foon, Chief of Service, Dept of Medicine, QEH
Protocol title and version	Research Protocol [3 rd version_23 January 2014]

HA(G) 1

Appendix 18: Ethical approval from the HK Polytechnic University



Approval from the Hong Kong Polytechnic University

To Tam Mee Ling Bonnie (School of Nursing) From KWONG Wai Yung, Chair, Departmental Research Committe Email hsenid@ Date 05-Nov-2013

Application for Ethical Review for Teaching/Research Involving Human Subjects

I write to inform you that approval has been given to your application for human subjects ethics review of the following project for a period from 29-Nov-2013 to 30-Jun-2015: Project Title: Effects of a transitional palliative care model on patients with end-stage renal failure

Department: School of Nursing Principal Investigator: Tam Mee Ling Bonnie

Please note that you will be held responsible for the ethical approval granted for the project and the ethical conduct of the personnel involved in the project. In the case of the Co-PI, if any, having also obtained ethical approval for the project, the Co-PI will also assume the responsibility in respect of the ethical approval (concerning the areas of expertise of respective Co-PI following the stipulations given by the approving authority).

You are responsible for informing the Departmental Research Committee in advance of any changes in the proposal or procedures which may affect the validity of this ethical approval. You will receive a separate email notification should you be required to obtain fresh approval.

KWONG Wai Yung Chair Departmental Research Committee

Page 1 of 1

Non-pharmacological measures for pruritis (Huizen, 2017)

- bathing in cool or lukewarm water before bed, using only moisturizing, scent-free soaps, baking soda, or colloidal oatmeal.
- applying glycerin based, oil- and alcohol-free moisturizers before bedtime, such as CereVe, Cetaphil or Eucerin
- using natural ointments and creams with vitamin E and aloe vera
- running a humidifier in the bedroom to moisten the air.
- applying a cool compress, such as a cold, damp cloth, to the skin before bed
- using a fan to create airflow and background noise as a source of mental distraction
- wearing gloves or mittens to avoid scratching, which can worsen symptoms
- utilizing meditation techniques when falling asleep
- practising relaxation techniques, such as visualization, before bed
- trimming the fingernails short to reduce the chances of further irritating the skin
- wearing loose-fitting clothing to allow the skin to breathe
- not allowing pets in the bedroom
- checking the bedroom for signs of bed bugs or other insect infestations, including fleas or biting ants
- Take a caffeine-free drink, such as chamomile or peppermint, before bedtime
- using 2 to 3 drops of a relaxing essential oil, such as lavender, on the pillow before bedtime.

Appendix 20: Non-pharmacological measures to reduce fluid intake

Non-pharmacological measures to reduce fluid intake

Non-pharmacological measures for reducing fluid intake (Mayo Clinic staff, 2014) include the follows:

- cutting down salt intake
- putting off body fluid
- doing regular exercise
- elevating both lower limbs while rest to promote venous return
- wearing supporting stockings
- moving around regularly
- avoiding extremes of temperature, such as hot baths, showers, and saunas
- dressing warmly in cold weather
- reduce the amount of fluid intake and is facilitated by using a small-size drinking utensil, taking a small ice cube or mouth rinsing in tackling thirst

Appendix 21: invitation for expert review of the research protocol



Invitation for Expert Review of the research protocol

Research title:

Effects of Transitional Palliative care model for patients with End-Stage Renal Failure: A pilot randomized controlled trial

Dear

I am TAM Mee-ling, Bonnie, PhD student supervised by Professor WONG Kam-yuet, Frances, School of Nursing in The Hong Kong Polytechnic University. I am going to conduct a randomized trial for ESRF patients receiving palliative care through a transitional care program. This is a collaborative study of Queen Elizabeth Hospital and the Hong Kong Polytechnic University.

The objectives of this study are to examine the effects of the transitional care model for patients with palliative care in a home-based environment. Upon the discharge of the patient, continuous follow-up and support are provided for the patients and their family caregivers through a thorough assessment, planning, implementation, and evaluation of care. A nurse case manager will be adopted for nurse-led management during the care delivery process with multi-disciplinary support. In aiming at a scientific and applicable study, a planned research protocol is attached for your comments. Please review and comment on the study proposal.

I would like to invite you to be on the expert panel and feedback on your expert opinions on the study protocols. Your valuable input would help improve my research study and make it more relevant when applied to execution.

Should you have any questions concerning the study, please feel free to contact me: 852-6126 ; e-mail: <u>b.tam@</u> Thank you for your generous support for this research.

Yours sincerely,

TAM Mee-ling, Bonnie PhD Student School of Nursing, The Hong Kong Polytechnic University
Comments of the expert panel

Rating of the study protocol by an expert panel

Title: Effects of Transitional Palliative care model for patients with End-stage Renal Failure.

	Completely irrelevant	Irrelevant	Relevant	Most relevant
Level of relevancy				

	Completely invalid	Invalid	Valid	Most valid
Content of validity				

Comments (please quote the items with your comments):

Appendix 22: Record of Home visit

Appendix 22

	Record assessment form (pre-discharge and nome visit)									
		Intervention						oblem rating for Outcome		
lai	Problems or	Targ	et(s) & Client-specific i	nformation Categories			J J			
Dor	Concepts	Teaching, guidance, & counseling	Treatments & procedure	Case management	Surveillance	DATE	Knowledg 1-5)	Behavio 1-5)	Status (1-5)	
	1. Income									
lenta	2. Sanitation									
wironn	Residence									
En	4. Neighborhood / workplace safety									
	 Communication with community resources 									
	Social contact									
	7. Role change									
20	 Interpersonal relationship 									
svcho	9. Spirituality									
P P	10. Grief									
	11. Mental health									
	12. Caretaking									
	13. Neglect									
	14. Abuse									

Record assessment form (pre-discharge and home visit)

Record assessment form (pre-discharge and home visit) (cont'd)

Appendix 22

		Problem classification					Duchlem natin-					
ain	Problems or		Modifi	Problem rating								
Dom	Concepts	Actual problem (Briefly describe the patient's needs & strength) To include H/L to indicate the priority of problems	Health promotion/ Potential/ Actual	Individual; family; or community	DATE	Knowledge (1-5)	Behavior (1-5)	Status (1-5				
	15. Hearing											
	16.Vision											
	17.Speech & language											
	18. Oral health											
	19.Cognition											
	20.Pain											
	21.Consciousness											
	22.Skin											
ological	23.Neuro-musculo- skeletal function											
Physi	24.Respiration											
	25.Circulation											
	26.Digestion-hydration											

Record assessment form (pre-discharge and home visit) (cont'd)

Appendix 22

		Problem classification				Problem rating					
B.	Problems or Concepts		Modifi	rionem rating							
Doma		Actual problem (Briefly describe the patient's needs & strength) To include H/L to indicate the priority of problems	Health promotion/ Potential/ Actual	Individual; family; or community	DATE	Knowledge(1-5)	Behavior(I – 5)	Status (1-5)			
	27. Bowel function										
	28.Urinary function										
logical	29.Communicable/ infectious condition										
Physio	30.Nutrition										
iors	31.Sleep & rest										
d hehav	32.Physical activity										
h relate	33.Personal care										
Healt	34.PSubstance use										

Record assessment form (pre-discharge and home visit) (cont'd)

Appendix 22

		Problem classification							Problem rating			
.в	Problems or					Modifiers		Froblem racing				
Domai	Concepts	(Briefly descri <i>To include H/L</i>	Actual problem cribe the patient's needs & strength) I/L to indicate the priority of problems			promotion/ tential/ Actual	Individual; family; or community	DATE	Knowledge(1-5)	Behavior(1-5)	Status (1-5)	
or	35.Family planning											
ed behavi	36.Health caresupervision											
alth relat	37.Medication regimen											
He												
		Intervention							Problem rating for			
in	Problems or		Target(s) & Client-specific information					Outcome				
Doma	Concepts	Teaching, guidance, & counseling	Treatments & procedure	Case managem	ent	Surv	eillance	DATE	Knowledge(1-5)	Behavior(1-5)	Status (1-5)	
lavior												
ed be												
alth relat												
Hei												

Problem Classification Scheme

The first set of *modifiers*, *Health Promotion*, *Potential and Actual*, *Health Promotion* defines a positive state of client need and the absence of risk factors or signs and symptoms, *Potential* is used for clients who are at risk for developing a problem, *Actual* is the most negative because one or more signs and symptoms are already present.

The second set of modifiers, Individual, Family and Community, comprises a continuum and suggest to whom the problem pertains.

Concepts and Rating Scale for Outcomes:

Concepts	1	2	3	4	5
Knowledge: The ability of the client to remember and interpret information					
Behaviour: Observable responses, actions, or activities of the client fit the occasional purposes					
Status: Condition of the client in relation to objective and subjective defining characteristics					

Study no.:

Date: _____

Name of nurse: _____





QUEEN ELIZABETH HOSPITAL

甚麼回讀人具照顧思者? 腎科紓緩治療組

伊利沙伯醫院腎科紓緩治療 組是由腎科醫生和腎科護士 組成,目的為末期腎衰竭病人 提供透析以外的另一選擇。



腎科紓緩治療理念

腎科紓緩治療的理念是 根據個別腎病病人的徵狀和 心情的困擾度,提供:

☆ 藥物治療

- ☆ 飲食指引
- ☆ 轉介服務和心靈關顧
- ☆ 減輕腎病所引致的不適
- ☆ 給予病者情緒支援
- ☆ 提高生活質素
- ☆ 給予照顧者及家屬情緒支援

為何選擇紓緩治療?

不論是腎臟透析或腎臟移植 都各有功用和限制,亦各有風險 和可能出現的併發症。

醫護人員會為各患者作詳細 的病況評估及解釋。當發現透析 和腎臟移植都不是適合患者的治 療方法時,紓緩治療便是合適的 選擇。

此外,患者在接受腎臟透析 治療中因出現很多併發症而未能 享受其好處時,亦可考慮選擇紓 緩治療。

合適患者

- ☆ 身體嚴重虛弱
- ☆ 同時患上其它嚴重不能痊愈 病症
- ☆ 洗腎加添壓力和沉重負擔
- ☆ 患者受其他病症漫長折磨
- ☆ 洗腎未能改善患者生活質素

腎科紓緩治療特色

一站式門診:一個早上完成

為方便病人及其家屬,減省多 次往返醫院,提供一站式服 務。

服務包括:

◆抽血



醫務社工

本院醫務社工會為合資格病 人提供經濟上的支援,如有需 要請聯絡本院醫務社工室 地點:伊利沙伯醫院 E 座地下 6 號房 電話: 2958 7021

轉介服務

紓緩治療科護士會因應病人 的情況給予轉介,如:

F ◆ 物理治療 ♦陪診 6 ◆ 送餐 ◆ 復康巴士、易達巴士 ◆ 心理輔導等

Appendix 24: Palliation of signs and symptoms of ESRF





病者應該:

- ✔ 瞭解各種治療方法的特性
- ✔ 坦誠與家人相討治療計劃
- ✔ 選擇合適個人的治療方案
- ✓ 遵從治療計劃
- ✓ 適當飲食
- ✔ 合適社交活動
- ✓ 定期覆診
- ✔ 立即處理緊急事故

如有任何<mark>查詢或疑問</mark>, 歡迎致電腎科紓緩治療 組



2958 6506

辦工時間:

- ◆ 星期一至六及公眾假期
- ◆上午8時至下午8時
- ◆ 星期日休息

如有緊急嚴重不適:

- 應往就近的急症室或
- 致電 999 求助。



☆ 腳腫



2. 用枕頭墊高水腫部位

1. 减少進食流質和鹽份

 由醫生按病況處方利尿藥(去水 九)



☆ 便秘 1. 在許可情況下作 適量的運動

- 根據醫護人員指示按病況進 食纖維食品
- 3. 由醫生按病況處方通便藥

紓緩徵狀小錦囊

☆失眠

1. 盡量避免日間小 睡



- 2. 保持心情平靜
- 3. 避免飲用含咖啡因的飲料
- 睡前避免收看刺激性的電視 節目

☆ **氣喘** 1. 減少進食流質和 鹽份

- 2. 打開窗戶,讓空氣流通
- 由醫生按病況處方利尿藥 (去水丸)

- 1. 用溫水洗澡
- 2. 塗潤膚膏減少皮膚乾燥
- 3. 常修剪指甲,以免抓傷皮膚
- 4. 由醫生按病況處方止痕膏或口 服藥物

1. 按時服止痛藥



 用冷敷、熱敷或按摩等方法 紓緩痛楚