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THE EFFECTS OF A NURSE-LED CASE MANAGEMENT PROGRAM ON HOME EXERCISE TRAINING FOR HEMODIALYSIS PATIENTS: A RANDOMIZED CONTROLLED TRIAL

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The Effects of a Nurse-led Case Management Program on Home Exercise Training for Hemodialysis Patients: A Randomized Controlled Trial

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

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CENTIFICATE OF ORIGINALITY

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Thesis title: The Effects of a Nurse-led Case Management Program on Home Exercise Training for Hemodialysis Patients: A Randomized Controlled Trial

Abstract

Background: Patients on maintenance hemodialysis experience diminished physical health. Exercise has been shown to be effective in improving physical function and optimizing well-being in this patient group. Nephrology nurses should be encouraged to promote it in the routine care of hemodialysis patients.

Aim: The aim of this study was to examine the effects of a 12-week nurse-led case management program on home exercise training among hemodialysis patients.

Methods: The study constituted a randomized, two-parallel group trial. One hundred and thirteen adult patients on dialysis treatment for more than three months were recruited from the hemodialysis units of two tertiary hospitals in Nanjing, China. They were randomly assigned to either an intervention group (n = 57) or control group (n = 56). Both groups underwent a brief weekly center-based exercise training session before their dialysis sessions for the first six weeks. The intervention group received additional nurse case management on home exercise weekly for the first six weeks and then biweekly for the following six weeks during their dialysis sessions. Outcome measures included gait speed, 10-repetition sit-to-stand performance, quality of life, self-rated health, depressive symptoms, physical activity level, and patient-perceived exercise benefits and barriers. Data were collected at baseline and at 6 and 12 weeks into the program.

Results: With regard to normal gait speed, repeated-measured analysis of variance revealed that patients in the intervention group demonstrated greater increases over time [$F_{(1, 111)} = 4.42$, $p = 0.038$] than those in the control group. No significant between-group effects were found in either fast gait speed or 10-STS performance ([$F_{(1, 111)} = 3.93$, $p = 0.050$]; [$F_{(1, 111)} = 3.92$, $p = 0.050$], respectively); but the increase trends of these two outcomes were faster for the intervention group than for the control group between weeks six to twelve. The results of Friedman tests showed a significant improvement in symptoms and problem domain of the quality of life. Patients in both groups showed improved self-rated health over time with no between-group differences. There were no group differences in depressive symptoms. Significant group differences were noted in physical activity levels upon completion of the program ($z = -4.897$, $p < 0.001$), with the intervention group reporting higher such levels. With regard to patient-perceived exercise benefits and barriers, there was a significant between-group effect [$F_{(1, 111)} = 4.45$, $p = 0.037$], with the intervention group reporting a greater reduction in perceived barriers to exercise.

Conclusions: Home exercise intervention delivered through the nurse case

management approach is promising to improve physical functioning and quality of life for hemodialysis patients. The case management approach was effective in helping hemodialysis patients to overcome identified barriers to exercise and subsequently engage in home exercise.

Publications arising from the thesis

1. Tao, X. J. (2012). Symptoms and associated health outcomes in patients undergoing renal dialysis: A literature review. *Journal of Nursing Intervention, 18* (S1), 58.

2. Tao, X. J., Chow, S. K. Y., & Wong, F. K. Y. (2014). Determining the validity and reliability of the Chinese version of the kidney disease quality of life questionnaire (KDQOL-36^{TM}). *BMC Nephrology, 15*, 115. doi:10.1186/1471-2369-15-115

3. Tao, X. J., Chow, S. K. Y., & Wong, F. K. Y. (2015). A nurse-led case management program on home exercise training for hemodialysis patients: a randomized controlled trial. *International Journal of Nursing Studies, 52* (6), 1029-1041. doi.org/10.1016/ j.ijnurstu.2015.03.013

Conference presentations

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2. Tao, X. J., Chow, S. K. Y. & Wong, F. K. Y (2014). The effects of a nurse-led case management program on home exercise training for haemodialysis patients: preliminary results. *Proceedings of the 17th East Asia Forum of Nursing Scholars, Manila, Philippines.* 20-21 February, 2014. [Oral presentation]

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LIST OF ABBREVIATIONS

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ADL	Activities of daily living
AHA	American Heart Association
BDI	Beck Depression Inventory
BDI-II	Beck Depression Inventory Second Edition
BP	Blood pressure
BRS	Baroreflex sensitivity
CBDI-II	Chinese version of the BDI-II
CI	Confidence interval
CKD	Chronic kidney disease
cm/s	Centimeters per second
COPD	Chronic obstructive pulmonary disease
CVD	Cardiovascular disease
DOPPS	Dialysis Outcomes and Practice Patterns Study
DPEBBS	Dialysis Patient-perceived Exercise Benefits and Barriers Scale
DUC	Dialysate urea clearance
EMS	Electrical myostimulation
ESAs	Erythropoiesis-stimulating agents
ESRD	End-stage renal disease
g/L	Grams per liter

HADS	Hospital Anxiety and Depression Scale
Hb	hemoglobin
HD	Hemodialysis
HPM	Health Promotion Model
HR	Hazard ratio
HRQoL	Health-related quality of life
ICF	International Classification of Functioning Framework
ICW/kg	Intracellular water volume per kilogram of body weight
ITT	Intention-to-treat
KDCS	Kidney Disease Component Summary
K/DOQI	Kidney Disease Outcomes Quality Initiative
KDQOL	Kidney Disease Quality of Life
KDQOL-36™	Kidney Disease Quality of Life Short Form
Kt/V	$(K_{urea} \times T_d)/V_{urea}$
LOCF	last observation carried forward
MAR	Missing at random
MCID	Minimal clinically important difference
MCS	Mental Component Summary
MDC	Minimal detectable change
MDC_{90}	Minimal detectable change at the 90% confidence interval
MET	Metabolic equivalent task
MI	Multiple imputation

m/s	Meter/second
NCM	Nurse case management
NKF-K/DOQI	National Kidney Foundation Kidney Disease Outcomes Quality Initiative
PCS	Physical Component Summary
PD	Peritoneal dialysis
PEDro	Physiotherapy Evidence Database
PP	per-protocol
PWV	Pulse wave velocity
RCTs	Randomized controlled trials
REXDP	Renal Exercise Demonstration Project
RLS	Restless leg syndrome
RM-ANOVA	Repeated-measures analysis of variance
RPE	Rate of perceived exertion
RR	Relative risk
SD	Standard deviation
SF-12	12-item Short Form Health Survey
SF-36	36-item Short Form Health Survey
SNOSE	Sequentially numbered, opaque, sealed envelopes
SPPB	Short physical performance battery
SRH	Self-rated health
STS	Sit-to-stand
STS-30	30-second STS
STS-60	60-second STS
TUG	Time-Up and Go
VO_{2peak}	Peak oxygen uptake

6-MWT	6-minute walking test
5-STS	5-repetition STS
10-STS	10-repetition of the sit-to-stand test

Chapter 1: Introduction

1.1 Introduction

This chapter begins with the background to the study, presenting the physical function issues that need to be addressed in the hemodialysis (HD) population, a brief review of the potential solutions available, and the proposal of a promising alternative to improving HD patients' physical health. It then turns to the study's aim and objectives, followed by a discussion of its significance. The chapter concludes with a thesis outline.

1.2 Background

1.2.1 Overview of hemodialysis therapy

End-stage renal disease (ESRD) is defined as stage 5 chronic kidney disease (CKD) with a glomerular filtration rate of less than 15 ml/min/1.73m^2 or the use of dialysis (National Kidney Foundation, 2002). This stage of the disease is characterized by an irreversible decline in kidney function sufficiently severe to be fatal in the absence of life-long dialysis or transplantation (Abbasi, Chertow, & Hall, 2010). Renal transplantation completely replaces native renal function, and is associated with better survival and increased quality of life (Landreneau, Lee, & Landreneau, 2010). However, the demand for kidneys far exceeds the available supply, and the high prevalence of morbidities in the dialysis population may further limit the use of transplantation. In 2004, approximately 77% of ESRD patients worldwide were receiving dialysis treatment. Of the total 1,371,000 dialysis patients, 89% (1,222,000) were on chronic HD (Grassman, Gioberge, Moeller, & Brown, 2005). Although an increase in the peritoneal dialysis (PD) rate has been noted in some countries (e.g., China, Vietnam, Taiwan, and Thailand) in recent years (Jain, Blake, Cordy, & Garg, 2012; Liang et al., 2011; Lo, 2009), in-center HD remains the predominant treatment modality for ESRD patients worldwide, except in Hong Kong (Yu, Chau, Ho, & Li, 2007), El Salvador, Mexico, and Guatemala (Jain et al., 2012).

HD is a process involving the bidirectional movement of molecules across an artificial semipermeable membrane outside the body (Ahmad, 2009). The National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF-K/DOQI) clinical practical guidelines for HD adequacy (Hemodialysis Adequacy 2006 Work Group, 2006) recommend a minimum of thrice weekly three-hour HD sessions for patients with little residual renal function. Conventional chronic HD treatment is normally performed in three- to four-hour sessions three times a week for patients' entire life or until they receive renal transplantation (Cheema & Singh, 2005).

Although HD is life-prolonging, and adequately replaces the filtration and waste elimination functions of the kidneys, it cannot compensate for the loss of endocrine function and metabolic activity (Fleming, 2011) or prevent cardiovascular complications (Spieldenner, 2006). HD patients are not only at risk of such possible dialysis-related symptoms as intradialytic hypotension, cardiac arrhythmias, muscle cramps, nausea, vomiting, dizziness, and headache (Al-Hilali et al., 2004; Davenport, 2006; Sherman, Daugirdas, & Ing, 2007), but they also face such life-threatening long-term complications as anemia, renal osteodystrophy, malnutrition, β^2-microglobin amyloidosis, and cardiovascular disease (CVD) (Blagg, 2001; Sherman et al., 2007). In addition, lifelong dependence on HD machines, regular compulsory hospital visits, maintenance of diet and fluid restrictions, reliance on caregivers, and the accompanying social limitations, disturbs the whole of a patient's life (Hagren, Pettersen, Severinsson, Lutzen, & Clyne, 2005). This patient group therefore undergoes a substantial and often fast-paced decline in quality of life. There is accumulating evidence to show that HD patients experience impaired self-reported physical, mental, and social wellbeing, as indicated by low scores on health-related quality of life (HRQoL) measures (Fukuhara et al., 2003; Mittal et al., 2001; Valderrabano, Jofre, & Lopez-Gomez, 2001).

HRQoL impairment is greater for physical health than mental health in the HD population. Yarlas et al. (2011) drew the conclusion that HD has a greater impact on physical outcomes than mental outcomes by analyzing 26 articles and calculating the effect sizes of each subscale and the summary scale of the 36-item Short Form Health Survey (SF-36) between control/normative and HD samples. The differences in mean scores between the control/normative samples and HD samples were extracted to compute effect size, with a large effect size indicating a greater health burden. Large effect sizes were found for the Physical Component Summary (PCS) scores in 88% of the studies reviewed and small or negative effect sizes for the Mental Component Summary (MCS) scores in 62% (Yarlas et al., 2011). These results therefore indicate that physical function is predominantly impaired in HD patients and that any improvement in such function may enhance their overall quality of life. Similarly, a systematic review using the same analyses to interpret HRQoL outcomes demonstrated that physical functioning (e.g., role-physical, vitality) is the most affected of all SF-36 domain scores for the ESRD population (Spiege, Melmed, Robbins, & Esrailian, 2008).

In addition, functional deterioration and limitation are major problems in the elderly at large. Owing to the aging of the general population, better survival rates in the HD population, and more liberal access to dialysis treatment for elderly patients, the average age of patients receiving dialysis has increased steadily over the past few decades (Canaud et al., 2011; Noordzij et al., 2014; United States Renal Data System, 2013). It is likely that kidney dysfunction accompanied by an older age may accelerate physical deterioration (Cook & Jassal, 2008). As the number of elderly dialysis patients grows and the long-term survival of those patients increases, the nephrology community is likely to face an accelerated number of physically challenged patients.

1.2.2 Consequences of physical impairment

Suboptimal physical function may impede patients' ability to perform self-care and participate in social activities, which has psychosocial ramifications, imposing additional burdens and costs on individuals, families, and healthcare services (Kutner, Brogan, Hall, Haber, & Daniels, 2000; Sankarasubbaiyan & Holley, 2000).

First, impaired physical functioning is a contributor to unemployment in working-age patients (< 65) (Curtin, Oberley, Sacksteder, & Friedman, 1996; Molsted, Aadahl, Schou, & Eidemak, 2004; van Manen et al., 2001). The reported unemployment rate among patients on dialysis ranges from 60-80% (Kutner, Bowles, Zhang, Huang, & Pastan, 2008; Markell et al., 1997). Owing to the breakdown of social networks, the loss of a paid job imposes an extra psychosocial burden on patients under the age of 65 (Theorell, Konarski-Svensson, Ahlmen, & Perski, 1991), as well as a heavy financial burden on their families and society at large. In a recently published cost-analysis study in Spain, the percentage of employed HD recipients was reported to be much lower than that of the general population in 2009 (21.7% versus 60.6%), according to global data reported by the National Statistics Institute, imposing an estimated mean annual cost of €6,547 per patient in lost labor productivity due to morbidity for this patient group (Julian-Mauro, Cuervo, Rebollo, & Callejo, 2013).

Second, the process of worsening functional limitation ultimately leads to disability and dependence in carrying out the activities of daily living (Altintepe et al., 2006). A recent observational study including over 99% of all prevalent HD patients in Taiwan used the Barthel Index to evaluate dynamic changes in their physical functional disabilities (Hung, Sung, Chang, Hwang, & Wang, 2014). The results revealed that patients initiating HD treatment at the age of 35 or above could expect at least three years of living with disabilities, and the proportion of functional disability increased with age. An earlier investigation of the pattern and proportion of elderly dialysis patients with one or more disabilities in performing daily living activities found 95% (152 out of 162) to be living with at least one (Cook & Jassal, 2008). Housework, shopping, and laundry were the most common daily living activities in which they experienced dependence.

Third, CKD itself, as well as its corresponding treatment, reduced social support, and concomitant risk of disability, increase the risk of depression. A prospective study on depression in the HD population found more than half of all participants (n = 159) to have possible depressive symptoms, with depression status remaining unchanged over the 12-month follow-up period (Ng, Tan, Mooppil, Newman, & Griva, 2014). Data analysis from a Taiwanese cohort study involving 888 HD patients from 14 hospitals revealed patients' mental health, as measured by the Beck Depression Inventory (BDI), to be significantly inversely correlated with the physical functioning domain of the SF-36 (Peng et al., 2010). In a more recent study, Zhang et al. (2014) reported that 43% of 72 relatively healthy HD patients were depressed according to their BDI scores, with a close association observed between impaired physical performance and depression.

Lastly, physical function deterioration is closely associated with a high risk of hospitalization and poor survival in patients with ESRD. PCS was found to be the strongest influential factor in hospitalization and mortality for patients on HD treatment in the Dialysis Outcomes and Practice Patterns Study (DOPPS), an international observational study with 10,030 HD patient participants (Mapes et al., 2003). Its predictive power was even greater than that of serum albumin, with a small change in PCS score having a greater impact on the risk of hospitalization and death than a small change in serum albumin. Compared with patients scoring more than 46 on the PCS, those scoring less than 25 had a 56% higher risk of hospitalization (relative risk [RR] = 1.56) and a 93% higher adjusted risk of death (RR = 1.93). The effects of PCS on both risks were found to be independent of the MCS, Kidney Disease Component Summary (KDCS) of the Kidney Disease Quality of Life (KDQOL), and serum albumin (Mapes et al., 2003). Similar findings were obtained from data on 13,952 dialysis patients in the U.S.: every one-point increase in PCS led to a 2% reduction in the odds of hospitalization after adjusting for potentially related demographic and laboratory data (Lowrie, Curtin, LePain, &

Schatell, 2003). Knight et al. (2003) reported the predictive value of self-reported physical function among 14,815 dialysis patients followed for up to two years. They observed that those who saw a decline in PCS over six months had an additional increased mortality risk. The negative impact of poor physical health on mortality has also been identified in the HD population in Asian countries. For example, data analysis of 527 diabetic Japanese patients on HD who participated in DOPPS revealed that PCS score predicted survival, with a 73% increase in mortality (hazard ratio [HR]: 0.27; 95% confidence interval [CI]: 0.08-0.96) for patients with a PCS score below or equal to the median (38) after multivariable adjustment (Hayashino et al., 2009) based on mortality data from 2001 to 2008, A retrospective study involving 888 stable HD patients in Taiwan provides further independent support for the predictive power of PCS score for mortality after adjusting for clinical characteristics in the Cox proportional hazard model (Peng et al., 2010). The risk of death for patients with PCS scores in the first quartile was 86% greater than that for those with PCS scores in the fourth quartile.

1.2.3 Proposed interventions to improve hemodialysis patients' physical health

As noted, there is an increasing burden of caring physically impaired HD patients. It is pivotal for healthcare providers to explore effective ways to improve physical functioning for this group of patients. Many factors affect HD patients' physical functioning and physical health. Observational studies indicate that demographic factors (e.g., age, sex, employment status, educational level, marriage status), biochemical markers (e.g., hematocrit, serum albumin, serum creatinine), clinical data (diabetes as a cause of ESRD, co-morbidity severity), and behavioral factors (e.g., intradialytic weight gain and physical activity level) are associated with self-reported physical health and physical functioning (Kaysen et al., 2011; Mittal et al., 2001; Okada & Nakao, 1998; Tentori et al., 2010). Some of these factors are unlikely to be modified by interventions, but such indexes as hemoglobin (Hb) and physical activity level are known to be responsive to appropriate treatments and interventions. Given the importance of physical functioning in patients with ESRD, researchers have examined a range of modifiable factors to enhance their physical health and quality of life.

Renal transplantation is the preferred treatment option for ESRD patients. Two systematic reviews reach the unified conclusion that, following renal transplantation, patients experience better physical functioning and quality of life, although the benefits in the psychological domain are less marked (Landreneau, Lee, & Landreneau, 2010; Liem, Bosch, Arends, Heijenbrok-Kal, & Hunink, 2007). It is worthy of note that the integrated studies in these reviews were cross-sectional in design or focused primarily on the early post-operational period without long-term follow-up. A longitudinal observational study following 102 kidney transplantation recipients over six years reported a decline in physical health from baseline to the six-year follow-up (PCS: 46.41 versus 41.37). Their mental health, in contrast, showed a significant improvement over time (MCS: 45.30 versus 50.57). PCS worsened for 53.3% of the 102 recipients over time, whereas 30.7% saw no change and 16% an improvement. The results of this study, carried out by Griva et al. (2011), indicate that HRQoL improvement in renal transplantation patients cannot be sustained over time, particularly in overall physical HRQoL, pain, and physical functioning, although improvements in the emotional dimension of HRQoL and vitality were documented. In sum, although kidney transplantation leads to improvements in both physical and mental HRQoL in the short term, whether those positive effects can be sustained over time remains unclear. Furthermore, the availability of organs for transplantation remains far from adequate to meet the rapid growth in the number of ESRD patients (Weisbord & Kimmel, 2008).

Increased HD dose and high-flux HD are reportedly associated with preserved physical functioning and improved survival. The Hemodialysis Study Group examined the effects of HD dose and membrane flux on patient outcomes in the U.S. and Europe, revealing the effects of a higher such dose on physical health to be limited (Unruh et al., 2004). In addition, no significant benefits were observed in any KDQOL domain in either the high HD dose or high membrane flux groups.

Frequent HD is assumed to improve patient outcomes by increasing solute removal and reducing the volume change in the long interdialytic interval. Relative to patients undergoing conventional three-times-per-week dialysis, those who underwent six-times-per-week in-center HD realized improvement in the physical domain of health, but not in the mental or cognitive domains, between baseline and the 12-month follow-up (FHN Trial Group et al., 2010). Surprisingly, no favorable results in objective physical performance were observed in a daily HD trial (Hall et al., 2012). Trials examining the effects of nocturnal HD performed five to six nights per week also failed to document favorable outcomes, with no improvements observed in either subjective and objective physical health following such frequent HD treatment (Culleton et al., 2007; Rocco et al., 2011). Although there are physical health-related benefits to daily HD (six days/week), those benefits are achieved at the cost of an increased frequency of vascular interventions, leading to more complications, a heavier treatment burden, and higher economic costs. The effects of frequent dialysis on patients' physical functioning remain inconclusive.

Anemia is well-recognized as an important contributor to impairment in physical functioning. Meta-analysis focusing on the effects of treatment with erythropoiesis-stimulating agents (ESAs) on exercise tolerance and physical functioning in patients with ESRD receiving dialysis surveyed the available literature from 1988 (the year in which ESAs were approved for use in the U.S.) to 2008 (Johansen, Finkelstein et al., 2010). The findings revealed the partial correction of anemia with ESAs to exert consistent positive impacts on both objective and subjective physical outcomes. However, compared with lower target Hb levels, higher ESA targets brought no additional benefits in terms of physical functioning improvement, meaning that gains in exercise tolerance and physical function were fewer than expected, with no additional benefits achieved with Hb levels > 120 grams per liter (g/L). Johansen, Finkelstein et al. (2010) concluded that factors outside the oxygen transport system, such as deconditioning due to sedentary behavior, cardiac dysfunction, muscle weakness, and psychosocial problems, were likely to result in impaired physical functioning. At the same time, despite anemia correction with ESAs leading to enhanced exercise capacity and physical functioning (Muirhead et al., 2010), Randomized controlled trials (RCTs) have demonstrated that higher-dose ESAs and Hb correction to nearly normal levels in CKD potentially increase the risk of cardiovascular events and even death (Besarab et al., 1998; Drueke et al., 2006; Singh et al., 2006). An appropriate Hb target that balances the physical benefits of ESA therapy with its potential risks deserves further investigation (Strippoli & Clinical Evaluation of the Dose of Erythropoietins Study Group, 2010). In addition, ESA therapy is expensive, with the mean annual ESA cost per patient ranging from €4,339 to €6,512 to achieve an Hb target of 110 g/L. The variances in cost could be related to the number of ESA-resistant patients (Perrinet et al., 2010).

Sedentary behavior is one of the modifiable factors that may be responsive to appropriate intervention, with low levels of physical activity associated with reduced functioning in HD patients (Brenner & Brohart, 2008; Johansen, Chertow, de Silva, Carey, & Painter, 2001; Josanhen, Chertow et al., 2010; Kutner, Zhang, & McClellan, 2000). Segura-Orti (2010) reviewed 14 RCTs involving a total of 640 adult HD patients between 2005 and 2009, and performed meta-analysis with physical functioning and HRQoL as the primary outcomes. Data were analyzed according to different types of interventions: aerobic, strength, and combined exercise. The results revealed that all of these forms of exercise training had positive effects on physical functioning, HRQoL, lower limb strength, and blood pressure (Bp) (Segura-Orti, 2010). Another systematic review and meta-analysis identified 15 RCTs comprising 565 HD patients (304 exercise participants and 261 control participants), and concluded that exercise training improves peak oxygen uptake (VO_{2peak}) and heart rate variety (Smart & Steele, 2011). Such training is also safe, with none of the studies considered reporting a death directly linked to exercise. A Cochrane Database review focusing on the effects of exercise training in CKD and kidney transplantation patients further confirmed that regular exercise has a significantly positive influence on physical fitness (e.g., aerobic fitness, walking capacity), cardiovascular parameters (e.g., Bp, heart rate), some nutritional indices (e.g., albumin, energy intake), and HRQoL (Heiwe & Jacobson, 2011).

1.2.4 Exercise programs for hemodialysis patients

Although exercise training results in improved physical functioning for patients receiving hemodialysis, exercise rehabilitation programs are still not commonly available in most hemodialysis facilities (Cheema, Smith, & Singh, 2005; Painter, Clark, & Olausson, 2014). There is no statistics regarding the worldwide prevalence of exercise programs, yet studies conducted in several developed countries support the claim that there is paucity of exercise programs for patients on dialysis. A survey by 48 nephrologists stated that 32% of the respondents said that exercise programs were offered at their dialysis centers as reported in the World Congress in Berlin. The majority of these centers were located in Germany (Krause, 2004). In Australia, only 3 out of 145 investigated hemodialysis units offered exercise programs to their patients (Cheema et al., 2005). Ma et al. (2012) reported that only 8 out of 58 dialysis facilities in Ontario provided exercise program clinically for patients.

The low prevalence of exercise programs for hemodialysis patients could be attributed to the absence of a guideline on exercise prescription, low involvement of health care service providers in promoting exercise, lack of professionals to supervise exercise programs, lack of financial supports, and lack of exercise equipment (Bennett et al., 2010; Cheema et al., 2005; Daul, Schafers, Daul, & Philipp, 2004; Krause, 2004; Ma et al., 2012). With regard to the exercise prescription for dialysis patients, a Cochrane Review concluded that exercising at least three times per week for greater than 30 minutes per session was effective at improving patients' physical functioning (Heiwe & Jacobson, 2014). The materials for patient education on starting an exercise program are easily accessible from Life Options, an organization that helps people live long and well with kidney diseases (www.lifeoptions.org).

To address the additional resources to implement center-based exercise programs, creative approaches on exercise deliveries are therefore encouraged (Painter, 2008). Home exercise, with its fewer resource requirements, is considered a possible alternative. A Cochrane review revealed that home and center-based exercise can achieve equal gains in both clinical and patient outcomes for patients with coronary heart disease (Dalal et al., 2010). Preliminary studies conducted in dialysis population also indicated that home exercise resulted in positive functional outcomes (Konstantinidou, Koukouvou, Kouidi, Deligiannis, & Tourkantonis, 2002), and the beneficial effects of home exercise was more likely to be sustained (Malagoni et al, 2008). From the patients' perspective, exercise at home gives them the flexibility to adjust exercise schedule to accommodate their fatigue due to dialysis treatments (Horigan, 2012). In addition, home exercise is recommended as a way to easily incorporate physical activity into an individual's daily life (Delgado & Johansen, 2012; Kontos et al., 2007). As individualized counseling and encouragement has shown to be effective to increase dialysis patients' physical activity at home (Painter, Carlson, Carey, Paul, & Myll, 2000b), home exercise programs with regular follow-ups and supports from healthcare providers has been recommended to be implemented for patients receiving hemodialysis (Kontos et al., 2007; Painter, 2008). Unfortunately, studies examining the effects of home exercise with individualized supports have not provided sound evidence on its benefits on physical functioning for this group of patients. With regard to the professional support for exercise program implementation, physiotherapists are regarded as the prime candidates to deliver and supervise exercise programs (Ma et al., 2012). Patients' exercise program should not be regarded as the exclusive focus of physiotherapists. All dialysis staff should regularly counsel and encourage dialysis patients to increase their level of physical activity, and to integrate physical function assessment in daily practice (K/DOQI Workgroup, 2005). Nurses are having responsibilities to help patients optimizing functioning, they are well positioned to assist patients to engage in exercise, as they have prolonged and sustained contact with patients and their family members.

1.3 Aim and objectives

Aim

The aim of the study reported herein was to examine the effects of a nurse-led case management program on home exercise training for HD patients. Its specific objectives were as follows.

Objectives

Primary objective

To examine whether the nurse-led case management program incorporating home exercise training resulted in better physical function than controlled care.

Secondary objectives

1) To examine whether the nurse-led case management program incorporating home exercise training resulted in a higher quality of life than controlled care.

2) To examine whether the nurse-led case management program incorporating home exercise training resulted in better perceived health than controlled care.

3) To examine whether the nurse-led case management program incorporating home exercise training resulted in fewer depressive symptoms than controlled care.

4) To examine whether the nurse-led case management program incorporating home exercise training resulted in higher levels of physical activity than controlled care.

5) To examine whether the nurse-led case management program incorporating home exercise training resulted in higher perceived benefits of and lower perceived barriers to exercise than controlled care.

1.4 Study significance

The benefits of increasing physical activity and engaging in exercise are well documented. Much of the exercise research on the HD population focuses on the efficacy of exercise training conducted during HD sessions, with studies evaluating the effectiveness of the clinical implementation of a home exercise program relatively scare. The question of whether home exercise training implemented via the nurse case management (NCM) approach is feasible among stable HD patients and can achieve positive health outcomes, particularly in the mainland Chinese population, remains effectively unanswered. The study carried out for this thesis has generated valuable findings on the efficacy of such an approach in improving dialysis patients' physical functioning and quality of life, both in the clinical community and general public.

From the patient perspective, research shows that HD patients are not fully aware of the benefits of exercise (Zheng et al., 2010), fear the possibility of exercise-related injuries or unwanted outcomes (Goodman & Ballou, 2004), and lack the knowledge and skills to safely and effectively engage in exercise (Zheng et al., 2010; Li, Li, & Fan, 2010). The clinical implementation of the present study raised awareness of the importance of physical activity among HD patients and their family members. At the same time, from the practitioner's perspective, research shows that healthcare providers are often concerned about the risks of exercise in this population and assume that HD patients might not exercise even if encouragement and counseling were offered (Delgado & Johansen, 2010). The findings of this study will boost the knowledge, skills, and confidence of clinical nurses in the provision of safe and appropriate exercise recommendations and counseling to stable patients undergoing HD treatment.

The clinical implementation of exercise programs and/or physical activity counseling is still not routine practice in HD units. The high health costs of HD treatment may impede the allocation of extra clinical investment in patient rehabilitation, and a lack of clinical practice guidelines may be another pivotal factor hindering the clinical initiation exercise programs (Segura-Orti, 2010). In fact, relatively few resources are required to commence and implement the home-based exercise program examined in this research. It thus provides a feasible alternative approach to dialysis providers looking to incorporate exercise into routine practice.

The translated exercise program materials used in this study were validated, and an interview protocol formulated, to guarantee its successful implementation. These materials and intervention guide can facilitate the wider clinical implementation of similar exercise programs in HD units in mainland China. Case management is a relatively new concept for the country's nursing field. The successful implementation of the proposed exercise program and the research results reported herein thus have the potential to facilitate the development of a new and more effective nursing care delivery model for the mainland Chinese HD population.

1.5 Thesis outline

This thesis consists of seven chapters. Following this introductory chapter, the remainder of the thesis is organized as follows. Chapter 2 presents the context of this research and the results of a comprehensive review of the literature on physical functioning and physical activity levels in HD patients, existing exercise programs, patient-perceived barriers to exercise, and the underlying theories of the case management approach and its application in nursing practice. Chapter 3 then describes the study design and the methods and procedures used in conducting the RCT, including sampling, procedures, interventions, outcome measures, and data collection and analysis. Next, Chapter 4 presents the psychometric properties of the validated instrument and the results of a feasibility study. Chapter 5 reports the results of the full study, and Chapter 6 discusses its main findings, limitations and implications for clinical practice. Finally, Chapter 7 draws the thesis to a close with a summary of the overall conclusions of the study.

Chapter 2: Literature review

2.1 Introduction

This chapter presents a comprehensive review of the literature on problems related to the physical function of HD patients and exercise interventions designed to help these patients to alleviate physical dysfunction. The chapter starts with the discussion on the functional problems encountered by HD patients, followed by physical activity levels of this patient group, the benefits of physical activity and exercise, and the NCM interventions. The chapter ends with a description of the study's conceptual framework.

2.2 Impaired physical functioning of hemodialysis patients

2.2.1 Physical functioning levels of hemodialysis patients

Physical functioning is the ability to meet the physical demands of daily life (Painter & Roshanravan, 2013). An overall view of HD patients' physical functioning can be collected from functional data through objective and subjective measures, including laboratory tests of exercise tolerance and self-reported instruments. For example, Painter (2005) found that more than 50% of ESRD patients are incapable of performing a symptom-limited exercise test, a test that measures cardio-respiratory fitness. In both Painter (2005) and other studies, even for those capable of performing the test, the values for VO_{2peak} collected during exercise on a cycle ergometer or treadmill were limited at about 50-60% of age-predicted values

(Johansen, Finkelstein et al., 2010; van den Ham et al., 2005). The VO_{2peak} level for HD patients was similar to that of patients with congestive heart failure and chronic obstructive pulmonary disease (COPD) (Painter, 2003).

The deterioration of physical functioning in HD patients is not only associated with reduced oxygen delivery to the muscle, as measured by VO_{2peak}, but is also related to impaired oxygen extraction owing to muscle dysfunction (van den Ham et al., 2005). Muscle strength, another determinant of physical functioning, is also reported to be impaired in patients undergoing maintenance HD treatment (Fahal, Bell, Bone, & Edwards, 1997; Johansen, 2007; Johansen, Sakkas, Doyle, Shubert, & Dudley, 2003; Sawant, Garland, House, & Overend, 2011; Storer, Casaburi, Sawelson, & Kopple, 2005). Matsuzawa et al. (2014) demonstrated that approximately half of the 190 stable HD outpatients in their study suffered severely reduced lower extremity muscle strength, based on a knee extensor strength measure.

The outcomes of physical performance tests further confirm the limited physical functioning of the HD population. Two physical performance tests, gait speed and the sit-to-stand test (STS) test, are commonly used measures for assessing physical functioning in dialysis patients. The average normal gait speed measured in a group of 131 HD patients was reported to be 90.5 ± 25.6 cm/s, which is 66.1% ± 17.5% of the normal age-expected values, whereas fast gait speed was 133.4 ± 37.6 cm/s, representing 64% ± 16% of normal values (Painter et al., 2000b). Researchers examining a resistance-training program observed that voluntary HD subjects' maximal gait speed at baseline was close to 79% of normal values (Headley et al., 2002). The STS test is a measure of lower extremity strength. Painter et al. (2000b) found the speed of completing 10-repetition of the sit-to-stand test (10-STS) achieved by 110 patients to be only 15% of the normal predicted values. In research with relatively young HD subjects, 10-STS performance was approximately 58% slower that age-predicted norms (Headley et al., 2002). Impairment in STS performance has been consistently reported in studies evaluating physical functioning in HD patients (Koufaki, Mercer, & Naish, 2002; Segura-Orti, Rodilla-Alama, & Lison, 2008; Sterky & Stegmayr, 2005; van Vilsteren, de Greeff, & Huisman, 2005). In the study carried out by Koufaki et al. (2002), these patients' STS performance (14.7 seconds) was almost as slow as that of COPD patients (14.1 seconds) in Jones et al. (2013). Sterky and Stegmayr (2005) reported that their elderly HD patients could complete only half the STS repetitions that sex- and age-matched healthy subjects could in a given time period. It was noteworthy that even relatively high-functioning dialysis patients, who were asymptomatic and reported to function well, exhibited subtle and significant deficits in both gait speed and STS performance (Blake & O'Meara, 2004).

HD patients' perceived functional ability is concordant with the results of objective measures. A self-reported PCS score derived from the SF-36 has been validated against objective data on physical performance among HD patients (Painter et al., 2000a). Patients in the lower-PCS group (< 34) achieved lower scores on all physical performance tests, including gait speed and STS tests. HD patients' PCS score thus provides a rough estimation of their objective physical function. The results of a number of descriptive studies reveal low self-reported PCS scores (ranging from 31.6 to 36.9) among patients receiving HD (Chiang et al., 2004; Gabbay, Meyer, Griffith, Richardson, & Miskulin, 2010; Knight et al., 2003; Lowrie et al., 2003; Mapes et al., 2003; Mittal et al., 2001). Compared to the general population norm in the U.S., the magnitude of the reduction in PCS scores (31.6 versus 50) among these patients is even greater than among patients with cancer, congestive heart failure, chronic lung disease, and limited limb use (Mittal et al., 2001). More recently, the results of randomized trials reported by the Frequent Hemodialysis Network confirm that patients on conventional dialysis (three times per week) have poor physical health, as measured by the SF-36, with an average self-reported PCS score of 38.4 ± 9.4 (Hall et al., 2012). In the Chinese HD population, SF-36 PCS scores are also lower than those in the general U.S. population, 36.3 versus 50 (Chiang et al., 2004).

The burdensome nature of functional impairment is further supported by evidence from patients' own experience in a cross-sectional survey (Ramkumar, Beddhu, Eggers, Pappas, & Cheung, 2005). Ninety-four percent of participants indicated that they would be willing to receive intense HD, i.e., daily two-hour dialysis session six times per week, if that treatment modality could potentially boost their energy levels.

It is noteworthy that advances in dialysis treatment have not contributed to improvements in HD patients' functional ability. Two retrospective studies have demonstrated that physical well-being impairment has remained unchanged over time. The first, which analyzed changes in physical health over a decade (1997 to 2006), suggested that advances in HD treatment have had little impact on improving HD patients' physical well-being, although the average PCS score showed a marginal increase, rising from 35.4 in 1997 to 36.2 in 2006 (a change of 0.8 points) (Gabbay et al., 2010). A five-point difference in the SF-36 is generally considered meaningful and clinically relevant (Ware, Kosinski, & Keller, 1994), and an 0.8-point improvement over a decade can thus be considered marginal. In the second more recent study conducted in the Netherlands, the researchers compared the SF-36 scores of 126 HD patients' assessed in 1995 with the scores of 515 patients assessed in 2006 (Mazairac et al., 2011). The results showed significant improvement in four domains (bodily pain, vitality, role-emotion, and mental health) of SF-36 over the 10-year period, but no change in physical functioning.

2.2.2 Physical functioning and age

Aging is accompanied by a deterioration in functional capacity, and elderly people with CKD may experience an accelerated functional decline process (Gopinath, Harris, Burlutsky, & Mitchell, 2013; Smyth et al., 2013). Investigating the relationship between functional decline and age, a longitudinal study of 1,813 HD patients ranging in age from 18 to 70+ observed the largest declines in PCS (1.2 points) over a three-year period in subjects aged 55-70 (Unruh et al., 2008). However, physical deficits exist even in younger HD patients with few comorbidities and high self-perceived functional ability (Blake & O'Meara, 2004), with the observed normal walking speed for this high-functioning group still lower than that of healthy controls, 1.31 m/s and 1.59 m/s, respectively. A prospective study following HD patients over the 12 months subsequent to dialysis initiation revealed that younger patients (< 65 year older) experienced a decrease in physical functioning after initiation, although no substantial such decline was observed in their older counterparts (Garcia-Mendoza, Valdes, Ortega, Rebollo, & Ortega, 2006). That study also reported that although the baseline physical functioning of the younger patients was better than that of the elderly patients, the difference was not significant. Twelve months after dialysis onset, the two groups had a similar functional status, which indicates that the physical decline of the younger patients was faster. The results of the study conducted by the U.S. Renal Data System on a cohort of 2,275 adult dialysis patients revealed that two-thirds of participants could be categorized as frail (Johansen, Chertow, Jin, & Kutner, 2007). Importantly, 44% of participants aged below 40 and over half those aged between 40 and 50 met the definition of frailty.

Traditionally, physical functioning has been regarded as an important prognostic indicator of hospitalization and mortality in the older population. However, in dialysis patients, a dose response relationship between PCS score and mortality has been found only in individuals younger than 55 (Knight et al., 2003). In that study, mortality risk increased with a decrease in PCS score for HD patients younger than 55, whereas no such graded relationship was observed in the elderly patient group. These results suggest that diminished physical functioning has greater predictive power for mortality among younger dialysis patients. Physical impairment is thus not a health problem limited to elderly HD patients, but affects all HD patients regardless of age (Kaysen et al., 2011; McAdams-DeMarco et al., 2012, 2013).

2.2.3 Physical functioning and inactive behavior

Painter, Stewart, and Carey (1999) stated that multiple factors affect an individual's ability to perform basic actions and complex tasks. Physical fitness, consisting of cardio-respiratory fitness, muscle function, and flexibility, is a main clinical determinant of poor physical functioning. Other factors, including such bodily symptoms as fatigue, muscle weakness, and cramps/aches due to uremic myopathy and neuropathy, as well as depression, behavior, and the environment may further limit physical functioning.

Johansen et al. (2001) demonstrated that the albumin concentrations of ambulatory patients on maintenance HD treatment are associated with the results of such objective physical performance measures as gait speed, stair climbing, and chair-rising tests; however, the significance of that association weakened when physical activity level was added to the predictive model. A similar pattern was identified in the effects of age and comorbidity on physical function, suggesting that physical inactivity has a substantial impact on physical performance in the HD population (Johansen et al., 2001). Using both self-reported and objective performance data, Kaysen et al. (2011) found HD patients to have poor physical health. In their study, body composition measured by the intracellular water volume per kilogram of body weight (ICW/kg) and phase angle were captured as predictors of lower-extremity function, as measured by a battery of physical performance tests. ICW/kg, a measure of body cell mass, was associated with both objective and self-reported physical function. Principal body cell mass varies with body muscle mass, and acidemia and physical inactivity can lead to a decrease in muscle mass. The results reported by Kaysen et al. (2011) imply that increasing the dialysis dose and facilitating physical activity may preserve muscle mass, and in turn improve physical status. They further suggest that, in addition to demographic, clinical, and laboratory indicators, being physically inactive may further aggravate the decline in physical functioning of patients regularly receiving HD treatment.

2.3 Physical activity of hemodialysis patients

2.3.1 Definition of physical activity

Physical activity is defined as any bodily movement produced by the contraction of skeletal muscle that increases energy expenditure above a basal level (Office of the US Surgeon General, 1996).

2.3.2 Low levels of physical activity among hemodialysis patients

HD patients have low levels of physical activity whether such activity is measured objectively or subjectively (Avesani et al., 2012; Kim et al., 2014). Painter et al. (2000b) demonstrated in the Renal Exercise Demonstration Project (REXDP) that 59% of 286 HD patients reported no participation in any activities other than the activities of daily living, with only 23% participating in low-level cardiovascular exercise. Johansen et al. (2000) conducted the first objective investigation of physical activity among HD patients in the U.S. using accelerometers. Their results, obtained from 34 chronic HD patients and 80 sedentary healthy controls, revealed the HD patients to be 35% less active than the controls (104,718 steps per week versus 161,255 steps per week). Data from a seven-day recall questionnaire in that study were in agreement with the objective outcomes. In a national study of dialysis outcomes in the U.S., only 14% of the 1,041 participating dialysis patients reported engaging in exercise at an intensity level equivalent to a 5.0 or greater metabolic equivalent task (MET) three or more times a week, an exercise dosage below which is regarded as a

CVD risk factor (Longenecker et al., 2002). The results thus indicated that patients on dialysis are at greater risk of developing CVD not only from the disease itself, but also from inactivity. Data from a prospective study of 4,024 dialysis patients found that of the 75.5% (3,522) who were ambulatory, more than 33% reported never or almost never participating in any exercise activity (O'Hare, Tawney,Bacchetti, & Johansen, 2003). Tentori et al. (2010) reported the international pattern of physical exercise among dialysis patients. Of the 20,920 respondents from a variety of countries, 43.9% reported never exercising. Just under half (47.4%) could be classified as regular exercisers, having reported exercising at least once a week. The Comprehensive Dialysis Study in the U.S., which surveyed 1,547 patients, documented very low levels of self-reported physical activity levels (Johansen, Chertow et al., 2010). These levels, for both men and women, were below the 25th percentiles for healthy individuals in all age groups. The majority of participants indicated that they could not climb 12 steps (one flight of stairs) without stopping, and 56.4% said they were unable to walk one block. Cupisti, Capitanini, Betti, D'Alessandro, and Barsotti (2011) reported that 62% of the 50 HD patients they investigated could be categorized as sedentary, with a mean daily MET value less than 1.4. In another study comparing the percentages of time spent on activities of different intensities using actigraphs, chronic HD patients recorded lower percentages for mild, moderate, and strenuous activities than either non-dialysis CKD patients or healthy controls, with mild activity levels of 167, 195, and 191 min/day, respectively; moderate activity levels of 83, 97, and 125 min/day, respectively; and strenuous activity levels of 10, 11, and 26 min/day, respectively (Agarwal & Light, 2011).

Further investigation of physical activity patterns suggests that HD patients spend a significantly greater percentage of time on sleep or engaging in either light or moderate daily activities compared to normal controls and that they are less physically active on dialysis than post-dialysis days (Kim et al., 2014). In addition, Stack and Murthy (2008) also observed low levels of physical activity in both chronic HD patients and patients new to dialysis. An epidemiological study of several thousand new dialysis patients in the U.S. revealed that 56% reported exercising less than once a week and 42% described severe limitations in moderate activities (Stack & Murthy, 2008).

In a cross-sectional study conducted in Beijing, 26.7% of 187 HD patients reported being inactive (Li et al., 2010). Of the remainder who were minimally active or active, transportation-related walking and household work were the dominant types of physical activity. Therefore, being physically inactive is considered highly prevalent in patients receiving HD treatment worldwide.

2.3.3 Physical activity and physical functioning

Low levels of physical activity are associated with reduced functioning in HD patients (Brenner & Brohart, 2008; Johansen et al., 2001; Johansen, Chertow et al., 2010; Kutner et al., 2000). A large U.S. study involving 1,547 newly initiated dialysis patients showed the level of self-reported physical activity to be extremely low in all age groups, with patients reporting little activity also tending to report poorer physical health (Johansen, Chertow et al., 2010). More recently, Kim et al. (2014) found that, compared to normal adult controls, HD patients had lower levels of physical activity (around 60% of normal values) and spent a greater proportion of their time sleeping. They also documented a significant association between daily physical activities and the results of the 6-minute walking test (6-MWT) in HD patients after adjusting for age, sex, and diabetes. In addition to this observational evidence, preliminary experimental results also suggest that increases in physical activity result in improved physical functioning, with the increase more profound in relatively low-functioning patients (Painter et al, 2000a).

Both diminished physical functioning and low levels of physical activity are associated with adverse clinical outcomes. Secondary analysis of data on the relationship between physical activity and mortality risk from the Dialysis Morbidity and Mortality Wave 2 Study of 2,507 dialysis patients showed more than half to exercise less than once a week and three-quarters to have limitations on vigorous physical activity (Stack, Molony, Rives, Tyson, & Murthy, 2005). Analysis further indicated that patients with severe limitations in either moderate or vigorous physical activity had a 72% and 51% greater risk of mortality, respectively (HR = 1.72 and HR = 1.51), than those reporting minimal or no limitations. Further results obtained from DOPPS also show a low level of physical activity in the HD population, with less than half (approximately 47%) of all participants (n = 20,920) categorized as regular exercisers (exercising at least once/week) and around 44% never exercising at all (Tentori et al., 2010). Patient-level mortality analysis with a median follow-up of 1.75 years revealed the regular exercisers to have a 27% lower risks of death than the non-regular exercisers (adjusted HR = 0.73), and a dose-dependent relationship between exercise frequency and survival benefits was documented. The regular exercisers also reported higher levels of HRQoL and physical functioning (Tentori et al., 2010). In addition to the two aforementioned large-scale studies, a Japanese study following 202 HD patients for seven years that monitored physical activity levels using accelerometers confirmed the association between physical inactivity and mortality risk, with a 10-min/day increase in physical activity duration reducing the all-cause mortality risk by 22% (HR = 0.78) after adjusting for potential confounders (Matsuzawa et al., 2012). More recently, Johansen et al. (2013) provided additional evidence of that association in a study of 1,678 dialysis patients in the U.S. with a median follow-up of 2.6 years. Physical activity was assessed using the Human Activity Profile, and data were transformed into three categories of fitness level: “low,” “fair,” and “average or above.” The majority (57.3%) of participants were categorized as "low." Further analysis confirmed the inverse and dose-dependent relationship between physical activity and mortality after controlling for known potential covariates. Patients with a low fitness level were at 3.5 times the risk of mortality than those with an average or above level (Johansen et al., 2013).

Of the various studies documenting low levels of physical activity in the dialysis population (Johansen et al., 2000; Li et al., 2010; Painter, Ward, & Nelson, 2011; Stack & Murthy, 2008), most have found almost any method of increasing physical activity likely to be beneficial, and there have been no reports of serious injury as a result of ESRD patients' participation in an exercise training program (Johansen, 2007). Preliminary studies show that most such patients are able to improve physical functioning by increasing their amount of physical activity (Painter et al., 2000b). A systematic review found approximately 75% of HD patients eligible to participate in exercise (Smart & Steele, 2011). As previously noted, the K/DOQI clinical practice guidelines on the management of CVD state that "all dialysis patients should be counseled and regularly encouraged by nephrologists and dialysis staff to increase their level of physical activity" (K/DOQI Workgroup, 2005).

2.4 Exercise as an intervention to enhance physical functioning

2.4.1 Definition of exercise

Exercise and physical activity are often used interchangeably in the literature.

Exercise is a subcategory of physical activity that is planned, structured, repetitive, and purposeful and undertaken to improve or maintain one or more components of physical fitness (Office of the US Surgeon General, 1996).

2.4.2 Benefits of physical activity/exercise for physical functioning

A comprehensive literature review was conducted to summarize and evaluate the effects of physical activity and/or exercise training on the physical functioning of patients receiving HD treatment. Physical functioning is defined as the ability to perform daily activities and tasks, including actions and activities that are needed to both maintain independence in living and maintain and optimize quality of life (Painter et al., 1999; Tawney et al., 2000).

2.4.2.1 Literature search

A systematic literature search was conducted via a number of electronic databases, including Medline, EMbase, CINAHL, PsycINFO, Cochrane Database, and the China Academic Journals (CAJ) Full-text Database, for the January 2000-July 2014 period. A combined search was performed using the following key search terms: “physical activity” or “physical activit*” or “exercise” or “exercis*” and “chronic kidney disease” or “renal failure” or “renal insufficiency” or “renal replacement therapy” or “renal dialysis” or “hemodialysis“ or “haemodialysis.” The strategy used for the Medline search is listed in Appendix 2.1 for illustrative purposes. Additional articles were identified by screening the reference lists of the retrieved articles.

2.4.2.2 Study selection

The criteria for study inclusion in this literature search were as follows: 1) Study design: RCT; 2) Participants: adults (age > 18) receiving maintenance HD treatment; 3) Intervention: any type of physical exercise or physical activity intervention; 4) Outcome measures: at least one physical health outcome assessed using either objective or subjective measures (objective measures included laboratory tests, such as treadmill testing or strength assessments, and physical performance tests designed to objectively evaluate an individual's ability to complete standardized tasks, such as walking, rising from a chair, and climbing steps (Painter et al., 1999); subjective measures included the SF-36 and KDQOL, with domains evaluating an individual's ability to perform certain activities); 5) Language: either English or Chinese; and 6) Availability of full texts. Studies evaluating the effects of exercise training programs on improving physical activity levels were also included in the review.

The exclusion criteria were as follows: 1) Participants: CKD patients receiving PD or not yet commencing dialysis treatment or renal transplant patients (studies including both HD and PD patients were also excluded); and 2) Intervention: exercise combined with other interventions such as nutritional supplements that might affect interpretation of the study results. Reviews, articles published in abstract format, and conference proceedings were also excluded.

The author of this thesis first screened the titles and abstracts according to the inclusion and exclusion criteria to decide whether the articles in question should be included in the review. If the articles appeared to be relevant, but she could not make a decision about their eligibility based on the titles and/or abstracts, the full texts were screened to make the final decision.

2.4.2.3 Quality assessment

Double-blinding is often not possible in the implementation of exercise programs due to the nature of the intervention (Bhogal, Teasell, Foley, & Speechley, 2005). It was thus important to adopt a methodological quality evaluation scale with different levels of blinding and allocation concealment accounted for. The Physiotherapy Evidence Database (PEDro) scale (Sherrington, Herbert, Maher, & Moseley, 2000), which provides a comprehensive measure of blinding, concealment, and attrition, was thus used to evaluate the methodological quality of each RCT in the current review. The PEDro scale includes 11 criteria for evaluating the internal and external validity of a study's conclusions. Item 1 is used to assess external validity, and Items 2-9 to assess internal validity. The remaining two items are criteria for determining whether there is sufficient statistical information available for interpretation of the study's results. The total PEDro score is 10. Item 1 concerning identification of the eligibility criteria is not taken into account when calculating the score because the inclusion and exclusion criteria influence the external, but not internal, validity of a trial. In addition to trial evaluation using the PEDro scale, the PEDro database (http://www.pedro.org.au/) was searched for each trial to determine whether it had been registered. The published PEDro scores for all trials available in the database are reported herein.

2.4.2.4 Results

2.4.2.4.1 Search results

The initial database search and manual search resulted in 452 publications, of which 32 were duplicates. After removing duplicates and studies published before 2000, and screening the titles and abstracts, 69 publications were identified as potentially eligible. After further inspection of the full texts, 21 RCTs published between January 2000 and July 2014 were finally included in the present review.

2.4.2.4.2 Study characteristics

The studies included were carried out in a variety of countries, including the U.S. (Chen et al., 2010; Tawney et al., 2000; Wilund et al., 2010), Greece (Konstantinidou et al., 2002; Kouidi, Grekas, Deligiannis, & Tourkantonis, 2004; Kouidi et al., 2010; Petraki, Kouidi, Grekas, & Deligiannis, 2008), Brazil (de Lima et al., 2013; Orcy, Dias, Seus, Barcellos, & Bohlke, 2012; Reboredo et al., 2010), Canada (DePaul, Moreland, Eager, & Clase, 2002; Parsons, Toffelmire, & King-VanVlack, 2004), Australia (Cheema et al., 2007; Koh, Fassett, Sharman, Coombes, & Williams, 2009), Denmark (Molsted et al., 2004), the Netherlands (van Vilsteren et al., 2005), Spain (Segura-Orti, Kouidi, & Lison, 2009), Turkey (Yurtkuran, Alp, Yurtkuran, & Dilek, 2007), the Czech Republic (Dobsak et al., 2012), Iran (Mortazavi et al., 2013), and Japan (Matsumoto et al., 2007). Only five RCTs involved more than one dialysis unit (Tawney et al., 2000; Segura-Orti et al., 2009; Chen et al., 2010; Koh et al., 2009; Mortazavi et al., 2013). The largest trial, which had over 100 (n = 103) participants allocated to either an intervention or control group, was conducted in the Netherlands (van Vilsteren et al., 2005). The sample sizes in the remaining RCTs varied significantly, ranging from 17 to 99 participants.

The 21 studies enrolled a total of 1,032 HD participants, who were randomly assigned to different trial groups. Nineteen trials reported the attrition rate, which ranged from 0% (Mortazavi et al., 2013) to 47.4% (DePaul et al., 2002). The main reasons for attrition were medical problems unrelated to the interventions, dialysis modality change, death from causes unrelated to exercise, lack of interest, non-adherence to exercise protocol, relocation, and scheduling or transportation concerns. The majority of studies (90.5%) did not adopt intention-to-treat (ITT) analysis, and the reported results were obtained from 800 participants, accounting for 77.5% of the total.

2.4.2.4.3 Methodological quality of studies

The mean PEDro rating for the studies included was 4.8 (standard deviation [SD] = 1.1; range of 3-7 out of 10). PEDro ratings for 11 trials (52.4%) were retrieved from the aforementioned PEDro database. All of the trials performed random allocation and provided information on measures of variability, such as SD and CIs, although only three implemented or reported allocation concealment during randomization. Six studies specified whether the data collectors were blinded to treatment allocation. Two (9.5%) reported prior sample size estimations (Koh et al., 2009; Orcy et al., 2012), and two had pre-specified primary outcomes (Koh et al., 2009; Chen et al., 2010). Only one study reported effect sizes along with the results of significance tests (van Vilsteren et al., 2005).

2.4.2.4.4 Patient characteristics

The mean age of the participants in all 21 studies was 53.12 (SD = 7.13), with ages ranging from 39.5 to 69. Most studies recruited more male than female patients, with males accounting for 52.3% to 74.4% of the total sample. Fourteen studies required participants to have been on dialysis treatment for at least three months for inclusion, of which four included only patients who have been on dialysis for at least six months. Two studies failed to provide detailed information on mean dialysis duration. The average duration of dialysis treatment varied considerably across studies, ranging from less than two years to 12.5.

2.4.2.4.5 Interventions

The duration of the physical activity or exercise interventions also varied considerably, ranging from eight weeks to four years. Only one study assessed the sustained effects of an exercise intervention after 12 weeks of training (DePaul et al., 2002). Eighteen (81.8%) of the 21 exercise programs implemented lasted at least 12 weeks.

The majority of those programs were carried out during dialysis sessions regardless of whether they used an aerobic or resistance training approach. One exercise program adopting yoga-based training was conducted either before or after dialysis sessions on dialysis days (Yurtkuran et al., 2007). Two studies examining the effects of a combination of aerobic and resistance exercise conducted the latter before or after dialysis sessions and the former during (DePaul et al., 2002; van Vilsteren et al., 2005). Two studies compared different modalities of exercise training: outpatient rehabilitation, intradialytic cycling, and home exercise using cycle ergometers or walking (Konstantinidou et al., 2002; Koh et al., 2009). Only one study employed physical activity-based counseling during HD sessions instead of directly providing exercise training (Tawney et al., 2000). That study adopted behavioral strategies and an educational approach to encourage participants to work up to 30 minutes of self-selected physical activities per day. The intervention was provided individually during dialysis sessions. The results showed individual counseling to be effective in boosting HD patients' physical activity levels.

There were three main types of exercise training program across the studies: aerobic exercise, resistance exercise, and a combination of the two. The majority of the exercise training programs investigated adopted a thrice weekly exercise protocol, with two providing training just twice a week (Yurtkuran et al., 2007; Chen et al., 2010). The intensity of all exercise programs was determined individually in accordance with each patient's capacity. The monitored rate of perceived exertion (RPE) and heart rate were the major criteria for determining the appropriate exercise intensity for each patient. A rating of 12 to 14 on the Borg Scale of Perceived Exertion was the most commonly adopted criterion of a moderate intensity level. Finally, with regard to supervision of the exercise training session, nine studies neglected to provide details of the professional identities of the supervisors. Of those that did provide such information, physicians, physiotherapists, kinesiologists, certified yoga teachers, and researchers were the most commonly reported exercise supervisors.

2.4.2.4.6 Physical functioning indices

A variety of physical functioning indicators were reported in the trials included in this review, which makes it extremely difficult to compare the results of their different interventions. The physical functioning-related outcome variables included results obtained from submaximal exercise tests; physical performance tests such as the 6-MWT, 10-STS, short physical performance battery (SPPB), time-up and go, and incremental shuttle walk; muscle strength tests such as the dynamometric test of leg extensors; and self-reported questionnaires such as the SF-36 and KDQOL.

2.4.2.4.7 Summary of study results

In light of the studies reviewed, the author of the thesis concludes that either aerobic or resistance exercise, or a combination of the two, can be effective in improving HD patients' physical functioning (Cheema et al., 2007; Chen et al., 2010; Matsumoto et al., 2007; Molsted et al., 2004; Petraki et al., 2008; Reboredo et al., 2010; van Vilsteren et al., 2005). However, the currently available evidence suggests that aerobic plus resistance exercise, i.e., combination training, has the most pronounced such effects. For example, Orcy et al. (2012) compared combined exercise training (aerobic plus resistance exercise) with intradialytic resistance training. Both training programs were conducted three times a week at the same exercise intensity for 10 weeks. The 6-MWT was the only outcome variable assessed, with the results revealing the combined program to produce greater improvement in 6-MWT performance.

In the studies under review, patients undergoing outpatient rehabilitation on non-dialysis days achieved greater improvements in physical functioning that those undergoing intradialytic or home exercise alone, possibly because of the high intensity of the exercise regimen. Of the three studies comparing different modalities of exercise (Koh et al., 2009; Konstantinidou et al., 2002; Kouidi et al., 2004), none of them blinded the data assessors or adopted ITT data analysis. Thus, the results should be interpreted with caution because of the questionable quality of some of the research designs, as indicated by their low PEDro scores, ranging from 4-5 out of 10. Although outpatient rehabilitation on non-dialysis days appears to be more effective in improving the functional status of HD patients, the high dropout rate may limit its clinical implementation (Konstantinidou et al., 2002).

Majority of the studies delivered exercise programs during dialysis sessions. Participants were closely supervised by such medical specialists as physiotherapists, trained physicians, and kinesiologists while performing exercises during their dialysis sessions. Exercise intervention has been long regarded as the domain of the physical therapist. However, with the shortage of physical therapists and the increasing limited hospital resources, other professionals should be involved in encouraging patients to be active (McLaughlin, Wittstein, White, Czaplinski, & Gerard, 2012). Optimizing patient ambulation and activity has long been considered as a part of nursing practice and is standard practice for patients in surgical units (McLaughlin et al., 2012). Thus, nurses are assumed as an ideal professional to lead exercise programs for patients and there are recent studies on nurse-led exercise programs in chronic disease population (Arslan & Oztunc, 2015; Chau, Shou, Ma, & Au, 2005; Ortega et al., 2014). Despite the widespread of exercise training led by nurses, the trial implemented in dialysis population was scarce and the effects of such program were unknown.

Supervised exercise programs led by either physiotherapists or nurses are often costly in terms of time and resources. There is a need to explore practical and inexpensive means to promote exercise initiation and engagement among dialysis population. Recently, the implementation of behavior change theory on exercise intervention has been advocated (Chapman, Campbell, & Wilson, 2015). In the recent decade, there was only one trial that assessed the effects of physical activity counseling, where patients in six dialysis units in the U.S. were encouraged to perform their preferred physical activities at home but received no supervised exercise training during dialysis sessions (Tawney et al., 2000). The results demonstrate that nine sessions of individualized physical activity counseling provided during dialysis sessions can improve moderate or vigorous activity levels in HD patients. However, Tawney et al. (2000) recorded no significant improvement in these patients' self-reported physical function over a six-month period. As no objective physical functioning outcomes were evaluated in this trial, the effects of exercise facilitated by the individualized physical activity counseling on patients' functional outcomes are unclear.

With regard to the site for exercise training, Konstantinidou et al. (2002) compared the effects of exercise programs delivered in different sites: supervised outpatient rehabilitation on non-dialysis days, intradialytic exercise, and home exercise. All participants were instructed to attend a six-month exercise training program. The results suggest that all three modalities increase exercise time and VO_{2peak}. The findings indicated that exercise training was effective in dialysis center, outpatient, and home-based setting. Koh et al. (2009) carried out a study to further explore the differences in physical function gains between intradialytic exercise and home exercise (walking). The study compared the functional gains of those receiving intradialytic exercise and home exercise (walking) with those achieved by a control group receiving usual care. No significant changes were identified among the groups in the 6-MWT, time-up and go test, or grip strength. Also, compared to the usual care group, a significant decrease in self-reported physical functioning was noted in the intradialytic exercise group, and subjective physical functioning remained unchanged for the home-based walking group. As this study was a pilot trial and was underpowered due to the small sample size, the effects of home exercise have not determined. Based on the evidence generated from the aforementioned three studies, the effects of home exercise for dialysis patients are optimizing, although the function gains from home exercise may be limited as compared with exercise rehabilitation conducted in inpatient or outpatient. It is documented that exercise training takes place at home may result in better long-term maintenance, as the lifestyle change occurs in a familiar environment (Rochester. 2003). A recent review from Capitanini and colleagues (2014) reported that patients participating in home exercise training program achieved dramatic improvements on physical function over a period of three months. As there is no detailed information on the study design and the outcome variables, it is difficult to evaluate the strength of the evidence. Thus, the effectiveness of incorporating home exercise recommendations into clinical practice deserves further exploration.

In summary, the studies included in this review supported the beneficial effects of exercise training for improving physical functioning of HD patients, nevertheless, the effects of home exercise training have not been thoroughly evaluated for its efficacy. To successfully implement home exercise programs, Painter (2008) recommended combining independent home exercise with regular follow-up and support from healthcare providers. Courneya (2010) also advocated the importance of incorporating behavior support to unsupervised exercise program, even for programs having shorter duration and behavior change being not the primary purpose. However, Tawney et al. (2000)'s study was amongst the few studies addressing HD patients' emotional and behavior difficulties participating exercise training. The results suggested that individualized counseling was effective at increasing HD patients' physical activity; whether the enhanced physical activity level can lead to an improvement of physical function deserves further study.

Although nurses are well positioned to provide exercise training and recommendation to HD patients due to their professional experience, the effects of a nurse-led exercise program have not been previously examined for this population. For details of all 21 studies reviewed, please refer to Table 2.1 and Table 2.2.

Table 2.1: Study characteristics of the 21 RCTs included in the review

Author(s), year	Study characteristics		
	Sampling	**No. of patients in primary data analysis**	**Dropouts & reasons**
Tawney et al., 2000	99 (51 and 48 in exercise and control groups, respectively)	82 (39 and 43 in exercise and control groups, respectively)	17 drop outs (17.2%); Reasons: 4 dialysis modality change, 7 refusal, 2 relocation, 4 death
Konstantinidou et al., 2002	58 (21 in outpatient rehabilitation; 12 in intra-dialytic exercise; 12 in home exercise; 13 in control group)	48	10 drop outs (17.2%); Reasons: voluntary withdrawal (lack of time, transportation difficulties, and medical reasons unrelated to exercise), died of causes unrelated to exercise
DePaul et al., 2002	38 (20 in exercise group, 18 in control group)	20 (10 in each group)	At week 12: 9 dropouts; At 5 months: 18 dropouts (47.4%); Reasons: stopped dialysis, refused ergometer test, medical reasons, unable to schedule, transplant, withdrawal
Parsons et al., 2004	18 (Information on the number of patients allocated to each group was not reported)	13 (6 in exercise and 7 in control group)	5 drop outs (27.8%); Reason: medical complications not related to study protocol

Author(s), year	**Study characteristics**		
	Sampling	**No. of patients in primary data analysis**	**Dropouts & reasons**
Kouidi et al., 2004	48 (24 in Group A: outpatient rehabilitation; 24 in Group B: intradialytic exercise group)	34 (16 in Group A;18 in Group B)	14 drop outs (29.2%): Group A (9, 37.5%); Group B (5, 21%); Reasons: lack of motivation (7), medical conditions (4), and death (3)
Molsted et al., 2004	33 (22 in exercise and 11 in control group)	17 (10 in exercise and 7 in control group)	13 drop outs (39.4%): 11 for exercise and 2 for control group ; Reasons: 8 regretting participation or lack of time, 3 medical complications not related to the intervention, 1 relocation, and 1 loss of interest
van Vilsteren et al., 2005	103 (60 in exercise group and 43 in control group)	96 (53 in exercise group and 43 in control group)	7 drop outs (6.80%) all from the exercise group; Reasons: 2 lack of motivation, 3 lack of transportation, 2 unstable health condition
Yurkuran et al., 2007	40 (20 in exercise and control groups, respectively)	37 (19 in exercise group and 18 in control group)	3 drop outs (7%): 1 from exercise and 2 from control group; Reason: missed three exercise sessions during 3 months
Matsumoto et al., 2007	55 (22 in exercise group and 33 in control group)	49 (17 in exercise group and 32 in control group)	6 drop outs (10.9%): 5 from exercise and 1 from control group; Reasons were not specified

Author(s), year	Study characteristics		
	Sampling	**No. of patients in primary data analysis**	**Dropouts & reasons**
Cheema et al., 2007	49 (24 in exercise group and 25 in control group)	49 (24 in exercise group and 25 in control group)	5 drop outs (10.2%): 4 from exercise and 1 from control group; Reasons: relocation; hospitalization due to depression; diagnosis of malignancy; and family reasons
Petraki et al., 2008	50 (26 in exercise group and 24 in control group)	43 (22 in exercise group and 21 in control group)	7 drop outs (14%): 4 from exercise and 3 from control group; Reasons: 2 refused to complete the final measurements; 1 not able to complete the training program due to hypertension; 1 could not repeat the final tests; 3 died from causes unrelated to the intervention
Segura-Orti et al., 2009	27 (19 in exercise group and 8 in control group) Two-group RCT	25 (17 in exercise group and 8 in control group)	2 drop outs (6.67%): both from exercise group; Reasons: lower limb amputation, lack of interest
Kouidi et al., 2010	50 (25 each in exercise and control groups)	44 (24 in exercise group and 20 in control group)	NA

Author(s), year	Study characteristics		
	Sampling	**No. of patients in primary data analysis**	**Dropouts & reasons**
Chen et al., 2010	50 (25 each in exercise and control groups)	44 (22 each in exercise and control groups): 11 patients did not complete the program, and others did not have test results	7 lost to follow-up & 4 discontinued intervention (12%): for exercise group: 4 lost to follow-up & 2 discontinued; control group: 3 lost & 2 discontinued; Reasons: 4 deaths, 3 medical unstable, 2 moved out of state, 1 switch to PD, 1 lost interest
Koh et al., 2009	70 (27 in Group A: intradialytic exercise group; 21 in Group B: home exercise group; 22 in Group C: control group)	46 (16 in Group A; 15 in Group B; 15 in Group C)	7 did not receive allocated intervention, 1 lost to follow-up & 16 discontinued intervention (34.3%)—Group A (6 discontinued); Group B (6 did not receive allocated intervention & 6 discontinued); Group C (1 did not receive allocated intervention, 1 lost, & 4 discontinued): Reasons: 1 nonadherence, 1 changed to PD, 9 personal reasons, 1 hospitalized, 5 transplants, 4 medical reasons, 1 frequent cramps, 1 personal commitments, 1 deceased
Wilund et al., 2010	17 (8 in exercise group and 9 in control group)	15 (8 in exercise group and 7 in control group)	2 (11.8%) dropouts: all from control group; Reasons: 1 hip fracture; 1 moved out of area.

Author(s), year	Study characteristics		
	Sampling	No. of patients in primary data analysis	Dropouts & reasons
Reboredo et al., 2010	28 (14 in exercise group and 14 in control group)	24 (12 in exercise group and 12 in control group)	2 lost to follow-up & 2 discontinued intervention (14.3%): 2 discontinued in exercise group; 2 lost in control group; Reasons: discontinued due to lack of adherence to protocol; lost due to CVD
Orcy et al., 2012	26 (13 in Group A: Combining aerobic and resistance exercise and 13 in Group B: Intradialytic resistance exercise only)	24 (12 in Group A and 12 in Group B)	2 dropouts (discontinued the intervention; 7.69%)—1 Group A & 1 Group B; Reason: change to PD or transplant
Dobsak et al., 2012	32 (11 in Group A: Aerobic exercise training; 11 in Group B: EMS; 10 in Group C: Controls)	32 (11 in Group A; 11 in Group B; 10 in Group C)	NA
de Lima et al., 2013	33 (11 in Group A: strength exercise; 11 in Group B: aerobic exercise; 11 in Group C: control)	32 (11 in Group A: strength exercise; 10 in Group B: aerobic exercise; 11 in Group C: control)	1 drop out (3.0%) from Group A; Reason: hospital admission

Author(s), year	**Study characteristics**		
	Sampling	**No. of patients in primary data analysis**	**Dropouts & reasons**
Mortazavi et al., 2013	26 (13 in exercise group and 13 in control group)	26 (13 in exercise group and 13 in control group); Two-group RCT	No dropouts

Note: NA: information not available.

Table 2.2: Intervention, outcome measures, and findings of the 21 RCTs included in the review

Author(s), year	Intervention(s)				Outcomes and findings	
	Types	Time	Frequencies	Duration	Outcome measures	Main findings
Tawney et al., 2000	Physical activity-based individual counseling plus educational materials	During dialysis	Nine sessions over 6 months	6 months	KDQOL-SF; RAND physical activity questionnaire; laboratory measures of adequate therapy	The differences in physical function improvement between the two groups trended toward significance. A significant increase in moderate or vigorous activity was reported in the exercise group. No significant effect on laboratory values was observed.
Konstantinidou et al., 2002	Outpatient rehabilitation: ergometer or treadmill, including calisthenics, steps, and flexibility exercises; Intradialytic exercise: bed bicycle ergometer, strength and flexibility; Home exercise: cycle ergometer, strength, and flexibility	Outpatient: on dialysis days; Intradialytic: during dialysis sessions	Outpatient: 3 times/week; home exercise: at least 5 times/week	6 months	Maximum heart rate; Exercise time; VO_{2peak} during treadmill testing	Participants in three intervention groups had significant improvements in exercise capacity compared with the control group. The outpatient rehabilitation had the most pronounced effects on both exercise time and VO_{2peak} with a higher dropout rate than the other two exercise modalities.
DePaul et al., 2002	Exercise group: combination of aerobic and resistance exercise; Control group: non-progressive, non-resistance, low-intensity range-of-motion exercise of the lower extremities and free upper extremities	Aerobic exercise performed in dialysis sessions; Strength exercise conducted before or after dialysis	3 times/week	8 months (12-week intervention; another 5-month follow-up)	Sub-maximal exercise test (tested before and after dialysis), Muscle strength, 6-MWT, Symptom questionnaire, SF-36	At week 12, significant group differences were noted in change scores on watt on sub-maximal exercise test and muscle strength. No significant difference was observed between the two groups on either 6-MWT or symptoms or quality of life. At month 5, no significant difference was identified on outcome variables.

Author(s), year	Intervention(s)				Outcomes and findings	
	Types	**Time**	**Frequencies**	**Duration**	**Outcome measures**	**Main findings**
Parsons et al., 2004	Cycle ergometry exercise	During dialysis	3 times/week	Total of 9 weeks—One week for baseline assessment & 8-week exercise training	Kt/V, dialysate urea clearance (DUC); pre & post-dialysis resting Bp; SF-36	No significant difference found on either Kt/V or resting Bp or any domains of SF-36 between the two groups at any time point or within group for each group. DUC changes over time were noted only in exercise group.
Kouidi et al., 2004	Group A: combination of aerobic, strength, and flexibility exercise; Group B: cycling exercise plus theraband resistance training and exercise for coordination	Group A: non-dialysis days; Group B: during dialysis	3 times/week	4 years	VO_{2peak}; Self-reported questionnaire for evaluating the perception of health and overall life situation	Significant improvements in VO_{2peak} and scores on perception of health and overall life situation were found for both groups at year 1 and year 4. Patients in the outpatient rehabilitation group had greater improvements in exercise time and gas exchange than patients in the intradialytic exercise group.
Molsted et al., 2004	Combination of aerobic and strength exercise	During dialysis	2 times/week	5 months	VO_{2max}; 2-minute stair-climbing test, squat test; SF-36; Average predialysis Bp for three consecutive HD sessions; Lipids	Both VO_{2peak} and self-reported physical functioning was better for exercise group than control group. A significant within-group difference was noted in both squat test results and PCS scores only for the exercise group, with no between-group difference. No significant results found in 2-minute stair-climbing test results, Bp, or lipids.

Author(s), year	Intervention(s)				Outcomes and findings	
	Types	**Time**	**Frequencies**	**Duration**	**Outcome measures**	**Main findings**
van Vilsteren et al., 2005	Combination of aerobic and strength exercise plus motivational interviewing	Aerobic exercise and motivational interviewing were delivered during dialysis; Strength exercise was carried out before dialysis	Exercise: 2-3 times/week; Counseling: total of 4 times	12 weeks	VO_{2peak}; 10-STS; SF-36; physiological indicators: Bp, cholesterol levels, heart rate, Hb, and Kt/V; and stage of change	Significant changes over time in STS performance, vitality, general health perception and health change (3 domains of SF-36), Kt/V, and stage of change were noted. No significant differences were found for physiological indicators.
Yurkuran et al., 2007	Modified yoga-based exercise training	Before or after dialysis	2 times/week	3 months	Visual analog scale for assessing fatigue, pain, and sleep disturbance; grip strength; laboratory data	Significant between-group differences in pain intensity, fatigue, sleep disturbance, grip strength, urea, creatinine, alkaline phosphatase, cholesterol, erythrocyte, and Hb were noted.
Matsumoto et al., 2007	Aerobic exercise training using a stationary cycle	Before dialysis	3 times/week	12 months	Laboratory data: albumin, creatinine generation rate; SF-36	Significant within-group differences on serum albumin and creatinine generation rate were noted only in exercise group. Significant increases in three physical domains and two mental domains of SF-36 were found only in exercise group.

Author(s), year	Intervention(s)				Outcomes and findings	
	Types	Time	Frequencies	Duration	Outcome measures	Main findings
Cheema et al., 2007	Progressive resistance exercise training	During dialysis	3 times/week	12 weeks	Primary outcomes: muscle quantity and quality; Secondary outcomes: muscle strength, exercise capacity, body circumference measures, pro-inflammatory cytokine, C-reactive protein, and SF-36.	Significant changes in muscle quality were found between the two groups. Significant and clinically meaningful increases were noted in total strength, body weight, BMI, and mid-arm and mid-thigh circumference in exercise group as compared with control group. Significant improvements in two of eight domains of quality of life (physical function and vitality) were found. No significant changes in habitual physical activity between groups were found.
Petraki et al., 2008	Combination of aerobic and strength exercise	During dialysis	3 times/week	7 months	Arterial baroreflex sensitivity (BRS); VO_{2peak}	Significant increases in BRS, exercise time and VO_{2peak} were found in exercise group.
Segura-Orti et al., 2009	Progressive resistance exercise	During dialysis	3 times/week	6 months	Primary: 10-STS & STS-60, 6-MWT, dynamometry; Secondary: Graded exercise test, SF-36	Significant improvements in STS and 6-MWT performance were found in exercise group, but no significant improvement in these two test results occurred in control group. No significant difference was noted in change over time between groups for time and METs obtained on the graded exercise test. Change over time was differed between the groups in right leg dynamometry. No significant change over time between the groups was identified for scores on either PCS or MCS.

Author(s), year	Intervention(s)				Outcomes and findings	
	Types	**Time**	**Frequencies**	**Duration**	**Outcome measures**	**Main findings**
Kouidi et al., 2010	Combination of aerobic and strength exercise	During dialysis	3 times/week	1 year	VO_{2peak}; heart rate variability; BDI, Hospital Anxiety and Depression Scale (HADS)	Significant improvements in VO_{2peak}, exercise time, and heart rate variability indices found only in exercise group. Over-time changes in depression and anxiety (improvement) status were also noted in exercise group.
Chen et al., 2010	Low-intensity strength exercise	During dialysis	2 times/week	6 months	Primary outcomes: Short Physical Performance Battery (SPPB); Secondary: knee extensor strength, lean and fat mass, SF-36, 7-day leisure time physical activity, and Activities of Daily Living (ADL)	A significantly greater improvement in SPPB was noted in the exercise group than the control group. There was greater enhancement in knee extensor low body strength, whole body lean mass, self-reported physical activity, PCS, and ADL disability in exercise group than in control group.
Koh et al., 2009	Aerobic exercise	During dialysis	3 times/week	6 months	Primary outcomes: 6-MWT, Aortic pulse wave velocity (PWV); Secondary: Time-Up and Go (TUG), peripheral PWV; peripheral and central Bp; physical activity & SF-36	No significant differences in changes on 6-MWD were noted between the groups. No intervention effects were found for either TUG or grip strength. Self-reported physical activity and physical function scores of SF-36 increased significantly for Group A over time, but not for Group B. No significant treatment effect found for any vascular parameters.

Author(s), year	Intervention(s)				Outcomes and findings	
	Types	Time	Frequencies	Duration	Outcome measures	Main findings
Wilund et al., 2010	Aerobic exercise	During dialysis	3 times/week	4 months	Incremental shuttle walk; Blood chemistry; Bp; Echocardiography data	Significant interaction effects were observed for shuttle walking performance. Exercise group had a significant increase of 15%, whereas no significant improvement was found in the control group. Significant interaction effects were also observed for serum oxidative substances and alkaline phosphatase. There was a significant interaction effect for epicardial fat thickness.
Reboredo et al., 2010	Aerobic exercise	During dialysis	3 times/week	12 weeks	VO_{2peak}	Significant interaction effects were found in work rate and VO_{2peak}.
Orcy et al., 2012	Combination of aerobic and resistance exercise versus aerobic exercise alone	During dialysis	3 times/week	10 weeks	6-MWT	There was a significant change over time in 6-MWT performance between the two groups (interaction effect). A significant increase in 6-MWT performance over time was found only in Group A.
Dobsak et al., 2012	Aerobic exercise versus EMS	During dialysis	3 times/week	20 weeks	Ergometer test, 6-MWT, dynamometric test of leg extensors; SF-36	Significant improvements in peak tolerance level, max muscle power, and 6-MWT performance over time were found in both intervention groups, although no significant between-group differences were noted for those variables. Significant improvements in PCS score were identified in the exercise group, and MCS improvements were noted in both intervention groups. No significant change occurred for Group C.

Author(s), year	Intervention(s)				Outcomes and findings	
	Types	**Time**	**Frequencies**	**Duration**	**Outcome measures**	**Main findings**
de Lima et al., 2013	Strength exercise versus aerobic exercise	During dialysis	3 times/week	8 weeks	Respiratory muscular strength, pulmonary function, step test for 4 min, lab examinations, KDQoL-SF1.3	Significant increases in total number of steps (a sub-maximal exercise test), respiratory muscle strength indices, and pulmonary function were observed only in two training group. A significant decrease in urea was noted in aerobic group only. A significant improvement in KDQOL in both training groups was noted compared to the control group. The strength group saw improvements in social support, patient satisfaction, and general health, and the aerobic group reported improvements in physical functioning, symptoms, pain, sleep, sexual function, and energy/fatigue domains.
Mortazavi et al., 2013	Aerobic exercise	During dialysis	3 times/week	16 weeks	Restless leg syndrome (RLS) questionnaire, SF-36	The changes in RLS were significantly different between the groups, with the exercise group having more pronounced improvement. No between-group difference in SF-36 was found.

Note: NA: information not available.

2.5 Behavioral issues in physical activity and exercise programs

Exercise is beneficial only as long as a person continues to engage in it. In other words, the benefits of exercise disappear if the patient stops performing it (Kouidi et al., 2004). As current guidelines recommend increasing dialysis patients' level of physical activity through regular counseling and encouragement (K/DOQI Workgroup, 2005), the challenge for both healthcare providers and dialysis patients is to improve adherence to a specific exercise training regimen and to make changes to a sedentary lifestyle.

2.5.1 Patient involvement and adherence

In most exercise training programs, therapists prescribe the exercise, provide exercise information, and demonstrate the necessary skills, and patients then simply follow orders. The exercise plan is not based on a therapeutic partnership or negotiated goals between therapist and patient, and adherence is judged by patients' behavior, specifically, their ability to follow the therapist's prescription. Further, that judgment is based on the extent to which the patient complies with the healthcare provider's treatment plan, and is thus based solely on the professional's point of view. The patient's perspective is not taken into account.

Lorig (2002) suggested that if therapists' expectations are unrealistic from the patient's perspective, the result will be non-adherence, as patients are the best judge of what is actually possible for them. Analysis from a qualitative study indicates that poor adherence often results from patients' inability to integrate the treatment regimen into their lifestyle (Costantini, 2006). It is also worth emphasizing that adherence is not restricted to just following instructions, but is a signal of patient involvement, encompassing patients' preferences, resources, and autonomy in the decision-making process (Sandman, Granger, Ekman, & Munthe, 2012). Patient involvement is fundamental to achieving success in any exercise program. Because an individual's internal perceptions may either impede or facilitate his or her desire to engage in exercise (Heiwe & Tollin, 2012), identifying patients' perceived barriers to exercise and incorporating their individual knowledge, beliefs, concerns, and resources into any exercise training program is imperative, particularly for HD patients whose lifestyle is already significantly restricted.

2.5.2 Hemodialysis patients' perceived barriers to exercise

The REXDP, which included a wide variety of patients in terms of co-morbidities and age, demonstrated that most patients on HD are able to participate in physical activity, in turn leading to improved physical functioning (Painter et al., 2000b). Despite the various benefits of exercise that have been documented, and widespread recommendations of exercise, only 8% of 100 dialysis patients in an investigation reported no barriers to participating in physical activity (Delgado & Johansen, 2012), and two previous studies documented an inverse relationship between perceived barriers and physical activity level (Delgado & Johansen, 2012; Goodman & Ballou, 2004). At the same time, other studies have found a majority of dialysis patients to be aware of the benefits of exercise and to indicate a desire to exercise (Bulckaen et al., 2011; Delgado & Johansen, 2012; Kontos et al., 2007). Identifying the barriers to exercise may thus help these patients to translate their interest in exercise into increased physical activity (Delgado & Johansen, 2012; Painter, 2003). The recommendations of recent meta-analysis of cardiac rehabilitation concur (Karmali et al., 2014). The aim of that study was to identify interventions that can effectively enhance patients' uptake of and adherence to cardiac rehabilitation. The results revealed that motivational communication and tailored rehabilitation can increase the uptake of such rehabilitation, whereas self-monitoring and an action plan lead to increased adherence. Karmali et al. (2014) emphasize the importance of identifying and targeting barriers to adherence on an individual basis, which they say increases the likelihood of a rehabilitation program's success.

2.5.2.1 Lack of knowledge and skills

Patients and their family members are typically unsure of the type of exercise that is appropriate for people undergoing dialysis treatment or even concerned whether any exercise is appropriate (Painter, 2003). A fear of possible injury has been cited as a barrier to exercise (Heiwe & Tollin, 2012), a fear expressed by 32% of the 63 HD patients investigated by Goodman and Ballou (2004). Worry about exercise that is associated with unwanted outcomes and a lack of knowledge and technical skills are reported to be the major factors impeding HD patients' participation in exercise in China (Li et al., 2010; Zheng et al., 2010). One investigation of Chinese HD patients found them to be aware of exercise benefits primarily for daily life improvement (i.e., improvement in appetite, maintaining body weight), but not to fully recognize the benefits specific to dialysis patients, such as improved Bp control and enhanced dialysis adequacy (Zheng et al., 2010).

2.5.2.2 Poor exercise capacity

Disease burden and such co-morbidities as CVD, hypertension, and malnutrition are common factors contributing to limited exercise capacity. Compared to the general population, dialysis patients have only 40-50% peak oxygen consumption, representing a 50% reduction in aerobic capacity and strength (Martin & Gaffney, 2003). Muscle weakness also limits these patients' exercise capacity. The presence of muscle weakness and progressive deterioration of muscle strength owing to morphological, electrophysiological, and metabolic changes in skeletal muscle are well documented (Cheema, 2008; Johansen, 2007; Johansen et al., 2003; Sawant et al., 2011). Cardiorespiratory fitness impairment, as measured by peak oxygen consumption and muscle strength, directly affects an individual's ability to perform exercise and even the activities of daily living in this patient group.

2.5.2.3 Presence of symptoms

Such symptoms as fatigue and shortness of breath are also commonly reported barriers to exercise/physical activity (Bossola et al., 2014; Delgado & Johansen, 2012; Fiaccadori et al., 2014; Painter, Carlson, Carey, Myll, & Paul, 2004; Zheng et al., 2010). Shortness of breath is associated with decreased physical activity, and patients' perceptions of fatigue also have a negative association with levels of such activity (Bossola et al., 2014; Delgado & Johansen, 2012; Gordon, Doyle, &

Johansen, 2011). In one qualitative study, the family care provider of a dialysis patient commented that dialysis saps energy (Kontos et al., 2007). Fatigue leads to sedentariness, and sedentariness then increases fatigue, thus creating a vicious circle (Goodman & Ballou, 2004). Chest pain and sadness have also been identified as barriers to exercise, and are independently associated with inactivity (Fiaccadori et al., 2014).

2.5.2.4 Lack of time and transportation concerns

Lack of time and transportation concerns have also been cited as perceived barriers. Dialysis is a time-consuming treatment, requiring patients to attend a facility three days a week. Patients in previous studies commonly point to the difficulties of making time for exercise, particularly on dialysis days (Kontos et al., 2007). Correlation analysis carried out by Delgado and Johansen (2012) shows that the barriers to exercise of a lack of time and perceived medical problems are both associated with reduced physical activity, although the authors found no negative relationship between physical activity levels and the actual number of comorbid conditions. As noted, transportation difficulties may further exacerbate HD patients' low degree of participation in exercise. Previous studies have revealed such difficulties to be associated with early sign-offs of dialysis treatment (Rocco & Burkart, 1993; Kontos et al., 2007). As patients may not regard exercise as a higher priority than the treatment itself, it is understandable that transportation concerns would prevent them from participating in exercise.

2.5.2.5 Lack of motivation

Lack of motivation appears to be the most frequently and strongly endorsed barrier to engagement in physical activity, and is correlated with the amount of exercise performed (Delgado & Johansen, 2012; Goodman & Ballou, 2004; Kontos et al., 2007). Goodman and Ballou (2004) proposed that motivators are more likely to foster exercise participation than concerns over barriers. As patients' exercise behavior can be influenced by the beliefs, attitude, and behavior of those around them, such as healthcare providers and other patients in the clinic, they will remain inactive if those individuals do not counsel and encourage them to increase their physical activity levels or engage in exercise (Painter, 2003; Painter et al., 2004).

2.5.3 Possible solutions to removing barriers

2.5.3.1 Individualized exercise plans

As the HD population is quite heterogeneous in its physical abilities and co-morbidities, specific exercise programs tailored to individual patients' exercise capacity has been recommended as the best approach (Johansen, 2007). DePaul et al. (2002) reported that more severely affected patients, such as those who are older and more disabled, are more likely to drop out of a therapist-prescribed exercise training program, possibly because they are unable to tolerate it. Walking may be less threatening to patients who are sedentary and have poor physical functioning, as it is less vigorous than typical exercise training programs (Johansen, 2007). A progressive exercise plan that incorporates walking as the aerobic exercise and takes patients' personal perceptions and abilities into account could be a promising approach to enhanced compliance. Given that patients receiving HD treatment may suffer from muscle weakness, resistance training could also be incorporated into the exercise program. Additionally, individualized exercises adapted to patients' condition could enhance their perceptions of their skills and competence, thereby motivating them to engage in exercise (Pender, Murdaugh, & Parsons, 2011).

2.5.3.2 Home exercise approach

Time and transportation issues may have implications for the design of exercise interventions. Neither the intradialytic exercise nor home exercise approaches impose additional time and transportation requirement. Exercise programs linking exercise with dialysis sessions have been proven effective. As intradialytic exercise involves exercise equipment that could impose a burden on dialysis staff (Kontos et al., 2007), and home exercise designed to incorporate physical activity into patients' daily life on non-dialysis days may thus be a promising alternative (Kontos et al., 2007; Delgado & Johansen, 2012).

Patients who are informed about the benefits of exercise often find time to increase their physical activity (Kutner, 2007). Advised home exercise may be a way for informed ambulatory patients to slip exercise into their daily routine without any extra time or transportation requirements. Given that fatigue is a frequently reported impediment to exercise, exercising at home can give patients the flexibility to adjust the timing and intensity of exercise to accommodate their fatigue levels (Horigan, 2012). For example, they can perform more strenuous strength exercises when they have more energy and less strenuous flexibility exercises when they have less.

The positive outcomes of home exercise have been reported in the cardiac rehabilitation, community-dwelling elderly adult, and dialysis populations. A systematic review and meta-analysis of home- versus center-based exercise in the cardiac disease population found the two forms of cardiac rehabilitation to have equal effects on patients' clinical and self-reported outcomes (Dalal et al., 2010). Moreover, a study conducted by Marchionni et al. (2003) reported that exercise tolerance was better maintained in patients participating in home exercise than in those attending hospital-based rehabilitation over the 12-month follow-up. With regard to adherence to exercise, another study found participants in home cardiac rehabilitation to achieve superior adherence than their center-based counterparts (Arthur, Smith, Kodis, & McKelvie, 2002). Similar results have been demonstrated in elderly adults participating in a physical activity program. Meta-analysis showed a home program with regular follow-up contacts to have considerably better adherence, and the positive benefits achieved for sedentary adults to be longer-lasting (Ashworth, Chad, Harrison, Reeder, & Marshall, 2005). In the HD population, DePaul et al. (2002) reported that the improvements in work output and muscle strength achieved during a 12-week supervised intradialytic exercise training program were not maintained after cessation of the intervention. In contrast, a home walking program prescribed in the hospital and performed at home by patients on their own was reported to have a long-term effect on improvements in the 6-MWT and quality of life in three domains (bodily pain, physical role, and mental health) measured by the SF-36, as well as decreasing post-dialysis fatigue and recovery time. A pilot study carried out by Koh et al. (2009) to compare functional gains among intradialytic exercise, home exercise, and control groups provided further evidence on the effects of the home exercise approach. In their study, home exercise was shown to be more effective in preserving self-reported physical functioning in HD patients than intradialytic exercise. As the study constituted a pilot trial, however, the functional benefits of home-based exercise for HD patients deserve further investigation. Other researchers following up the survival of HD patients for 19 months found patients in an exercise group to maintain an active lifestyle, whereas their control group counterparts maintained a sedentary lifestyle (Malagoni et al., 2008). The exercise was prescribed in the hospital and performed at home by patients. Malagoni et al. (2008) shed light on the feasibility and preliminary efficacy of a home exercise program for dialysis patients. However, their study did not adopt a randomized design, and the beneficial effects of a home walking program, the modality they tested, therefore needs further evidence obtained from a study with rigorous methodology and a larger sample size. Based on the consistent results reported in the aforementioned studies, a tentative conclusion can be drawn: the benefits of home exercise are similar to or even better than those of hospital-based exercise for HD patients.

2.5.3.3 Structured counseling

Patients' knowledge and skills can be improved through education and training, although improved knowledge and skills alone may be inadequate to elicit behavioral change (Egan, 1999). Integrating physical activity assessments into daily care and training patient care staff in counseling are both strongly recommended (Jonas, Phillips, & American College of Sports Medicine, 2009; Painter, 2003; Painter et al., 2004). Van Vilsteren et al. (2005) incorporated motivational interviewing techniques into a low- to moderate-intensity exercise program for HD patients. Their results suggest that exercise counseling can drive changes in physical activity behavior, thus supporting the efficacy of including counseling in exercise training programs aimed at the HD population. However, at present, dialysis staff rarely encourages patients to exercise. An investigation of 505 nephrologists working in a range of countries revealed that only 38% responded "almost always" or "often" when asked whether they assessed patients' physical activity levels and counseled inactive patients to increase their activity (Johansen et al., 2003). In another investigation involving different types of HD staff, including registered dietitians, licensed vocational nurses, registered nurses, and patient care technicians, 76% stated that they had time in their working schedules to discuss exercise, 81% indicated that they had opportunities to encourage patients, and 71% perceived themselves to have the ability and skills to counsel patients, but only 32% of the 130 staff members interviewed said they regularly encouraged patients to exercise (Painter et al., 2004). Following the recommendation of exercise counseling in the KDOQI cardiovascular guidelines, 40% of 198 nephrologists who participated in an international survey remained concerned about the risks of exercise, and over 50% expressed the belief that dialysis patients would not perform exercise even if counseled to do so (Delgado & Johansen, 2010). Interestingly, even though healthcare providers in dialysis facilities believe that exercise is beneficial for HD patients, and recognize that they have opportunities and the ability to provide exercise counseling, few actually encourage patients to perform exercise in daily clinical practice.

2.6 Nurses' role in promoting physical activity/exercise

Physical activity is a type of behavior that can neither be driven solely by an individual's inner force nor automatically shaped by external stimuli. It is a dynamic process of interaction between personal factors and the environment (Pender, Murdaugh, & Parsons, 2002). Patients need support from both their care providers and the surrounding health system. Healthcare providers constitute a part of the interpersonal environment, exerting an influence on patients' behavior. Currently, exercise is not a routine practice in dialysis centers worldwide. The limited involvement of healthcare providers and/or a lack of financial support to promote physical activity or exercise programs could be contributing factors to this phenomenon (Cheema et al., 2005).

In previous studies, physician- and physiotherapist-led exercise programs have proved effective in improving HD patients' physical functioning. However, not all dialysis centers or units have the resources to hire physiotherapists. In addition, exercise should not be regarded as the exclusive domain of physiotherapists. The entire nephrology team can advise, encourage, and facilitate patients' ability to engage in physical activity, and should regard these activities as an integral part of the patient care plan (Smith & Burton, 2012). As nurses have prolonged and sustained contact with HD patients during their treatment sessions. They can play a pivotal role in encouraging patients to increase their levels of physical activity (Bennett et al., 2010; Kontos et al., 2007). Their professional experience and ongoing interpersonal relationships with patients enable them to provide support and encouragement for patients to live as fully as possible on dialysis (Polaschek, 2003a). Being guided by a humanistic philosophy, caring is a core attribute of nursing practice. The goal of nursing is not solely on treatment and diseases but focusing on human responses to actual or potential health problems (Cumbie, Conley, & Burman, 2004). A study investigating the effects of the advanced practice nurse-nephrologist care model in Canada revealed that nurses are more likely to discuss patient outcomes with both patients and their family members, whereas physicians tend to be more interested in conducting invasive procedures (Harwood, Wilson, Heidenheim, & Lindsay, 2004). In the dialysis setting, physicians have been found more likely to engage in such activities as overseeing care plans than in face-to-face contacts with patients (Plantinga et al., 2004). With regard to communication styles, Collins' (2005) analysis of doctor-patient and nurse-patient conversations revealed that doctors tend to direct the whole sequence of topics, leaving little room for patients to expand upon their problems, whereas nurses tend to encourage patients to expand upon topics during communication, thereby allowing more in-depth explanation and illumination of problems. The study found that patients were more likely to discuss their responsibilities and behavior with nurses than doctors.

2.7 Nurse case management

2.7.1 Nurse-led care

Caring for patients receiving dialysis treatment is considered a great challenge because of these patients' multiple co-morbidities and need for various health services. In addition, faced with a growth trend in the dialysis population, the demand for healthcare services is expected to exceed the services that can be provided by trained clinical physicians. In these circumstances, nurses have been suggested as ideal care providers who can offer direct care and coordinate patient care with the other members of the nephrology team (Bodenheimer, MacGregor, & Stothart, 2005; Cairoli, 2006; Compton, Provenzano, & Johnson, 2002; Wingard, 2009). Thus, innovative approaches to nursing practice are being tested and employed in countries worldwide. These innovations primarily focus on a shift in care responsibilities, with nurses regarded as appropriate alternative healthcare providers to physicians in providing high-quality care at reduced cost (Temmink, Hutten, Francke, Abu-Saad, & van der Zee, 2000). The interventions often adopt a multidisciplinary care team led by nurses, offering a collaborative approach to identify a patient's needs, establish an appropriate plan, implement and monitor his or her progress, and make adjustments when necessary. Nurse-led services have been recommended, and are currently being implemented, in a range of patient populations, particularly such chronic disease populations as diabetes, hypertension, cancer, rheumatoid arthritis, heart disease, and CKD (Clark, Smith, Taylor, & Campbell, 2011; Courtenay & Carey, 2006; Lambrinou, Kalogirou, Lamnisos, & Sourtzi, 2012; Lewis & Hendry, 2009; Ndosi, Vinall, Hale, Bird, & Hill, 2011; Neyhart et al., 2010).

2.7.2 Case management

Case management is considered to be a suitable delivery mode in nurse-led care, particularly for handling complex situations in which a single standard protocol cannot be adequately managed (Van Mierlo, Merland, Van Hout, & Droes, 2014). Unlike traditional healthcare delivery focusing on pharmacologic and technologic interventions, case management provides individualized care to patients with a one-to-one approach (Khanassov, Vedel, & Pluye, 2014). It is concerned with the optimization of multidisciplinary treatment focused on all aspects of the patient, including quality of life and psychological functioning, not merely on his or her disease (Latour et al., 2007). Case management has five essential features: (1) identification of eligible patients, (2) assessment, (3) development of an individualized care plan, (4) implementation of that care plan, and (5) monitoring of outcomes (Norris et al., 2002).

2.7.3 Effects of nurse case management programs in chronic kidney disease population

NCM, an individualized approach to multidisciplinary care that emphasizes modifiable aspects that matter to the patient and is aligned with disease-based treatment strategies, is strongly recommended in the care of both the CKD and HD populations owing to the complex and multifaceted nature of kidney disease (Bennett & Neil, 2008; Bowling & O'Hare, 2012; Saxena & Rizk, 2014). A multidisciplinary care team led by nurses offers a collaborative approach to identifying the patient's needs, establishing an appropriate plan, implementing that plan, monitoring the patient's progress, and making adjustments when necessary.

In the CKD population, Harris, Luft, Rudy, Kesterson, and Tiernay (1998) carried out the first prospective clinical RCT of a multidisciplinary case management intervention aimed at maintaining renal functioning and controlling costs. However, they were unable to demonstrate the intervention's effectiveness during the five-year follow-up. The program they assessed was patient-initiated, mainly led by a nephrologist, and focused on medication monitoring. An accompanying editorial written by Wrone and Hornberger (1998) expressed the view that the trial's disappointing results could partly be attributed to the dominant role of primary physicians, with the multidisciplinary team's recommendations not given priority and the primary physician maintaining control over whether those recommendations were implemented.

A series of studies have reported conflicting results on the effects of NCM in the CKD population. In a study examining a multidisciplinary pre-dialysis care program, for example, patients were cared for by a team comprising a nephrologist, nurse educator, social worker, dietitian, and pharmacist who met together to negotiate patients' care plan to optimize the clinical results (Goldstein, Yassa, Dacouris, & McFarlane, 2004). The study participants were retrospectively selected and regularly followed up after they began dialysis. The results revealed that patients who had been exposed to the program had better blood parameters such as serum albumin and calcium at the start of dialysis than those who had not, although no detectable differences between them were identified six months after dialysis initiation. However, fewer hospitalizations and a lower mortality risk were observed in the exposure group during a three-year follow up. Similar results were found in a two-country case control observational study in which patients who were exposed to multidisciplinary care provided by a nephrologist, nurse, nutritionist, psychologist, social worker, and pharmacist prior to dialysis enjoyed a survival advantage over a standard care group (Curtis et al., 2005). The difference in survival was observed when the two groups were followed up for a median of 14 months after the start of dialysis, with an HR of 2.17 (95% CIs: 1.11-4.28). A case management program implemented in 39 outpatient clinics also successfully improved survival rates and lowered hospitalization rates during the one-year follow-up (Wingard et al., 2007). The case managers in this program, generally nurses, integrated patient education, encouragement, and support with evidence-based practice. The findings of all of these studies highlight the positive impact of individualized NCM in the CKD population.

In addition, a pre-post single-group study using a nurse-led multidisciplinary team to support PD patients' self-management attained satisfactory clinical outcomes by enhancing patients' self-efficacy levels and self-management capacities (Su, Lu, Chen, & Wang, 2009), whereas a cohort study based on retrospective analysis demonstrated that application of an NCM model in outpatient dialysis care can achieve improvements in hospitalization and mortality outcomes (Steele, Hamilton, & Arnaout, 2007). The findings of another retrospective cohort study on dialysis patients also support the efficacy of a case management model in which a nurse coordinates a multidisciplinary team in reducing hospital admissions and costs (Dixon, Borden, Kaneko, & Schoolwerth, 2011).

In Hong Kong, there is preliminary evidence to suggest that a mixed model of specialty and general nurses involved in an intervention is adequate to bring about positive effects in self-care management, aspects of quality of life, and satisfaction with care for CKD patients (Wong, Chow, & Chan, 2010). A randomized controlled study further confirmed that the NCM approach is useful in enhancing the well-being of PD patients in the transition from hospital to home (Chow & Wong, 2010; Wong et al., 2010). In mainland China, Li et al. (2014) reported that a post-discharge nurse-led telephone intervention combined with an NCM approach is effective in improving PD patients' quality of life and reducing the 84-day clinic visit rate. These results indicate that NCM is appropriate for and applicable in the Chinese population and mainland healthcare system.

2.8 Knowledge gap

Physical functioning deterioration is a vexing and highly prevalent problem in the HD population. Exercise is widely recognized as an effective approach to enhancing physical functioning, and to potentially reducing the psychological burden in this population, as most patients on HD treatment lead sedentary lives. Exercise training, regardless of whether it involves aerobic or resistance exercise or a combination of the two, is effective in improving HD patients' physical functioning. Further, the combined modality, that is, aerobic plus resistance exercise training, has been shown to have more pronounced effects on such improvement. Given the small sample sizes and relatively poor methodological quality of the available RCTs outlined in this chapter, it is imperative that clinical trials with a larger sample size be carried out to test the clinical implementation, and further confirm the beneficial effects of exercise programs on physical functioning.

Most of the trials outlined herein investigated the effects of supervised exercise training programs, with participants closely supervised by such medical specialists as physiotherapists, trained physicians, and kinesiologists. Such interventions are resource-intensive, which may limit their use in daily practice, particularly in dialysis units with limited budgets. It is important to develop an exercise program that is effective and efficient for incorporation into daily clinical practice without excessive resource requirements.

Intradialytic exercise as an approach to enhancing patient participation has gained popularity in recent years, but it requires intensive resources such as exercise equipment and space and trained personnel to provide onsite supervision. Evidence shows that both home exercise and in-center programs can achieve positive outcomes in cardiorespiratory capacity and have similar adherence rates. Home exercise is thus a promising alternative to helping HD patients to maintain and/or regain physical functioning; however, studies investigating the effects of home exercise on physical functioning for renal patients have not provided sound evidence of its benefits for this patient group.

The majority of physical activity or exercise training programs provided to HD patients focus on direct supervised training without addressing their emotional or behavioral difficulties in participating in daily activities. The exercise training programs considered in this chapter were mostly delivered in the form of "therapist prescribes and patient follows." As patients are the best judges of what is actually possible for them, a patient-oriented approach that emphasizes partnership, collaborative care, participatory decision-making, and personal responsibility should be integrated into any exercise training program. Given that exercise constitutes a lifestyle change, and HD patients face many barriers to exercise, incorporating individualized strategies and behavioral change strategies into exercise counseling and training is likely to enhance exercise adoption and maintenance. Based on the literature review, exercise programs with individualized strategies and focusing on behavior changes have not been fully explored.

Finally, nurses play a pivotal role in encouraging patients to increase their level of physical activity, and NCM could thus improve both clinical and patient outcomes in the CKD population. However, studies demonstrating the effects of nurse-led exercise training programs are scarce.

In order to fill in the knowledge gap, this study aimed to determine the effects of a nurse-led case management home exercise program for patients undergoing hemodialysis treatment.

2.9 Conceptual framework

The conceptual framework of this study was constructed based on Courneya's (2010) conceptualization of exercise trials. According to Courneya (2010), studies of exercise trials can be classified into "health outcome trials" or "behavioral change trails" depending on the primary outcome. The primary purpose of health outcome trials is to examine the effects of the exercise intervention on health outcomes such as physical fitness, biomarkers, or disease states, whereas the aim of behavioral change trials is to evaluate the effects of a behavioral support intervention on exercise behavior. Courneya (2010) argued that behavioral support is regarded as necessary for reinforcing adherence to exercise, particularly unsupervised home exercise. As summarized in the literature review, though exercise training can improve the physical functioning of HD patients through participation, the patients found it difficult to change their behavior and reported barriers to continuing to engage in physical exercise. It is pivotal for health care professionals to help patients address their behavioral difficulties, particularly in the case of home exercise programs. The conceptual framework, Figure 2.1, guides the development of a trial that incorporates behavioral support interventions in a traditional exercise trial to examine the resulting health outcomes. Three components make up the framework: exercise guides for dialysis patients (Painter, 1999), Pender' health promotion model (HPM) (Pender, Murdaugn, & Parsons, 2011), and nurse case management.

2.9.1 Painter's exercise guides for dialysis patients

According to Painter (1994), individuals who have been diagnosed with ESRD experience a prolonged period of reduced activity and bed rest, resulting in an inactive lifestyle that leads to a downward spiral of deconditioning. The deconditioning subsequently restricts the ability of the patients to perform the activities of daily life, resulting in reduced physical functioning. Exercise, as a way of increasing physical activity, can break the cycle of deconditioning to optimize physical functioning. This study is essentially an exercise trial, the primary purpose of which is to examine the effects of a home exercise intervention on the physical functioning of patients.

As exercise capacity is significantly low in hemodialysis patients and individual patients may response differently to exercise therapy, it is recommended that a tailored exercise prescription based on individual interests, health needs, and clinical conditions should be adopted with regular reassessments (Durstine et al., 2000; Painter & Hanson, 1987). Inactive HD patients suffer from a diverse range of secondary complications, such as reduced maximum oxygen uptake, muscle atrophy, and bone or joint diseases (Painter & Hanson, 1987). In order to facilitate the prescription of individualized exercise regimens to HD patients, Painter (1999) developed and published an exercise guide entitled *Exercise: A Guide for People on Dialysis*. His exercise program, which includes aerobic, strength, and flexibility exercises, can accommodate the pathophysiology of kidney disease and its treatment (Painter & Hanson, 1987). The exercise program requires little exercise equipment and can be performed by patients themselves at home with appropriate guidance. Most importantly, this exercise guide has been shown to optimize physical functioning for HD patients. In the study of Painter et al. (2000b), those participants who received training according to the exercise guide for eight weeks in the dialysis center and who practiced exercising at home for another eight weeks experienced significant improvements in both objective physical performance and self-reported physical functioning after the 16-week intervention (Painter et al., 2000b). As both supervised and home exercise interventions were provided, the functional gains that were achieved cannot be generalized to home exercise programs for HD patients. Based on the promising findings achieved in this study, the present study hypothesized that patients who perform home exercises based on Painter's exercise guide will experience improved physical functioning.

2.9.2 Pender's health promotion model

Courneya (2010) emphasized the importance of behavioral support for unsupervised exercise, even for interventions of a short length. In order to facilitate the engagement of HD patients in home exercise, behavioral supports were incorporated into the current study. The design of the behavioral support strategies in this study were guided by the HPM developed by Pender in 2011 (Pender et al., 2011). The HPM provides a framework for integrating nursing and behavioral science perspectives, taking into account social context (Lim, Waters, Froelicher, & Kayser-Jones, 2008). The model posits that the likelihood of an individual changing his or her behavior depends on selected individual characteristics, cognitions, and affect. Of these variables, the components for cognition and affect are considered to have the greatest motivational significance (Pender et al., 2011). In addition, specific patient characteristics could influence exercise behavior and should be taken into consideration when nurses provided interventions to individual patients.

The six variables within the HPM model were used to guide the intervention design in this study. They were: the perceived benefits of action, perceived barriers to action, perceived self-efficacy, activity-related affect, interpersonal influences, and commitment to a plan of action. These variables were operationalized into corresponding actions and activities of behavior support strategies. Perceived benefits of action were specified into patient education and discussion on perceived exercise benefits after home exercise participation. The exploration of potential barriers to exercise and problem solving were strategies aiming to decrease patients' perceived exercise barriers. The identified barriers were handled through negotiating coping plans, collaborations between health professionals, patients, and family members, as well as medical referrals. Perceived self-efficacy and active-related affect were operationalized into actions, such as individualized exercise prescription, discussion on the positive experiences of home exercise participation, and showing acknowledgement of improvements in home exercise performance. Mutual goal setting and action plans were interventions to increase patients' commitment to plan of action and actual engagement in home exercise. Interpersonal influences consisted of the attitudes, belief, and actions of others on a particular behavior, such as health care providers, family members, and peers. In the current program, throughout the nurse-patient interactions, nurses were regarded as a major influence on the patients in terms of changing their understanding of exercise behavior. The positive beliefs and attitudes of the nurses towards exercise played an important role in motivating the patients to initiate and maintain home exercise.

2.9.3 Nurse case management

The Case Management Society of America defines case management as "a collaborative process which assesses plans, implements, coordinates, monitors and evaluates options and services to meet an individual's health needs through communications and available resources to promote quality, cost effective outcomes." In this definition, the case manager's central role is to collaborate and coordinate among different parties. However, Hamric, Spross, and Hanson (2005) emphasized that providing direct clinical practice is considered the central competency of the nurse case manager. Case management in this study serves as a practice framework.

Nurse case management herein integrated general and advanced concepts of nursing to provide individualized care to patients in holistic way with continuity. It was employed as a platform to implement both home exercise intervention strategies and behavioral support strategies directly on the individuals, with the primary aim of enhancing the physical functioning of the patients. They conducted a detailed assessment of the patients' health status, exercise capacity, prior exercise experience, knowledge and attitudes towards exercise, and current exercise practice behavior. Based on the assessment data, the case managers developed mutually agreed-upon exercise plans and action plans with the patients to target at managing identified barriers to exercise. Furthermore, they were responsible for monitoring the patients' progress toward their goals, evaluating the effects of interventions, and linking the patients to appropriate resources by making referrals or seeking family support for ongoing management. In this study, nurse case management offers an opportunity to provide interventions to overcome obstacles that patients face to participating in exercise, through the provision of individualized exercise prescriptions, the multidisciplinary coordination of care, counseling, and continuous monitoring.

In conclusion, the conceptual framework guided the development of this study. It incorporated Painter's exercise guide, HPM, and NCM, with the aim of improving the physical functioning of HD patients. It was hypothesized that NCM can help patients to adhere to home exercise behavior at a recommended level to achieve improvements in physical functioning. Other related outcomes include improvements in quality of life, self-rated health, depressive symptoms, levels of physical activity, and patient perceptions of the benefits and barriers to exercise.

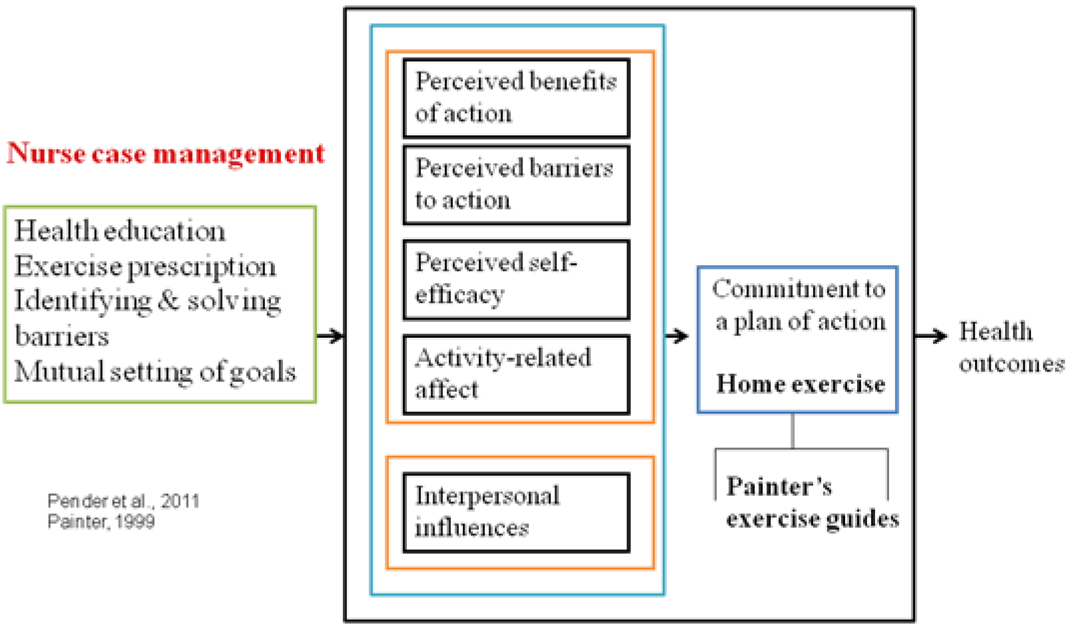

Figure 2.1: Conceptual framework of the study

Chapter 3 Methodology

3.1 Introduction

This chapter states the research question and study hypotheses, and introduces the study design that was adopted to answer that question, followed by detailed elaboration of the study settings, ethical considerations, sampling method, intervention, outcome measures, and methods of data collection and analysis. The design and procedures of the randomized controlled trial (RCT) are presented in accordance with the 2010 CONSORT statement (Moher et al., 2012). The chapter concludes with a brief summary.

3.2 Research question and hypotheses

3.2.1 Research question

The research question guiding this study is: What effect does a nurse-led case management home exercise training program exert relative to brief in-center group exercise training with regard to (a) physical functioning, (b) HRQoL, (c) self-rated health and depressive symptoms, (d) physical activity levels, and (e) patient-perceived exercise benefits and barriers in patients undergoing chronic HD treatment

3.2.2 Null hypotheses

1) There is no significant difference in physical functioning between participants participating in the nurse-led home exercise training program and those receiving controlled care.

2) There is no difference in quality of life between participants participating in the nurse-led home exercise training program and those receiving controlled care.

3) There is no difference in perceived health between participants participating in the nurse-led home exercise training program and those receiving controlled care.

4) There is no difference in depressive symptoms between participants participating in the nurse-led home exercise training program and those receiving controlled care.

5) There is no difference in physical activity levels between participants participating in the nurse-led home exercise training program and those receiving controlled care.

6) There is no difference in perceived benefits and barriers to exercise between participants participating in the nurse-led home exercise training program and those receiving controlled care.

3.3 Operational definitions

Physical functioning: Physical functioning in this study refers to the ability to perform daily activities and tasks, it includes actions and activities that are required for independent living and to optimize quality of life (Painter et al., 1999; Tawney et al., 2000). There are different tools for assessment of physical functioning; including questionnaires relating to an individual's ability to perform daily activities and direct measurement of physical performance. Physical performance tests require patients to perform specific tasks, which eliminates the confusion that could occur with self-reported questionnaires (Painter, Stewart, & Carey, 1999). Moreover, physical performance tests may capture quantitative information of the patient's physical limitations that might not be detected through subjective reports (Blake & O'Meara, 2004). In this study, gait speed and 10-repetition sit-to-stand test (10-STS) were chosen as outcomes for measuring physical functioning. Walking ability and moving from a seated to standing position are tasks being considered necessary for the activities of daily living. The two tests have been validated in patients with CKD (Headley et al., 2002; Painter et al., 2000b). They are able to be performed by majority of the dialysis patients, and have been associated with all-cause mortality in the CKD population (Painter & Marcus, 2013). In addition, these measures are widely used in previous studies that provide databases for comparison (Headley et al., 2002; Painter et al., 2000b; Segura-Orit et al., 2009; Storer et al., 2005; van Vilsteren et al., 2005).

Case management: It is a collaborative process of assessment, planning, facilitation, care coordination, evaluation, and advocacy for options and services to meet an individual's and family's comprehensive health needs through communication and available resources to promote quality, cost-effective outcomes (Case Management Society of America, n.d.). In the current program, it is a direct patient care delivery integrating general and advanced concepts of nursing to provide continuous individualized patient care in a holistic approach. Care coordination was facilitated through medical referrals.

Physical activity: Physical activity is defined as any bodily movement produced by the contraction of skeletal muscle that increases energy expenditure above a basal level (Office of the US Surgeon General, 1996).

Exercise: Exercise is a subcategory of physical activity that is planned, structured, repetitive, and purposeful and undertaken to improve or maintain one or more components of physical fitness (Office of the US Surgeon General, 1996).

Exercise capacity: It refers to the point of maximum ventilatory oxygen uptake or the highest work intensity that can be achieved (Fletcher et al., 1992).

Flexibility exercise: It is a form of exercise designed to help the joints work smoothly and tendons become flexible through gently stretching muscles and performing slow movements (Painter, 1999).

Strength exercise: It is a form of exercise designed to strengthen muscles by using resistance to make them work harder (Painter, 1999).

Aerobic exercise: It is a form of exercise intended to strengthen an individual's cardiorespiratory system through sustained, rhythmic movements of the arms and legs (Painter, 1999).

In-center group exercise: exercise program provided in centers on dialysis days before dialysis sessions.

Intradialytic exercise: It refers exercise that be performed during dialysis at the treatment facility (Ma et al., 2012).

Home exercise: Home exercise in this study refers to exercise that performed by patients at home between dialysis treatments without onsite supervision.

3.4 Study design

The study constituted a randomized, two-group parallel study. Eligible participants were randomly assigned to either the intervention group or control group in a 1:1 ratio to receive the corresponding interventions. Both groups received in-center group exercise training. That received by the control group participants was limited to flexibility and strength exercise. No aerobic exercise suggestions or prescriptions were offered to these patients. In addition, over the whole 12-week study period, no case management or follow-up was available for this group. Patients in the intervention group, in contrast, received additional home exercise NCM in the form of nurse-patient interviews. The aim of this case management was to encourage patients to adopt and maintain regular exercise at home in addition to the brief weekly center-based group exercise in which they took part. A comprehensive exercise program including flexibility, strength, and aerobic exercise was incorporated into the nurse-patient interviews.

This study adopted a control group that received a different intervention dose. Patients in the control group were offered some intervention, namely, brief in-center group exercise training, whereas the intervention group received an intervention that combined both brief group exercise training and home exercise NCM. This design was adopted for two main reasons. First, the use of a control group receiving a treatment with a different dose is recommended to alleviate ethical concerns when the treatment is known to have beneficial effects on patients' prognosis (U.S. Department of Health and Human Services Food and Drug Administration, 2001). The favorable effect of exercise for the HD population in terms of physical function, quality of life, lower limb strength, and blood pressure has been confirmed by several systematic reviews (Cheema & Singh, 2005; Heiwe & Jacobson, 2014; Segura-Orti, 2010; Smart & Steele, 2011). As exercise is imperative for dialysis patients, it would be unethical to have a control group in which subjects were completely excluded from the exercise program. Second, the specific intervention that was assumed to be effective for the study outcomes was the NCM with a home exercise component. Regular nurse-patient interviews facilitate interpersonal influences between nurses and patients, and also serve as a platform for nurse case managers to enhance patients' knowledge of exercise benefits, help them to overcome exercise barriers, and improve their self-efficacy in consistently performing exercise at home through individualized exercise prescription and mutual goal-setting. To enhance design rigor, it is necessary to include a control group to eliminate potential intervention effects (Kinser & Robins, 2013). However, it is a fundamental principle that all elements of the intervention and control groups should be equivalent except for the active intervention components related to the target outcomes (Lindquist, Wyman, Talley, Findorff, & Gross, 2007).

3.5 Study settings

This study was conducted in the HD units of two hospitals in Nanjing, the capital of Jiangsu Province. Nanjing has a population of 3.624 million, with an estimated adult dialysis population of 1,603 in 2009 (Nanjing Daily, 2009). Both study hospitals are tertiary hospitals affiliated with Nanjing Medical University. The first is the largest hospital in Jiangsu Province. It is located in the city center and responsible for medical care and teaching and research. Its blood purification center was one of the first dialysis centers in the province, and it today has approximately 250 chronic HD patients. The second study hospital is located in the city's north-west. Its blood purification center is the largest dialysis center in Jiangsu Province, providing various blood purification services to about 500 regular HD patients. Both hospitals indicated their interest in research collaboration and willingness to participate in the study. They offer similar healthcare practices, and no exercise education or exercise training services are provided in daily routine care.

3.6 Study sample

Patients were considered eligible if they were medically stable as determined by the physicians. A consecutive sampling approach was adopted to recruit all patients who met the inclusion criteria over the study period (Polit & Beck, 2012; Portney & Watkins, 2009). Data collection took place from January to December 2013. Participants meeting the following inclusion criteria were recruited from the eligible patient pool by the student investigator.

Inclusion criteria:

- Starting HD more than three months ago and having treatment three times a week
- Aged 18 or above
- A Kt/V index greater than 1.2
- A Hb level greater than 80 g/L
- Ambulatory without assistance
- Able to communicate in Chinese

- Willing and able to provide informed consent

  Note: Kt/V represents the dose of HD. An abbreviation of $(K_{urea} \times T_d)/V_{urea}$. K_{urea} (milliliters/minute), it is the delivered dialyzer urea clearance accumulated over the entire HD session. T_d (minutes) represents the time calculated from the beginning to end of dialysis, and V_{urea} (milliliters) is the patient's volume of urea distribution (National Kidney Foundation, 2002).

Exclusion criteria:

- Unstable physical condition or severe musculoskeletal disease that might hinder exercise training (Refer to Appendix 3.1 for the contradictions to exercise)
- Diagnosis of mental illnesses
- Severe hearing problem affecting communication
- Engagement in regular exercise that meets or exceeds the recommended amount, i.e., 30 minutes per day for three days per week

A priori sample size calculation, i.e., estimating the number of participants that need to be recruited, is an indispensable process of any research design. The sample size determined is expected to have adequate statistical efficacy to achieve reliable research conclusions (Kim & Seo, 2013; Scales & Rubenfeld, 2005; Schulz & Grimes, 2005). Sample size calculation formulae differ, depending on the study design and primary outcome measures (Farrokhyar, Reddy, Poolman, & Bhandari, 2013; Noordzij et al., 2010). An appropriate level of statistical significance, testing power and effect size are the major components required to calculate the sample size in a randomized trial (Devane, Begley, & Clarke, 2004; Noordzij et al., 2010).

Conventionally, a statistical significance level of 0.05 and power of 0.8 are considered acceptable (Schulz & Grimes, 2005). Polit and Beck (2008) define effect size as "a statistical expression of the magnitude of the relationship between two variables, or the magnitude of the difference between groups on an attribute of interest; also used in meta-synthesis to characterize the salience of a theme or category" (p. 726) Effect size is a standardized index that enables cross-study comparisons on the direction and strength of the relationship between variables or magnitude of the difference between populations (Berben, Sereika, & Engberg, 2012; Olejnik & Algina, 2003).

In this study, sample size calculation was based on the primary outcome variable: gait speed. The effect size was estimated on the basis of the normal gait speed reported by Painter et al. (2000b). G*Power 3, a noncommercial program for conducting power analysis, was used to perform the effect size and sample size calculations. The program is user-friendly and available for a free download from http://www.gpower.hhu.de/en.html. It is specifically designed for the social, behavioral, and biomedical sciences (Faul, Erdfelder, Buchner, & Lang, 2009). Repeated-measures analysis of variance (RM-ANOVA) showed the required total sample size to be 96, 48 for each group to adequately detect between-group difference. The design achieved 80% power with a 5% significance level, assuming the correlation of the repeated measures was 0.8. According to a previous study, the dropout rate of 17% was observed for patients on home exercise (Konstantinidou et al., 2002). As a dropout rate of around 17% was anticipated, a total of 112 subjects were required for the study.

3.7 Randomization

3.7.1 Sequence generation

As the number of HD patients in the two study sites was not equal, at approximately

250 and 500, respectively, two sets of randomization sequences were generated from the website: www.randomization.com (Haahr, 1998) based on the estimated sample size. Each sequence set was generated via block randomization, with random block sizes of 2, 4, and 6. The sequential assignments consisted of a series of “A” (intervention group) and “B” (control group). The sequences were printed out on several sheets of A4 paper.

3.7.2 Allocation concealment

The random assignments were cut out sequentially from the A4 sheets. To ensure allocation and assignment concealment, assignments was rolled in additional sheets of paper thick enough to be impermeable to light and then in consecutively numbered, opaque envelopes before commencing data collection. The student investigator did not retain a copy of the randomization sequence, and, as noted, the envelopes were placed in a locked drawer to which only those responsible for allocation had access.

3.7.3 Implementation

The student investigator was responsible for both randomization sequence generation and patient enrollment. After participants had been enrolled, signed consent forms and completed the baseline assessment, the student investigator wrote their names and corresponding dialysis schedules on the envelopes and opened them. Envelopes were always opened sequentially, from the lowest to the next highest number. In accordance with computer assignments, participants were randomly assigned to either the intervention group (those with the letter A) or control group (those with the letter B).

3.8 Intervention

The intervention lasted 12 weeks, with data collected at three time points: baseline (before the intervention, T0) and at weeks 6 (T1) and 12 (T2). The intervention had two major components: brief in-center group exercise training and NCM incorporating home exercise. The aim of case management was to facilitate exercise progression. The intervention group received both group exercise training and NCM, whereas the control group received only the former. See Figure 3.1.

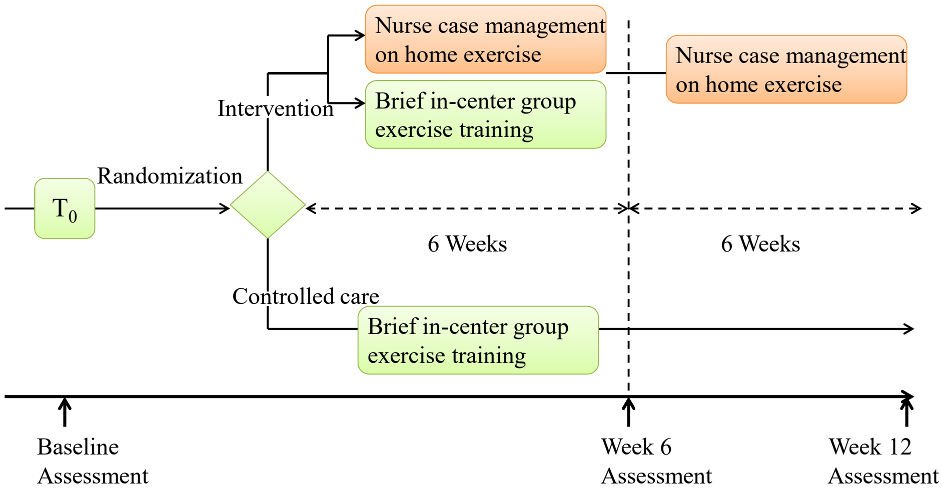

Figure 3.1: Study design.

As noted, brief in-center exercise training was made available to all participants. It comprised flexibility and strength exercise, and was conducted by the student investigator in groups of four to six participants prior to HD treatment. Each session lasted about 20 minutes. All participants were provided with opportunities to take part in the training sessions once a week for the first six consecutive weeks. The investigator performed the exercises together with the participants and emphasized the importance of self-monitoring exercise intensity. Participants were instructed to start with flexibility exercises to warm up, following by strength exercises, and finally a repeat of the flexibility exercises as a cool-down. Such symptoms as chest pain, dyspnea, dizziness, and leg cramps were checked prior to exercise and monitored throughout the session. The session was stopped immediately if a patient experienced shortness of breath, chest pain or pressure, irregular heartbeat, leg cramps, dizziness or lightheadedness, blurred vision, or any other discomfort. Recommendations for the number of repetitions of each exercise movement were in accordance with the patient's exercise capacity and health condition. Participants were advised to start slowly and progress gradually, and the sequence of exercise movements was arranged according to the difficulty level, from the easiest to the most difficult exercise. For example, patients were instructed to start a relatively advanced flexibility or strength exercise only after they had completed an easy exercise three times. A perceived effect scale was used to help patients to self-evaluate how hard they were exercising on a scale ranging from "resting" to "very, very light," "fairly light," and "somewhat hard." A booklet with exercise illustrations was also provided to each participant.

Intervention group

In addition to attending the in-center group exercise training, participants in the intervention group took part in face-to-face interviews conducted by designated nurse case managers during their HD sessions every week for six weeks and then every other week for another six weeks, for a total of nine interviews. The interviews normally took place within the first two hours of HD treatment because dialysis-related symptoms such as cramps, hypotension, and dizziness are common toward the end of dialysis sessions (Caplin, Kumaar, & Davenport, 2011).

In the first interview, case managers developed an individualized exercise plan with the patient. In addition to the flexibility and strength exercises learned in the group training sessions, patients were instructed to start their preferred type of aerobic exercise such as jogging, cycling, or brisk walking at home for a short duration and then gradually progress to a recommended level of 30 minutes without stopping at least three to four times per week (Painter, 1999). Patients were recommended to perform strength exercises twice a week and flexibility exercises every day. The key elements of the first interview, which lasted approximately 30 minutes, included: 1) an assessment of patients' exercise knowledge and behavior and their attitudes, beliefs, and feelings about being physically active; 2) exploration of patients' self-reported barriers to and the perceived benefits of exercise; 3) reinforcement of the benefits of exercise if needed; 4) development of mutual goals in an exercise plan; 5) explanation of the purpose of keeping an exercise log and instruction in the correct way of doing so; and 6) discussion of the support and resources available to motivate patients to initiate and maintain exercise, i.e., the center-based exercise program and support from family members, healthcare providers, and other patients.

In the subsequent interviews, the case managers reviewed participants' exercise logs with them, discussed positive exercise-related experiences and participants' exercise progress, and provided encouragement. Depending on the progress participants had made, exercise goals and plans were renewed or revised as needed. Referrals were also made as needed. For instance, is a participant had symptomatic hypertension, he or she was referred to the physician in charge for follow-up. The average duration of each follow-up interview was approximately 15 minutes.

Control group

As noted, the control group patients participated only in the in-center exercise training program once a week prior to their HD session for six weeks. Each exercise session, comprising flexibility and strength training alone, lasted about 20 minutes, and patients were advised to perform the exercises at home and increase their daily activity levels. No NCM or follow-ups were offered to these patients throughout the study period.

Weeks	Control group: Intervention	Control group: Time & Frequency	Intervention group: Intervention	Intervention group: Time & Frequency
1-6	**In-center group exercise training** Flexibility & strength exercise	**Weekly** 20 minutes/session	**In-center group exercise training** ✓ Flexibility & strength exercise	**Weekly** 20 minutes/session
			Nurse case management on home exercise ✓ Flexibility, strength & aerobic exercise • Patient education • Barrier identification & solving • Mutual goal setting • Exercise prescription • Monitoring	**Weekly** 20-30 minutes for the 1^{st} session; 15 minutes for 2^{nd}-6^{th} sessions;
7-12	No intervention		**Nurse case management on home exercise** ✓ Flexibility, strength & aerobic exercise • Patient education • Barrier identification & solving • Mutual goal setting • Exercise prescription • Monitoring	**Biweekly** 15 minutes

Figure 3.2: Interventions for the trial groups

Note: Demographic and clinical data were collected at week 0. Outcomes were assessed at weeks 0, 6, and 12.

3.8.1 Protocol development

The research team developed comprehensive intervention protocols based on up-to-date evidence and guidelines to govern implementation of the planned measures.

3.8.1.1 Exercise protocol

The exercise protocol was developed in accordance with a handbook published by Patricia Painter (1999) entitled *Exercise: A Guide for the People on Dialysis*, which is available for free download at http://lifeoptions.org/catalog/catalog.php?prodCat=booklets. Its contents include the recommended duration, frequency, intensity, and modality of the exercise training program, ways to deliver and supervise it, and instructions on home exercise. The program was validated in a U.S. HD population study conducted by Painter et al. (2000b). The student investigator received permission to translate the handbook into Chinese from the Medical Education Institute for the Life Options Program and its author (Appendix 3.2), and her translation was then evaluated by a Hong Kong physical therapist with 23 years of clinical rehabilitation experience to ensure consistency with the original.

In addition to linguistic accuracy, this therapist also assessed the exercise motions, prescription, and plan and suggested ways of making progress to determine whether they were feasible and safe for implementation in a Chinese population. A bilingual expert panel in mainland China comprising physical therapists, renal nurses, and academic staff were then invited to make further comments on the cultural relevance and safety of the exercise program for the Chinese HD population, as well as the handbook's translation and feasible ways of incorporating exercise training into a patient care plan. Several additional revisions were made at this point. For instance, some of the types of aerobic exercise recommended in the original, such as water aerobics, are not commonly adopted by the Chinese HD population. To enhance cultural relevancy, an exercise that offers a similar amount of energy expenditure, namely, square dancing, was used in the Chinese version.

Based on the translated handbook, the researchers developed two exercise protocols (Appendix 3.3a, 3.3b): one including only flexibility and strength training for use in the center-based exercise training, and the other comprising flexibility, strength, and aerobic exercise for use by the case managers during the interview sessions. Both exercise protocols were tested for feasibility and safety in a pilot study.

3.8.1.2 Nurse case management protocol

The design of the case management protocol was based on the Pender HPM (Pender et al., 2011), with HPM variables such as the perceived benefits of and barriers to action and perceived self-efficacy embedded therein. As shown in Figure 3.2, the major content of the nurse-patient interviews comprised rapport development, exercise benefit and barrier exploration, problem identification and solving, mutual goal setting, and exercise safety monitoring.

A trusting relationship between patients and care providers promotes optimal communication (Roberts, Wheeler, & Neiheisel, 2014), and there is a documented association between trust in healthcare providers and patients' adherence behavior (Kerse et al., 2004; Zolnierek & Dimatteo, 2009). A recently published study examining adherence to prescribed home rehabilitation exercise among musculoskeletal injury patients confirmed the patient-practitioner relationship to be a predictor of adherence behavior (Wright, Galtieri, & Fell, 2014). In addition, trust between patient and healthcare provider creates opportunities for the former to discuss his or her beliefs and concerns about exercise behavior. Exploring patients' previous exercise behavior and the perceived barriers to engaging in a target behavior are conducive to effecting behavioral change. It allows patients and care providers to discuss ways of overcoming potential obstacles to generate effective strategies for realizing such change (Elder, Ayala, & Harris, 1999). Pender et al. (2011) remind us that a commitment without specified strategies often leads to “good intentions” alone. However, it is important to keep in mind that patients have the right not to accept treatment advice (Wright, 1998), even if doing so would be beneficial to their health status. The care model has shifted from the simple enforcement of a therapeutic prescription to negotiated care that seeks to accommodate patients’ own perspectives in the therapeutic regimen (Polaschek, 2003a). In this paradigm, healthcare providers need to engage patients in a discussion of their goals and plans for achieving a targeted behavior. Mutual goal setting in which nurses and patients collaboratively define goals and reach agreement on those that can be attained is also an essential problem-solving process (Maves, 1992). Evidence is accumulating that patients with specific, attainable goals can achieve desirable health outcomes such as a better diet and more physical activity (Calfas et al., 2002; Shilts, Horowitz, & Townsend, 2004).

In the first interview in this study, the nurse case managers employed an open-ended communication style to encourage patients to discuss their health concerns, which helped to facilitate a trusting nurse-patient relationship and gave the nurses a comprehensive understanding of patients' concerns about and perceived barriers to engaging in exercise. A brief assessment of patients' exercise behavior, including their current physical activity level, prior exercise experience, patient-perceived health, and potential problems that might impede exercise participation, such as fatigue, pain, and/or sleep problems, was incorporated into the discussion. After establishing a trusting relationship, the nurses then directed the conversation toward exploring patient-perceived exercise benefits and provided education tailored to their existing knowledge. During this process, the nurses emphasized the benefits of exercise to encourage patients to initiate regular exercise. Patients were then invited to explore what might help them to engage in exercise, such as family support, more readily available exercise facilities, and daily reminders. The nurses worked with patients to analyze possible barriers to exercise and come up with possible solutions. Attainable goals were mutually negotiated based on the patient's current exercise capacity, and a suitable action plan set. Examples of such goals include "I will walk for 5 minutes twice a day" and "I will walk three days a week after dinner at home."

During the follow-up interviews, the nurses reviewed patients' performance and compared it to the goals in the prescribed exercise plan. Patients who met the pre-established goals were encouraged to discuss the feeling of being active and to make further progress gradually. If patients failed to make changes or achieve their goals, the nurse case managers explored the specific problems that may have led to that failure, provided emotional support, and encouraged them to discuss their feelings and any barriers they had encountered. New exercise goals and plans were negotiated based on patients' condition. Home exercise safety was also closely monitored during each follow-up, and referrals to the physicians in charge were made as needed for participants who had experienced any change in their health condition such as abnormal Bp fluctuations.

Because the interviews adopted a person-centered approach to facilitating exercise progression through establishment of a trusting partnership, a very structured protocol was not feasible. Therefore, the researchers generated the protocol (Appendix 3.4) listing key points for the nurse case managers to refer to in the interview, such as assessing physical activity level, discussing exercise benefits, exploring exercise barriers, setting mutual goals and an action plan, and evaluating confidence levels, based on the study's conceptual framework. The protocol' clinical application was tested in the pilot study.

3.8.2 Preparation of student investigator

As noted, the in-center exercise training program was administered by the student investigator, who learned and practiced the exercise under the supervision of an experienced Hong Kong physiotherapist during the study's preparatory phase. Repeat demonstrations were performed to ensure that she was capable of teaching the exercises competently and accurately. She also discussed safety issues, exercise prescription, and frequently asked questions with the physiotherapist to be able to take the necessary safety precautions during the program and address any questions raised by the participants. In addition, the investigator kept in close contact with the physiotherapist to gain further support and advice whenever needed during the study period.

To obtain interviewing skills, and thus be able to pass them on to the participating nurse case managers, the student investigator attended a training course on the theories and practice of counseling for health professionals provided by the author/student investigator's affiliated university. Basic counseling skills were practiced in the classroom through demonstration and role-plays under the supervision of the lecturer. Learning strategies included video-recording of basic counseling skills through role-plays and self-evaluation and self-reflection. Individualized feedback was received from the lecturer after he reviewed the videos and reflective reports. The student investigator also attended a workshop on motivational interviews during which motivational interviewing skills were practiced through role-plays. The teacher gave individualized feedback in face-to-face discussions after the workshop.

3.8.3 Preparation of nurse case managers

Eight nurse case managers were recruited from the two study sites. To be eligible for participation, a nurse had to have attained at least a Bachelor's degree (or its equivalent) in nursing and have at least three years of experience working in an HD unit. He or she also had to have the following attributes: able to provide genuine care through nurse-patient communication and attentive and responsive to patients' diverse needs. Potential nurse case managers were recommended by the head nurses at the study sites.

The student investigator administered a mandatory 12-hour comprehensive structured training program for all selected nurse case managers. It consisted of four parts: introduction, nursing case management, exercise training, and interview skills (see Appendix 3.5 for the training plan). The training included theoretical input, case scenario training, and a review. To ensure the case managers' competency to carry out the study interventions, their skills were evaluated according to the key objectives identified for each training session. Self-study materials were also provided for self-directed learning and reference.

3.8.3.1 Part I Introduction (1.0 hours)

The introduction session consisted of an overview of the study aims, objectives, conceptual framework, and interventions and the roles and responsibilities of the nurse case managers. To facilitate clinical implementation of the interventions, the student investigator elaborated upon each intervention component using evidence-based information and examples.

3.8.3.2 Part II Nursing case management (5 hours)

The trainees attended five hours of training on nursing case management, including theoretical input and case analysis and review. The first part of the program focused on the philosophy, guiding principles, functions, and activities of nursing case management. The trainees were taught how to differentiate the NCM model from the traditional model of care delivery. The second part of this training primarily addressed the activities of nursing case management, including: 1) patient assessment; 2) use of intervention protocols; 3) achieving shared goals with patients; 4) follow-up skills; 5) available referral resources; 6) and formal intervention documentation.

3.8.3.3 Part III Exercise program (3.5 hours)

The exercise program consisted of three parts: exercise guides for dialysis patients, instructions on home exercise, and safety issues. As case managers were required to assess participants' ability to perform home exercises during the interview sessions, they needed to be competent in exercise prescription and supervision. In accordance with the exercise protocols, the student investigator provided a demonstration of the flexibility and strength exercises. The remainder of this session focused mainly on the exercise prescription, including types, frequency, duration, and intensity of exercise in accordance with an individual's ability. Safety and monitoring issues were also discussed.

3.8.3.4 Part IV Interview and communication skills (2.5 hours)

The training session on interview skills included theoretical input, practice, and review and focused on the basic communication skills needed to negotiate behavioral change, establish a trusting relationship, build confidence, and exchange information. The HPM was discussed, along with such corresponding intervention elements as exercise benefit and barrier exploration, problem-solving, and mutual goal setting. After theoretical instruction, the nurses practiced the skills they had learnt using a case scenario and role-plays. The investigator and their fellow trainees observed and reviewed the role-plays with the training objectives in mind and feedback provided.

All of the nurse case managers took a case scenario-based exit examination to ensure their competence and the consistency of the interventions among managers. Each case manager received supportive tools following the training program, including a patient education leaflet, instructions on interview techniques, an intervention checklist, and a record chart. They were asked to keep a record of all information collected during the interviews, such as mutual goals, the action plan, barriers identified, and patient's confidence in engaging in home exercise. Formal documentation was required to ensure the consistency of intervention delivery. The student investigator reviewed this documentation periodically for quality control. Regular monthly meetings were organized with the case managers to discuss any difficulties they encountered and devise potential solutions. Case managers could also contact the student investigator at any time throughout the study period.

3.8.4 Rationale of the interventions

The American Heart Association (AHA) recommends using a combination of at least two cognitive-behavioral strategies, for example, motivational interviewing, goal setting, self-monitoring, follow-up, and self-efficacy, in an intervention to counsel individuals on dietary and physical activity changes (Artinian et al., 2010). Evidence from a Cochrane review on effective strategies for promoting physical activity in community-dwelling adults indicates that interventions incorporating professional guidance, self-direction, and ongoing professional support are most likely to achieve increased self-reported physical activity and measured physical fitness (Foster, Hillsdon, Thorogood, Kaur, & Wedatilake, 2005). With regard to delivery, the AHA recommends both individual-oriented sessions and group-based strategies (Artinian et al., 2010). In chronically ill populations, interventions combining goal setting, contracting, feedback, self-monitoring, and prompts have been found to be related to physical activity behavior change, with a systematic review and meta-analysis indicating that self-reported physical functioning improvement occurred over the course of at least three months of exercise training for HD patients and that three months of exercise achieved a significant increase in walking capacity in adults with CKD and in renal replacement patients (Cheema & Singh, 2005; Heiwe & Jacobson, 2011). In the present study, intensive behavioral support interventions such as goal setting, self-monitoring, and regular follow-ups were adopted to achieve a high level of adherence with the three-month exercise intervention.

As dialysis patients are often fearful of injury and lack the knowledge and skills required to perform exercise, an exercise demonstration with professional guidance can enhance their confidence and competency to perform exercise. An individualized exercise plan in accordance with the patient's capacity and weekly supervised exercise can also alleviate patients' safety concerns and provide a successful exercise experience (Ruppar & Conn, 2010). Interventions aimed at behavioral change, mutual goal setting, self-monitoring, and feedback were adopted to facilitate behavioral change and patients' commitment to an action plan. Ongoing contact not only successfully effects behavioral change, but also helps to establish trust between nurse and patient (Artinian et al., 2010). Chow and Wong (2010) found a six-week NCM program to be effective in providing support for dialysis patients. In the present study, weekly follow-ups were offered for the first six weeks. As Artinian et al. (2010) found that an achieved behavioral change often diminishes over time when interventions cease, biweekly follow-ups were offered for the subsequent six weeks to help patients to maintain their new exercise habits.

3.8.5 Special features of the intervention

3.8.5.1 Personalized care to improve self-efficacy

The exercise program delivery in this study encouraged patients to participate in the decision-making process and their own self-care. Before initiating an exercise plan, the nurse case managers conducted a comprehensive assessment of patients. Being tied to a dialysis machine and dependent on care providers with whom they have limited communication, CKD patients often have the feeling of being the "object" of care rather than a person being cared for (Hagren et al., 2005; Polaschek, 2003b). Individualized interviews were offered to allow patients to share their experience and barriers and to encourage an ongoing trusting relationship with case managers.

Face-to-face interviews during the dialysis sessions strengthened communication between nurses and patients. Intra-dialytic conversation can also be an effective way of distracting patients from the feeling of being attached. In the interviews, patients' unique life situation, disease, and treatment conditions related to a change in physical activity were explored to gain an understanding of the individual as a whole and to involve patients in decision-making about their exercise goals and plans.

The exercise plans were delivered on an individual basis and tailored to patients' capacity. Patients with impaired exercise capacity were instructed to slowly increase the length of time they exercised. When they felt comfortable and could easily perform a set of exercises for a certain number of repetitions, e.g., hold each stretch for 10 to 20 seconds and perform at least three repetitions, they were instructed to increase the number. Bandura's (1977) self-efficacy theory (1977) posits that an experience of success has a great impact on patients' beliefs about what they can achieve, whereas the experience of frustration when pushed too hard without concern for their individual health condition reduces their perceived self-efficacy.

Individualized exercise adapted to a patients' condition enhances their perceived skill and competence and motivates them to engage in exercise (Pender et al., 2011).

3.8.5.2 Supportive care

As nurses act as "go-betweens" between patients and other healthcare providers, patients with HD experience a sense of being supported when nurses show understanding of and respect for their life with dialysis (Hagren et al., 2005). Patients undergoing dialysis have ambiguous experiences, such as struggling to balance restrictions and a normal life, dependence and autonomy, isolation and closeness, and having a life-threatening illness and hope (Makaroff, 2012). The nurse case managers in this study were in a position to support patients on their disease journeys by accepting and acknowledging their difficulties in living with dialysis.

Group exercise has a positive psychosocial impact, providing a platform for patients to interact with others whose condition is similar and share their difficulties to alleviate psychological distress and gain support. Learning from others can also facilitate individual progress, and patients can establish positive social roles by contributing to the group (Reed, Harrington, Duggan, & Wood, 2010). In addition to the opportunity for social interaction, exercising with other patients with a similar health condition can boost motivation (Hellem, Bruusgaard, & Bergland, 2012).

In the weekly training sessions, the patients had an opportunity to review the exercises with the investigator to ensure they were performing them properly, as patients receiving dialysis often experience memory difficulties (Tryc et al., 2011), and retraining was provided as needed. Also, according to mastery learning theory, individuals learn at different speeds but everyone can master something if given multiple opportunities (Baker et al., 2011). A feeling of mastery and success in performing an exercise reduced patients' safety concerns and gave them the confidence to engage in regular exercise.

3.8.6 Fidelity of intervention

Sidani and Braden (2011) proposed that intervention fidelity comprises two levels: the theoretical level and the operational level. Theoretical fidelity refers to agreement between the designed intervention components and specified active elements in the intervention theory, i.e., whether the intervention represents and is coherent with the ingredients in the theoretical model, whereas operational fidelity is the extent to which the intervention is implemented as planned. The intervention design in this study was based on the active components specified in the HPM, each variable of which was operationalized with a series of actions and activities. Also, intervention consistency was ensured through the aforementioned mandatory training for the nurse case manager participants. During the implementation process, the nurse case managers were also required to perform self-monitoring in accordance with the protocol and keep careful records. In addition, the student investigator attended interview sessions randomly to assess the extent to which the nurse case manager's performance conformed to the protocol, with acknowledgement and feedback provided immediately. She also reviewed all interview records to identify any possible deviations or omissions (see Appendix 3.6 for interview records). Finally, the investigator and case managers met periodically throughout the study period to discuss the cases and any problems and devise potential solutions.

3.9 Outcome measures

Various types of data collection tools were used to measure the outcomes. A self-developed questionnaire (Appendix 3.7) was used to collect demographics and clinical information of the participants. It includes questions on age, sex, marital status, education level, primary cause of CKD, complications, and dialysis duration. The physical performance tests (gait speed and the sit-to-stand test) were used to collect objective data for physical functioning. Other measurement scales were employed to measure the subjective outcomes. These outcomes were quality of life, depressive symptoms, self-rated health, perceived exercise benefits and barriers. Both the subjective and objective data were measured at three time points. The exercise log was used to record patients' physical activities level at home.

3.9.1 Gait speed

Gait speed was employed as the primary outcome measure in this study to assess patients' physical functioning. A primary outcome is the outcome used to determine the overall results of a study (Stanley, 2007). As the major purpose of this study was to examine the effects of NCM on home exercise training for HD patients in terms of their physical functioning, patients' physical functioning was regarded as the primary outcome. The direct testing of physical fitness based on laboratory parameters, such as VO_{2peak} and symptom-limited VO_{2peak}, is regarded as the gold standard for physical functioning measurement. However, HD patients' inability to perform maximal exercise testing due to leg fatigue before achieving a plateau in oxygen uptake, and the need for special high-cost equipment, limits the use of VO_{2peak} in clinical practice for these patients (Miller & Ahmad, 2003; Reboredo et al., 2010). Also, in patients with low levels of VO_{2peak}, this laboratory parameter may be insufficiently sensitive to detect any improvement in ability to carry out daily living activities (Painter et al., 2002). Physical performance tests that capture patients' actual ability to perform certain tasks, and the extent to which they can do so, are thus a good alternative and are less influenced by cognitive impairment and educational background (Painter et al., 1999). The use of previously developed and validated scales is recommended to enhance measurement quality and allow cross-study comparison (Streiner & Norman, 2008).

To evaluate gait speed, patients were instructed to walk along a corridor for a distance of 10 meters twice, once at a comfortable speed (normal gait speed) and once at the maximum walking speed they could tolerate (fast gait speed). Both the normal and fast gait speed were recorded in centimeter per second (cm/s), with faster speed indicating better physical functioning. This test has been shown effective in differentiating differences in physical functioning levels, both between groups and within groups, across a time interval in HD patients (Headley et al., 2002; Painter et al., 2000b). It is a quick, inexpensive measure that is strongly associated with leg strength and patients' ability to perform daily activities (Painter et al., 1999). Both the comfortable and maximum gait speed measures have demonstrated a high degree of test-retest reliability (intra-session reliability), with intra-class correlation coefficient (ICC) values ranging from 0.90 to 0.98 (Bohannon, 1997; van Loo, Moseley, Bosman, de Bie, & Hassett, 2004). Inter-rater reliability of 0.98 has been reported in patients with spinal cord injury (van Hedel, Wirz, & Dietz, 2005). Normal gait speed alone, with a cut-off value of 1.0 meter/second (m/s), can discriminate between different levels of functional status (higher and lower levels). Its discriminative power is similar to a combined score from seven performance measures, suggesting that normal gait speed not only represents lower extremity function, but also reflects general physical performance and overall functional status (Seino et al., 2012). The results of a systematic review and meta-analysis indicate that individuals in the older community-dwelling population who are within the slowest 25% in terms of walking speed have a higher mortality rate than those within the fastest quarter, after adjusting for age, sex, and body size (Cooper, Kuh, Hardy, Mortality Review Group, & FALCon and HALCyon Study Teams, 2010). Furthermore, research on the responsiveness of comfortable gait speed in different populations found the minimal clinically important difference to range from 0.10 to 0.21 m/s (Palombaro, Craik, Mangione, & Tomlinson, 2006; Seino et al., 2012; van Iersel, Munneke, Esselink, Benraad, & Olde Rikkert, 2008).

3.9.2 10-repetition sit-to-stand test (10-STS)

Standing up from a chair is an essential activity in independent daily living. STS performance is a proxy measure for lower-extremity strength (Csuka & McCarty, 1985), and has been accepted as an index of functional status for the elderly (Gross, Stevenson, Charette, Pyka, & Marcus, 1998) and for functionally impaired populations such as those with COPD (Jones et al., 2013; Ozalevli, Ozden, Itil, & Akkoclu, 2007) cardiac diseases (Puthoff & Saskowski, 2013), cancer (Bertheussen et al., 2012; Peddle-McIntyre, Bell, Fenton, McCargar, & Courneya, 2012), and CKD (Painter et al., 1999). It is evaluated by using the time taken to complete a given number of STS repetitions or a certain number in a given amount of time (Takai et al., 2009). The timed 10-repetition STS test (10-STS) is recommended for use in the ESRD population (Brodin, Ljungman, & Sunnerhagen, 2008; Painter et al., 1999), and has been included in a battery of tests for evaluating the effects of exercise training programs for HD patients (Painter et al., 2000b; Headley et al., 2002; Segura-Orti et al., 2009). The 10-STS is easy to use in clinical practice with an armless chair and a stopwatch. In this study, it was performed with a 43-cm height standard chair without an arm rest. Patients were asked to begin in a sitting position with both arms held across their chest, and then to rise up to a full stand as quickly as possible 10 times without using their arms. The time taken to complete the task was recorded in seconds, with less time reflecting better physical functioning. The test-retest reliability of the 10-STS in the HD population is acceptable, with an ICC value of 0.88, and the minimally detectable change score at 90% CIs is 8.4 seconds (Segura-Orti & Martinez-Olmos, 2011).

3.9.3 Health-related Quality of Life

Patients undergoing HD treatment generally experience marked HRQoL impairment (Chiang et al., 2004; Fukuhara et al., 2003; Lan, Zhang, & Li, 2007), and there is a well-documented close association between impaired HRQoL and clinical outcomes in the CKD population, such as increased hospitalization and mortality (Brown, 2009; Mapes et al., 2003; Thong et al., 2008). Exercise has been recommended as an effective approach to enhance HRQoL in HD patients (Heiwe & Jacobson, 2011; Segura-Orti, 2010).

The Kidney Disease Quality of Life Short Form (KDQOL-36^{TM}) was adopted in this study to assess patients' HRQoL. It comprises the 12-item Short Form Health Survey (SF-12) as a generic component and 24 items designed specifically for dialysis patients. The 24 items comprising three subscales: Symptoms and Problems List (SPL; 12 items), Burden of Kidney Disease (BKD; 4 items), and Effects of Kidney Disease (EKD; 8 items) (Schatell & Witten, 2012). The raw scores are transformed linearly to a range of 0 to 100, with higher scores indicating better HRQoL. Items in the same scale are averaged to create a subscale score (Hays et al., 1997). The results of the SF-12 instrument are summarized into the PCS score and MCS score. The standard scoring of the KDQOL-36^{TM} was developed by the KDQOL Working Group (See: http://www.rand.org/health/surveys_tools/kdqol.html).

The original KDQOL-36^{TM} is in English, but it has been translated into Chinese by Amgen, Inc. and the MAPI Institute. Information on the translation procedures and translated version of the KDQOL-36^{TM} (Appendix 3.7) can be obtained from www.gim.med.ucla.edu/kdqol, and the scale and scoring manual can be downloaded from the same website for non-commercial use. Information on reliability and validity is not available for the translated version, and the research team thus conducted psychometric testing prior to its use in the main study.

3.9.4 Self-rated health

Self-rated health (SRH) is a patient's personal assessment of his or her overall health status (Heo, Moser, Riegel, Hall, & Christman, 2005). It is measured by asking patients to rate their general health status (from excellent to poor) and can be evaluated by one item in the KDQOL-36^{TM} (Ricardo et al., 2013), with possible scores ranging from 0-100, with a higher score reflecting better perceived health. The validity of employing a single-item scale to assess SRH has been confirmed by its impacts on mortality and quality of life. Studies have indicated that SRH, which incorporates multiple dimensions of health, is a predictor of mortality (DeSalvo, Fan, McDonell, & Fihn, 2005; Jylha, 2009). With regard to its impact on HRQoL, previous research has revealed all subscales of an established HRQoL measure to be independently correlated with SRH in cancer patients (Mavaddat et al., 2011) and CKD patients (Abd ElHafeez et al., 2012, Ricardo et al., 2013).

3.9.5 Depressive symptoms

Depression is a commonly reported psychiatric illness in the dialysis population

(Kimmel & Peterson, 2006), and leads to impaired quality of life and increased mortality risks (Kimmel et al., 2000; Rosenthal Asher, Ver Halen, & Cukor, 2012). It is estimated that approximately 25% of ESRD patients suffer from depression (Halen, Cukor, Constantiner, & Kimmel, 2012). Previous small-sized RCTs and uncontrolled studies have demonstrated that regular exercise training for HD patients can yield a depression improvement trend (Oh-Park et al., 2002; Ouzouni et al., 2009; Suh, Jung, Kim, Park, & Yang, 2002). Therefore, a valid instrument for measuring depressive symptoms, the Beck Depression Inventory (BDI-II) was adopted to further examine the psychological benefits of exercise training for the patients in this study.

The BDI-II has been validated and is commonly used in patients with ESRD (Wilson et al., 2006). It is a self-report instrument comprising 21 items on cognitive, affective, and somatic symptoms, and is used to assess the presence and intensity of depression in clinically depressed or non-depressed patients. Each item is measured on a four-point scale (0-3) corresponding to a symptom of depression, with item scores then summed for a single BDI-II score. The total score ranges from 0 to 63, with a higher score reflecting a worse depressive symptom. The internal consistency of the original English version ranges from 0.89 (Steer, Rissmiller, & Beck, 2000) to 0.94

(Arnau, Meagher, Norris, & Bramson, 2001).

Arnau et al. (2001) reported the mean BDI-II scores of patients with a diagnosis of a major depressive disorder to be significantly higher than those without such a diagnosis, providing evidence for the instrument's criterion-related validity. Its convergent validity comes from data showing that the BDI-II total and subscale scores are strongly correlated with the mental health subscale of the Medical Outcome Study Short-Form Health Survey (SF-20) (r = -0.65) (Arnau et al., 2001). Chilcot, Wellsted, and Farrington (2008) assessed the predictive validity of the BDI-II, with a cut-off of 16 adopted for a diagnosis of depression in dialysis patients. The results were compared with results achieved using a structured interview called the Mini International Neuropsychiatric Interview. A cut-off value of 16 on the BDI produced acceptable sensitivity (88.9%), specificity (87.1%), positive predictive value (88.8%), and negative predictive value (87.0%). Concerning the timing of BDI-II to assess dialysis patients, close agreement has been observed between on- and off-dialysis assessments, and the timing of off-dialysis assessment (before or after dialysis) appears to have no influence on BDI scores (Chilcot et al., 2008).

The Chinese version of the BDI-II (CBDI-II) can be used to assess depressive symptoms as a self-administered inventory (Appendix 3.7). The Cronbach's alpha coefficient of the CBDI-II in this study was 0.94 (Wang et al., 2011). The inter-item correlations of the 21 items ranged from 0.18 to 0.71, and item-total correlations from 0.56 to 0.82 (Wang et al., 2011). The test-retest coefficient was 0.55 (Wang et al., 2011). Because the subjects in Wang et al. (2011) study were depressed patients currently receiving treatment, changes in depression levels may have led to the low test-retest reliability. The correlation between the scores of the CBDI-II and Hamilton Depression Scale was 0.67 ($p < 0.01$); and the construct validity was supported by the exploratory factor analysis approach (Wang et al., 2011).

3.9.6 Physical activity level

Patients' physical activity level at T1 and T2 were evaluated according to the total time engaged in aerobic exercise per week. The information was retrieved from patients' exercise logs (Appendix 3.8) or collected by the data collectors through face-to-face interviews. The exercise log was designed according to Painter's exercise guides (Painter, 1999). Participants were instructed to record the frequency and duration of their home exercise to allow the identification of changes in their physical activity levels across the study period. The logs also helped patients to stay motivated and achieved their exercise goals by tracking their progress over time.

3.9.7 Perceived exercise benefits and barriers

A majority of HD patients are aware of the benefits of exercise and indicate a desire to exercise (Bulckaen et al., 2011; Delgado & Johansen, 2012; Kontos et al., 2007). However, such good intentions may fail to be translated into exercise behavior owing to a range of barriers such as a lack of knowledge, fear of injury, lack of motivation, and disease symptoms (Delgado & Johansen, 2012; Goodman & Ballou, 2004; Painter, 2003; Zheng et al., 2010). The nurse-patient interviews in this study were designed to enhance participants' knowledge of exercise and help them to remove potential exercise barriers to facilitate exercise progression.

The Dialysis Patient-perceived Exercise Benefits and Barriers Scale (DPEBBS) was used to evaluate patients' exercise behavior through perceived benefit and barrier analysis (Appendix 3.7). The scale was originally developed in Chinese, it comprises 24 items, with 12 items for both the benefits and barrier domains, rated on a four-point Likert-type scale ranging from 1 ("strongly disagree") to 4 ("strongly agree") and two open-ended questions (Zheng et al., 2010). The scores of barrier items were reversely coded. The total scores of both benefit and barrier items ranges from 12 to 48, with a higher score reflecting more perceived exercise benefits and fewer barriers. Item scores were then summed for a single DPEBBS score. The total score ranges from 24 to 96. The Cronbach's α coefficient for the total scale was 0.87 in Zheng et al. (2010)'s study, and test-retest reliability was 0.84. Exploratory factor analysis extracted six common factors explaining 57% of the total variance, and the correlation coefficients for each of the factors and the total scores ranged from 0.33 to 0.91 (Zheng et al., 2010). Confirmatory factor analysis further supported the six-factor structure and a higher-order model (Zheng et al., 2010). In Zheng et al. (2010), the overall correlation coefficient between the DPEBBS and seven-day physical activity recall was 0.64 and that between the DPEBBS and the Exercise Benefits/Barriers Scale was 0.81.

3.10 Data collection

Data were collected at three time points: before intervention initiation (T0) and at weeks 6 (T1) and 12 (T2). T0 provided baseline data collected before randomization. Chow and Wong (2010) found NCM to be effective in providing support for dialysis patients through weekly follow-ups for six weeks. T1 data were collected immediately after participants had completed the center-based exercise training. They were used to examine the effects of six weeks of NCM on home exercise. Evidence indicates that self-reported physical functioning improvement occurs over the course of at least three months of exercise training for HD patients and that three months of exercise can achieve significant improvement in walking capacity in adults with CKD and in renal replacement patients (Cheema & Singh, 2005; Heiwe & Jacobson, 2011). Finally, T2 data were collected upon participants' completion of the intervention and uses to assess the effects of low-intensity NCM on home exercise.

Two data collectors, one at each study site, received training before the study and were provided with a data collection manual for reference. They were blinded to treatment allocation throughout the study period, and participants were advised not to discuss the intervention with the data collectors. Inter-rater reliability was evaluated to ensure consistency in data collection. All data were collected in the HD centers through primarily self-administered questionnaires, although the data collectors interviewed patients who needed assistance using the questionnaires. After collection, the collectors inspected each questionnaire and gathered data on any missing items through face-to-face interviews during the dialysis sessions. The physical performance tests, such as gait speed and the 10-STS, were conducted prior to dialysis. As patients may experience symptom fluctuations in longer inter-dialytic intervals, these tests were carried out in the second or third HD session within the data collection week.

3.11 Data analysis

3.11.1 Data screening and cleaning

3.11.1.1 Data accuracy

To enhance the validity of data analysis, data screening and cleaning were performed before analysis (Van den Broeck, Cunningham, Eeckels, & Herbst, 2005). Descriptive statistics, including means, standard deviations, and maximum and minimum values for each of the continuous variables, and frequency counts for the categorical variables were inspected for the accuracy of data input (Portney & Watkins, 2009; Tabachnick & Fidell, 2001). Values that appeared outside the possible range for each variable were assessed for potential errors and corrected accordingly if needed.

3.11.1.2 Missing data

After ensuring that all data had been correctly entered, any missing data were examined. With regard to the demographic and clinical variables, the overall percentage of missing values was 1.47%, with one item related to the types of medication currently being taken accounting for the most non-responses. Because 36.3% of the participants failed to respond to this item, and no detailed information from patients' medical records could be identified, this variable was deleted from data analysis. The remaining 0.21% missing values were imputed by either the mean or median of the other participants for those particular variables.

With regard to the outcome variables, two types of missing data occurred: first, when participants were unwilling to respond to one or more items, and, second, when patients did not attend the physical performance tests or withdrew from the study. There were missing data for both the KDQOL-36™ and BDI-II. According to the score manual of the KDQOL-36™, missing data should not be taken into account when calculating the scale score (Hays et al., 1997). Missing data in the BDI-II were substituted by the mean score of valid data on each item (Lowe et al., 2009; Mota, Pimenta, & Piper, 2009; Wagena, Arrindell, Wouters, & van Schayck, 2005; Werrij, Mulkens, Hospers, & Jansen, 2006). Eight participants failed to perform all three physical performance tests, four failed to respond to the questionnaires at week 6; and nine participants failed to attend the physical performances tests, and six failed to provide questionnaire data, at week 12 (5.31%). Table 3.1 provides more details on missing data, and Table 3.2 the related reasons. Data were missing from 7.08% of participants at week 6 and from 7.96% at week 12.

Table 3.1: Percentage of missing data

Time point	Variable	Total no. of data fields	No. of missing data fields	Percentage of missing data fields
T1	Participant characteristics	3, 277	48	
	Normal gait speed	113	0	
	Fast gait speed	113	0	
	10-STS	113	0	
	KDQOL-36^{TM}	4,068	54	
	BDI-II	2,373	15	
	DPEBBS	2,712	0	
Sub-total		12,769	152	1.19%
T2	Normal gait speed	113	8	
	Fast gait speed	113	8	
	10-STS	113	8	
	KDQOL-36^{TM}	4,068	188	
	BDI-II	2,373	99	
	DPEBBS	2,712	96	
Sub-total		9,492	407	4.29%
T3	Normal gait speed	113	9	
	Fast gait speed	113	9	
	10-STS	113	9	
	KDQOL-36^{TM}	4,068	144	
	BDI-II	2,373	252	
	DPEBBS	2,712	133	
Sub-total		9,492	556	5.88%
Total		31,753	1,115	**3.51%**

Note: 10-STS: 10-repetition sit-to-stand test; KDQOL-36^{TM}: Kidney Disease Quality of Life-Short Form; BDI-II: Beck Depression Inventory-II; DPEBBS: Dialysis Patient-perceived Exercise Benefits and Barriers Scale.

Table 3.2: Reasons for missing data on outcome variables

Pattern	N	%	Baseline	6 weeks	12 weeks	Reason
1	100	88.5	—	—	—	
2	4	3.5	—	×	×	Withdrawal (3) & transfer to another hospital (1)
3	2	1.8	—	—	×	Hospitalization
4	3	2.7	—	—	＊	Did not attend tests
5	4	3.5	—	＊	—	Did not attend tests

Note: — *= data available,* × *= data missing for both physical performance tests and questionnaires,* ＊ *= data missing only physical performance tests.*

Various types of adjustment for missing data are now available, and appropriate selection depends on the missing data pattern (Little et al., 2012). Tabachnick and Fidell (2001) stated that "if only a few data points, say, 5% or less, are missing in a random pattern from a large data set, the problem [is] less serious and almost any procedure for handling missing values yields similar results" (p. 59). For outcome variables with more than 5% missing data, dummy variables (0 and 1) for cases with and without missing data can be created to evaluate the pattern of missing data. In addition, a *t*-test for continuous variables or chi-square test for categorical variables can be performed to compare the dependent variables for two groups (Abu-Bader, 2010; Duffy, 2006; Tabachnick & Fidell, 2001). Both tests were performed in this study to determine whether any difference existed between patients with and without missing outcome variables. No significant differences in baseline data were found between the two groups, suggesting similar baseline characteristics. According to Little et al. (2012), if similar baseline characteristics between dropout and non-dropout participants are observed, the data are likely to be missing at random (MAR) and can thus be modeled from the outcomes of similar participants with available data. The pattern of missing data on the outcome variables in this study was regarded to be random. Studies comparing multiple imputation (MI) with other imputation methods reveal estimations generated from the former to be less biased (Houck et al., 2004; Liu & Gould, 2002; Tang, Song, Belin, & Unutzer, 2005). Hence, MI, a data replacement method deemed valid under the MAR assumption, was employed for primary data analysis. Imputation models were established by relating the primary outcomes to covariates and other observed intermediate outcome values (Wood, White, & Thompson, 2004). In general, five datasets are considered to be adequate iterations to obtain sound results (Osborne, 2013; Schafer, 1997). Accordingly, in this study, five parallel sets of imputed data were created based on such independent variables as age, group, sex, and Hb level, as well as baseline and intermediate observations of the dependent variables.

3.11.1.3 Outliers

Outliers can bias the results of statistical analysis (Barnett & Lewis, 1994; Osborne, Jason, & Amy Overbay, 2004). Variables were standardized into *z* scores and inspected for possible outliers. A raw score with an absolute *z* score greater than 3 is commonly regarded as an outlier (Abu-Bader, 2010). In this study, outliers were checked separately for each trial group, with 0.05% outliers found in the whole dataset. Potential outliers were further examined for data accuracy. Outliers that did not arise from sampling error or entry error, but rather constituted legitimate data, were retained in the dataset for the subsequent data analysis.

3.11.1.4 Normality

Various parametric tests make assumptions about normally distributed data (Atkinson, Pugh, & Scott, 2010). The normality of variables can be assessed by graphic methods (e.g., histograms, Q-Q plots), numerical methods (skewness and kurtosis values), and normality tests. Graphic methods may not provide sufficient evidence to make a conclusion about normality (Razali & Wah, 2011), but a *z*-test can be applied as a normality test using skewness and kurtosis, which are the two major criteria of normality. *Z*-scores obtained by dividing skewness or kurtosis values by their standard errors were calculated, with an absolute z-value greater than 1.96 for either skewness or kurtosis regarded as non-normal distribution of the variables (Abu-Bader, 2010; Ghasemi & Zahediasl, 2012; Kim, 2013). The Shapiro-Wilk and Kolmogorov-Smirnov tests are the most common tests used to assess the pattern of data distribution, although Razali and Wah (2011) suggested that the former is the more powerful of the two, and it was thus used in this study. Normality was checked for each trial group separately. The normal Q-Q plot was first examined to judge the normality of the data. Due to the subjectivity of the Q-Q plot, the absolute values of the skewness and kurtosis data were then calculated to support the data distribution decision. When the two approaches yielded different results, the Shapiro-Wilk test was performed to make the final determination. If the p value of the test was greater than 0.05, the data were judged to be normally distributed. If it was less than 0.05, that constituted evidence that the data were heavily skewed and that logarithmic transformation could be applied to adjust the data distribution. The aforementioned methods were applied separately to assess the data distribution of the transformed data for each group. If the transformed data were normally distributed, parametric statistics were employed for data analysis; if heavily skewed, non-parametric statistics were performed after logarithmic transformation.

3.11.2 Statistical analysis

Descriptive statistics were obtained for patients' demographic and clinical characteristics. For normally distributed data, RM-ANOVA with between-subject (group, with two levels) and within-subject (time, with three levels) factors was performed to determine the intervention impact (Portney & Watkins, 2009). Two-way RM-ANOVA was conducted to examine changes in the mean scores of the dependent outcome variables between the intervention and control groups over time.

The validity of RM-ANOVA use rests on several assumptions, including independence of the observations, normality of the dependent variables in the population for each group, participants representing a random sample of the population, and homogeneity of variances (Green & Salkind, 2011; Portney & Watkins, 2009; Stevens, 2002). The assumption of the homogeneity of variance is also known as sphericity (Leech, Barrett, & Morgan, 2008). Each assumption was checked prior to performing RM-ANOVA in this study. Normal *Q-Q* plots, skewness and kurtosis values, and Shapiro-Wilk test results were all examined to ensure fulfillment of the normality assumption. The assumption of sphericity was inspected through the results of Mauchly's test of sphericity. If the assumption of sphericity is violated (Mauchly's test of sphericity, $p < 0.05$), Greenhouse-Geisser correction can be adopted to adjust for unequal variances (Leech et al., 2008). Because the trial groups in this study had an unequal sample size, the assumption of the homogeneity of the variance-covariance matrices was also evaluated using the results of Box's M test, for which a *p* value greater than 0.001 indicates assumption fulfillment (Abu-Bader, 2010).

Because RM-ANOVA is an omnibus statistical test, it cannot determine where the differences lie. Significant results in two-way RM-ANOVA mean rejection of the null hypothesis and conclusion that the two population means are not equal, but do not illustrate exactly where the mean differences occur (Portney & Watkins, 2009). Separately, one-way ANOVA was performed to evaluate the within-time effects for each trial group. When one-way ANOVA yielded significant results, pairwise comparisons for each trial group among the three time points were carried out (T0 versus T1, T0 versus T2, T1 versus T2), and Bonferroni correction was employed to control Type I error. Because there were three comparisons, the value for α was divided by 3. A *p* value of $0.05/3 = 0.017$ or less was considered significant (Portney & Watkins, 2009). Independent *t*-tests were employed to examine the differences between the intervention and control groups at each time point. Bonferroni adjustment was applied, and a p value of $0.05/2 = 0.025$ or less was regarded as significant.

For heavily skewed data, data transformation was first performed to adjust the skewness. If the abnormally distributed trend could not be adjusted after data transformation, the Friedman test was adopted to examine the differences among the three time points, and group differences at each time point were evaluated by using the Mann-Whitney U-test (Green & Salkind, 2011). Friedman tests were performed for each trial group to examine the overall within-group effect for either the intervention or control group. A p value of 0.25 ($0.05/2 = 0.25$) or less for the overall comparison within each group was considered significant. The two time-point comparisons within each trial group were analyzed by the Wilcoxon signed-rank test (which is considered significant if the p value $< 0.05/3 = 0.017$). With regard to the Mann-Whitney U-test for evaluating group differences at each time point, a p value less than $0.05/2 = 0.025$ (with Bonferroni adjustment) was considered significant.

Statistical significance testing is useful for determining whether an observed effect is real or due to chance, although such testing alone is insufficient for evaluating practically meaningful differences in the results (Maher, Markey, & Ebert-May, 2013). Effect size for quantifying the magnitude of the treatment effect and the relationship between variables is recommended as a measure of reflecting practical significance of the results (American Psychological Association, 2010; Hojat & Xu, 2004; Maher et al., 2013; Schulz et al., 2011; Tressoldi, Giofre, Sella, & Cumming, 2013). In this study, effect size was estimated by calculating the partial eta squared, which is the mostly commonly used effect size statistic for group comparisons, indicating the percentage of variance in a dependent variable that can be explained by the independent variable (Pallant, 2007). The value of partial eta squared ranges from 0 to 1, with values of 0.01, 0.06, and 0.14 generally interpreted as small, moderate, and large effect sizes, respectively (Cohen, 1988). Another effect size measure, Cohen's *d*, was calculated for comparisons of the mean changes between different pairs of time points within each group. With regard to between-group comparisons at each time point, Hedges' *g* was calculated for effect size estimation because the two trial groups were unequal in size (Maher et al., 2013). Values of 0.2, 0.5, and 0.8 are conventionally regarded as small, medium, and large effect sizes, respectively (Cohen, 1988).

ITT analysis was adopted during data analysis to avoid the bias associated with between-group incomparability resulting from non-random patient drop-outs (Lachin, 2000; Lewis & Machin, 1993). ITT also enables estimation of treatment effects that mimic how treatment might be implemented in the target population in clinical practice (DeSouza, Legedza, & Sankoh, 2009). During ITT analysis, all data were analyzed according to the participant's original group assignment. Because ITT analysis included noncompliant subjects, its estimation of treatment effect is generally conservative (Gupta, 2011). Both ITT and per-protocol (PP) analyses were performed in the current program. The effectiveness of intervention was further confirmed when the ITT and PP analyses achieved similar conclusions (Day, 2008). Data analysis was carried out using SPSS 20.0 (IBM PASW, USA). All statistical tests were two-tailed, and $p < 0.05$ was considered statistically significant.

3.12 Ethical considerations

Before commencing data collection, approval to conduct the study was obtained from both the Human Subjects Ethics Sub-committee of the Hong Kong Polytechnic University and the study hospitals (Appendix 3.9a and 3.9b). The student investigator approached all eligible patients and provided them with information on the research. Patients were informed of the study's purpose, procedures, and confidentiality measures adopted. It was made clear that participants' privacy would be protected and that all data would be coded and processed anonymously. Participants were informed that their participation was voluntary and that they could withdraw at any stage with no consequences for the treatment they received. In addition, they were provided with the researchers' contact information in case they had any future enquiries. All study-related information was clearly explained to the patients by the student investigator verbally, and a study information sheet (Appendix 3.10) was provided for further reference. After being so informed, patients who indicated their willingness to participate were asked to sign consent forms (Appendix 3.11) and return them to the researcher. During the data collection process, the interviews were discontinued immediately if participants gave any sign of emotional disturbance or physical discomfort. All data collected were anonymous and locked in a cabinet to protect confidentially. The student investigator and her supervisors alone had access.

3.13 Summary

This chapter provides the justifications for employing an RCT to evaluate the effect of a NCM program on home exercise training for HD patients. The intervention design, including protocol development, has been elaborated upon, backed up by supportive theories and evidence, and details of patient recruitment, sampling, randomization, sample size estimation, case manager selection, and training presented. The strategies adopted to ensure intervention fidelity have also been described. The chapter concludes with information on the outcome measures employed to assess the treatment effects, data collection procedures, data analysis methods, and ethical considerations.

Chapter 4 Pilot Study

4.1 Introduction

This chapter presents the design and results of the pilot study. It begins with a description of that study's design, followed by investigation of its validity and reliability and that of the Chinese version of the KDQOL-36^{TM}. The chapter ends with the implications of the pilot study for the main study.

4.2 Design of the pilot study

The aim of the pilot study was to enhance the success of the main study's implementation through pre-testing of the instrument to be used, assessment of the study design's feasibility in clinical practice, validation of the protocols guiding the study intervention, and evaluation of the management procedures and resources needed to carry out the study. Pilot studies are a fundamental research process, with two major conventional purposes: sample size estimation and pre-testing of main study design and implementation feasibility (Lancaster, Dodd, & Williamson, 2004; Thabane et al., 2010; van Teijlingen & Hundley, 2002). However, sample size calculation based on pilot studies needs to be interpreted with caution because of its likely inaccurate estimation of the true effect size

(Kraemer et al., 2006). It is recommended that a pilot study be used to ensure the feasibility of the main study's success, but not for hypothesis testing to generate significant findings (Becker, 2008; Jairath, Hogerney, & Parsons, 2000; Leon, Davis, & Kraemer, 2011; Moore, Carter, Nietert, & Stewart, 2011).

The pilot study carried out for this research comprised two parts. The first focused on determining the validity and reliability of the Chinese version of the KDQOL-36^{TM}, and the second part on the feasibility of the RCT design in the clinical HD population.

4.3 Instrument validation

The availability of psychometrically sound instruments is a prerequisite for generating valid inferences from clinical trials. Coster (2013) noted that the effects of a particular intervention may be inaccurately evaluated or even lead to distorted results if the measurements adopted are unable to capture the impact of the intervention. A series of instruments, including gait speed, 10-STS, KDQOL-36^{TM}, BDI-II, and DPEBBS, were adopted in this study to determine the effects of the program. These instruments have been validated in Chinese populations, with the exception of the Chinese version of the KDQOL-36™ whose psychometric properties have yet to be confirmed. Its validity and reliability therefore had to be established before initiating the RCT. As noted in the previous chapter, the Chinese version of the scale was translated by Amgen, Inc. and MAPI Institute, and can be downloaded from the RAND Corporation website (http://www.rand.org/health/surveys_tools/kdqol.html) for non-commercial use. The pilot study set out to determine the validity and reliability of translated version of the KDQOL-36™ for use in a Chinese CKD population.

4.3.1 Methods

4.3.1.1 Sampling and data collection method

One hundred and three patients with mild-to-severe CKD were recruited from the renal wards and outpatient dialysis clinics of a tertiary hospital in mainland China through convenience sampling. Data were collected from February to April 2013. Both CKD patients who had commenced dialysis treatment and those who had not were recruited. The criteria for inclusion were a diagnosis of CKD, age of 18 or above, and ability to respond to the questionnaire. The criteria for exclusion were a diagnosis of a mental illness and inability to respond to the questionnaire. To estimate the test-retest reliability of the questionnaire, a sub-sample of 28 patients was asked to respond to the KDQOL-36™ in self-administered format twice within a 10- to 14-day interval.

4.3.1.2 Sample size calculation

As noted above, 103 patients were recruited for this component of the pilot study. Hobart, Cano, Warner, and Thompson (2012) suggested that the minimum sample size required to test the validity and reliability of an instrument is 80 and 20 subjects, respectively. Further, 50 subjects or more are required to determine the internal consistency of a five-point scale (Javali, Gudaganavar, & Raj, 2011). The number of subjects needed to determine the test-retest reliability of the KDQOL-36™ was estimated using the ICC value. To achieve specificity of 0.95 and power of 0.5, assuming an ICC value of 0.8 for the instrument with two occasional observations, a sample size of 22 suffices to allow for observations of ICC values of 0.5 or greater (Walter, Eliasziw, & Donner, 1998).

4.3.1.3 Psychometric testing of KDQOL-36™

4.3.1.3.1 Validity tests

Validity is defined as the extent to which an instrument measures what it purports to measure (Kimberlin & Winterstein, 2008). In the pilot study, the research team conducted different validity tests to examine the KDQOL-36^{TM} constructs.

Content validity concerns whether a scale adequately samples all possible and relevant questions that exist in terms of its content (Bannigan & Watson, 2009). An expert panel comprising two academic researchers, two clinical renal nurses, and a renal physician was formed to examine the instrument's translation equivalence and content. "Bowling" and "playing golf" as examples of "moderate activities" in one of the items were considered uncommon activities for Chinese people, and it was suggested that "playing badminton" and "swimming" would be suitable substitutes. However, several panel members pointed out that those activities, too, were unlikely be the preferred forms of exercise for most CKD patients. Based on the Compendium of Physical Activities (Ainsworth et al., 1993, 2000), "walking" and "Tai Chi" were determined to have similar levels of energy expenditure to "bowling" and "playing golf," and hence they were included in the scale instead. Similar amendments have been reported for different versions of the KDQOL-36^{TM}, such as the Korean, Filipino, Portuguese, and Egyptian versions (Abd ElHafeez et al., 2012;

Bataclan & Dial, 2009; Duarte, Ciconelli, & Sesso, 2005; Park et al., 2007). After these revisions, the panel determined the content validity using a 4-point Likert scale (1 = "not relevant," 2 = "somewhat relevant," 3 = "quite relevant," 4 = "very relevant"). Both the item- and scale-level content validity index were 1.0, indicating that the items were relevant and representative of the measurement constructs (Polit, Beck, & Owen, 2007).

Convergent validity involves investigating correlational evidence on a measurement under development using another scale (Bannigan & Watson, 2009). Previous studies have shown depressive symptoms among the CKD population to be strongly associated with poor HRQoL in multiple domains (Abdel-Kader et al., 2009; Kalender, Ozdemir, Dervisoglu, & Ozdemir, 2007; Lee, Kim, Cho, & Kim, 2013; Vazquez et al., 2005). The research team hypothesized that patients with lower subscale scores on the KDQOL-36™ would report higher levels of depressive symptoms, as represented by a high BDI-II score. In addition, the correlation between the overall health rating and the KDQOL-36™ was examined. The overall health rating was examined through the first item of the KDQOL-36™ (Ricardo et al., 2013), a global measure of an individual's HRQoL (Ismail, 2011). Previous studies have shown all subscales of an established HRQoL measure to be independently correlated with SRH in cancer patients (Mavaddat et al., 2011) and in CKD patients (Abd ElHafeez et al., 2012; Ricardo et al., 2013). On the basis of this evidence, the research team hypothesized that each subscale score of the KDQOL-36^{TM} would be positively correlated with the overall health rating.

Known-group comparison is an approach used to detect differences in mean scores between groups that are known to exhibit different traits on a measurement construct (Terwee et al., 2007). In this study, the hypothesis that there would be differences in scores between patient subgroups in terms of demographics and clinical status was tested. Based on previous studies, it was assumed that HRQoL scores would be lower among the elderly, women, the poorly educated, the unemployed, and those without government health insurance (Laudanski, Nowak, & Niemczyk, 2013; Lopes et al., 2007; Morsch, Goncalves, & Barros, 2006; Mujais et al., 2009). It was also expected that patients who had been hospitalized in the past six months and those who had undergone dialysis for longer would report poorer HRQoL (Lopes et al., 2007; Morsch et al., 2006; Paniagua et al., 2005).

4.3.1.3.2 Reliability tests

Reliability pertains to an instrument's ability to consistently measure a given attribute (DeVon et al., 2007). In this study, evidence of reliability was derived by examining internal consistency and test-retest reliability with an interval of 10-14 days. Internal consistency reliability is used to evaluate the equivalence of sets of items from the same test, whereas test-retest reliability is the stability of a measure administered to the same subjects using the same standard at two different time points (Kimberlin & Winterstein 2008).

4.3.1.3.3 Acceptability

Acceptability was assessed by examining the completion rates and missing data, and identifying the ceiling or floor effects. The response burden was also evaluated by one question: "Please evaluate the level of difficulty in responding to this questionnaire." The available choices were "easy," "moderate," and "difficult."

4.3.1.4 Instruments

Please refer to 3.9, 3.9.3, 3.9.4, and 3.9.5 for questionnaires that collected the demographic and clinical characteristics of subjects, KDQOL-36^{TM}, self-rated health, and BDI-II.

4.3.1.5 Data analysis

Data analyses were carried out using SPSS 20.0. All statistical tests were two-tailed, and $p < 0.05$ was considered statistically significant. Data completeness was evaluated by examining the missing data for each individual item. According to the KDQOL-36™ score manual, missing data should not be taken into account when calculating the scale scores (Hays et al., 1997). The percentages of patients achieving the highest and lowest scores were calculated to examine the questionnaire's ceiling and floor effects. Descriptive statistics, such as mean, standard deviation, and percentage, were used to examine the demographic information, and the levels of skewness and kurtosis were used to inspect the normality of each variable (Ghasemi & Zahediasl, 2012).

Internal consistency reliability was evaluated using the Cronbach's alpha coefficient calculated separately for each subscale. A coefficient alpha of 0.70 or greater is generally considered to be acceptable (Bland & Altman, 1997). Test-retest reliability was estimated by calculating the ICCs based on two-way mixed ANOVA ($ICC_{3,1}$).

An ICC above 0.75 indicates excellent test-retest reliability, whereas 0.40 to 0.75 are considered to be good and values below 0.4 indicate weak agreement (Bataclan & Dial, 2009). For convergent validity, Spearman's correlation coefficients were used to examine the relationships between the KDQOL-36^{TM} subscales and the hypothesized measures. A correlation of 0.40 is considered substantial for conceptually related scales (Kaasa et al., 1995; Lim, Seubsman, & Sleigh, 2008). Independent *t*-tests and ANOVA were performed for the continuous variables to evaluate the differences between the hypothesized "known" groups when the data were normally distributed.

4.3.2 Results

4.3.2.1 Characteristics of study subjects

The characteristics of the 103 patients recruited for this part of the pilot study are shown in Table 4.1. Their mean age was 47.6 years, and more than half were men (55.3%). The majority were married (79.6%) and not working (60.2%). With regard to their clinical characteristics, chronic glomerulonephritis was the most common cause of CKD (52.4%). Among patients receiving dialysis, the mean duration of treatment was 45.9 months.

Table 4.1 Patient characteristics (*n* = 103)

Characteristics		*n* (%)
Sex	Male	57 (55.3%)
	Female	46 (44.8%)
Age (Mean, SD)		47.6 (14.2)
Marital status	Married	82 (79.6%)
	Singled	16 (15.5%)
	Divorced/widowed	5 (4.8%)
Education	Primary school or below	13 (12.6%)
	Secondary school	60 (58.3%)
	College or above	30 (29.1%)
Employment status	Employed	41 (39.8%)
	Unemployed	62 (60.2%)
Health insurance status	Government insurance	73 (70.9%)
	Self-paying	27 (26.2%)
	Other	3 (2.9%)
Primary renal disease	Chronic glomerulonephritis	54 (52.4%)
	Hypertension	12 (11.7%)
	Gouty kidney	10 (9.8%)
	Unknown etiology	8 (7.8%)
	Diabetes	6 (5.8%)
	Systemic lupus erythematosus	4 (3.9%)
	Other	9 (8.7%)
Dialysis	CKD (stage 1-4) not commencing dialysis	27 (26.2%)
	HD	27 (26.2%)
	Peritoneal dialysis (PD)	49 (47.6%)
Dialysis duration (months)		45.9 (41.4)

4.3.2.2 Acceptability and descriptive statistics of the scale

The completion rates were high for nearly all of the items in the KDQOL-36^{TM}, with the exception of the item on sex life, which received no response from 38.9% of the sample. None of participants selected "difficult" for the subjective burden of answering the questionnaire, and 57.3% chose "moderate." Ceiling effects were noted in the SPL (2.9%) and BKD (1%) domains. Also, floor effects were evident for both the EKD (1%) and BKD (13.6%) subscales. The mean scores for each subscale of the KDQOL-36^{TM} ranged from 33.07 to 74.22. The descriptive statistics of the KDQOL-36^{TM} are summarized in Table 4.2.

Table 4.2 Descriptive statistics of KDQOL-36^{TM}

Subscales	Mean	SD	Minimal (Floor%)	Maximal (Ceiling%)
Symptoms/problems list	74.22	15.24	37.50 (1)	100 (2.9)
Effects of kidney disease	54.78	20.10	00.00 (1)	96.88 (1)
Burden of kidney disease	33.07	23.31	00.00 (13.6)	100 (1)
Physical Composite Sore	36.60	7.83	17.05 (1)	54.92 (1)
Mental Composite Score	46.82	9.81	22.17 (1)	65.09 (1)

4.3.2.3 Validity tests

With regard to convergent validity, significantly positive correlations were found between all of the subscale scores and the overall health rating score ($p < 0.01$). Significantly negative correlations were found between all of the disease-specific domain scores and the BDI score, from 0.395 to 0.654, whereas the correlation coefficient found between the MCS and BDI scores was higher than that between the PCS and BDI scores. These results support the hypotheses on convergent validity. For further details, refer to Table 4.3.

Table 4.3 Correlations between KDQOL-36^{TM} domains and overall health rating and BDI-II scores

KDQOL^{TM}-36 subscales	Overall health rating score	BDI-II score
Symptoms/problems	0.462**	-0.506**
Effects of kidney disease	0.314**	-0.654**
Burden of kidney disease	0.447**	-0.621**
Physical Composite Sore	0.499**	-0.395**
Mental Composite Score	0.377**	-0.483**

$^{**}p < 0.01$.

With regard to known-group comparisons, female patients and those who had been hospitalized in the past six months had lower scores on the perceived BKD items ($p < 0.05$), and those who had been undergoing dialysis for longer reported lower scores on SPL ($p < 0.05$), supporting the known-group validity of the KDQOL-36^{TM}. With regard to the instrument's generic core, working patients and those who had been undergoing dialysis for less time had significantly higher PCS scores ($p < 0.05$), whereas patients without government health insurance had significantly lower MCS scores ($p < 0.05$). Compared with the PD patients and CKD patients who had not yet commenced dialysis treatment, HD patients had higher PCS and MCS scores (p = 0.036, p = 0.006, respectively). The results revealed no significant differences among the age groups for any of the scores. For details, refer to Table 4.4.

Table 4.4 Subgroup comparisons of KDQOL-36™

	KDQOL-36™ subscales (Mean, SD)				
	Symptoms/problems	Burden of kidney disease	Effects of kidney disease	PCS	MCS
Age					
Age≤45 (*n*=46)	73.95 (15.19)	36.55 (24.26)	55.97 (20.61)	36.52 (7.45)	46.35 (9.82)
Age=46-59 (*n*=36)	73.90 (15.92)	31.60 (34.00)	52.59 (20.28)	37.81 (7.81)	45.66 (10.08)
Age≥60 (*n*=21)	75.34 (14.82)	27.98 (19.53)	55.93 (19.25)	34.72 (8.62)	49.84 (9.11)
P value	0.071	0.341	0.724	0.356	0.275
Sex					
Female (*n*=46)	72.89 (15.51)	27.04 (21.65)	53.63 (18.09)	36.15 (7.96)	47.26 (9.42)
Male (*n*=57)	75.29 (15.07)	37.94 (23.65)	55.71 (21.69)	36.97 (7.77)	46.46 (10.18)
P value	0.431	0.018*	0.604	0.600	0.683
Working status					
Working (*n*=41)	77.08 (15.36)	55.14 (21.78)	38.72 (24.81)	38.81 (7.95)	45.28 (9.95)
Not working (*n*=62)	72.32 (14.98)	54.55 (19.08)	29.33 (21.67)	35.14 (7.45)	47.84 (9.66)
P value	0.121	0.884	0.045	0.019*	0.196
Health insurance					
Government-paid (*n*=73)	74.95 (15.76)	55.25 (19.42)	34.16 (22.29)	36.42 (8.13)	48.33 (9.66)

Self-paid (*n*=30)	72.44 (13.97)	53.65 (21.97)	30.42 (25.83)	37.06 (7.13)	43.15 (3.92)
P value	0.452	0.715	0.462	0.709	0.014*
History of hospitalization					
Yes (*n*=34)	75.54 (13.93)	25.92 (20.65)	53.56 (18.76)	34.80 (7.60)	46.11 (10.37)
No (*n*=69)	73.56 (15.90)	36.59 (23.88)	55.38 (20.83)	37.49 (7.84)	47.17 (9.58)
P value	0.539	0.028*	0.667	0.101	0.607
Disease stage					
CKD 1-4 (*n*=27)	77.10 (14.50)	30.79 (24.75)	55.52 (24.11)	36.71 (8.88)	43.08 (10.38)
PD (*n*=27)	69.75 (14.26)	26.39 (18.62)	48.96 (16.22)	33.46 (5.70)	44.84 (7.65)
HD (*n*=49)	75.09 (14.50)	38.01 (24.13)	57.58 (19.32)	38.27 (7.84)	49.97 (9.70)
P value	0.179	0.096	0.198	0.036*	0.006*
Dialysis duration					
≥60 months (*n*=24)	68.06 (15.49)	35.16 (21.87)	54.22 (17.63)	33.99 (8.48)	49.22 (9.99)
<60 months (*n*=52)	75.56 (13.60)	33.29 (23.54)	54.66 (19.24)	37.76 (6.73)	47.66 (9.03)
P value	0.036*	0.744	0.926	0.040*	0.501

*$p < 0.05$.

4.3.2.4 Reliability tests

With regard to internal consistency, the Cronbach's alpha coefficient for the subscales ranged from 0.69 to 0.78. The subscale for PCS marginally met the recommended criterion for internal reliability. With regard to test-retest reliability, the ICCs ranged from 0.70 to 0.86 for the subscale scores. Please refer to Table 4.5.

Table 4.5 Reliability of KDQOL-36™ subscales

Scale (No. of items)	Cronbach's α (*n* = 103)	ICC (*n* = 28)
Symptoms/problems (12)	0.78	0.84
Burden of kidney disease (4)	0.76	0.86
Effects of kidney disease (8)	0.77	0.85
Physical Composite Score (6)	0.69	0.70
Mental Composite Score (6)	0.72	0.81

4.3.3 Discussion

The pilot study demonstrated that the 36-item KDQOL™ was well accepted by and linguistically and culturally relevant to Chinese CKD patients. All items were considered to be appropriate and relevant, producing evidence of the excellent content validity of the Chinese version of the KDQOL-36™.

The perceived level of difficulty of answering the questionnaire was moderate, and the overall percentage of items to which no response was given across the instrument was low, indicating that the CKD patients were able to decide on appropriate responses concerning their quality of life. However, the item related to sex life had a non-response rate of over 20%, which is similar to the percentage reported in previous studies (Abd ElHafeez et al., 2012; Cheung, Seow, Qu, & Yee, 2012; Kontodimopoulos & Niakas 2005; Pakpour et al., 2011; Park et al., 2007). One reason for the missing data on this item could be that 20.3% of the subjects were divorced or widowed. In addition, 87.5% of the patients who did not respond to this item were receiving dialysis treatment, and many patients undergoing dialysis suffer from sexual dysfunction (Navaneethan et al., 2010), another possible reason for the non-response (Bataclan & Dial, 2009).

The convergent validity of the KDQOL-36^{TM} supported the hypothesis that patients experiencing a better quality of life had a higher overall health rating. The overall health rating reflects an individual's feelings and provides an estimate of his or her subjective perception of his or her health status (Barotfi et al., 2006). Substantial correlations were observed between overall health and the SPL, BKD, and PCS subscales ($p < 0.01$), confirming that the KDQOL-36^{TM} and overall physical health rating are conceptually related. The non-substantial correlation between the MCS score and overall health score may be related to how an individual perceives his or her overall health. Previous studies have suggested that among the general adult population (Onadja, Bignami, Rossier, & Zunzunegui, 2013) and among patients with advanced cancer (Shadbolt, Barresi, & Craft, 2002), the overall health rating principally reflects the physical dimension of health. Moreover, there was a non-substantial correlation between the EKD subscale and overall health rating. As ESRD patients get used to the idea that they will need life-long treatment (Schatell & Witten, 2012), living on dialysis becomes their “normal way of being” (Rittman, Northsea, Hausauer, Green, & Swanson, 1993). To help them to increase their confidence in maintaining their health, some patients even come to consider dialysis a part-time job (Yu & Petrini, 2010). However, patients receiving dialysis cannot avoid fluid or dietary restrictions even if their condition improves. Therefore, changes in a patient’s perception of his or her overall health may not have a direct or strong relationship with his or her perception of the EKD, which is consistent with this study’s results.

The convergent validity of the KDQOL-36^{TM} also supports the hypothesis that patients with lower subscale scores on that instrument would have a higher BDI-II score. With the exception of the PCS, all of the disease-specific domains and MCS showed substantial inverse correlations with the BDI score. A possible explanation is that the diverse patient groups in the study experienced different stressors. The psychological stress of patients who had not yet commenced dialysis treatment might not be related to impaired physical functioning, but rather to the need for obligatory hospital visits or fear of becoming dependent on dialysis (Gyamlani et al., 2011).

The KDQOL-36^{TM} demonstrated evidence of known-group validity, as the scale scores were able to discriminate between subgroups of patients. Women, the unemployed, and patients who had been undergoing dialysis for longer tended to report poorer HRQoL. The results corroborate those of previous studies evaluating quality of life in CKD patients, which reported sex, employment status, and dialysis duration to influence HRQoL scores (Anees, Hameed, Mumtaz, Ibrahim, & Saeed Khan, 2011; Lopes et al., 2007; Mujais et al., 2009; Paniagua et al., 2005). Contrary to expectations, no significant age-related differences were found in any of the KDQOL-36^{TM} subscale scores. A possible explanation is that only 20.4% of the study participants was older than 60. In addition, the hypothesis that dialysis patients experience poorer HRQoL than those who have not yet commenced dialysis was not supported, possibly because the non-dialysis CKD patients recruited were hospitalized, whereas the dialysis patients were not. Hospitalized patients generally report poorer HRQoL (Lacson et al., 2010).

With regard to test-retest reliability, an ICC of 0.70-0.86 demonstrated the stability of the scale over time (Bannigan & Watson 2009), and the Cronbach's alpha values suggested that the scale is internally reliable. The internal reliability of all of the subscales exceeded 0.7, with the exception of the PCS (0.69), which approached the minimum desirable standard. The acceptable levels of internal consistency suggest that all of the items in each subscale of the KDQOL-36^{TM} fit together conceptually and measure the same construct (DeVon et al., 2007).

4.4 Feasibility study

The second aim of the pilot study was to test the feasibility of the study design for clinical implementation among the HD population.

4.4.1 Objectives of the feasibility study

1) To determine the feasibility of patient recruitment.

2) To assess the acceptability of the intervention to both nurses and participants, evaluated by: (a) the attendance rate of the group-exercise training; (b) nurse case managers' workload in delivering the intervention; and (c) feasibility of carrying out the nurse-patient interviews during dialysis sessions.

3) To evaluate the feasibility of the data collection procedures.

4) To test the feasibility of the exercise and interview protocols.

4.4.2 Design of the feasibility study

The pilot study was conducted prior to the main study, and was implemented in one of the study sites. The patient recruitment process, exercise protocols, and interview protocols were identical to those used in the main study. A total of five patients (three men and two women) were recruited for both the intervention (n = 3) and control groups (n = 2) to examine the feasibility of implementing the research program in the clinical HD population.

4.4.3 Procedures of the feasibility study

The participating physicians and experienced clinical nurses screened patients for eligibility by reviewing their medical histories. The student investigator then approached eligible patients to invite them to participate. An information sheet was provided after orally explaining the study purposes, procedures, and confidentiality issues, and consent forms were obtained from those who indicated willingness to participate. Participants were invited to provide baseline data by taking part in physical performance tests and completing questionnaires. All physical functional tests were administered before the dialysis sessions by the data collector, and questionnaires were distributed to participants with specific instructions. All questionnaires were collected at the following HD session. The data collector assisted patients in completing any incomplete items through face-to-face interviews to ensure no missing items in the questionnaires. After finishing the baseline assessment, participants were assigned to either an intervention or control group according to the pre-generated random assignment. The student investigators arranged weekly center-based group exercise training for all participants, and a nurse case manager was assigned to each intervention group patient. The designated nurse initiated the first interview within the week that the patient finished the first session of exercise training. To avoid possible intervention contamination from the nurse-patient interviews, patients from the intervention and control groups were kept as far apart as possible during the dialysis sessions with the help of the head nurse. Both baseline data and outcome measures at week 6 were collected to determine to feasibility of the data collection method. Based on the results of the feasibility study, the research plan for the main study was refined as needed.

4.4.4 Results of the feasibility study

As noted, the major purpose of the second part of the pilot study was to evaluate the feasibility of the study design rather than to determine the efficacy of the intervention. Therefore, statistical analysis was not performed for this small sample. Descriptive information is presented in this section.

4.4.4.1 Feasibility of patient recruitment

A total of 25 HD patients were assessed for eligibility, 17 of whom did not meet the inclusion criteria. Of the eight eligible patients, three (37.5%) declined to participate because of a lack of time (two patients) or interest (one patient). The three male and two female patients who agreed to participate in the pilot study, and who accounted for 62.5% of all patients who met the eligibility criteria, provided written consent.

The mean age of the participants was 62.6, with a range from 60 to 66, and the average HD duration was 107.4 months, with a range from 12 to 276 months.

4.4.4.2 Feasibility of the intervention

In-center group exercise training

The student investigator provided six sessions of in-center group exercise training to all five participants. The average attendance rate was 86.7%, with three patients attending all six sessions. The remaining two patients attended four out of six sessions, accounting for 66.7%. The reasons for failure to attend included late arrival for HD treatment due to traffic congestion and pre-dialysis hypertension.

Nurse-patient interviews

The nurse case managers successfully conducted 18 interview sessions, as stipulated by the intervention protocol. There were six interview sessions for each participant in the intervention group. The average duration of the first interview was approximately 20 to 25 minutes, and the follow-up sessions lasted about 10 to 15 minutes. The case managers indicated that they were able to incorporate the interviews into their daily practice without delaying patients' usual dialysis care.

With regard to the workload, they reported that they could handle about two interviews per HD session. All participants completed the six-week follow-up, with no withdrawals.

4.4.4.3 Feasibility of data collection

Data collection was performed at two time points, baseline and at week 6. All enrolled patients finished the physical performance tests safely and effectively before HD treatment. It took around five minutes for each participant to complete both the gait speed and 10-STS tests.

4.4.4.4 Feasibility of the intervention protocols

Feasibility of the exercise protocols

Each exercise training session included flexibility and strength exercises and lasted approximately 20 minutes. Flexibility exercises were performed as a warm-up and cool-down in each session, and the intensity of the strength exercises was increased gradually from three repetitions to six. Patients were allowed to choose individualized repetitions according to their exercise capacity (Painter, 1999). All participants were able to perform the exercise movements safely and correctly.

No adverse effects such as dizziness, chest pain or shortness of breath related to the exercise training occurred at home or in the center during the intervention period in the pilot study, although one patient in the control group reported a Bp rise immediately after training. Some patients also reported intermittent muscle soreness and fatigue, particularly in the first several weeks. The group exercise and/or individualized exercise prescription was adjusted when patients reported muscular soreness. The home exercise prescription for patients in the intervention group was gradually increased according to their exercise capacity.

Feasibility of the interview protocols

The nurses indicated that they experienced no difficulty in discussing exercise with the patients and/or their family members, as most were aware of the general benefits of exercise. The past therapeutic relationship established between the patient and nurse facilitated the interview process. The nurses reported that all interviews were conducted smoothly without interruption and that patients experienced no emotional disturbances or treatment-related discomfort. The nurses were thus able to successfully record the content of all interviews, including current exercise level, exercise plan and confidence level. On the basis of patients' exercise logs, the average adherence rate for the negotiated exercise plans was deemed to be 80%. One patient in the intervention group experienced uncontrolled hypertension on non-dialysis days, and was referred to the physician in charge for Bp control. The nurse case manager instructed the patient to stop aerobic and strength exercise until her Bp fell to an acceptable level as determined by the physician.

4.4.5 Discussion

The design of the exercise program was considered safe and was well received by the patients, which implied that it could be successfully implemented in clinical practice. Previous pilot studies have documented adherence, patient safety, and time required to deliver an intervention as important for evaluating the feasibility of an intervention (Broderick et al., 2013; Fan, Sidani, Cooper-Brathwaite, & Metcalfe, 2013; Kosse, Dutmer, Dasenbrock, Bauser, & Lamoth, 2013; Wesson et al., 2013; Yeagley et al., 2012). Adherence was determined in two respects: adherence to supervised in-center group exercise training (attendance) and adherence to the prescribed home exercise. Attendance also served as an indicator for assessing the acceptability of the intervention (Tang, Gillard, et al., 2005). The attendance rate for the group exercise was calculated using the number of sessions actually performed divided by the total number of sessions that the patient was required to attend.

Adherence to the supervised group exercise was acceptable, with a mean attendance rate of 86.7%. As noted, 100% of patients in the intervention group participated in all six training sessions. In addition, all participants in both groups completed the six-week intervention, and provided both baseline and week 6 data. Various adherence rates have been noted among studies reporting data on HD patients' adherence to exercise programs. For example, in Storer et al. (2005), HD patients were instructed to perform endurance exercise training during HD sessions, with adherence calculated by the number of days of training divided by the total number of planned training days during the weeks that patients completed. The average adherence rate for the training sessions in that study was 88%. Koh, Fassett, Sharman, Coombes, and Williams (2010) reported a 75% mean attendance rate for a supervised intra-dialytic exercise training program (three times per week over six months). Another study evaluating the effects of 12-week aerobic exercise training during dialysis sessions reported 81.4% adherence (three times per week over 12 weeks) (Reboredo et al., 2010). Unlike the case with intra-dialysis exercise, the participants in the current study were required to arrive at the center 30 minutes before their HD treatments, which meant that extra time was needed to participate in group exercise training. A previous study revealed that an exercise program delivered on non-dialysis days had a low attendance rate compared to an intra-dialytic exercise program (dropout rate of 24% versus 17%), concluding that it was difficult to expect HD patients to take extra time to attend an outpatient training program (Konstantinidou et al., 2002). Although the frequency of the exercise training sessions in this study was lower than those in previous studies, the exercise adherence rate in the pilot study was comparable to the rates reported for supervised intra-dialytic exercise programs.

The validity of the exercise protocols for use in the Chinese HD population was further confirmed in the feasibility study. As noted, no adverse exercise-related effects were reported, and exercise has been confirmed beneficial for CKD patients in a series of systematic reviews (Cheema & Singh, 2005; Heiwe & Jacobson, 2011; Segura-Orti, 2010; Smart & Steele, 2011). The beneficial effects of exercise can be realized only through patient participation. The participants in the feasibility study commented that they experienced a feeling of relaxation and sense of achievement after exercise, felt more energetic, and slept better. Some also mentioned that exercise relieved the symptoms of constipation. These subjective comments were obtained from the open-ended questions in the DPEBBS at week 6. Although the efficacy of the entire research program could not be determined from this small-scale pilot study, these qualitative data provided preliminary evidence on the effects of the exercise program.

4.4.6 Implications for the main study

The results obtained from the feasibility study provided evidence that the implementation of the in-center group exercise training and nurse-patient interviews were feasible and acceptable in a clinical setting. Eligible HD patients were able to understand the research process with appropriate oral explanation by the student investigator and the aid of a written information sheet. There was also no difficulty in obtaining patient consent. The acceptable attendance rate for group exercise training and high retention rate throughout the feasibility study also suggest that the program is acceptable to clinical HD patients.

One of the questions addressed in the feasibility study was the safety and appropriateness of the exercise protocol for use in a Chinese HD population. As noted, no exercise-related injury or adverse effects were reported, indicating that the exercise program can be safely performed by HD patients either in-center or at home with appropriate supervision and monitoring. It must be emphasized that the feasibility study participants may not be representative of the broader HD population owing to the very limited sample size. Therefore, close monitoring of safety was created throughout the program in the main study.

Three trained nurse case mangers conducted the nurse-patient interviews during the feasibility study period, and, as noted, none reported any difficulties with regard to incorporation into their daily practice or the time allotment. The student investigator randomly observed several interview sessions and reviewed the interview records to ensure intervention consistency among case managers and between the intervention and the study protocols, and provided the case manager with feedback directly after the observation. A case conference was also held to discuss actual or potential difficulties encountered during the interviews. One potential difficulty raised was the achievability of the recommended level of aerobic exercise, as patients would have to cease such exercise if they experienced dialysis-related symptoms such as hypertension, which could influence their exercise progression. The case managers were reminded that the purpose of the interviews was to facilitate each patient's exercise progression toward the recommended level. It was likely that patients would experience ups and downs in physical and emotional status during the study period, and the case managers were thus instructed to adjust the exercise prescriptions accordingly and encourage patients to keep as active as possible.

The feasibility study lasted six weeks instead of 12, as in the main study. As its aim was to test the feasibility of the study design for clinical implementation, six weeks were sufficient to include all components of the full-scale study. To ensure successful clinical implementation in the main study, the maximum patient load for data collectors and case managers was deemed to be two cases per dialysis session.

4.5 Summary

The two-phase pilot study confirmed the reliability and validity of the KDQOL-36^{TM} for use in the Chinese HD population, and informed the research personnel of the feasibility of executing the entire research program in clinical practice. Qualitative feedback from the study participants provided preliminary evidence of the intervention's effectiveness in enhancing patients' energy level. A full-scale study was then carried out to test and confirm the effects of the NCM program home exercise training for the HD patient group.

Chapter 5 Results

5.1 Introduction

This chapter reports the results of this study. The results were yielded from the study's RCT on the following outcome variables: normal and fast gait speed, 10-STS, quality of life, SRH, depressive symptoms, physical activity level, and patient-perceived exercise benefits and barriers. This chapter begins with a description of the subject recruitment flow chart, followed by the baseline demographic and clinical characteristics for each trial group. Comparative results between the trial groups and within the three data collection points, as well as the interactive effects on different outcome variables, are presented in detail. The chapter concludes with a summary.

5.2 Subject recruitment

Information on the patient recruitment process is relevant to the study's external validity (Egger, Juni, Bartlett, & the CONSORT Group, 2001), and relates to the generalizability of the trial results, indicating the extent to which the participants are representative of the general population (Gross, Mallory, Heiat, & Krumholz, 2002; Moher et al., 2012; Van Spall, Toren, Kiss, & Fowler, 2007; Wright et al., 2006).

Detailed information on patient enrollment is reported in accordance with the CONSORT flow diagram in Figure 5.1 (Moher et al., 2012).

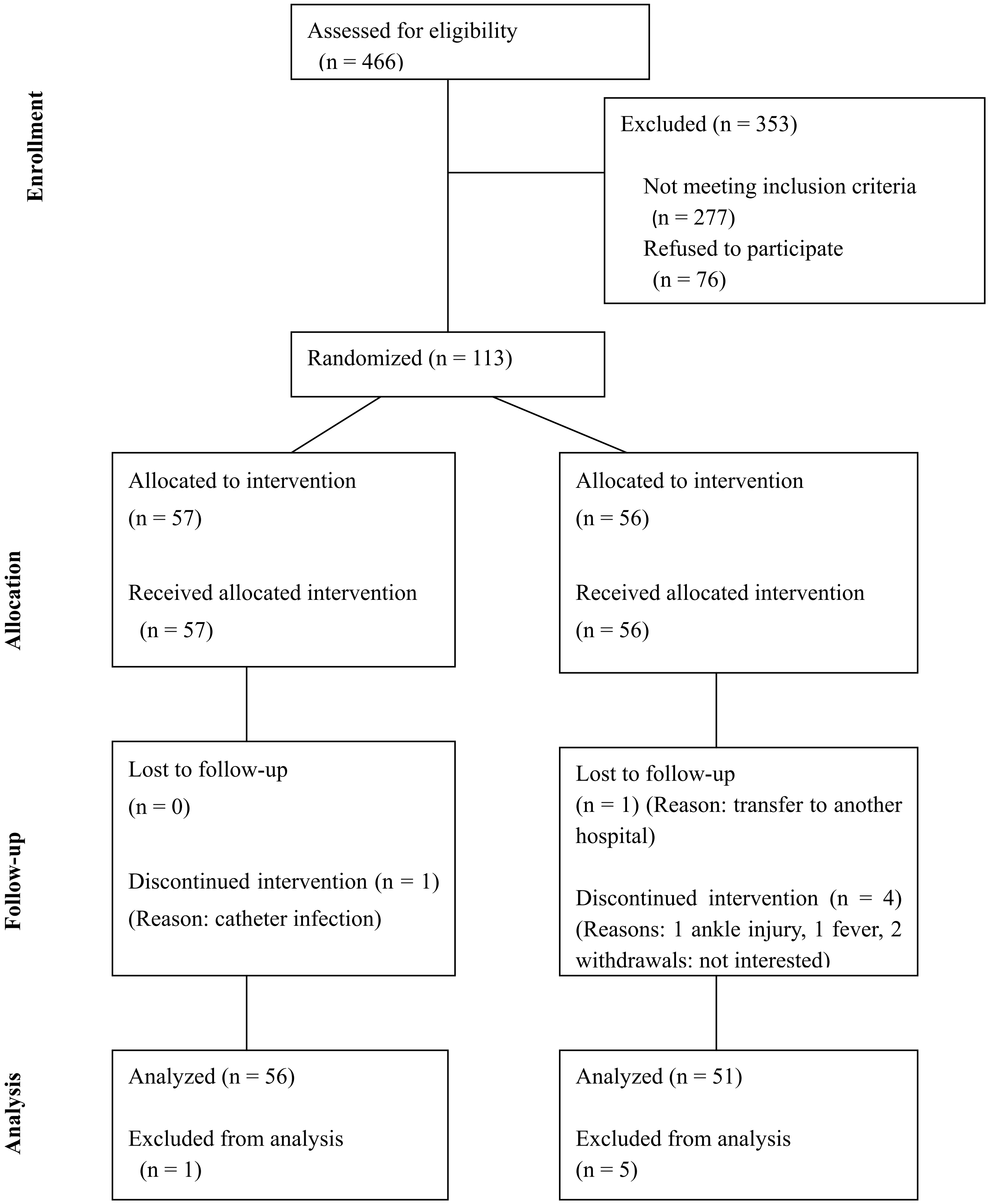

Figure 5.1: CONSORT flow diagram

Over the eight-month patient recruitment period (March to October 2013), 466 HD patients were assessed for eligibility, 277 of whom failed to meet the inclusion criteria. Of the 189 eligible patients, 76 (40.2%) declined to participate in the study. The primary reason for refusing to participate was a lack of time. One hundred and thirteen patients agreed to participate in the study, accounting for 59.8% of all those who met the eligibility criteria. All recruited patients finished the baseline assessment and were randomly assigned to either the intervention group (57 patients) or control group (56 patients) after which they received the corresponding interventions. By week 6, five patients in the control group had discontinued participation or been lost to follow-up. Two patients withdrew from the study because of a lack of interest. One patient was lost to follow-up because she transferred to another hospital to continue HD treatment, and one discontinued the intervention due to an unrelated ankle injury. At week 12, another two patients discontinued the intervention, and one in the intervention group was hospitalized due to HD catheter infection. One patient from the control group was hospitalized with fever.

5.3 Results

5.3.1 Baseline demographic and clinical characteristics

Table 5.1 presents the demographic and clinical characteristics of all randomized patients. Of the 113 participants who completed the baseline assessment, 59 were male (52.2%) and 54 (47.8 %) were female, with a mean age of 54.8 (SD = 10.8; range = 27-74). The majority (82.3%) were married and had had a secondary school education (72.5%). Most of the participants were retired (71.7%), with less than 10% employed, and the majority had government insurance (86.7%). In terms of disease-specific characteristics, chronic glomerular nephritis was the primary cause of ESRD for over one-quarter of the participating patients. The average duration of HD treatment was 84.1 months (SD = 65.8; range = 5-334 months). Approximately three-quarters of participants were also suffering from diseases other than renal failure. Only 26.3% had no other co-morbidities. The baseline characteristics of the two trial groups were comparable. No statistically significant differences were identified in majority of the demographic and clinical data, except for marital status. The participants in the intervention group had more single status than the control group (see Table 5.1). Though proper random assignment may not be able to guarantee group equivalence at baseline, the process is able to prevent selection bias (Moher et al., 2010).

Table 5.1: Baseline demographic and clinical characteristics

Characteristics	Intervention (n = 57)	Control (n = 56)	Total (n = 113)	p-value
Age (Years; M, SD)	53.02 (11.62)	56.68 (9.67)	54.83 (10.81)	0.072 [c]
Sex (Male)	29 (50.9%)	30 (53.6%)	59 (52.2%)	0.774[a]
Marital status				0.010[b]
Married	42 (73.7%)	51 (91.1%)	93 (82.3%)	
Single	7 (12.3%)	0 (0.0%)	7 (6.2%)	
Divorced/Widowed	8 (14%)	5 (8.9%)	13 (11.5%)	
Education level				0.710[b]
Primary or below	4 (7.0%)	4 (7.2%)	8 (7.1%)	
Secondary	43 (75.4%)	39 (69.6%)	82 (72.5%)	
Tertiary or above	10 (17.5%)	13 (23.2%)	23 (20.4%)	
Employment				0.220[b]
Full-time	4 (7.0%)	2 (3.6%)	6 (5.3%)	
Part-time	1 (1.8%)	2 (3.6%)	3 (2.7%)	
Retired	36 (63.2%)	45 (80.4%)	81 (71.7%)	
Homemaker	6 (10.5%)	2 (3.6%)	8 (7.1%)	
Other	10 (17.5%)	5 (8.9%)	15 (13.3%)	
Insurance				0.395[a]
Government insurance	47 (82.5%)	52 (91.0%)	98 (86.7%)	
Self-pay	10 (17.5%)	5 (9.0%)	15 (13.3%)	
Financial status				0.090[a]
More than sufficient	9 (15.8%)	8 (14.3%)	17 (15.0%)	
Barely sufficient	27 (47.4%)	37 (66.1%)	64 (56.6%)	
Insufficient	12 (21.1%)	9 (16.1%)	21 (18.6%)	
Extremely insufficient	9 (15.8%)	2 (3.6%)	11 (9.7%)	
Primary cause of renal failure				0.329[a]
Chronic glomerular nephritis	13 (22.8%)	16 (28.6%)	29 (25.7%)	
Hypertension	10 (17.5%)	16 (28.6%)	26 (23.0%)	
Diabetes	7(12.3%)	9 (16.1%)	16 (14.2%)	
Gout	9 (15.8%)	5 (8.9%)	14 (12.4%)	
Unknown	13 (22.8%)	6 (10.7%)	19 (16.8%)	
Other	5(8.8%)	4 (7.2%)	9 (8.0%)	
Comorbidity				

No other diseases	16 (23.5%)	19 (29.2%)	35 (26.3%)	0.612[a]
Hypertension	30 (44.1%)	26 (40.0%)	56 (42.1%)	0.593 [a]
Cardiac disease	15 (22.1%)	11 (16.9%)	26 (19.5%)	0.433 [a]
Diabetes	5 (7.4%)	3 (4.6%)	8 (6.0%)	0.480 [a]
Other	2 (2.9%)	6 (9.2%)	8 (6.0%)	0.289[b]
HD duration (Months; M, SD)	83.46 (61.37)	84.70 (70.55)	84.07 (65.78)	0.902[d]
Hb (g/L; M, SD)	105.19 (11.89)	106.91 (13.28)	106.05 (12.57)	0.470 [c]
Weekly EPO dosage (U; M, SD)	5315 (3470)	5482 (3816)	5398 (3630)	0.944[d]
Pre-dialysis blood pressure (mm Hg)				
Systolic pressure (M,SD)	133.77 (19.90)	137.29 (17.12)	135.51 (18.58)	0.317 [c]
Diastolic pressure (M,SD)	81.67 (12.14)	84.1 (9.83)	82.88 (11.08)	0.243[c]

***Note**: Primary school in China refers Grade 1 to Grade 6 or Elementary school. Some participants suffered several comorbidities, causing the number of comorbidities to be greater than the number of patients in each trial group. * p< 0.05.*

M = Mean; SD = Standard deviation; EPO = Erythropoietin.

a=Person Chi-Square Test

b=Fish's Exact Test

c=Independent Sample T-Test

d=Mann-Whitney U-Test

5.3.2 Comparison of outcome variables at baseline

Table 5.2 displays the group comparisons at baseline with regard to normal gait speed, fast gait speed, 10-STS, quality of life, self-rated health, BDI, and patient-perceived exercise benefits and barriers. There were no significant differences identified in any of the outcome variables between the two groups at baseline.

Table 5.2 Comparison of outcome variables of the two groups at baseline

	Intervention group (n=57)	Control group (n=56)	t-value/ z-score	p-value
Normal gait speed, mean (SD) cm/s	120.88 (25.46)	116.65 (27.53)	-0.848	0.398
Fast gait speed, mean, cm/s (SD) cm/s	167.57 (37.92)	159.71 (40.40)	-1.067	0.288
10-STS※, mean (SD) seconds	19.78 (6.57)	21.86 (16.55)	0.573	0.568
KDQOL-36™				
BKD, mean rank	54.29	59.76	-0.89	0.374
EKD, mean rank	52.34	61.74	-1.526	0.127
SPL, mean rank	59.58	54.38	-0.845	0.398
PCS, mean rank	55.26	58.77	-0.569	0.570
MCS, mean rank	57.79	56.20	-0.258	0.796
SRH, mean rank	60.30	53.64	-1.217	0.224
BDI-II, mean rank	61.90	52.01	-1.606	0.108
DPEBBS	68.11 (6.08)	66.91 (5.61)	-1.096	0.276
Benefit score	36.42 (3.77)	35.36 (3.66)	-1.588	0.115
Barrier score	31.68 (3.59)	31.55 (3.42)	-0.178	0.859

Note: Independent t test for normal gait speed. Fast gait speed, 10-STS, DPEBBS. Mann-Whitney U test for KDQOL-36™, SRH, and BDI scores.

5.3.3 Results of outcome variables in ITT analysis

This section presents the results for all of the dependent variables outlined in Chapter 4. The aim is to examine the effects of the NCM program on home exercise for HD patients by comparing the two trial groups over time.

5.3.3.1 Results on normal gait speed

The RM-ANOVA indicated that a significant main effect of time (overall significance among the three time points), $F_{(1.88,\ 208.09)} = 8.67$, $p < 0.001$, with a moderate effect size (partial eta squared = 0.072), and a significant between-group main effect, $F_{(1,\ 111)} = 4.42$, $p = 0.038$, with a small effect size (partial eta squared = 0.038). There was a significant interaction effect between both time points and groups, $F_{(1.88,\ 208.09)} = 3.30$, $p = 0.042$, partial eta squared = 0.029, which means the groups experienced different degrees of change in normal gait speed over time (see Table 5.3). The changes in normal gait speed between the two groups were significantly different between T0 and T1 ($p = 0.008$). In other words, the mean difference in normal gait speed between the two groups was not the same at week 6 as it was at baseline. Significantly different between-group changes were also observed between T0 and T2 ($p = 0.001$).

One-way RM-ANOVA indicated a significant improvement in normal gait speed over time for the intervention group, $F_{(2,\ 112)} = 9.53$, $p < 0.001$. Pairwise comparisons found that normal gait speed for the intervention group increased between T0 to T2 ($p = 0.001$, Cohen's d = 0.45), with an average improvement of 12.02 ± 3.03

centimeters per second (cm/s). No significant change over time was noted for the control group: $F_{(1.75,\ 96.40)} = 0.87$, $p = 0.41$ (see Table 5.4 & 5.5, and Figure 5.2).

With regard to the group comparisons at each time point, there was a significant difference at T2: $t = -2.80$, $p = 0.006$, Hedges' $g = 0.52$. The normal gait speed for the intervention group was faster than that for the control group, as shown in Table 5.6.

Table 5.3 Overall results of RM-ANOVA on normal gait speed

Effect	df1	df2	F ratio	*p-value*	η_p^2
Between-group (Group)	1	111	4.422	0.038*	0.038
Group × Time	1.875[a]	208.086	3.300	0.042*	0.029
Within-group (Time)	1.875[a]	208.086	8.668	<0.001*	0.072

[a]. The degree of freedom of F ratio is evaluated by Greenhouse-Geisser correction as estimates of adjustment (epsilon), if Mauchly's sphericity is not assumed. * *p< 0.05.*
η_p^2, partial eta squared

Table 5.4 Post hoc analyses for the two groups

Group	df1	df2	F ratio	*p-value*
Intervention	2	112	9.528	<0.001*
Control	1.753[a]	96.403	0.871	0.409

[a]. The degree of freedom of F ratio is evaluated by Greenhouse-Geisser correction as estimates of adjustment (epsilon), if Mauchly's sphericity is not assumed.
Significant level for Bonferroni adjusted t-test was set at 0.025 (0.05/2).

Table 5.5 Post-hoc pairwise comparison between times

Group	Time	Mean difference	*P value*
Intervention	T0 & T1	-7.566	0.009*

T0 & T2	-12.017	0.001*
T1 & T2	-4.451	0.373

Significant level for Bonferroni adjusted t-test was set at 0.0167 (0.05/3).

Table 5.6 Comparison between groups at the three time intervals

Group	T1	T2
Intervention, mean (SD)	128.44 (24.00)	132.90 (27.89)
Control, mean (SD)	119.19 (23.44)	119.38 (23.18)
t-value (*p-value*)	-2.074 (0.040)	-2.800 (0.006)*

Significant level for Bonferroni adjusted t-test was set at 0.025 (0.05/2).

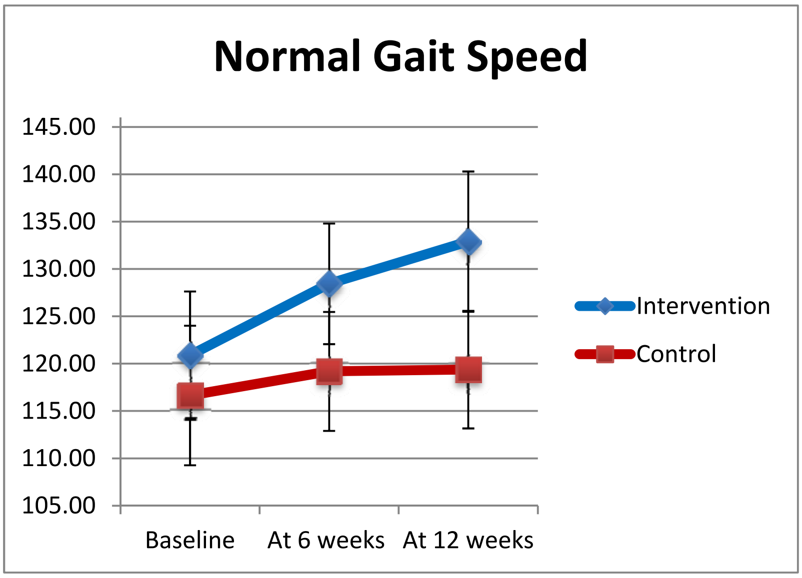

Figure 5.2 Normal gait speed results

5.3.3.2 Results on fast gait speed

The results of two-way RM-ANOVA on fast gait speed revealed a significant overall within-group effect ($F_{(1.81, 201.26)} = 4.67$, $p = 0.013$, partial eta squared = 0.040), and interaction effect ($F_{(1.81, 201.26)} = 4.21$, $p = 0.019$, partial eta squared = 0.037); but a non-significant between-group effect ($F_{(1, 111)} = 3.93$, $p = 0.05$, partial eta squared = 0.034), as shown in Table 5.7. Please refer to Appendix 4.1 for one-way ANOVA results.

Multiple comparisons across the three time points for the intervention group indicated an increase in fast gait speed from T0 to T1 ($p = 0.037$). The increasing trend continued to T2, and a significant change from T0 to T2 was identified, $p = 0.005$, Cohen's d = 0.29, with an average improvement of 11.08 ± 3.32 cm/s (See Table 5.8 and Figure 5.3). No significant difference was found between the two groups at T1 ($t = -1.91$, $p = 0.059$), but significant between-group differences were found at T2 ($t = -2.73$, $p = 0.007$, Hedges' $g = 0.51$), as shown in Table 5.9.

Table 5.7 Overall results of RM-ANOVA on fast gait speed

Effect	df1	df2	*F* ratio	*p-value*	η_p^2
Between-group (Group)	1	111	3.928	0.050	0.034
Group × Time	1.813[a]	201.262	4.209	0.019*	0.037
Within-group (Time)	1.813[a]	201.262	4.670	0.013*	0.040

[a]. The degree of freedom of F ratio is evaluated by Greenhouse-Geisser correction as estimates of adjustment (epsilon), if Mauchly's sphericity is not assumed. * $p < 0.05$.
η_p^2, partial eta squared

Table 5.8 Post-hoc pairwise comparison between times for the intervention group

Group	Time	Mean difference	*P value*

Intervention	T0 & T1	-6.964	0.037
	T0 & T2	-11.075	0.005*
	T1 & T2	-4.111	0.213

Significant level for Bonferroni adjusted t-test was set at 0.0167 (0.05/3).

Table 5.9 Comparison between groups at the three time intervals

Group	T1	T2
Intervention, mean (SD)	174.54 (35.54)	178.65 (37.66)
Control, mean (SD)	161.36 (37.96)	159.73 (35.85)
t-value (*p-value*)	-1.906 (0.059)	-2.734 (0.007) *

Significant level for Bonferroni adjusted t-test was set at 0.025 (0.05/2).

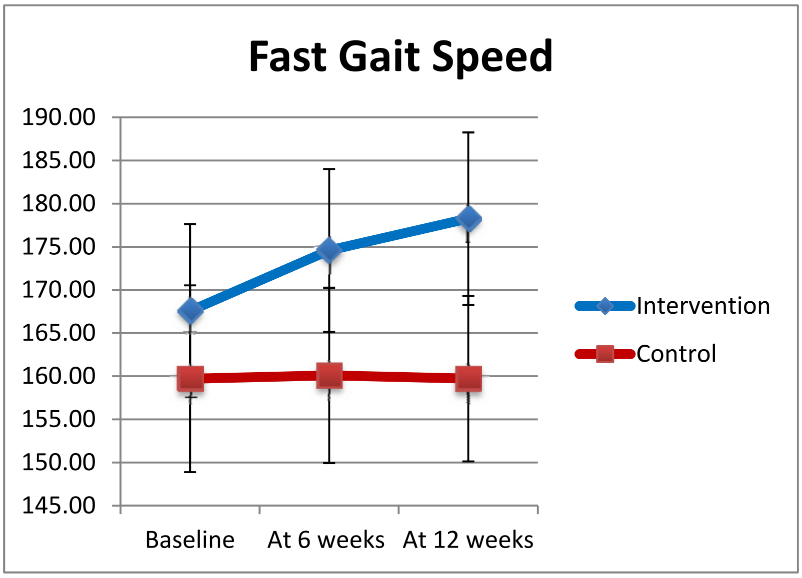

Figure 5.3 Fast gait speed results

5.3.3.3 Results on 10-STS

The normality assumption for the data on the 10-STS was violated. The z-scores of skewness ranged from 4.10 to 19.21, whereas the absolute values for kurtosis were all greater than 1.96, ranging from 2.75 to 37.53, and the results of the Shapiro-Wilk test were all significant. Logarithmic transformation was performed to reduce the skewness of the data. Results of two-way RM-ANOVA on the transformed data revealed significant differences on the overall time effect ($F_{(1.65, 182.66)} = 96.23$, $p < 0.001$), with a non-significant difference found between the two groups ($F_{(1, 111)} = 3.92$, $p = 0.050$) over time. A significant interaction effect ($F_{(1.65, 182.66)} = 6.11$, $p = 0.005$) was also observed, as shown in Table 5.10. Please refer to Appendix 4.1 for one-way ANOVA results.

Pairwise comparisons within the intervention group found that the mean actual improvement from baseline to week twelve was 5.75 (±3.88) seconds. The control group experienced a similar trend in 10-STS performance, but no significant within-group difference was noted from T1 to T2 ($p = 0.093$). Please refer to Appendix 3.1 for the change of the control group. (See Table 5.11 & 5.12, and Figure 5.4).

Group comparisons were carried out for each time point, with no significant between-group difference found at T1, $t = 2.05$, $p = 0.043$, but a significant such difference at T2 ($t = 2.95$, $p = 0.004$). The participants in the intervention group took less time to finish the 10-STS test than the control group. Please refer to Table 5.14.

Table 5.10 Overall results of RM-ANOVA on 10-STS

Effect	df1	df2	*F* ratio	*p-value*
Between-group (Group)	1	111	3.924	0.050
Group × Time	1.646[a]	182.661	6.114	0.005*
Within-group (Time)	1.646[a]	182.661	96.230	<0.001*

[a]. The degree of freedom of F ratio is evaluated by Greenhouse-Geisser correction as estimates of adjustment (epsilon), if Mauchly's sphericity is not assumed. * $p < 0.05$.

Table 5.11 Post-hoc pairwise comparison between times for the intervention group

Group	Time	Mean difference	*P value*
Intervention	T0 & T1	4.165	<0.001*
	T0 & T2	5.751	<0.001*
	T1 & T2	1.586	<0.001*

Significant level for Bonferroni adjusted t-test was set at 0.0167 (0.05/3).

Table 5.12 Comparison between groups at the three time intervals

Group	T1	T2
Intervention, mean (SD)	15.62 (5.87)	14.03 (4.97)
Control, mean (SD)	18.31 (9.66)	16.93 (6.24)
t-value (*p-value*)[#]	2.050 (0.043)	2.950 (0.004) *

Significant level for Bonferroni adjusted t-test was set at 0.025 (0.05/2). [#] independent t-test performed on the transformed data.

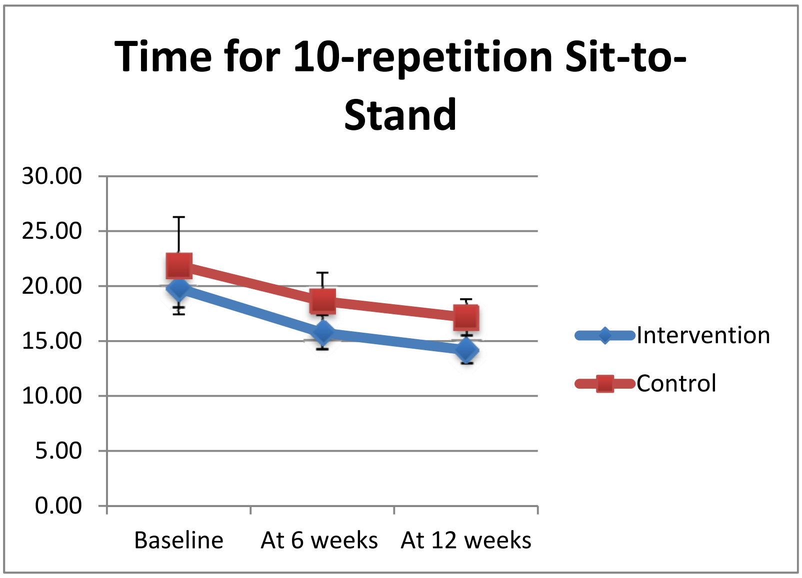

Figure 5.4: 10-STS results

5.3.3.4 Results on health-related quality of life (KDQOL-36™)

With regard to the BKD subscale, Friedman test indicated a statistically significant overall difference for the intervention group across the three time points: $\chi^2(2, n = 57) = 9.31$, $p = 0.01$. The median values indicated an increase in the BKD score from T0 (median = 37.50) to T1 (median = 43.75), and a further increase at T2 (median = 50.00). The results of Wilcoxon signed-rank tests revealed that the intervention patients' perception of BKD decreased from T0 to T2; $z = -2.51$, $p = 0.012$. Please refer to Table 5.13 & 5.14 and Figure 5.5. No significant difference in within-group effects was noted in the control group, and there was no significant between-group difference in BKD scores. Please refer to Appendix 4.1.

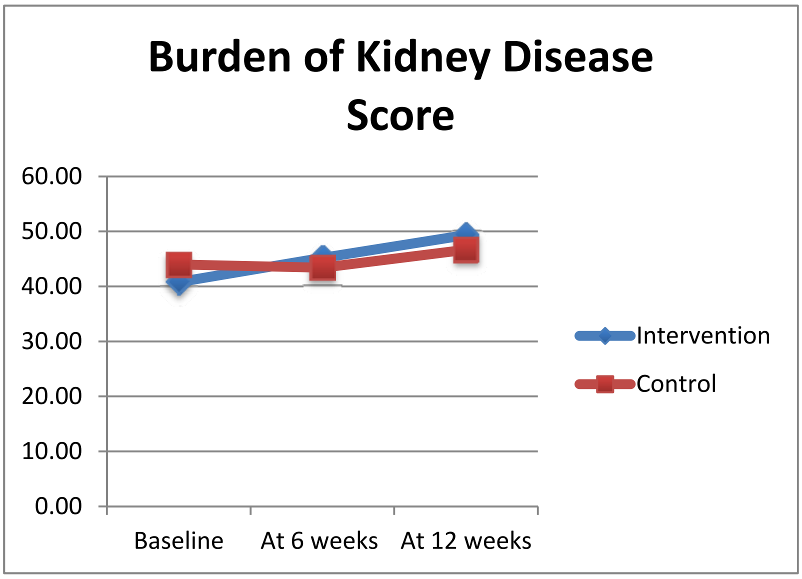

Figure 5.5 BKD results

A significant within-group effect for the EKD subscale was also found only in the intervention group: χ^2 (2, n = 57) = 11.08, p = 0.004. Wilcoxon signed-rank tests for that group across the three time points revealed that the EKD subscale scores increased from T0 (median = 57.14) to T2 (median = 65.63), z = -2.81, p = 0.005, but no change was observed from T0 to T1 (median = 60.71), z = -2.29, p = 0.022. Please refer to Table 5.13 & 5.14 and Figure 5.6. The control group realized no significant change over time, and no significant between-group difference was found at any of the time points. Please refer to Appendix 4.1.

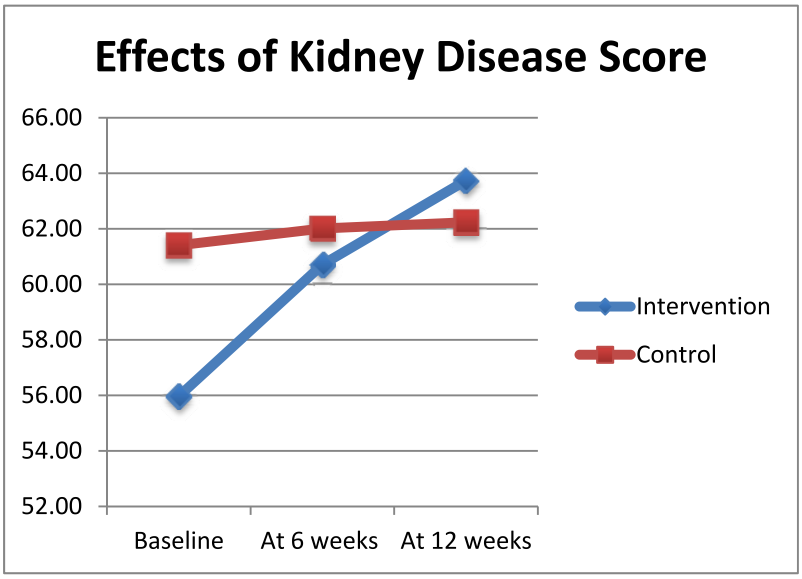

Figure 5.6: EKD results

The SPL subscale results showed a significant between-group difference at T2, z = -2.36, p = 0.019. There was a significant within-group difference for the intervention group, χ^2 (2, n = 57) = 7.92, p = 0.019, with pairwise comparisons further indicating a significant improvement in SPL for that group between T1 (median = 79.17) and T2 (median = 83.33), z = -2.53, p = 0.011. Please refer to Table 5.13, 5.14, 5.15 and Figure 5.7. No improvement over time on the SPL subscale was observed for the control group, and no between-group difference was seen at any time point. Please refer to Appendix 4.1.

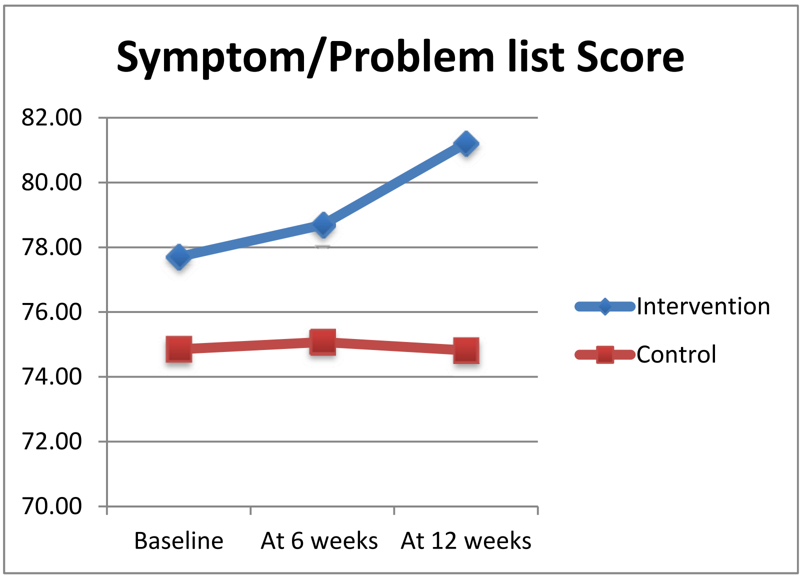

Figure 5.7: SPL results

Neither a between-group nor within-group effect was found for the PCS or MCS subscale scores. Please refer to Appendix 4.1, and Figure 5.8 & 5.9.

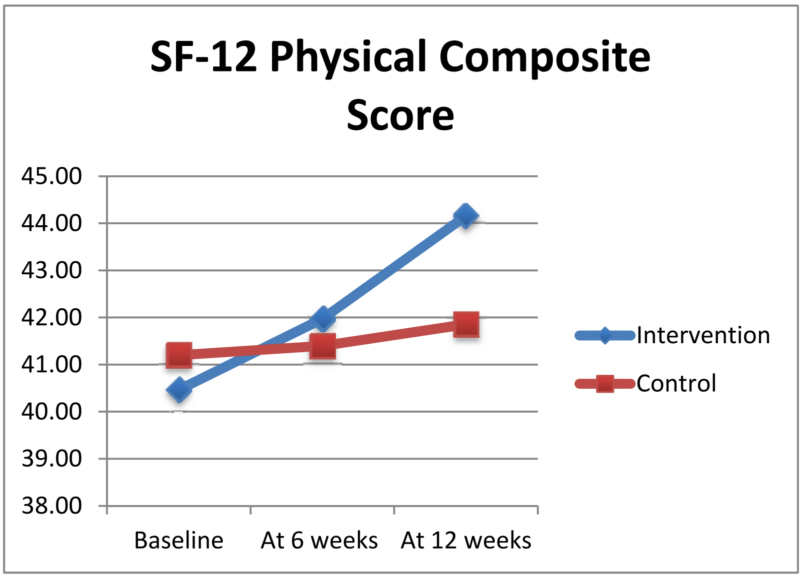

Figure 5.8: PCS results

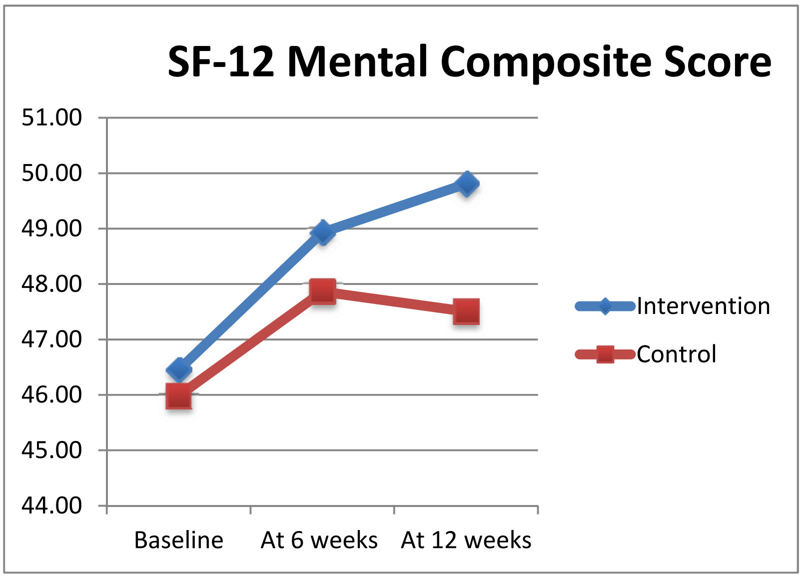

Figure 5.9: MCS results

Table 5.13 Within-group analyses on the subscale scores of the KDQOL-36™ for the intervention group

Group	Subscales	df	*n*	χ^2	*p-value*
Intervention	BKD	2	57	9.310	*0.010
	EKD	2	57	11.078	*0.004
	SPL	2	57	7.916	*0.019

Significant level for Bonferroni adjusted t-test was set at 0.025 (0.05/2).

Table 5.14 Post-hoc pairwise comparison between times for the intervention group

Group		Time	Mean rank	z-score	*P value*
Intervention	BKD	T0 & T1	21.85	-1.755	0.079
		T0 & T2	26.50	-2.508	0.012*
		T1 & T2	21.90	-1.550	0.121
	EKD	T0 & T1	24.05	-2.289	0.022
		T0 & T2	24.20	-2.813	0.005*
		T1 & T2	19.58	-2.055	0.040
	SPL	T0 & T1	28.50	-0.259	0.796
		T0 & T2	27.11	-2.311	0.021
		T1 & T2	20.31	-2.532	0.011

Significant level for Bonferroni adjusted t-test was set at 0.0167 (0.05/3).

Table 5.15 Comparison between groups at the three time intervals

Subscales		Intervention mean rank	Control mean rank	Z-score	p-value
SPL	T0	59.58	54.38	-0.845	0.398
	T1	61.00	52.93	-1.311	0.190
	T2	64.18	49.69	-2.355	0.019*

Mann-Whitney U-tests were performed on the non-abnormally distributed data. Significant level for Bonferroni adjusted t-test was set at 0.025 (0.05/2).

5.3.3.5 Self-rated health

The results yielded from the non-parametric tests revealed a significant improvement in SRH over time for the intervention group, χ^2 (2, n = 57) = 20.13, p < 0.001, with post hoc comparisons using Wilcoxon signed-rank tests further indicating that that improvement took place between T0 (median = 25.00) and T2 (median = 50.00), z = -3.58, p < 0.001. The improvement from T1 to T2 was also significant, z = -3.11, p = 0.002. The control group, too, saw a significant change over time, χ^2 (2, n = 56) = 12.21, p = 0.002, with improvement effected between both T0 and T2 (z = -3.35, p = 0.001) and T1 and T2 (z = -2.48, p = 0.013). Please refer to Table 5.16 and 5.17. However, the Mann-Whitney U-tests for between-group comparisons identified no significant difference between the two groups at T1 or T2. Please refer to Appendix 4.1.

Table 5.16 Within-group analyses on the SRH scores

Group	df	*n*	χ^2	*p-value*
Intervention	2	57	20.133	<0.001*
Control	2	56	12.205	0.002*

Significant level for Bonferroni adjusted t-test was set at 0.025 (0.05/2).

Table 5.17 Post-hoc pairwise comparison between times

Group	Time	Mean rank	z-score	*P value*
Intervention	T0 & T1	11.83	-2.188	0.029
	T0 & T2	14.40	-3.576	<0.001*
	T1 & T2	6.00	-3.114	0.002*
Control	T0 & T1	13.64	-1.237	0.216
	T0 & T2	13.75	-3.353	0.001*
	T1 & T2	12.00	-2.482	0.013*

Significant level for Bonferroni adjusted t-test was set at 0.0167 (0.05/3).

5.3.3.6 Results on depressive symptoms (BDI-II)

The results of the non-parametric statistics revealed a significant improvement over time for the intervention group, χ^2 (2, n = 57) = 16.75, p < 0.001, as shown in Table 5.18. Post hoc comparisons using Wilcoxon signed-rank tests further indicated that the intervention patients' depressive symptoms decreased from T0 (median = 14.00) to T1 (median = 9.00), z = -2.55, p = 0.011, as well as from T0 to T2 (median = 7.35), z = -3.44, p = 0.001. Please refer to Table 5.19 and Figure 5.10. However, no significant within-group effects were noted in the control group. Mann-Whitney U-tests for between-group comparisons showed no significant difference between the two groups at T0, T1, or T2. Please refer to Appendix 4.1.

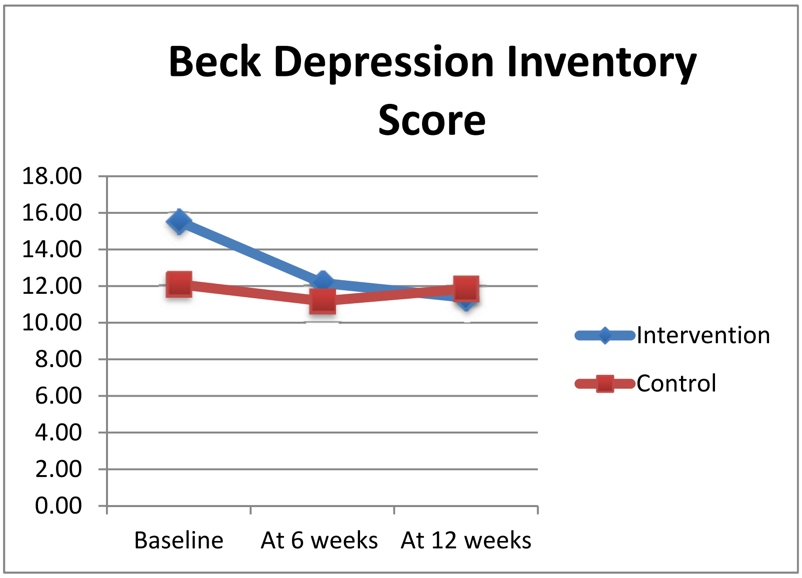

Figure 5.10: BDI-II results

Table 5.18 Within-group analyses on the BDI-II scores

Group	df	*n*	χ^2	*p-value*
Intervention	2	57	16.752	*<0.001
Control	2	56	2.174	0.337

Significant level for Bonferroni adjusted t-test was set at 0.025 (0.05/2).

Table 5.19 Post-hoc pairwise comparison between times for the intervention group

Group	Time	Mean rank	z-score	*P value*
Intervention	T0 & T1	28.32	-2.547	0.011
	T0 & T2	27.17	-3.437	0.001*
	T1 & T2	26.21	-1.184	0.236

Significant level for Bonferroni adjusted t-test was set at 0.0167 (0.05/3).

5.3.3.7 Results on physical activity level

One patient was lost to follow-up because she transferred to another hospital to continue dialysis treatment. The missing data for this patient were imputed by group mean.

The Mann-Whitney U-test results for the between-group comparisons showed no significant difference between the two groups at T1, z= -1.93, p = 0.054, although there was a significant such difference at T2, z = -4.897, p < 0.001. The weekly duration of aerobic exercise reported by the intervention group was greater than that reported by their control group counterparts. The control group actually saw a significant decrease in weekly aerobic exercise over time, z = -3.43, p = 0.001, whereas no significant change was noted in the intervention group, z = -1.91, p = 0.056. The results are presented in Table 5.20.

Table 5.20: Comparison of physical activity level by group over time

Physical activity level	After 6 weeks	After 12 weeks	Within Groups
	mean rank	mean rank	Z (p-value)
Intervention	62.84	51.05	-1.908 (0.056)
Control	71.82	41.91	-3.432 (*0.001)
Z (p-value)	-1.929 (0.054)	-4.897 (*0.000)	

* $p < 0.05$.

5.3.3.8 Results on DPEBBS scores

The DPEBBS score results obtained from two-way RM-ANOVA on the transformed data showed significance differences in the main time effect ($F_{(1.88,\ 208.17)} = 30.07$, $p < 0.001$), with both groups achieving an increase across the three time points. The main group effect ($F_{(1,111)} = 4.45$, $p = 0.037$) was significant, suggesting differences in the effectiveness of the two types of intervention on DPEBBS scores. No significant difference in the interaction effect ($F_{(1.88,\ 208.17)} = 1.25$, $p = 0.288$) was identified. Please refer to Table 5.21. One-way ANOVA results were attached in Appendix 4.1.

In the intervention group, one-way RM-ANOVA indicated a significant change over time ($F_{(2,\ 112)} = 19.79$, p < 0.001). Please refer to Appendix 4.1. Multiple comparisons further revealed that the mean score of the DPEBBS in this group increased from T0 to T1, $p < 0.001$. The mean changes from T0 to T2 were also significant, $p < 0.001$. Significant changes over time ($F_{(2,\ 110)} = 10.93$, p < 0.001) were also noted in the control group. Please refer to Table 5.22 and Figure 5.11. Slight increases in the DPEBBS mean scores were observed for both groups, suggesting an improvement in self-perceived exercise benefits and a decline in self-perceived exercise barriers for both. No significant between-group difference was found at T1 (t = -1.51, p = 0.133), although there was a significant such difference at T2 (t = -2.56, p = 0.012), as shown in Table 5.23.

Table 5.21 Overall results of RM-ANOVA on the scores of DPEBBS

Effect	df1	df2	*F* ratio	*p-value*
Between-group (Group)	1	111	4.453	0.037*
Group × Time	1.875[a]	208.166	1.246	0.288
Within-group (Time)	1.875[a]	208.166	30.065	<0.001*

[a]. The degree of freedom of F ratio is evaluated by Greenhouse-Geisser correction as estimates of adjustment (epsilon), if Mauchly's sphericity is not assumed.

Table 5.22 Post-hoc pairwise comparison between times

Group	Time	Mean difference	*P value*
Intervention	T0 & T1	-3.632	<0.001*
	T0 & T2	-5.298	<0.001*
	T1 & T2	-1.666	0.134
Control	T0 & T1	-2.968	0.002*
	T0 & T2	-3.393	0.001*
	T1 & T2	-0.424	1.000

Significant level for Bonferroni adjusted t-test was set at 0.0167 (0.05/3).

Table 5.23 Comparison between groups at the three time intervals

Group	T1	T2
Intervention, mean (SD)	71.74 (6.74)	73.40 (6.82)
Control, mean (SD)	69.88 (6.98)	70.30 (6.50)
t-value (*p-value*)[#]	-1.513 (0.133)	-2.563 (0.012)*

Significant level for Bonferroni adjusted t-test was set at 0.025 (0.05/2). [#] independent t-test performed on the transformed data.

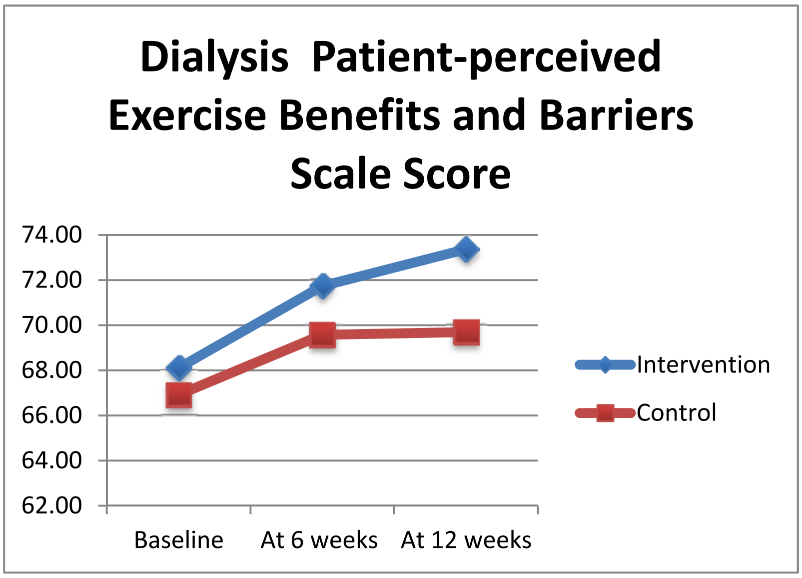

Figure 5.11: DPEBBS results

5.3.4 Results of outcome variables in PP analysis

The results of PP analyses on outcomes revealed significant between-group effects on both normal and fast gait speed ($F_{(1, 105)} = 4.93$, $p = 0.029$; $F_{(1, 105)} = 4.35$, $p = 0.039$). There was significant interaction effect on 10-STS performance, $F_{(1.65, 173.12)} = 5.10$, $p = 0.010$. Follow-up analyses indicated that both group performed equally well on STS at weeks six, but the intervention group performed considerably better than the control group at weeks twelve. With regard to quality of life, a significant between-group effect was found on subscales of "Symptom and Problem list" of the KDQOL-36^{TM} (z = -2.27, $p = 0.024$.). Similar to the ITT analysis results, no between-group effects were identified in either SRH or depressive symptoms; and both group reported improvements on SRH. There was a significant decrease in physical activity level noted in the control group, z = -3.04, p = 0.002; and the Mann-Whitney U-test showed a significant difference between the two groups at T2, z = -4.58, $p < 0.001$. With regard to scores on DPEBBS, the results obtained from two-way ANOVA revealed marginal significant overall differences between the two groups ($F_{(1, 105)} = 4.10$, $p = 0.045$); with the intervention group reporting higher perceived benefits and lower perceived barriers. Please refer to Appendix 4.1 for the results of PP analyses on outcomes.

Overall, consistent results were found in ITT and PP analysis on the outcome variables, except the fast gait speed. A significant between-group effect was noted from the results of PP but not ITT analysis.

5.3.5 Compliance of the intervention

Follow-up compliance with the primary outcomes at week 12 was 92.0%. Adherence to the in-center group exercise program was calculated by the number of sessions in which patients participated divided by the total number of sessions provided multiplied by 100. The average adherence rate of the in-center group exercise training for all participants was 82.7%, with 84.2% for the intervention group and 81.2% for the control group.

All patients in the intervention group took part in nurse-patient interviews, as previously noted. Nurse case managers negotiated exercise goals with the individual patient in each contact. The goal was specified in a FITT format (frequency, intensity, type and time) as indicated in Appendix 3.6. Patient adherence to home exercise prescription was determined through comparing the home exercise patients performed in the previous week to the exercise goal developed in the last contact. On the basis of patients' exercise logs, the average adherence rate for the negotiated exercise plans was 78.9%. The main reasons for non-adherence included fistula problems, muscle cramps after dialysis treatment, knee pain, and short-term hospitalization. At the end of the program, 47.4% of the participants in the intervention group either met or exceeded the minimal exercise goal of the aerobic exercise; being totally 90 minutes per week. There were significantly more patients met the goal in the intervention group as compared to those in the control group, $\chi^2 = 8.41$, $p = 0.004$.

5.4 Summary

This first part of the chapter has presented the results of data analysis on a series of dependent variables, revealing that the patients in the intervention group, who received brief in-center exercise training and took part in NCM on home exercise, had significantly higher normal gait speed, a higher patient-perceived EBBS score, and higher physical activity level than those in the control group provided with the training alone. No significant between group differences but an improved trend in fast gait speed, 10-STS performance, quality of life and depressive symptoms were observed in the intervention group. Patients from both groups reported improved self-perceived health over time, with no between-group difference identified.

Chapter 6 Discussion

6.1 Introduction

Patients on HD treatment experience physical dysfunction, which leads to substantially diminished HRQoL and increases the risks of hospitalization and mortality. Regular exercise has been shown to be safe and effective in restoring physical functioning and preventing functional decline in this patient group, and there is a growing body of evidence emphasizing the importance of physical activity and/or exercise for HD patients and documenting their urgent and unmet need for functional rehabilitation (Bennett et al., 2010; Cheema, 2008; Cupisti et al., 2013; Intiso, 2014; Johansen, 2008; Johansen & Painter, 2012; Painter, 2005; Painter, Clark, & Olausson, 2014). However, most dialysis patients continue to lead a sedentary lifestyle, and exercise recommendations and counseling are rare in most dialysis centers. Intradialytic exercise is a time-saving exercise modality recommended in the literature, yet its major shortcoming is its heavy resource requirement. Home exercise is a possible alternative, but studies examining its effects on physical function (Koh et al., 2009; Malagoni et al., 2008) have yet to provide solid evidence of its benefits for dialysis patients. Previous findings on the effects of NCM on self-management abilities, HRQoL, patient satisfaction, and re-hospitalization among CKD patients are encouraging, but these positive results cannot be generalized to the implementation of a home exercise program for HD patients. To the best of the author's knowledge, the effects of NCM on facilitating the initiation and implementation of home exercise in this patient group in clinical nursing care have yet to be explored. The study reported in this thesis was one of the first experimental studies in mainland China to adopt an NCM approach to improving the physical functioning of HD patients by encouraging them to play an active role in engaging in regular exercise at home.

Weekly center-based group exercise training and NCM were the two major components of the intervention that were investigated. The control group received group exercise training only, whereas the intervention group was exposed to both group exercise training and NCM. The NCM framework was formulated on the basis of the features of case management, the HPM, and Painter's exercise guides (Norris et al., 2002; Painter, 1999; Pender et al., 2011). Care coordination and facilitation, home exercise prescription, and exercise behavior support were the main responsibilities of the participating nurse case managers. To achieve positive functional results, they collaborated with the patient and his or her family and healthcare team in developing an individualized home exercise plan. Adherence to that plan was pivotal to the patient achieving the desired functional outcomes. Thus, behavioral support strategies based on the HPM were incorporated into the intervention. The specific behavioral support activities performed by the nurse case managers included patient education, the identification and solution of barriers to exercise by the individual concerned, mutual goal setting, continuous monitoring, and the arrangement of services as needed. Each nurse case manager was the educator, facilitator, and advocate of his or her patients. The overarching aim of the study was to improve the physical functioning of the patients through participation in regular home exercise. The primary NCM mechanism was to encourage the participating HD patients to initiate home exercise and then make gradual progress toward a recommended level at home to achieve functional improvement. Physical functioning was the study's primary outcome, and depressive symptoms, SRH, quality of life, physical activity, and patient-perceived exercise benefits and barriers were the secondary outcomes.

The results of the RCT indicated that such NCM of home exercise for HD patients was promising in enhancing physical functioning, and effective at improving patient-perceived exercise benefits and barriers scores than brief center-based group exercise training. The case management program was able to help the patients maintain the levels of physical activity that they had achieved. At the same time, NCM tends to be effective at reducing depressive symptoms, and achieving better HRQoL. The brief center-based group exercise shows promise for boosting patients' SRH. The flexibility and strength exercise showed beneficial effects on patients' 10-STS performance.

This chapter contains an interpretation of the results presented in Chapter 5 in light of previous literature and the features of the intervention. This is followed by a discussion of NCM as a care delivery approach for behavioral support. The chapter concludes with a description of the generalizability of the findings and a summary.

6.2 Outcomes of NCM on home exercise

The home exercise modality itself has been shown to have a number of advantages. At the system level, exercising at home requires few resources compared with either supervised intradialytic exercise or outpatient rehabilitation. The home-based model is also more cost-effective than supervised rehabilitation (Buker et al., 2014). In mainland China, the cost of rehabilitation after discharge from hospital is not reimbursed by either employers or insurance companies (Wang, Chair, Thompson, & Twin, 2009). The home exercise program reported herein constitutes feasible, and culturally relevant rehabilitation program for Chinese dialysis patients. At the personal level, home-based exercise offers patients the flexibility to select the timing of exercise in accordance with their fatigue levels and alleviates any time and transportation concerns. Home-based exercise is considered an easy way to integrate physical activity into daily life and promote a physically active lifestyle (Geraedts, Zijlstra, Bulstra, Stevens, & Zijlstra, 2013). Previous research has also indicated that patients have higher levels of well-being and less fatigue on non-dialysis days than on dialysis days (Song et al., 2011), which may further facilitate their engagement in exercise at home. In addition, there is evidence that exercising on non-dialysis days produces more health-related benefits than does intradialytic exercise (Konstantinidou et al., 2002).

The findings of the present study suggested that NCM on home exercise is highly promising to improve physical functioning, and shows promise for improving quality of life and alleviating depressive symptoms for patients on maintenance HD treatment. Patients' SRH could be improved through group exercise participation; and NCM intervention did not have extra beneficial effects on improving patients' self-perceived health.

6.2.1 Effects of the program on physical functioning

6.2.1.1 Effects of the program on gait speed

The primary objective of this study was to examine whether a nurse case management program on home exercise training would result in a higher level of physical functioning than controlled care. The statistically significant between-group difference in normal gait speed improvement over time disproves the hypothesis stating that there would be no significant difference in physical functioning between the participants receiving the NCM on home exercise training program and those receiving controlled care. After the 12-week NCM intervention that facilitated regular engagement in home exercise, the intervention group realized greater improvements in normal gait speed than the control group that received six weeks of center-based group exercise training alone.

In experimental studies, a clinically meaningful change, together with the results of hypothesis testing, is imperative for evaluating the value of the findings (Haley & Fragala-Pinkham, 2006). As there was no information on the normal gait speed criteria for identifying a meaningful improvement in the dialysis population (Painter & Marcus, 2013), the cutoff points for the elderly population and non-dialysis-dependent CKD patients were used to interpret the results on the normal gait speed for the HD population in this study. A change of 10 cm/s (equivalent to 0.1 m/s) in normal gait speed was proposed to be clinically meaningful, as such a gain has been shown to be a useful predictor of well-being and all-cause mortality in adults aged 65 and above (Chui, Hood, & Klima, 2012; Hardy, Perera, Roumani, Chandler, & Studenski, 2007; Perera, Mody, Woodman, & Studenski, 2006). In the non-dialysis-dependent adult CKD population, each 10 cm/s decrease in normal gait speed carries an approximately 26% (95% CI: 9-47%) greater risk of mortality (Roshanravan et al., 2012). The magnitude of the predictive power of normal gait speed on the risks of three-year mortality have been identified as greater than that of the estimated glomerular filtration rate (an index of kidney function) and other biomarkers such as Hb and albumin (Roshanravan et al., 2012). It is worth noting that absolute gait speed varies between different ethnic groups (Aoyagi et al., 2001; Auyeung, Lee, Leung, Kwok, & Woo, 2014; Seino et al., 2014). Elderly Chinese tend to walk slower, but the decline of gait speed is more rapid than Western population (Auyeung et al., 2014). Although there is no data on clinically meaningful changes in normal gait speed for the Chinese population, a decrease of 10 cm/s in normal gait speed was adopted as a risk factor to predict adverse events among elderly population in both Western and Asian courtiers (Lo-Ciganic et al., 2015; Matsuzawa et al., 2014; Studenski et al., 2011). Hence, a cutoff value of 10 cm/s was used to interpret such results at both the group and individual levels.

The improvement in normal gait speed realized in this study was not only statistically significant, but also clinically relevant at both the group and individual patient levels. At the group level, patients in the intervention group saw a more pronounced increase in normal gait speed than did those in the control group. Moreover, the intervention group also achieved a significant increase in normal gait speed over time, with a mean change of 12 cm/s from baseline to week 12, suggesting that the improvements were clinically significant. At the individual level, 56.1% of the patients in the intervention group demonstrated an individual change exceeding the clinically meaningful change (10 cm/s), whereas only 28.6% of their counterparts in the control group did so. The between-group difference in the number of patients exhibiting an improvement exceeding the cutoff for a clinically meaningful change in normal gait speed reached statistical significance ($\chi^2 = 8.79$, $p = 0.003$). This finding is consistent with the results of RM-ANOVA showing the intervention group to have achieved greater enhancement in normal gait speed than the control group.

The improvements in physical function achieved through the home exercise approach are in line with previously published data on the effects of other exercise programs for HD patients. For example, the increased walking speed reported by

Headley et al. (2002) and Storer et al. (2005) was achieved through supervised exercise training during dialysis sessions. The gains they documented were similar to those reported here. Headley et al. (2002) conducted a pre-post one-group trial primarily to explore the effects of a 12-week resistance training program delivered during HD sessions based on the results of the 10 HD patients who completed the study. Their normal gait speed increased significantly, from 121.1 cm/s to 131.3 cm/s, following the training. Both the baseline and post-intervention gait speed were similar to those in the current study.

Painter et al. (2000b) reported an improvement in gait speed after patients had completed an eight-week individualized home exercise program followed by an eight-week intradialytic cycling exercise program. Although the intervention patients in the current study's program mainly performed exercises at home on their own, their improvement in normal gait speed (12 cm/s) was greater than the 9 cm/s change in the intervention group reported by Painter et al. (2000b). There was also a discrepancy between the results of the control group in this study and those of Painter et al. (2000b), with a slight, albeit non-significant increase in normal gait speed noted in the former, and a decline in the latter. One possible explanation for this is the relatively higher functional ability of the participants in the current study. The baseline mean normal gait speeds reported in Painter et al. (2000b) was 90.5 ± 25.6 cm/s, compared with 118.8 ± 26.5 cm/s in this study. Previous studies have shown slow normal gait speed to be associated with disability, with a cutoff of 100 cm/s a predictor of mobility disability (Cesari et al., 2005, 2009; Rosano, Newman, Katz, Hirsch, & Kuller, 2008). These results suggest that patients who have a slow gait speed, particularly one below 100 cm/s, and who do not receive any exercise training are likely to suffer from functional deterioration. Painter et al. (2000b) recruited relatively frail patients, and the natural functional decline of those in the control group may have contributed to the observed decrease in normal gait speed. The slight increase observed in the control group in this study, in contrast, could be the result of the provision of brief in-center group exercise training for six weeks.

Even though a non-significant between-group effect was found on the fast gait speed in this study; the changes between the two groups at weeks twelve were greater than that in weeks six. The fast gait speed of the participants increased significantly from 182.9 to 195.9 cm/s, following the NCM interventions. The average improvement of 11 cm/s was still less than that reported in previous studies (Headley et al., 2002; Painter et al., 2000b; Storer et al., 2005). For example, Store et al. (2005) reported a 19% increase (from 164 to 194.2 cm/s, $p = 0.03$) in fast walk velocity in exercise training patients (12 HD patients) after 10 weeks of intradialytic endurance training. The magnitude of the improvement that they reported was greater than that achieved by the home exercise program in this study, with an 8.6% rise in fast gait speed—from 168 to 179 cm/s ($p = 0.005$)—in the intervention group. That greater improvement can be attributed to the high intensity of the endurance exercise training adopted in Store et al. (2005). In that study, the patient-perceived exercise intensity was rated as “very hard” in terms of RPE, whereas an RPE of “somewhat hard” was employed in the present study due to safety concerns.

6.2.1.2 Effects of the program on 10-STS performance

With regard to 10-STS performance, both groups in the current study achieved statistically significant improvements cross the three time points. However, no between-group effect on 10-STS performance was identified. Nevertheless, follow-up analyses revealed that the increase trend in fast gait speed was faster for the intervention than the control group.

Apart from hypothesis testing, researchers recommend analyzing the percentage of patients who exceed the minimal detectable change (MDC) and minimal clinically important difference (MCID) thresholds to gain more insight into interpretations of the results of a study (Haley & Fragala-Pinkham, 2006; Hays & Woolley, 2000; Schmitt & Di Fabio, 2004). The MDC beyond individual variability and measurement error for 10-STS in HD patients is suggested to be 8.4 seconds, an MDC at a 90% CI (MDC_{90}) (Segura-Orti & Martinez-Olmos, 2011). At the individual level, 19.3% of the patients in the intervention group demonstrated an individual change that exceeded the MDC on 10-STS performance, whereas only 8.9% of those in the control group did so. These results imply that a number of participants in both groups failed to improve their 10-STS performance over the study period. There was no significant difference between the groups in the number of patients exhibiting an improvement exceeding MDC_{90} in this assessment ($\chi^2 = 2.50$, $p = 0.114$). The consistency between the RM-ANOVA results and the number of patients showing an increase in their 10-STS score greater than the MDC implies that the possibility of a chance variation or random measurement error cannot be excluded, and the findings cannot be interpreted as clinically relevant improvements. As there is no information on the MCID of the 10-STS in the HD population, no interpretation can be made of whether the improvement in lower extremity strength was meaningful by either the patients themselves or their healthcare providers.

Changes in functional performance are sensitive to the starting function level, with highly functional individuals having limited room for improvement (Prodoehl et al., 2015). A previous study documented a nonlinear relationship between leg strength and STS performance until leg strength fell below a certain level, after which the corresponding relationship became linear (Ferrucci et al., 1997). It is possible for patients with a high degree of physical functioning to fall into the "plateau region" of the relationship between the time required to complete the 10-STS and leg strength. In addition to muscle strength, such psychological factors as mood are also known to be associated with STS performance (Lord, Murray, Chapman, Munro, & Tiedemann, 2002). Approximately one-quarter of all participating patients had a baseline 10-STS performance exceeding age-predicted values, according to the prediction equations developed by Csuka and McCarty (1985). Thus, the small mean change in 10-STS performance in this study could be the result of the heterogeneity of the study participants in terms of functional ability and psychological status during data collection.

Although the improvement in 10-STS performance did not exceed the MDC for this test, the mean decrease of 5.8 seconds in 10-STS completion in the intervention group was greater than that in previous studies, where decreases ranging from 2.5 to 5.4 seconds were recorded (Headley et al., 2002; Painter et al., 2000b; Segura-Orti et al., 2009; van Vilsteren et al., 2005). The performance achievement in this study was closest to that in Segura-Orti (2009), who reported a 5.4-second enhancement in 10-STS performance after patients had received 24 weeks of supervised resistance training during dialysis sessions, suggesting that the NCM of home exercise supplemented with six weeks of in-center group exercise training can achieve comparable gains to a six-month supervised intradialytic resistance exercise program.

The enhanced STS performance in the control group is most likely due to the provision of weekly center-based group exercise training. Previous studies have revealed that flexibility and/or strength exercises can effectively increase STS performance (Bates et al., 2009; Bird, Hill, Ball, & Williams, 2009). In a study with a pre-test/post-test design, Bate et al. (2009) observed an improvement in STS-30 performance in elderly adults who had participated in a 10-week strength exercise program offered weekly in the community, suggesting that weekly exercise is sufficient to improve STS performance. In the current study, the control group patients were provided with both flexibility and strength exercise training in weekly center-based group exercise sessions for six consecutive weeks, which can also be considered sufficient.

STS ability is essential for daily activities, and clinical interventions that improve the STS performance of patients are meaningful for clinical practice, the patients themselves, and their families. STS ability, as reflected by lower limb strength and muscle power (Bohannon, 1995), has been shown to be a predictor of falls and the ability to perform daily activities in the elderly population (Buatois et al., 2008; Wilson et al., 2011; Zhang, Ferrucci et al., 2013). Thus, the improvement in the ability to perform daily activities that was observed in the current study can be interpreted as meaningful for the HD patients in helping them to maintain their functional ability and lead independent lives.

Based on currently available data and evidence on normal and fast gait speed, as well as 10-STS performance, it is not possible to infer whether the gains in physical functioning achieved by the current program are clinically significant for HD patients, but we can at least conclude that the program helps such performance to remain stable over time. Painter (2008) posited that a minimal or even no change in physical functioning can be considered a positive outcome for the CKD population, as the natural course of the disease leads to progressive deterioration, and by this measure the program was clearly a success.

Evidence indicated that physical functioning improvement occurs over a course of at least three months of exercise training for hemodialysis patients (Cheema & Singh, 2005; Heiwe & Jacobson, 2011). The duration of the intervention of the current program was three months; while home exercise prescriptions were made progressively. Participants exercised at relatively low dosages at the beginning to increase their self-confidence in performing exercise at home; and to progress gradually to minimum exercise goals. By the end of the program, only 47.4% of the patients in the intervention group had achieved or exceeded the recommended goal of engaging in 90 or more minutes of aerobic exercise per week. The finding suggests that over half of participants exercise at a dose lower than the recommended level throughout the 3-month study period. Therefore, it is possible that the NCM intervention was not long enough to facilitate patients to maintain the recommended exercise level for over three months to bring out the beneficial effects.

Importantly for our purposes, the current program results in a significantly more pronounced improvement in normal gait speed; and faster increase trends in both fast gait speed and 10-STS performance for the intervention group than the control group. The findings indicated that if the NCM interventions were maintained for a longer duration, or patients maintained or progressed in their home exercise behavior after the withdrawal of the intervention, the effects on physical functioning could be more promising.

6.2.3 Effects of the program on health-related quality of life

A significant between-group effect was found in the subscale score for "Symptoms and Problems list"; but not in other domains of the KDQOL-36^{TM}. Thus, the null hypothesis stating that there would be no difference in quality of life between those participants receiving the NCM of the home exercise training program and those receiving controlled care cannot be fully rejected.

The improvements in patients' perception of symptoms and problems of the kidney disease could be attributed to two factors. First, exercise has been shown to be effective in alleviating dialysis-related symptoms such as fatigue and sleep disturbance (Afshar, Emany, Saremi, Shavandi, & Sanavi, 2011; Chang, Cheng, Lin, Gau, & Chao, 2010; Cho & Song, 2014; Malagoni et al., 2008; Maniam et al., 2014). The results indicate that NCM effectively helped the patients to regularly engage in home exercise and led to gradual improvements in their dialysis-related symptoms. Second, during the individualized nurse-patient interviews the patients in the intervention group were encouraged to discuss the potential barriers that they faced to engaging in exercise. The barriers that were identified included clinical problems such as hypertension and diabetes-related hypoglycemia. Appropriate referrals were then made by the case managers. As a result, the patients' perceptions of the severity these symptoms and of the barriers to exercise improved.

Non-significant between-group, but significant within-group differences on other two kidney disease-specific domains of the KDQOL-36^{TM} were noted in the intervention group. The significant improvements in quality of life observed in the intervention group over time suggest that except for symptoms alleviation, the NCM on home exercise program ~~has~~ may have positive effects on patients' perception of

EKD and BKD. These improvements could be attributable to several factors. First, the success of NCM in helping patients to integrate home exercise into their daily lives provided patients with better perceptions of the EKD. The items in the EKD subscale describe an individual's perception of being bothered by kidney disease in their daily life, for example, by the concomitant fluid and dietary restrictions, inability to travel, dependency on doctors and other medical staff, stress and worry, poor sex life, and worsened personal appearance (Schatell & Witten 2012). Engaging in regular exercise helps patients to restore their functional ability, which subsequently enables them to actively participate in outdoor activities and interact with others, in turn reducing the stresses and worries caused by kidney disease. Second, the nurse case managers provided structured follow-ups of the patients' progress in the exercises and in their physical and psychological status. During each contact, they discussed with the patients the exercise goals that could actually be accomplished. Such discussions can be helpful for patients living with disease and lifestyle changes, and may contribute to perceptions of an improvement in their burden and in their EKD (Carmichael, Popoola, John, Stevens, & Carmichael, 2000). Frequent contacts between case managers and patients may also have psychologically favorable effects, further resulting in improvements in the patients' overall perceptions of BKD.

The improvements in the kidney disease-specific domains of HRQoL that were observed in this study are in agreement with the findings of Wu, He et al. (2014), who reported an increase in most of the disease-specific domains of the KDQOL after a 12-week supervised intradialytic cycling training program. A slight but not significant increase in the sub-score for the BKD was reported in Tawney et al.

(2000), in which HD patients in the intervention group were provided with physical activity-based counseling during dialysis sessions. In contrast, no increases in the disease-specific domains of the KDQOL were reported in a study examining a five-month intradialytic supervised training program combining aerobic and resistance exercise (Parsons, Toffelmire, & King-VanVlack, 2006). Similarly, a recently published study exploring the differing effects of aerobic exercise and resistance exercise revealed no effect on the disease-specific domains of HRQoL (de Lima et al., 2013).

There are also conflicting findings on the effects of exercise programs for HD patients on the generic domains of quality of life. There were no significant differences over time in these domains for either group in this study, although clear benefits in terms of objective physical performance were seen in the intervention group. The contradictory findings on self-reported physical health and objective functional results could be due to sensitivity of the measurement tools. It is suggested that physical performance tests could detect functional deficits for asymptomatic individuals who reported functioning well (Blake & O'Meara, 2004). Consistently, several previous studies observed no concomitant change in generic quality of life and objective functional data. DePaul et al. (2002) reported a negative finding on both the PCS and MCS of the SF-36 after a 12-week aerobic and resistance training program delivered during dialysis sessions, even though they found large and statistically favorable effects on the sub-maximal exercise test and muscle strength in the experimental group. Segura-Orti et al. (2009) reported similar results, with no significant change over time noted for either PCS or MCS between an intervention group provided with resistance training during dialysis sessions and a control group performing low-intensity aerobic exercise, although the former saw a significant enhancement in STS and 6-MWT performance. In contrast, Painter et al. (2000b) reported a significant increase in the PCS score (35.1 to 38.3, $p < 0.001$) of the SF-36 after a combined program comprising eight weeks of intradialytic cycling and eight weeks of home exercise, although no significant improvement was seen in the MCS domain compared with a control group that received no exercise training. An improvement in the physical but not mental domain of quality of life measures was also documented in other studies exploring the effects of different exercise programs on HD patients (Cheema et al., 2007; Chen et al., 2010; Koh et al., 2009; Molsted et al., 2004; Ouzouni et al., 2009; van Vilsteren et al., 2005), whereas others found improvements in both mental and physical health following short-term exercise training (Levendoglu et al., 2004; Matsumoto et al., 2007; Song & Sohng, 2012; Suh et al., 2002).

The mixed HRQoL findings in studies on the benefits of exercise for dialysis patients could be due to variations in the exercise interventions. Both Tawney et al. (2000) and the present study provided exercise information and counseling, and psychological counseling has been shown to help patients improve their perception of the burden or effects of their disease (Carmichael et al., 2000). Another possible explanation is diverse participant characteristics, particularly baseline variations in functional ability. Painter et al. (2000b) reported greater functional achievements from an exercise training program for low-functioning HD patients than for their high-functioning counterparts, suggesting that improvements in objective physical performance have a more pronounced effect on perceived quality of life for the most disabled patients. To explore whether patients with poorer physical functioning experienced a greater improvement in self-reported physical health in this study, a subgroup analysis was performed on low-functioning patients with a baseline PCS score below the 75th percentile. However, no significant difference in PCS scores at week 12 was found between the two groups of low-functioning patients (intervention and control). Accordingly, it cannot be concluded that the documented non-significant increase in the PCS score was the result of including few patients with poor physical functioning. However, because only 28 patients (24.8%) had a PCS score below the 75th percentile, the negative result could have been due to the small sample size and underpowered statistical analysis. In fact, two previous studies documented a positive HRQoL for patients who reported high baseline PCS scores (46.6 and 46.5, respectively) (Dobsak et al., 2012; Molsted et al., 2004). Therefore, variations in baseline functional ability cannot account for the conflicting HRQoL findings for different exercise programs in the HD population.

Another potential reason for the discrepancy could be the diverse exercise dosages adopted in different programs. Currently, there is no recommended exercise regimen available for HD patients, and the aforementioned studies employed different exercise durations, intensities, and modalities. In addition, the methodological quality of these studies varied greatly, which is a further possible cause of the conflicting findings. In sum, the effects of exercise training on the HRQoL of HD patients remain inconclusive. The evidence presented herein indicates that home exercise delivered through the NCM approach does have a positive impact on the HRQoL of such patients. These results are encouraging, but a firm conclusion awaits further high-quality experimental studies with HRQoL as the primary outcome.

6.2.4 Effects of the program on self-rated health

In the current study, both patient groups reported improved SRH after the 12-week intervention, with no difference observed between them. This finding thus supports the null hypothesis of no difference in SRH between participants receiving the nurse-led home exercise training program and those receiving controlled care. One possible interpretation is that the SRH finding stems from the participation in group exercise. During the group exercise training sessions, all of the patients had opportunities to communicate with one another and compare their exercise performance with that of their less healthy peers. Such interactions may have caused the patients to change the value that they placed on health by redefining what health really is or readjusting their internal criteria of how it is rated (Arnadottir, Gunnarsdottir, Stenlund, & Lundin-Olsson, 2011), thus adopting a more positive attitude toward their own health, resulting in good SRH. Moreover, both exercise and total physical activity from all domains of life have been shown to be associated with good SRH (Sodergren et al., 2008). Even non-reported physical activity such as that involved in carrying out domestic duties may contribute to enhanced SRH (Vestergaard, Kronborg, & Puggaard, 2008). Although higher levels of physical activity were found in the intervention group as compared to the control group, non-leisure time and occupational physical activity were not measured. These non-measured activities could be one of the reasons for the improved SRH.

As SRH has different meanings for different individuals, interpretations of mean SRH differences need to be made with caution (Schuz, Wurm, Scholgen, & Tesch-Romer, 2011). A previous study indicated that the overall health rating principally reflects the physical domain of health (Onajia, Bignami, Rossier, & Zunzunegui, 2013). As noted, no significant improvements in self-reported physical health were found, even though an increase in normal gait speed was documented. Therefore, no between-group effects on SRH in this study are possibly due to the program effects on SRH being undetected. Nevertheless, given the known relationship between SRH and a diverse range of health outcomes, it can be speculated that the positive finding documented in the present study shows that improved SRH for both groups is beneficial to decreasing the functional decline, mortality, hospitalization, and mortality associated with ESRD and its treatment.

6.2.5 Effects of the program on depressive symptoms

No significant between-group effect on depressive symptoms was noted during the study period. Thus, the null hypothesis predicting that there would be no difference in depressive symptoms between those participants who received the NCM home exercise training program and those who received controlled care cannot be rejected.

The non-significant effects on depressive symptoms observed in this study are in agreement with the findings of previous studies, where exercise training was provided for two to four months. For example, Suh et al. (2002) observed a non-significant trend, as indicated by a reduced BDI score after a 12-week intradialytic cycling program, although it is worth pointing out that only 14 patients completed the program. No significant changes were noted in depression scores measured by a 20-item self-rated depression scale in an RCT examining the effects of a 12-week intradialytic cycling program combined with a pre-dialysis resistance training program (van Vilsteren et al., 2005).

The negative findings on depressive symptoms in this study conflicts with several exercise studies for HD patients. For example, Ouzouni et al. (2009) documented a significant (39.4%) mean decrease in BDI scores in a trial examining the effects of a 10-month exercise training program during HD sessions relative to a group without exercise training. Moreover, positive findings were reported by a non-randomized control trial in which the researchers observed an improvement in depressive symptoms, as indicated by a 35% reduction in BDI scores, after a one-year intradialytic exercise training program for HD patients (Kouidi et al., 2010).

These inconsistent findings may be the result of the different exercise dosages adopted in exercise programs. Mitrou et al. (2013) suggested that there could be a threshold for the dosage of exercise required for a psychological benefit to occur for renal patients. Thus, the exercise dosage for patients in this study may not reach the potential threshold. Meanwhile, different assessment tools adopted in the studies to assess depressive symptoms could provide different interpretations. It is possible that the observed improvement in mean BDI scores may stem from the items that measured such somatic symptoms as tiredness or fatigue and changes in sleep patterns, which it has been suggested would improve after participation in exercise programs (Afshar et al., 2011; Chang et al., 2010; Cho & Sohng, 2014; Malagoni et al., 2008; Maniam et al., 2014).

It is worth noting that a within-group difference in BDI scores was observed in the intervention group alone. The 12-week home exercise program did lead to a 27.2% reduction in the level of depressive symptoms in the intervention group. It has been suggested that there is a bi-directional relationship between depressive symptoms and functional ability (McKnight & Kashdan, 2009), indicating that the improved physical function may lead to an alleviation of depression, or vice versa. The non-significant between group effects but significant within-group effects on depressive symptoms in the intervention group are consistent with the findings on fast gait speed and 10-STS performance. Thus, the NCM on home exercise with a longer duration of the interventions could be promising at improving depressive symptoms for HD patients.

As the BDI scores of the participants ranged from 0 to 54, it means that both patients with no depressive symptoms and those with severe depressive symptoms were included in the study. Thus, the program's effects on managing depression cannot be determined and is beyond the scope of this thesis. Concerning the beneficial effects of home exercise on the patients' perceptions of their depressive symptoms, however, the results are encouraging. It would be desirable in future to target patients who have been diagnosed with depression to elucidate the program's effects on that population.

6.3 NCM as the platform for behavior support

This RCT differed from previous studies on exercise among the HD population by introducing the NCM approach and integrating an exercise intervention with regular behavioral support. While the NCM approach has been shown to enhance adherence by patients with chronic diseases (Sutherland & Hayter, 2009), previous studies have indicated that behavioral support is necessary to achieve patient adherence to home exercise with limited supervision (Courneya, 2010; Latham et al., 2014). The higher levels of physical activity achieved by the intervention group relative to the control group implies the effectiveness of NCM in providing behavioral support for home exercise training programs.

The results show that the duration of engagement in weekly exercise in the intervention group remained unchanged from week 6 to week 12, whereas it decreased in the control group. A significant difference between the two groups in the total weekly duration of engagement in aerobic exercise was observed at week 12 but not at week 6. Thus, the null hypothesis stating that there would be no difference in physical activity levels between participants who received the NCM on a home exercise training program and those who received controlled care cannot be fully rejected. Weekly center-based group exercise training was offered to all participants in the first six weeks, with such training withdrawn from the control group after week 6. In contrast, the intervention group was provided with the NCM in addition to the group exercise training, and took part in the NCM for the entire 12-week period. All patients were motivated to increase their activity levels through participating in group exercises in the first six weeks, contributing to the non-significant between-group difference in exercise duration at week 6. However, it is well recognized that a newly acquired behavior often diminishes over time when an intervention is withdrawn (Artinian et al., 2010). After the group exercise training was removed from the control group participants, their passion for being active may gradually have diminished, as indicated by a significant decrease in their exercise duration over time. However, professional guidance and ongoing support have been shown to be effective at encouraging engagement in physical activity (Foster et al., 2005). Patients in the intervention group received ongoing support and encouragement in follow-ups, which was likely beneficial in helping them to maintain their newly established healthy behavior. The positive effects of NCM in facilitating home exercise behavior are in agreement with the evidence reported in a systematic review (Viswanathan et al., 2012), which identified case management with behavioral support as an effective intervention for improving patients' adherence to exercise.

In this study, NCM interventions targeted the multiple factors that affect patients' adherence to exercise. Kammerer et al. (2007) suggested that all possible barriers to adherence should be considered to improve a patient's ability to follow a treatment regimen and that the intervention needs to encompass patient, care provider, and healthcare system factors. The World Health Organization (2004) also advocates improving adherence by evaluating the individual barriers to adherence and designing interventions with multiple components targeting different levels. Therefore, identifying barriers and solving problems, negotiating exercise plans, and ongoing professional support were the components that were embedded in the NCM approach to help patients adhere to home exercise.

6.3.1 Identifying barriers and solving problems

Incorporating solutions to exercise barriers in the design of the intervention underscores the importance of understanding factors related to the individual that impede that individual's participation in regular exercise. The patients' perceptions of the barriers to their engaging in exercise were managed directly by negotiating coping plans with the patients, and indirectly by enhancing their self-efficacy. Nurse case managers explored possible solutions to the barriers cited by the patients, and together they reached agreement on a corresponding action plan. Perceived self-efficacy has a known impact on perceived barriers to action, with a higher level of self-efficacy resulting in a reduction in such perceptions (Pender et al., 2011). The nurse case managers used a number of approaches to enhance the patients' self-efficacy, including discussing positive experiences of participating in home exercises and providing feedback on the patients' exercise performance in accordance with exercise goals, based on regular monitoring and check-ups. The identification and management of barriers were implemented through the development of coping plans. Patients were asked to describe scenarios in which they were impeded from performing home exercises and to develop one or more corresponding plans to cope with those impediments. Luszczynska, Schwarzer, Lippke, and Mazurkiewicz (2011) demonstrated that an individual's perceived self-efficacy acts as a moderator in the relationship between planned interventions and physical activity behavior. Although perceived self-efficacy was not defined as an outcome variable in the current study, it was regarded as a variable that facilitates the management of exercise barriers.

Referrals to suitable healthcare providers were made when a barrier that was identified, such as Bp fluctuations, could not be handled by the nurse case managers or patients themselves. The role of the case managers was to assist the patients in seeking follow-up services and coordinating those services. For example, if a patient experienced symptomatic hypertension that impeded participation in exercise, the designated case manager discussed ways of managing blood pressure problems with the physician in charge, and then coordinated with the inpatient renal department if inpatient services were needed. Further referrals to other medical departments were made by physicians if needed. The case managers also kept in close contact with physicians to facilitate and monitor the implementation of the care plan. To ensure better utilization of health insurance, the nurse case managers held discussions with a nurse who was familiar with health care reimbursements to help patients to determine feasible and cost-saving ways of obtaining the required medications. In China, there is an upper limit on health insurance reimbursements of the costs related to dialysis treatments. In Nanjing, the city in which the study was carried out, that limit is RMB12,000 (US$1,929) per patient per year for medical examinations and medications and RMB63,000 (US$10,125) for actual dialysis treatments. Common drugs are cheaper in community hospitals than in tertiary hospitals because the percentage of reimbursement is higher for medications purchased in the former than in the latter (Nanjing Municipal Human Resources and Social Security Bureau, 2013). The efficacious use of medical insurance enables patients to obtain sufficient medications to manage their disease and to treat related complications, such as anemia and hypertension. This, in turn, can help to alleviate such symptoms as fatigue and headache, which are commonly cited barriers to exercise engagement by HD patients.

A significant between-group effect on DPEBBS scores indicates that NCM is effective at raising patients' awareness of the benefits of exercise and reducing their perceptions of the barriers to engaging in exercise. It is worth noting that being aware of exercise benefits alone is not enough to prompt an individual to actually engage in exercise (Dishman et al., 1985). Delgado and Johansen (2012) found that although the majority (98%) of HD patients in their study understood the benefits of exercise, a large proportion still led sedentary lives, with only 46% walking or engaging in light leisure activities for more than 30 minutes per week. Reges et al. (2013) recently reported the limited effects of belief in the benefits of exercise on an active lifestyle. In their study, patients with a strong perception of such benefits tended to participate in the rehabilitation program, but did not necessarily engage in exercise on their own. Based on the current findings on DPEBBS scores, it is impossible to determine the relationships among patients' perceived exercise benefits, perceived barriers to exercise, and physical activity level.

6.3. 2 Negotiating exercise plans

Exercise is a personal health behavior, over which the individual should have personal control (Simons-Morton, 2013). Kutner, Zhang, McClellan, and Cole (2002) documented an association between patients' perceptions of control over their future health and their adherence behavior, suggesting the importance of patient involvement in the design of treatment regimens. In this study, the nurse case managers drew upon their existing relationships with patients to negotiate exercise goals and plans with them, rather than forcing the patients to comply with their orders. Approaching 80% of the negotiated home exercise goals were achieved during the study. It proved to be possible to use this negotiated approach to individually address the patients' physical and psychological barriers to exercising, and subsequently to improve their physical and overall well-being. These findings are in accordance with those of previous experimental studies showing that negotiated care and active patient involvement in treatment regimens are effective in improving adherence behavior (Cooper et al., 2011; Quan et al., 2006; Wilson et al., 2010). In a study of adherence behavior among HD patients, Cvengros et al. (2004) revealed a lower degree of patient-perceived control to be associated with poor adherence. Qualitative findings have consistently shown that the failure of patients to comply with a treatment regimen stems from disagreements between them and their healthcare providers on the goals and strategies of treatment (Tovazzi & Mazzoni, 2012).

To achieve the desired level of adherence to a treatment plan, it is important to ensure that the treatment goals and plans are in accordance with what is possible for patients (Leonard & Miller, 2012; Mok et al., 2013). By collaborating with the patient and his or her caregiver, the case manager gains insights into the former's habits, lifestyle, and particular barriers to initiating and maintaining exercise at home. In this study, based on the initial assessment of the patients' overall condition and the barriers that were identified to exercising at home, the case managers further communicated with physicians and nurses to assist patients in accessing services as needed. Each patient's individualized exercise plan was therefore determined not only by his or her functional needs, but also by his or her psychosocial and financial circumstances. Patients were encouraged to choose their preferred form of aerobic exercise, such as walking, brisk walking, jogging, or cycling. Their exercise goals and plans were then negotiated based on the patient's physical condition, self-efficacy, exercise capacity, and level of family support in both financial and psychological terms.

6.3. 3 Ongoing professional support

Implementation of the negotiated exercise plans and patient safety were closely monitored, and encouragement was provided during each proactive follow-up session. Individualized attention and an ongoing relationship between patient and nurse are known to facilitate adherence behavior (Kutner, 2001; Sabate, 2003). Regular assessments of the knowledge and motivation of patients are needed to elicit behavioral change (Jaarsma, Nikolova-Simons, & van der Wal, 2012). As misunderstandings of treatment plans and a lack of skills to execute the behavior in question have been shown to be related to adherence behavior (Riegel et al., 2006), the case managers in this study reviewed and updated the exercise plans as the patients progressed. If a patient was unable to achieve the targets of the pre-established exercise plan, the case manager explored the potential reasons for this failure and provided encouragement to help him or her regain the confidence necessary to try again. The patients' understanding of the home exercise plans and their exercise skills were revaluated during each interaction, with information provided and specific exercise skills reinforced as needed. Such symptoms as fatigue and shortness of breath were frequently cited barriers to participating in exercise at home, which is consistent with previous reports (Delgado & Johansen, 2012; Zheng et al., 2010). As noted, the case managers addressed the services that patients needed, based on the symptoms that were identified as impeding their engagement in exercise, by collaborating with the physician and nurse in charge. Such symptoms as hypotension-related dizziness were also taken into consideration when the physician prescribed patients' dialysis dose during treatment sessions and made adjustments to medications. The case managers also held discussions with clinical nurses to better understand the patients' dietary and fluid restrictions to help the patients address symptoms such as shortness of breath. Exercise is a promising way of reducing symptoms such as sleep disturbance and fatigue in HD patients (Maniam et al., 2014), and the case managers discussed with patients the benefits of engaging in exercise in a sustained manner in terms of alleviating symptoms. Moreover, social support influences a patient's intention to initiate and maintain physical activity (Riegel et al., 2006). Thus, the case managers collaborated on an ongoing basis with their patients' caregivers to increase the level of support that the patients were receiving and decrease overprotection. Any changes in plan were negotiated with a patient based on information from all parties, including physicians, nurses, and family members.

In conclusion, NCM providing various behavioral supports is effective at facilitating the adherence of patients to home exercise. The present findings echo previous recommendations for encouraging changes in physical activity behavior, in which multi-component strategies for improving adherence were advocated (Artinian et al., 2010; Foster et al., 2005; Miller, Hill, Kottke, & Ockene, 1997). For example, the American Heart Association recommends a combination of at least two cognitive-behavior strategies such as motivational interviewing, goal setting, self-monitoring, follow-up, and increasing self-efficacy in counseling interventions aimed at promoting dietary and physical activity changes (Artinian et al., 2010). The evidence from a Cochrane review of effective strategies for promoting physical activity in community-dwelling adults indicates that interventions incorporating professional guidance, self-direction, and ongoing professional support are likely to boost both self-reported physical activity and measured physical fitness (Foster et al., 2005). In the chronically ill population, interventions combining goal setting, contracting, feedback, self-monitoring, and/or prompts have been found to be related to changes in physical activity behavior (Conn, Hafdahl, Brown, & Brown, 2008). It is worth noting that the present findings suggest that NCM is successful at addressing patients' perceptions of the barriers to engaging in exercise. However, whether alleviating these perceived barriers directly contributed to increased levels of physical activity remains inconclusive.

6.4 Nurses as appropriate agents for delivering exercise programs

In this study, expanding the clinical responsibilities of nurses to include empowering patients to engage in home exercise under the NCM practice framework was shown to be effective at facilitating patients' home exercise engagement. Nursing science could, by its nature, play a pivotal role in the success of the current program. First, nursing is guided by a humanistic philosophy and focuses on the holistic needs of patients rather than solely on their diseases (Cumbie et al., 2004). The professional experience of nurses enables them to explore with patients potential barriers to exercise from different perspectives. Second, a relationship of trust established between the nurse case manager and the patient though sustained contacts enables open communication to take place, which permits mutual exploration of the factors that actually or potentially influence adherence. Importantly, individualized attention and an ongoing relationship between the patient and the nurse are known to facilitate adherence behavior (Kutner, 2001; Sabate, 2003). Third, exercise is a personal health behavior, over which the individual should have personal control (Simons-Morton, 2013). In this study, the nurse case managers drew upon their existing relationships with the patients to negotiate exercise goals and plans with them, rather than coercing the patients to comply with their advice. The results corroborated those of previous studies that showed negotiated care and active patient involvement in treatment regimens to be effective at improving adherence behavior (Cooper et al., 2011; Quan et al., 2006; Wilson et al., 2010).

This study also adds important insights to the current discussion on the possibility of implementing exercise programs in the clinical settings. Nurses are able to fill the treatment gap between scientific evidence and clinical practice in dialysis units. A recent qualitative study identified varying levels of confidence among dialysis care providers in recommending physical activity owing to limited resources, such as a lack of information pamphlets or standardized protocols (Painter et al., 2014). These providers felt uncomfortable talking with patients about this topic without standardized procedures or information. They believed that non-standardized care was not supported by the organization, and was possibly even unsafe, and thus implementing it posed a potential risk to their professional development. To boost the confidence of nurses in providing exercise recommendations and counseling, before commencing this study a structured training program and standard exercise protocols were provided to the nurses in this study with the support of both the dialysis units and head nurses. The findings of this study indicate that structured training is required for clinical nurses to competently implement exercise programs for HD patients.

6.5 The link between conceptual framework and the findings

The current program implies that nurses worked as case managers were capable of delivering behavior support interventions and prescribing individualized exercise regimens; which subsequently resulted in improving trends on a variety of health outcomes for patients on HD treatment. In order to properly interpret the findings, it is important to align the results with the conceptual framework of the study.

The development of the trial incorporating the behavior support interventions into a home exercise trial. Six cognitive and affect variables in the Pender's HPM that are modifiable through nursing intervention were used to guide the development of the behavior support strategies, as noted in Figure 2.1. Nurse case managers prescribed home exercise regimens, and developed mutual goals with patients according to the Painter's exercise guides for dialysis patients. It was hypothesized that NCM can help patients to adhere to home exercise behavior at a recommended level as indicated by Painter's exercise guides to achieve improvements in health outcome. The findings indicate that NCM act as a platform to deliver a combination of behavior support intervention and home exercise prescription is effective to improve physical activity levels. The improved home exercise engagement is highly promising to improve physical functioning, quality of life and depressive symptoms; if the program was provided with a longer duration or the patients maintained the home exercise after withdrawal of the NCM interventions.

However, the relationships between Pender's HPM and the home exercise behavior were underdetermined; even though higher levels of physical activity were reported from the patients in the intervention group as compared to the control group. DPEBBS and patients' adherence to mutually agreed exercise goals, being corresponding to perceived benefits of action, perceived barriers to action, and commitment to a plan of action in the Pender's HPM, were evaluated as outcome measures in this study. A significant between-group difference was found in DPEBBS scores; and approximately 80% mutually agreed home exercise goals were achieved throughout the whole study process. The results indicated that NCM was able to increase patient-perceived exercise benefits and reduce perceived barriers to exercise, and facilitate patients' home exercise behavior. Three other cognitive variables: perceived self-efficacy, activity-related affect, and interpersonal influence, were not measured, although they were specified into actions and activities of the NCM intervention. Therefore, the relationships between the intervention components that derived from Pender's HPM and the improved physical activity levels are unknown.

6.6 The role of aerobic exercises

Apart from the relationships between the intervention elements and outcomes, the role of aerobic exercise in this study should be highlighted. The NCM intervention on comprehensive home exercise is considered a core component that differentiated the exercise therapy between the two trial groups. As noted, individualized home exercise prescription for the intervention group comprised aerobic, strength, and flexibility exercises. On the other hand, although the brief group exercise training was made available for all participants; patients in the control group were exposed to strength and flexibility exercise only.

Because patients on HD treatment suffer from progressive loss of muscle strength, a combined prescription of aerobic and strength exercise was recommended for this patient group (Heiwe & Jacobson, 2014). Based on the current findings, it is unable to determine whether the encouraging functional improvements were attributable to patients' engagement of the comprehensive exercise program or aerobic exercise only. As noted, the program effects derived from a combination of the intervention comprising both behavior support interventions and a comprehensive home exercise prescription. Whether patients' engagement in aerobic exercise under the NCM can achieve the encouraging health outcomes is beyond the scope of this thesis.

It is worth noting that patients in the intervention group reported longer weekly duration of aerobic exercise and more patients exceeded the recommended level of aerobic exercise as compared with patients in the control group. Thus, the effects of a NCM on home-based aerobic exercise are considered promising.

6.7 Knowledge generated from the current study

The findings of this study add to the knowledge base on exercise training for HD patients in four important ways. First, NCM combining behavior support intervention and home exercise prescription is able to assist HD patients to restore or maintain physical functioning. This claim is grounded in the fact that the improvements in normal gait speed exceeded the levels suggested in prior research for indicating meaningful change (Headley et al., 2002; Painter et al., 2000b; Segura-Orti et al., 2009; Storer et al., 2005; van Vilsteren et al., 2005); and the increase trends in both fast gait speed and 10-STS performance. Second, the findings show that home exercise is safe for stable HD patients if ongoing monitoring is provided. There was no adverse event reported throughout the program implementation period. Third, the trained clinical nurses were found to be capable of expanding their roles to deliver home exercise intervention during daily clinical practice with support from other healthcare providers, the patients' caregivers, and the research team. This was indicated by the improvements that were observed in a number of outcome variables, such as normal gait speed, quality of life, and physical activity levels. Finally, and most importantly, the program was well-received by the participants, as indicated by the dropout rate of just 5.3%.

6.8 Generalizability of the findings of the study

RCTs are regarded as the most reliable research method for comparing interventions and determining their effects, owing to their potential to optimize internal validity. However, the most commonly cited criticism of RCT designs is their limited external validity (Feinstein & Horwitz, 1997; Rothwell, 2005). In the realm of clinical research, maximizing the external validity of RCTs whenever possible is recommended to bridge the gap between research and real-world practice (Del Boca & Darkes, 2007). The external validity of the current study is elaborated upon in the following paragraphs.

6.8.1 Patient engagement

One hundred and eighty-nine of the 466 HD patients assessed for eligibility during the study period met the criteria for inclusion in this study, accounting for 59.4% of those who were approached. Seventy-six eligible patients declined to participate, resulting in a 59.8% participation rate among eligible patients, which is comparable to the 43.5-62.8% reported in previous studies investigating the effects of exercise programs in the HD population (Cheema et al., 2007; Chen et al., 2010; Orcy et al., 2012; Reboredo et al., 2010; Segura-Orti et al., 2009). The relatively high participation rate suggests that the program was acceptable to patients. One hundred and thirteen patients were actually randomized into either the intervention or control condition, yielding an overall participation rate of 24.2%, which is similar to the 20% reported by Chen et al. (2010), but slightly lower than the 32.5-45.8% reported in other studies (Cheema et al., 2007; Orcy et al., 2012; Segura-Orti et al., 2009; Reboredo et al., 2010). A possible reason for the relatively low overall participation rate was the study's stringent exclusion criteria, which were adopted to address safety concerns over the home exercise approach. Because participants were required to engage in home exercise without onsite supervision, only stable HD patients judged by physicians to be capable of safely performing exercises alone at home were deemed eligible.

6.8.2 Program adherence

The attendance rate of the in-center group exercise training was 82.7% for all participants, which is comparable to the 75-88% reported in other studies on exercise training programs (Koh et al., 2010; Reboredo et al., 2010; Storer et al., 2005). The adherence rate in the current study was slightly lower than the 88% reported by

Storer et al. (2005) in their study of supervised intradialytic endurance exercise. The adherence rate in that study was calculated by the number of training days actually attended by the patients divided by the total number offered over the 10-week study period. In another supervised exercise training program offered during dialysis sessions three times per week for 12 weeks, an adherence rate of 81.4% was reported (Reboredo et al., 2010), whereas a lower attendance rate (75%) was reported in a study evaluating the effects of intradialytic exercise over a six-month period (Koh et al., 2010). The slightly lower adherence rates in those two studies relative to the present study suggest that the duration of the intervention period could be a potentially influential factor in adherence behavior. Unlike previous studies, in which exercise training was provided during dialysis sessions, the patients in the current study were required to engaged in supervised exercise before their dialysis sessions, and thus had to arrive at the dialysis centers 30 minutes before treatment. The relatively high attendance rate therefore implies that the center-based group exercise training was well-received.

6.8.3 Adverse events

In the literature on cardiac rehabilitation, the safety of exercise training has been related to the selection of participants, the type and intensity of the training, and the availability of monitoring (Fletcher et al., 2001). The home exercise program adopted in this study, which was translated from Painter's (1999) booklet and comprises flexibility, strength, and aerobic exercises, was safe and well-tolerated by the patients in the intervention group. Exercise was prescribed individually in accordance with the patient's capacity for exercise, and the dosage was gradually increased. Patients in an unstable condition were excluded from participating. Nurse case managers conducted regular follow-ups to monitor the patients' condition and adjust their exercise dosage, and to ensure safety. Patients were advised to gradually increase their home exercise dosage by adjusting the duration, frequency, or intensity of the exercises that they performed. No adverse events occurred among the patients allocated to the intervention group, although one patient in the control group experienced atrial fibrillation. A possible explanation for the latter could be the inappropriate progression of exercise in the absence of regular follow-ups. The patient had a history of atrial fibrillation and had increased both the duration and intensity of exercise on her own at home. This constitutes further evidence of the necessity of providing appropriate monitoring and follow-up to HD patients exercising at home. The results of this study indicate that a home exercise program delivered via NCM can be safely implemented in daily practice and that the benefits of home exercise far outweigh the risks for stable HD patients.

6.9 Summary

In conclusion, a home exercise intervention delivered through the NCM approach can achieve meaningful functional gains in normal gait speed, and a trend of improvement in fast gait speed, 10-STS performance for patients undergoing HD treatment. The findings of this study suggest that home exercise is promising at improving the physical functioning of HD patients. Trained nurses are able to adopt NCM as a care delivery tool to encourage patients to make progress in their exercises to a recommended level. The improved levels of physical activity and reduced perceptions of barriers to exercise provide further evidence of the effectiveness of the NCM approach in helping HD patients to overcome barriers to exercise and engage in it. The beneficial effects of NCM in terms of functional outcomes and adherence behavior are in line with the findings of a structured review on the impact of nurse case managers in improving health outcomes for patients with three chronic diseases: diabetes, COPD, and coronary heart disease (Sutherland & Hayter, 2009).

The limited availability of and poor access to intradialytic exercise programs are impeding the widespread use of exercise interventions to sustain and restore physical functioning in the HD population. In the present study, clinical nurses received structured training that enabled them to serve as case managers and bring about positive health outcomes for HD patients. The home exercise modality was well-received and safe for stable patients of a broad range of ages. In light of these encouraging findings, the researcher proposes the widespread clinical adoption of NCM incorporating home exercise to improve the access of HD patients to exercise interventions.

6.10 Limitations

Although the results of this study are positive and encouraging, the following limitations must be acknowledged.

6.10.1 Sustained effects of the program undetermined

The major limitation of this study is a lack of a follow-up assessment after completion of the interventions as a part of the study design. The last point of observation was made immediately after the intervention. Whether positive effects of the nurse-led NCM home exercise being maintained beyond the program remains unknown; this restricts the author’s ability to draw a final conclusion on the sustainability of the program. The lack of a longitudinal scope impedes drawing any conclusion on the program's long-term effects. Further study is needed to explore the sustainability of the effects identified in this study to strengthen the credibility of the current findings. It is worth noting that ESRD patients need life-long dialysis treatment until they received renal transplantation; brief exercise counseling should be made available for patients at each nurse-patient contact during dialysis sessions. The current program showed that the average duration of the nurse-patient interview in the follow-up sessions required about 15 minutes. Therefore, incorporating NCM on home exercise into routine nursing practice could be feasible and effective to maintain patients' exercise behavior and achieve functional gains.

6.10.2 Factors influencing program effects

As there are several factors that may have influenced the effects of the intervention, any interpretation of the results should take those factors into consideration. First, "patient not meeting recommended physical activity levels" was one of the inclusion criteria adopted in the screening of participants in this study, and it allowed the inclusion of patients with a broad range of physical activity levels. Because information on participants' baseline physical activity levels was not available, it is possible that variations in those levels influenced the program effects. However, the NCM approach was adopted to deliver an individualized home exercise intervention and behavioral support feasible for use in clinical practice. It was therefore justified to include patients currently performing some exercise and none, as variations in activity levels reflected the target group of HD patients.

Second, there was possible contamination from communication between participants in the two groups, as patients scheduled on the same dialysis shifts participated in the in-center group exercise sessions together. It is possible that patients may have discussed exercise issues with one another. In addition, the research team was unable to arrange for patients to be interviewed in separate cubicles in accordance with their group allocation because of logistical difficulties. To minimize possible intervention contamination, patients from the two groups were kept as far apart as possible in the dialysis room to prevent control group patients from overhearing the nurse-intervention patient interviews with the cooperation of head nurses.

6.10.3 Issues with sample representativeness

Another potential source of bias is the possibility that only patients interested in exercise may have wanted to participate in the program, meaning that participants were more likely to initiate home exercise than patients who declined to join the program. Such inclusion of only patients with positive attitudes toward exercise would likely overestimate the program effects. However, as participants had an equal chance of being allocated into either the intervention or control group, the potential for such bias was minimized. Still, the gains achieved in physical, mental, and overall health in this study were probably generated from those patients who had generally positive attitudes toward exercise.

Further, lower-educated and multiple-comorbidity groups were under-represented in this study. However, the inclusion of patients with low education levels would been challenging in a real clinical setting such as this one, as such patients may have had difficulties comprehending the exercise booklets and keeping exercise logs. Patients with multiple co-morbidities were excluded out of safety concerns, as home exercise was performed without direct supervision.

Finally, the study results tended to stem from a relatively young HD patient group, as the mean age of participants was around 55. However, the safety of the home exercise intervention was the first priority, meaning patients with an unstable condition and contraindications to exercise had to be excluded. As elderly patients commonly suffer from physiological impairments and have a high prevalence of comorbidities, they were more likely to meet the exclusion criteria than their younger counterparts. The provision of exercise for frail elderly patients on dialysis constitutes a challenge, and a directly supervised exercise program may be an alternative for this patient group.

6.10.4 Single-blind rather than double-blind design

Because of the nature of the intervention, the study was able to blind neither the participants nor nurse case managers, which may have created bias. The patients were informed that there were two groups, but were not informed of their group allocation, and both groups participated in the group exercise training sessions for the first six weeks of the study. Awareness that they were receiving exercise intervention may have increased the motivation of participants in both groups, thus causing effects in subsequent data collection. To avoid or minimize social desirability bias, both objective and subjective outcome measures were used to evaluate physical function ability. The objective such measures, e.g., gait speed and 10-STS, captured subjects' actual performance.

6.10.5 Effects of complex interventions rather than single elements

The intervention in this study had multiple components, including exercise intervention and behavioral support strategies implemented with the case management approach. Case management itself is a complex intervention (Sandberg, Jakobsson, Midlov, & Kristensson, 2014). It is a dynamic intervention with an ongoing decision-making process by the case manager in conjunction with each individual patient (Goodwin et al., 2003). The interactions between each element and the flexibility of intervention implementation add to the complexity of the action that produces the program effects. In the current study, it is impossible to determine how each component of the interventions contributed to program effectiveness and which elements were most essential. To answer the primary question concerning the functional outcome, it is necessary to ensure adherence to exercise through behavioral support. Although the complex intervention makes it difficult to pinpoint the single effects, it is valuable to address an individual's barriers to exercise, negotiate personalized exercise dosages, and provision professional support through nurse case management to foster motivation and adherence to unsupervised home exercise.

6.10.6 Interactions between outcomes underdetermined

There were six dependent variables in this study. The statistical results only addressed the program effects of each variable; while the relationships among the variables were not evaluated. It would be informative and valuable to further explore the interactions between the outcome measures with larger sample size to be analyzed with modern data analytic approaches, such as mixed modeling.

6.11 Implications

6.11.1 Clinical implications

The adverse consequences of being sedentary and the benefits of exercise for HD patients have been demonstrated in a large body of evidence. The results of the current study reveal that HD patients had reduced physical function prior to the exercise program and that most of those in the intervention group were not fully aware of the benefits of exercise and had encountered barriers to exercise. This clinical situation indicates that exercise promotion and counseling are needed in clinical practice.

6.11.1.1 Encouragement of physical activity as part of routine practice

The K/DOQI clinical practice guidelines for CKD in dialysis patients (K/DOQI Workgroup, 2005) state that "all dialysis patients should be counseled and regularly encouraged by nephrology and dialysis staff to increase their levels of physical activity." However, the provision of physical activity assessment and counseling is not currently a routine practice in dialysis facilities worldwide (Painter et al., 2014). The home exercise recommendations and prescriptions implemented via the NCM approach in this study were proved able to be integrated into nurses' daily care practice with few extra time requirements, indicating that the intervention is feasible, achievable, and realistic in clinical practice. Therefore, it is strongly recommended that exercise counseling be incorporated into daily care, particularly for stable and younger dialysis patients. Patients who are elderly and frail, and thus unable to exercise on their own, may require medical referrals to the clinical rehabilitation department.

6.11.1.2 Nurses play pivotal role in exercise promotion

Health promotion is a major goal of professional nursing practice, and nursing science defines health promotion as optimizing functioning through expanding the positive potential for health (Smith, 1990). Nurses' professional experience can enable them to provide support to patients that helps them to live as fully as possible on dialysis. The aim of exercise promotion is to restore and optimize physical functioning for patients on HD treatment. It is therefore recommended that nurses take responsibility for advising, encouraging, and helping patients to engage in exercise to restore, maintain, or improve physical function.

The results of this study demonstrate that nurses are able to offer a structured home exercise program with promising outcomes for physical function and mental and overall well-being. The nurse-led exercise intervention was well-received by patients, as indicated by the low dropout rate. These findings imply that nurses are well-positioned to counsel patients' on physical activity behavior and provide exercise interventions to stable HD patients with support from other care providers.

Painter et al. (2014) reported that dialysis care providers are often uncomfortable about discussing physical activity with patients, and have varying levels of confidence in providing exercise counseling. A previous qualitative study carried out in mainland China revealed that nurses consistently perceive themselves to have insufficient knowledge and competency to provide rehabilitation services to patients with coronary heart disease (Wang et al., 2009). In the current study, clinical nurses were provided with structured training in the delivery of a home exercise program. They were also offered a program manual and intervention protocols and received ongoing support from the research team to enhance their confidence and competency in counseling HD patients on exercise behavior. Therefore, the provision of education to all clinical nurses working with HD patients with respect to the importance of physical activity, function assessment and monitoring, exercise prescription and behavioral counseling strategies is needed to ensure that exercise promotion practice reaches a broad range of such patients.

6.11.1.3 Home exercise prescription for stable HD patients

Although outpatient rehabilitation on non-dialysis days has been shown to produce more pronounced improvements in HD patients' physical function, that exercise model suffers from a low patient adherence rate because of time constraints and transportation issues (Konstantinidou et al., 2002). Exercise during dialysis sessions constitutes a creative and practical exercise modality that achieves positive benefits, but its implementation is resource-intensive (Painter, 2008). The results of the present study demonstrate that an independent home exercise program with encouragement, support, and regular follow-up from nurse case managers is feasible and results in improved normal gait speed and a trend of improvement in quality of life and depressive symptoms for HD patients. The home exercise modality was also well-received in this study, as indicated by the dropout rate of just 5.3%. These positive findings have important implications for the implementation of exercise programs at dialysis facilities, particularly in those with limited resources and a restricted budget. To prevent functional deterioration in HD patients, dialysis facilities should offer independent home exercise recommendations and prescriptions to all patients who have a stable condition and able to engage in exercise without direct supervision.

6.11.2 Research implications

The results and limitations of this study shape the further research agenda. It can be concluded from the results that NCM of home exercise is promising in improving HD patients' physical function and quality of life within 12 weeks. However, the long-term effectiveness of self-directed exercise on HD depends on the degree of patients' adherence to exercise and lifestyle changes after intervention completion (Pisters et al., 2010). The effectiveness of the program discussed herein was limited to the intervention period; whether the achieved beneficial effects can be sustained after cessation of interventions requires further studies with follow-up assessment.

The clinical nurses in this study expanded their roles to act as case managers and provide home exercise instruction to HD patients. Further qualitative evaluations of the program's impacts on both nurse case managers and participants would be useful to determine the acceptability of clinical nurses acting as case managers to deliver an exercise program.

The cost-effectiveness of the program was not analyzed in this study. As the home exercise modality is suggested to be less resource-intensive, and the NCM approach has been documented to contain healthcare costs though effective care coordination (Buker et al., 2014), future research analyzing the cost of resource utilization for both program implementation and patients' medical services is warranted. Such cost-effectiveness analysis can determine whether the NCM approach to home exercise is beneficial to both patients and the healthcare system.

To substantiate the findings of this study, there is a need for a larger-scale RCT with a broader range of HD patients in terms of demographic and clinical characteristics, such as education level, co-morbidities, and age. In addition, patients and clinicians in rural areas may face distinct challenges. Conducting similar research in dialysis centers in both urban and rural areas would be valuable for further establishing the effects of the NCM program examined herein. Meanwhile, the use of a control group being offered a brief in-center group exercise training due to ethical concerns may dilutes the program effects. As noted, the brief in-center group exercise training could be effective to the SRH and 10-STS performance. A NCM on home exercise program with a waiting list control deserves further exploration.

Finally, future studies of NCM of home exercise for HD patients could be improved by incorporating process evaluation into the study design, which would aid in illuminating how specific interventions contributed to the program outcomes and assessing intervention fidelity (Saunders, Evans, & Joshi, 2005).

6.11.3 Health policy implications

The beneficial effects on the physical function HD patients achieved through the current NCM home exercise program indicates that nurses are able to provide effective and safe home exercise interventions with support from physicians, other clinical nurses, and patients' family members to patients in a stable clinical condition. The program's successful implementation in this study implies the need for nurses to play a greater role in promoting physical activity and/or exercise for HD patients. In the present program, clinical nurses received structured training on intervention implementation, and then delivered the intervention during their daily practice with the support of head nurses. Although exercise is recognized as an effective way to optimize health for HD patients, its low administrative priority poses a major obstacle to the establishment of exercise programs in clinical practice (Wang et al., 2009). To facilitate clinical implementation of such programs, it is necessary to motivate clinical nurses to take responsibility for providing exercise interventions to HD patients. Rehabilitation services for HD patients deserve high administrative priority.

Furthermore, the rehabilitation services that patients receive after discharge from hospitals are not currently covered by the reimbursement system in mainland China

(Wang et al., 2009). As most HD treatments are provided in outpatient clinics, the current service reimbursement provision is questionable. HD patients clearly need adequate medical reimbursement for exercise programs to alleviate their financial burden.

Chapter 7 Conclusion

Motivated by the need to restore and improve physical function among HD patients, the study reported herein was designed to test the effects of a NCM on home exercise for this patient group. The primary outcome was physical function measured by normal gait speed. The results revealed the patients in the intervention group walk significantly faster than those in the control group upon study completion. Despite the small to moderate effect sizes for normal gait speed found for both the between-group effect at week 12, the improvement in normal gait speed from baseline to week 12 for the intervention group was clinically meaningful, indicating the exercise program's beneficial effects for HD patients. The faster increase trends in both fast gait speed and 10-STS performance in the intervention group relative to the control group further supports the program's positive functional gains. Another positive outcome was the higher level of physical activity and reduction in perceived exercise barriers reported by the intervention group relative to the control group upon program completion, further evidence that NCM is able to help patients to overcome exercise barriers and engage in home exercise, resulting in improved physical function However, no between-group effects were found in either SRH or depressive symptoms; suggesting that the exercise dosage of the current program could be not sufficient to bring about an overall and psychological benefits for HD patients. Meanwhile, the brief group exercise training shows promise for boosting patients' SRH; and flexibility and strength exercises could have beneficial effects on 10-STS performance.

This study is the first RCT conducted in mainland China that evaluates NCM of home exercise for clinically stable HD patients. The positive effects identified suggest that home exercise interventions can be implemented routinely for low-risk patients who are able to perform self-directed exercises. HD patients who are able to perform self-directed exercises should be encouraged and motivated to initiate and maintain regular home exercise. Because of the existence of multiple co-morbidities in HD patients and the nature of HD treatment, these patients have fluctuations in their physical condition. Individualized exercise prescriptions are needed to accommodate patients' health condition. Case management that allows flexible adjustments to exercise regimens is recommended as a care delivery approach for implementing home exercise programs. For patients who cannot safely perform unsupervised home exercise, alternative exercise modalities should be explored, such as in-center supervised exercise training. Moreover, group exercise training should be considered for patients in HD centers if resources permit.

Rehabilitation services remain under-developed in mainland China (Wang et al., 2009), with no physiotherapists currently located in dialysis centers. The results of this initial study examining the effects of NCM are encouraging. They suggest that nurses are able to implement individualized home exercise regimens and provide behavioral support through the case management approach to improve the physical function of HD patients. It is strongly recommended that nurses expand their role in providing rehabilitation services to HD patients. Further research should be conducted to determine the long-term effects of the program considered in this study with a larger sample size and broader range of HD patients in terms of demographic and clinical characteristics. Case management is still a new concept in mainland China, and its effectiveness in various chronic disease groups deserves further exploration. As case management is a complex intervention, it is strongly recommended that process evaluation be combined with an RCT design to explore the effects of the complex interventions and further support intervention fidelity.

Appendices

Appendix 2.1

Search strategy used for the Medline search

Search carried out in Medline (1946+) via OvidSP

Data of search 11/7/2014

#	Searches	Results
1	exercise/	67588
2	exercise$.ab,ti.	199728
3	physical activity.mp.	58239
4	physical activit$.ab,ti.	60139
5	1 or 2 or 3 or 4	260120
6	chronic kidney disease.mp.	20148
7	renal failure.mp. or Renal Insufficiency/	81652
8	renal replacement therapy.ab,sh,ti.	8345
9	renal dialysis.sh.	73117
10	hemodialysis.ab,ti.	46602
11	haemodialysis.ab,ti.	11919
12	6 OR 7 OR 8 OR 9 OR 10 OR 11	171487
13	5 AND 12	1849
14	13 AND "Adult" [Subjects]	730
15	14 AND "Randomized Controlled Trial" [Publication Type]	82

Appendix 3.1

Contraindications to exercise

1	Unstable hypertension
2	Congestive heart failure (NYHA grade > II)
3	Cardiac arrhythmias (>= III according to Lown)
4	Ischemic heart disease, recent myocardial infarction , cerebrovascular accident of less than 6 months
5	Unstable diabetes mellitus
6	Being in a catabolic state (including malignancies, HIV, active liver disease, infections, etc) within 3 months before enrollment
7	Peripheral vascular diseases
8	Arthritic or orthopedic disorders limiting exercise or exacerbated by activity
9	Chronic lung disease that resulted in shortness of breath at rest
10	Documented renal osteodystrophy (history of bone pain or fractures)
11	Hemodynamic instability

Note:

NYHA, the New York Heart Association Functional Classification (The Criteria Committee of the New York Heart Association, 1964)

NYHA Class	Symptoms
I	Patients have cardiac disease but without the resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnoea or anginal pain
II	Patients have cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnoea or anginal pain
III	Patients have cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary physical activity causes fatigue, palpitation, dyspnoea or anginal pain
IV	Patients have cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary physical activity causes fatigue, palpitation, dyspnoea or anginal pain

Lown's classification for ventricular arrhythmias (Lown & Wolf, 1971)

Grade 0: No ventricular ectopic beats

Grade Ⅰ: Occasional, isolated Ventricular premature beats (VPB)

Grade Ⅱ: Frequent VPB, >1/min or 30/hr

Grade Ⅲ: Multiform VPB

Grade Ⅳ: Ⅵa, Couple; Ⅵb Salvos

Grade Ⅴ: Early VPB

>>> Patricia Painter <@hsc.utah.edu> 6/2/2012 4:55 AM >>>
Hello Susan,

sorry for the delay in getting back to you on this... have been at a meeting with intermittent access to email.

sounds like things are going well for you.
Probably the best time to exercise is on a non-dialysis day, but on a dialysis day, it would be fine to exercise them before dialysis... after they may be fatigued and may experience hypotension with exercise... (after they remove so much fluid, they 'clamp' down or vasoconstrict their peripheral vessels to maintain blood pressure - exercise causes dilation of vessels in the working tissues, and that could result in drop in blood pressure.

as for the exercise manual. There have been no updates, since there is no new data that would indicate that any updates are necessary. This is a conservative, and comprehensive approach that will be appropriate for most patients, allow for success, and gradual progression.

as for translation of this book, you need permission form the Medical Education Institute that provides access to the manual on the website Lifeoptions.org. Please contact Paula Alt (copied on this email) for information about translation (Paula Alt <@meiresearch.org>)

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Anticipated use of the booklet: For research purpose in China

Authorized Life Options Signature: Date: 5 June 2012

Exercise Protocol for In-center Group Exercise

The in-center group exercise training is open to all participants regardless of their group allocation. The training sessions are provided before dialysis sessions with the supervision of the research personnel.

Aim: To demonstrate flexibility and strength exercises for participants and provide group exercise supervision of those exercises.

Duration: 6 weeks

Frequency: Weekly

Content:

1. Monitor exercise-related symptoms and signs experienced during self-performed exercise, if any (if the patient reports that any of the following symptoms begins during exercise, he or she will be required to cool down or stop).

    - Shortness of breath
    - Chest pain or pressure
    - Irregular heartbeat
    - Nausea
    - Muscle cramps
    - Dizziness or lightheadedness
    - Pain or pressure in the neck or jaw
    - Excess fatigue
    - Blurred vision
    - Fever
    - Exercise-related pain

2. Measure patients' weight, blood pressure, and heart rate.

3. Exercise demonstration:

- Flexibility exercises
    - ✓ Neck Stretch
    - ✓ Arm/Hand Stretch
    - ✓ Shoulder Shrug & Rotation
    - ✓ Chest & Upper Back Strength
    - ✓ Side Stretch
    - ✓ Single Knee Pull
    - ✓ Leg Stretch
    - ✓ Calf Stretch
- Strength exercises
    - ✓ Arm Curl
    - ✓ Arm Extension
    - ✓ Lower Leg Extension
    - ✓ Straight Leg Extension
    - ✓ Seated Marching
    - ✓ Back Leg Swing
    - ✓ Heel Raise
- Provide exercise supervision to correct exercise movements and ensure safety.

5. Cool down with flexibility exercise (5 minutes).

6. Record exercise movements and symptoms (if any).

透析中心小组运动方案

所有参与者（包括研究者和对照组）均建议参加透析中心小组运动训练。该运动训练在常规透析治疗开始前半小时进行，由研究人员提供监督。

目的：指导患者正确地进行柔韧性运动和肌力训练；强化运动过程中的注意事项；监督患者的运动剂量。

时间：6 周

频率：每周一次（确保每名参与者每周都有一次小组运动训练的机会）;

内容：参照以下运动监督方案

1. 如果患者上周有自主运动，询问患者在运功的中有无下列症状或体征（如果患者出现下列症状或体征，建议其减低运动剂量或停止）
   - 呼吸困难
   - 胸痛或闷
   - 不规律的心跳
   - 恶心
   - 腿抽筋
   - 头晕或脚步轻浮
   - 颈部或下巴疼痛或闷
   - 过度疲劳
   - 视物模糊
   - 发烧
   - 运动诱发疼痛
   -

2. 监测体重、血压及心率

3. 运动训练（由研究人员示范每一个动作并讲解注意事项）
   - 柔韧性运动（按以下顺序进行）
     - ✓ 颈部牵伸
     - ✓ 手臂牵伸
     - ✓ 耸肩&旋转

- ✓ 胸部和上臂牵伸
- ✓ 侧伸展
- ✓ 单膝拉伸
- ✓ 腿部伸展
- ✓ 小腿伸展

- ▪ 肌力锻炼（按以下顺序进行）
  - ✓ 臂部弯曲
  - ✓ 臂部伸展
  - ✓ 小腿伸展
  - ✓ 直腿伸展
  - ✓ 坐位步行
  - ✓ 后摆双腿
  - ✓ 提踵
- ▪ 在运动过程中监督患者的运动动作是否正确，有无不适反应

5. 以5分钟柔韧性运动结束小组运动。

6. 记录参与者运动情况。

Appendix 3.3b

Exercise Protocol for Nurse Case Management

The exercise protocol for nurse case management constitutes flexibility, strength, and aerobic exercise. Nurse case management is available only to patients in the intervention group.

Aim: To establish an individualized exercise regimen for each patient according to his or her exercise capacity and personal preferences.

Content

1. Exercise program

The exercise program for patients exposed to nurse case management includes three kinds of exercise: flexibility, strength, and aerobic. Patients should be instructed to spend the most time on aerobic exercise.

With regard to instructions on the flexibility and strength exercise, please refer to the exercise protocol for in-center group exercise training and exercise guidelines for dialysis patients (Painter, 1999).

With regard to aerobic exercise, please discuss the activities that are most enjoyable, affordable, and convenient for the patient. Examples of aerobic exercise include walking, brisk walking, stair stepping, cycling (stationary or outside), jogging, dancing, and badminton. Walking is the easiest exercise modality for most individuals to incorporate into daily life.

2. Exercise prescription

Home exercise plans are negotiated with consideration paid to the frequency, intensity, type, and timing of exercise, namely, the FITT principles.

Frequency: how often to exercise. It refers to the number of exercise sessions performed per week. Regularity is the first priority of any exercise prescription.

Intensity: difficulty of exercise. It refers to the perceived level of exertion required for an individual to perform an exercise. Intensity can be monitored via the work effect scale.

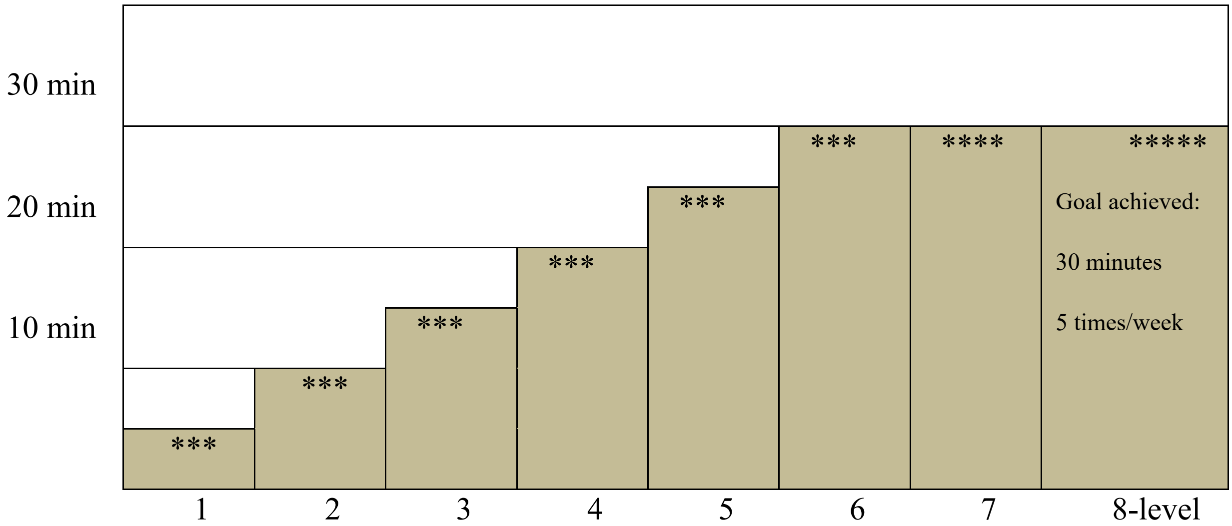
Type: which exercise modality to choose. The home exercise program includes three modalities: flexibility, strength, and aerobic exercise. For examples of each exercise type, please refer to the exercise booklet and nurse case management manual.

Time: how long to exercise. It refers to the duration of exercise that can be sustained; in other words, to the duration of each exercise bout.

3. Exercise progression

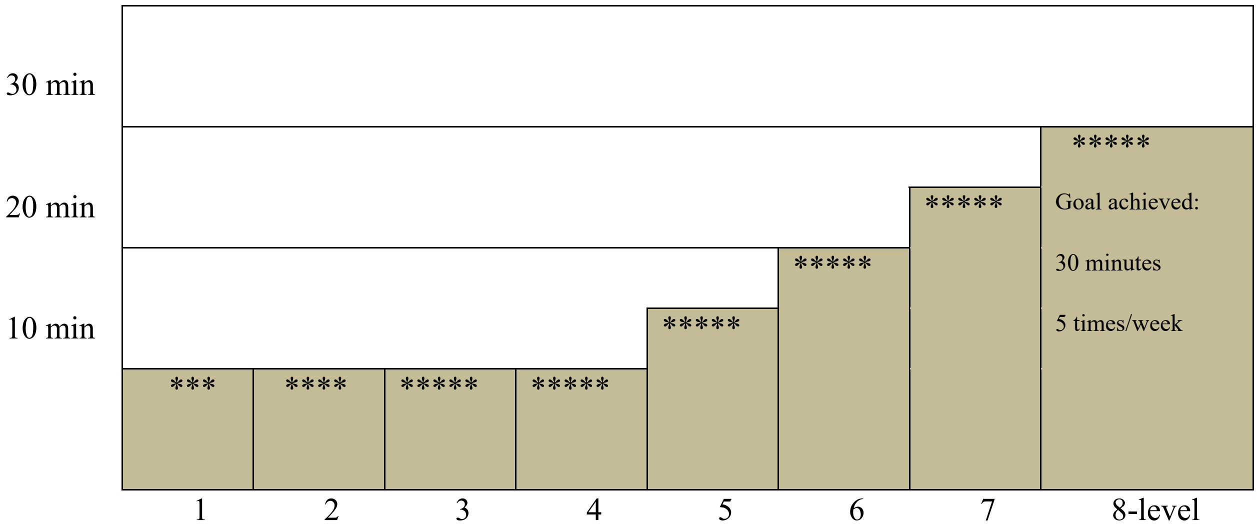
Exercise should begin slowly and progress gradually in accordance with the individual's condition. Exercise progression can be made by increasing the intensity, duration, or frequency of exercise training. It is recommended that only one dimension of the exercise prescription be adjusted at a time. For example, do not prolong the exercise duration and increase exercise frequency at the same time. In addition, the magnitude of exercise progression should be less than 10%. For example, if the duration of walking in the first week is 30 minutes, the increased duration of walking in the second week should not exceed 3 minutes. The following are some examples.

1) Duration path for aerobic exercise



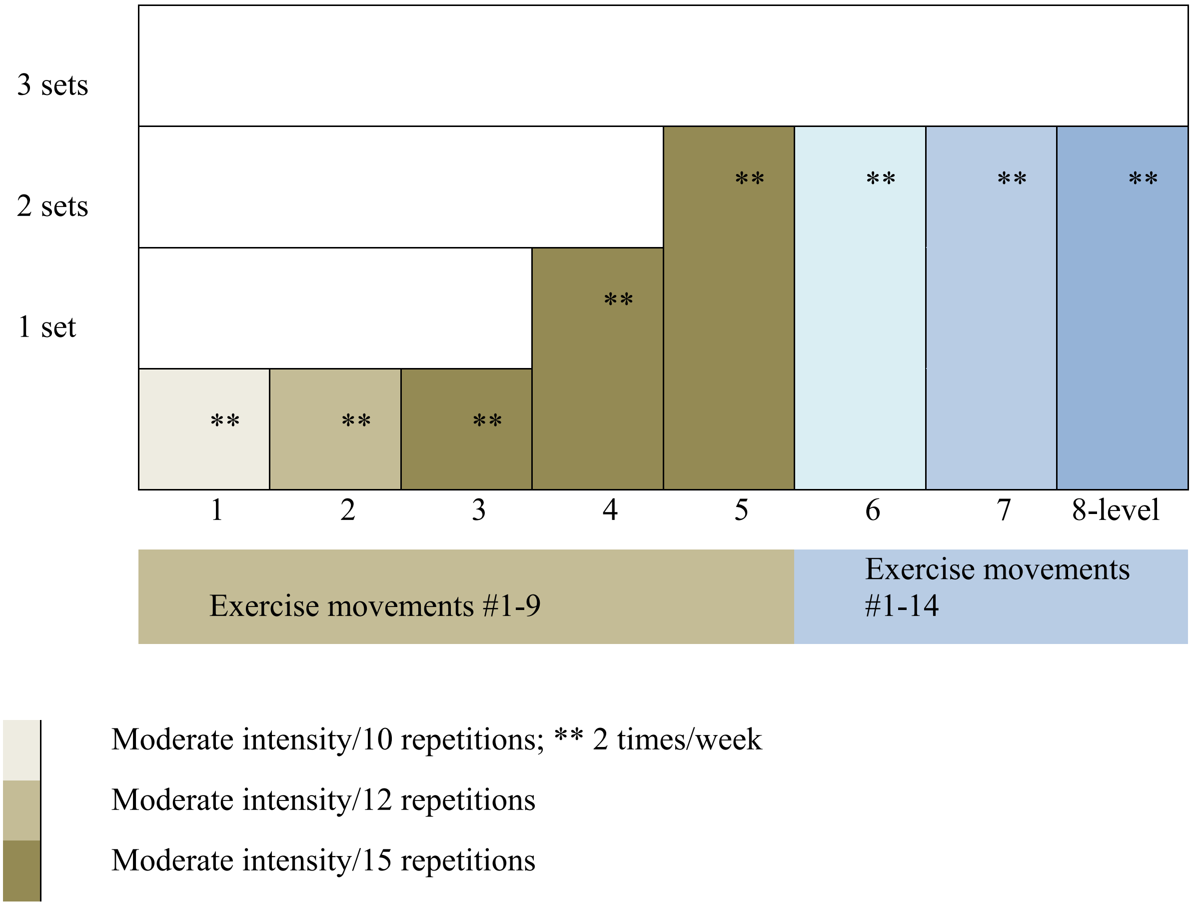
Moderate intensity; *** 3 times/week; **** 4 times/week; ***** 5 times/week.

2) Frequency path for aerobic exercise



Moderate intensity; *** 3times/week; **** 4 times/week; ***** 5 times/week.

3) Exercise progression for strength exercise



Please suggest to patients that they start with strength exercise #1 and repeat it as many times as they can, up to 10 times. Then, they should move on to exercise #2, and so on. Ten repetitions of each basic exercise (Exercises #1 to #9) constitute one set. Patients should gradually increase the number of repetitions from 10 to 15, and then increase the number of sets from one to two. When the patient can comfortably and easily do three sets of the basic exercises (with 15 repetitions of each), he or she can add the intermediate exercises (#10 to #14). When he or she can comfortably do three complete sets (15 repetitions each) of all exercises (#1 to #14), he or she is ready to add weights.

Sample strength training

Week	Exercise movement	Repetitions	Set(s)	Weight
1	#1-#9	10	1	-
2	#1-#9	12	1	-
3	#1-#9	15	1-2	-
4	#1-#9	15	2	-
5	#1-#9	15	2-3	-
6	#1-#9	15	3	-
7	#1-#9	15	3	-
8	#1-#14	10	3	-
9	#1-#14	12	3	-
10	#1-#14	15	3	-
11	#1-#14	10	3	0.5 Kg
12	#1-#14	12	3	0.5 Kg
13	#1-#14	15	3	0.5 Kg
14	#1-#14	10	3	1.0 Kg
15	#1-#14	12	3	1.0 Kg
16	#1-#14	15	3	1.0 Kg

4) Exercise progression for flexibility exercise

When an individual can comfortably and easily hold each stretch for 10 to 20 seconds and do at least three repetitions of each, he or she is ready to add new stretches. Please start the flexibility exercise with the head and neck, and then work down to the legs.

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个案管理运动方案

个案管理运动方案仅用于被随机分配至干预组的患者。此方案包含柔韧性运动，肌力锻炼及有氧运动建议。

目的：根据患者的运动能力及个人偏好，与患者共同商讨并制定个体化的运动方案。

内容：

1. 运动计划

居家运动计划需要包含柔韧性运动、肌力锻炼及有氧运动三中运动类型；但是应指导患者将运动的重心放在有氧运动上。柔韧性运动及肌力锻炼动作及每个动作的锻炼顺序请参照“透析中心小组运动方案”。有氧运动的种类，请与患者商讨选择患者的喜欢且方便的运动方式；如散步、快走、骑车、慢跑、跳舞等。其中散步是最常见，也是最容易开始并融合进日常生活的运动形式

2. 运动处方的制定

个案护士与患者一同商讨居家运动处方。运动处方以 FITT 原则（频率、强度、类型及时间）制定。

频率 Frequency： 每周运动的次数。平均地分配一周运动量，勿将一周的运动量集中于某一天或是两天！这样可以让机体有足够的时间适应和调整，从而降低运动损伤的风险。特别是失能的个体，间断性不规律地突然增加运动量会增加运动的风险。

强度 Intensity：运动的费力程度。我们可以使用“说话试验”或是“自觉费力量表”这些主观测评方法来判断个体运动的费力程度。

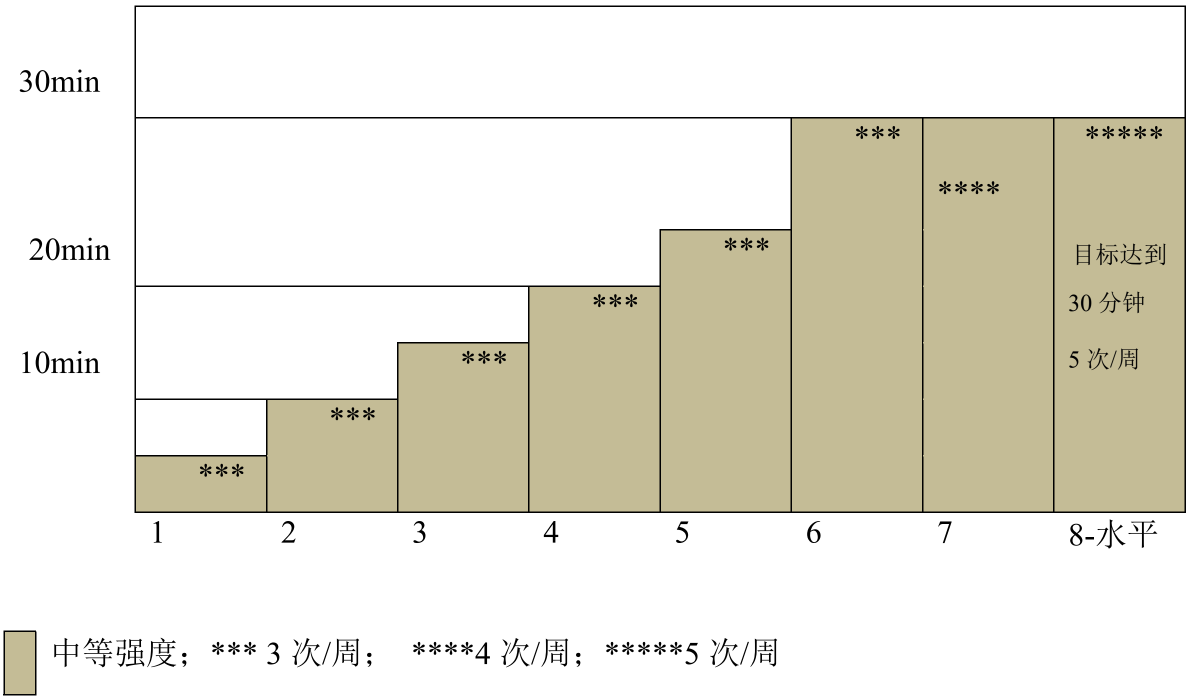
时间 Time：运动的持续时间。一般来说，通过累积持续超过 10 分钟的连续不中断运动的得到当天运动的总时间。

种类 Type：运动的种类。居家运动方案包含柔韧性运动、肌力锻炼及有氧运动。每类运动的动作或项目请参照《透析患者的运动指引》。

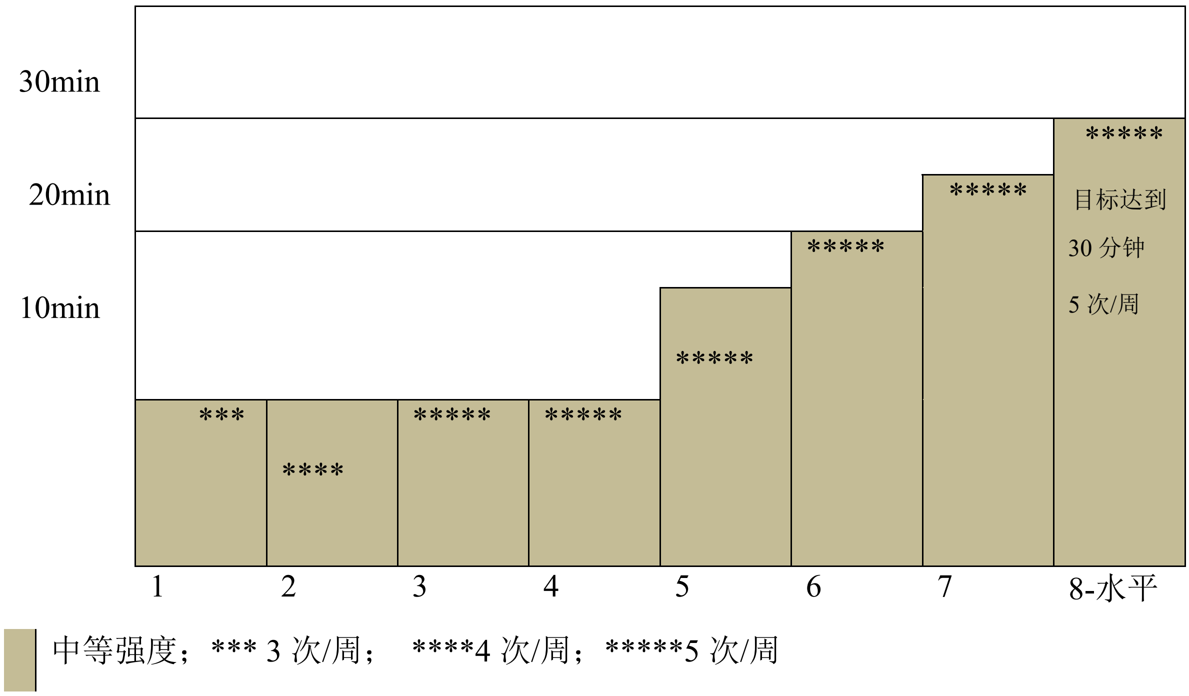
3. 运动进阶

根据患者的身体状况，逐渐地增加运动剂量。一般来说，每次仅仅在运动计划的一个维度进行调整（如，频率或是持续时间），不要同时地增加两个维度的活动量（如，延长活动时间的同时增加一周的活动频率）。每周增加的幅度控制在10%以内；例如，第一周活动 30 分钟，第二周增加至 33 分钟。如果该患者每周运动三次，每次 10 分钟，那 3 分钟可以加于一周中的第三次运动中。下一次增加的 3 分钟不应再加于第三次运动，而应增加到前面两次，确保一周中每次运动量的相对一致性。

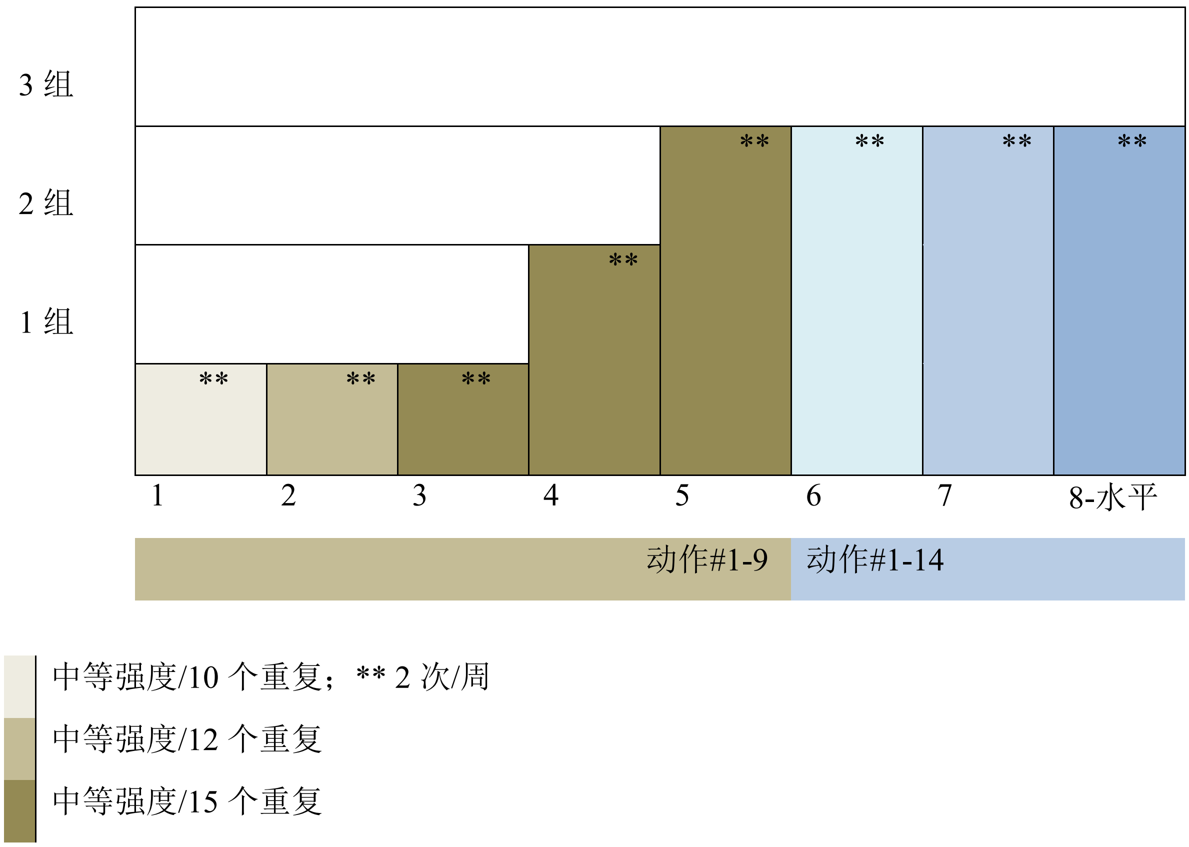
1）有氧运动——逐渐增加持续时间路径



2）有氧运动——逐渐增加运动频率路径（The frequency path）



3）肌力锻炼的进阶



动作#1-9 是肌力训练的基本动作，#10-14 是中间级别的动作。

从第一个动作开始，尽量多的重复这个动作（可多达 10 次）。完成后进行下一个动作。每个基本动作（动作 1-9）重复做 10 次。这样是一组。缓慢地增加重复次数，从 10 次增加到 15 次。然后增加组数，从做一组增加到做两组。当患者可以舒适地完成三组基本动作（每个动作重复 15 次）时，便可以加入中间级别的动作（动作 10-14）。当患者能够舒适地完成三整组（1-14 的）所有动作（每个动作重复 15 次），患者可以进行负重练习。

肌肉力量训练计划样表

星期	动作	重复次数	组数	重量
1	#1-#9	10	1	-
2	#1-#9	12	1	-
3	#1-#9	15	1-2	-
4	#1-#9	15	2	-
5	#1-#9	15	2-3	-
6	#1-#9	15	3	-
7	#1-#9	15	3	-
8	#1-#14	10	3	-
9	#1-#14	12	3	-
10	#1-#14	15	3	-
11	#1-#14	10	3	0.5Kg
12	#1-#14	12	3	0.5Kg
13	#1-#14	15	3	0.5Kg
14	#1-#14	10	3	1.0Kg
15	#1-#14	12	3	1.0Kg
16	#1-#14	15	3	1.0Kg

4）柔韧性运动的进阶

当患者能够舒适、轻松的保持每个姿势 10-20 秒并能最少完成每个动作三次，您就可以增加新的动作。柔韧性运动的动作进阶请参照《透析患者的运动指引》。

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Appendix 3.4

Interview protocol

Aim: To facilitate patients' initiation and adoption of exercise

Duration: 12 weeks

Frequency: Weekly for first six weeks; biweekly for subsequent six weeks

Timing: Duration of dialysis treatment

Content:

1st interview: Evaluation, education, and counseling
Part I: Evaluation
Aim: To explore patients' attitudes and intentions toward exercise, evaluate their exercise knowledge and skills, and evaluate their physical activity levels.

1. Attitude toward exercise
   - Exercise and its benefits to health
   - Significance of exercise
   - Significant others' attitudes toward exercise

2. Exercise-related knowledge and skills
   - What is exercise?
   - Recommended exercise for dialysis patients:
     - ✓ Types of exercise
     - ✓ Frequency of exercise
     - ✓ Time and duration of exercise
   - Benefits of exercise

3. Prior exercise experience
   - Types of exercise:
     - ✓ Aerobic exercise
     - ✓ Strength exercise
     - ✓ Flexibility exercise
     - ✓ Other
   - Time, intensity, frequency, and duration of exercise

4. Current physical activity/exercise level (in past three to six months)
   - Type, time, intensity, frequency, duration, and progression of exercise

5. Symptoms or problems experienced during previous exercise
   - Chest pain
   - Pain in neck or jaw

- Irregular heartbeat
- Uncommon fatigue and/or shortness of breath during daily activity or rest
- Dizziness or lightheadedness
- Blurred vision
- Intense headache
- Leg cramps or pain (when walking a short distance)

6. Medications
   - Types of medication
   - Adherence to medication regimen

Part II: Health education

Aim: to provide health information to facilitate behavioral change (through behavioral change strategies, including interventions targeted at multiple levels such as the patient and environmental levels).

1. Provide health information
   - What is exercise?
   - Recommended exercise for dialysis patients:
     - ✓ Types of exercise
     - ✓ Frequency of exercise
     - ✓ Time and duration of exercise
   - Benefits of exercise
   - Exercise precautions

2. Discuss intention to exercise
   - Does not exercise now, and will not initiate exercise
   - Does not exercise now, but is considering starting exercise slowly
   - Exercises irregularly, and does not plan to increase exercise
   - Exercises irregularly, but plans to increase exercise

3. Explore resources available to patient
   - Community activities
   - Places to exercise
   - Family members or friends to exercise together with
   - Other

4. Discuss potential barriers to exercise
   - Symptoms such as fatigue
   - Concerns about safety and unwanted injuries
   - Lack of exercise suggestions
   - Lack of time
   - Lack of social support
   - Lack of motivation

5. Negotiate exercise plans
   - Develop individualized exercise plans and goals
     - ✓ Select types of exercise with a relatively low risk, e.g., walking

    - ✓ Start with a low exercise dosage and progress slowly
- ▪ Discuss action plans and coping plans
    - ✓ Action plan: specify types of exercise, time, place, etc.
    - ✓ Coping plan: explore possible solutions to identified barriers to exercise

6. Instruct patients in exercise self-monitoring
    - ▪ Exercise correctly and breathe correctly
    - ▪ Safe exercise environment, facilities, clothing, and timing
    - ▪ Symptom monitoring and coping mechanisms
    - ▪ Body weight and blood pressure management
    - ▪ Exercise record

7. Provide written exercise goals, action plans, and coping plans

2nd to 9th Interviews: Provide feedback support and monitor progression

Aim: To evaluate patients' understanding of exercise knowledge and suggestions, monitor their implementation of exercise plans and action plans, provide encouragement and support, and facilitate exercise progression to the recommended level.

1. Identify problems that require a referral

- Abnormal weight gain
- Hemoglobin level below 80 g/L
- Uncontrolled hypertension
- Pain
- Pruritus
- Other

2. Evaluate symptoms or problems experienced during previous exercise

- Chest pain
- Pain in neck or jaw
- Irregular heartbeat
- Uncommon fatigue and/or shortness of breath during daily activity or rest
- Dizziness or lightheadedness
- Blurred vision
- Intense headache
- Leg cramps or pain (when walking a short distance)
- Fever (> 38.3℃)

3. Evaluate exercise skills

- Flexibility exercise: simple rules
- Strength exercise: simple rules
- Aerobic exercise: evaluation of exercise intensity

4. Evaluate exercise performed in past week

- Flexibility exercise: movements, repetitions, sets, and frequency
- Strength exercise: movements, repetitions, sets, and frequency
- Aerobic exercise: frequency, duration, intensity, and types

5. Evaluate whether the patient has experienced the following situations during exercise in the past week

- Feels exercising is extremely difficult
- Feels shortness of breath when speaking during exercise
- Unable to continue exercising after previous exercise session because of muscle soreness
- Feels unrecovered one hour after exercise
- Aforementioned symptoms or problems occurring during exercise

6. Discuss patients' exercise experience in the past week

- Emphasize positive experiences with patients

7. Provide feedback based on a comparison of the established exercise plan with the exercise completed

- Completed established exercise plan
  - ✓ Provide affirmation
  - ✓ Discuss the exercise progression for the next week
- Failed to complete established exercise plan
  - ✓ Provide emotional support
  - ✓ Explore reasons for failure
  - ✓ Readjust the exercise plan with the patient

8. Negotiate exercise plans

- Develop individualized exercise plans and goals
  - ✓ Select types of exercise with a relatively low risk, e.g., walking
  - ✓ Start with a low exercise dosage and progress slowly
- Discuss action plans and coping plans
  - ✓ Action plan: specify types of exercise, time, place, etc.
  - ✓ Coping plan: explore possible solutions to identified barriers to exercise

9. Provide written exercise goals, action plans, and coping plans

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个案护士访谈方案

随访目的：促进患者运动行为的建立和维持。

随访持续时间：12 周

随访频率：前 6 周每周一次；后六周每两周一次

随访时间：透析治疗期间（上机后，下机前的 4 小时期间）

随访内容：

第 I 次访谈：评估、教育和咨询

第一部分：评估

目的：了解患者对提高体力活动水平、参与运动锻炼的态度和意向；评价患者目前体力活动水平和运动相关的知识与技能。

1. 对运动锻炼的态度
   - 对运动锻炼的看法：对身体健康是否有益
   - 运动锻炼对个人健康的重要性
   - 身边重要他人（家庭成员）对运动的看法

2. 运动相关知识和技能
   - 对运动的理解：什么是运动锻炼？
   - 接受血液透析治疗的慢性肾脏疾病患者的推荐体力活动水平
     - ✓ 运动的方式
     - ✓ 保持躯体功能的运动频率（一周几次）
     - ✓ 每次运动锻炼持续的时间及强度
   - 锻炼对自身健康的益处

3. 以前（接受透析治疗前/患病前）的运动经历
   - 运动的种类
     - ✓ 有氧运动
     - ✓ 肌力锻炼
     - ✓ 柔韧性运动
     - ✓ 其他
   - 运动的方式、频率、持续时间和强度

4. 现阶段（过去 3-6 个月内）的体力活动水平
   - 体力活动的种类，频率，强度，持续时间，进阶

5. 在过往运动过程中或者日常生活中有无出现下列症状或体征
   - 胸口疼痛/胸绞痛
   - 颈部，下巴或手臂疼痛
   - 不规律的心跳

- 日常活动或休息时中出现不寻常的疲劳或呼吸困难
- 头晕或脚步轻浮
- 眼花
- 较大强度的头痛
- 小腿部抽筋或烧灼感（步行短距离出现）

6. 现阶段药物使用情况
   - 药物的种类
   - 服药依从性：种类、剂量、时间、途径

第二部分：健康教育
目的：通过一系列行为改变的策略帮助患者建立运动习惯。。

1. 提供运动相关健康资讯
   - 什么是运动锻炼？
   - 接受血液透析治疗的慢性肾脏疾病患者的推荐体力活动水平
     - ✓ 运动的方式
     - ✓ 保持躯体功能的运动频率
     - ✓ 每次运动锻炼持续的时间及强度
   - 运动锻炼对透析患者的益处
   - 参与运动锻炼的注意事项

2. 讨论运动锻炼的意向
   - 现阶段没有运动，也不想开始运动锻炼
   - 现阶段没有运动，但是正考虑开始慢慢运动
   - 间或有运动锻炼，现在不准备增加运动量
   - 间或有运动锻炼，且考虑增加运动量
   - 有规律运动，且打算继续

3. 发掘患者周围可利用的运动锻炼资源
   - 社区集体活动
   - 锻炼场所
   - 家人、朋友陪伴
   - 血液透析中心运动项目

4. 讨论患者自觉运动锻炼的障碍（个人感受）
   - 身体状况，如疲乏
   - 安全及运动相关损伤的担忧
   - 缺乏运动锻炼的相关指导、建议
   - 缺乏时间
   - 缺乏社会支持
   - 缺乏个人动力

5. 协议运动方案
   - 制定个体化的运动方案和目标
     - ✓ 选择相对低风险的运动方式，如散步
     - ✓ “低剂量开始，缓慢增量”

- 商讨行动计划及应对计划
  - ✓ 行动计划：明确运动的种类、时间、地点等
  - ✓ 应对计划：寻找对预期运动种可能出现的障碍的应对措施

6. 运动监测指导
   - 正确地做运动，正确地呼吸
   - 安全的运动环境、设施、衣着和时间
   - 自我监测及应对
   - 体液和血压的控制
   - 运动日志的记录

7. 提供书面的运动方案、行动计划和应对计划

第 II~IX 次访谈：反馈、支持和推进

目的：评价患者对运动相关知识与建议的理解程度；前一次随访中制定的行动计划的实施进展、协议目标的实现情况；据此提供持续的支持，推动患者改变体力活动习惯，达到推荐运动量。

1. 需要转介的临床问题
   - 透析间期体重增长异常
   - 血红蛋白水平低于 80 g/L
   - 疼痛
   - 皮肤瘙痒
   - 其他，如异常血压升高

2. 前一周中有无出现下列症状或体征
   - 呼吸困难
   - 颈部或下巴疼痛或闷
   - 不规律的心跳
   - 过度疲劳/休息或日常活动时感到呼吸困难
   - 头晕或脚步轻浮
   - 视物模糊
   - 头痛/运动诱发疼痛
   - 腿抽筋或疼痛（行走短距离即出现）
   - 发烧（体温超过 38.3℃）

3. 运动锻炼的技巧
   - 柔韧性运动：简单规则
   - 肌力训练：简单规则
   - 有氧运动：评估患者自我监测运动强度的能力

4. 前一周实际完成的运动剂量（运动日志）
   - 柔韧性运动：一周锻炼频率
   - 肌力训练：动作、重复次数、组数；一周锻炼频率
   - 有氧运动：频率、持续时间、强度

5. 前一周的运动过程中有无出现下列症状或体征
   - 感到“非常辛苦”或“非常，非常辛苦”时
   - 说话时呼吸困难
   - 运动后次日由于肌肉酸痛而无法继续运动
   - 运动 1 小时后感觉还没有充分恢复
   - 心跳异常加速

6. 讨论上周的运动经历

   - 居家运动前、中、后的个人感受，强调正性情绪。

7. 对照上次运动计划和目标，评估前一周运动锻炼的实施情况；给予相应反馈

- 完成计划运动方案
  - ✓ 给予肯定
  - ✓ 商讨下周的进阶
- 未达到既定运动计划
  - ✓ 情感支持
  - ✓ 讨论原因：身体问题（症状困扰）、社会支持、天气。。。
  - ✓ 调整运动方案

8. 协商运动计划

- 制定个体化的运动计划及目标
  - ✓ 选择锻炼的动作及有氧运动方式
  - ✓ 从低剂量开始，并缓慢进阶
- 商讨行动计划及应对计划
  - ✓ 行动计划：明确运动的种类、时间、地点等
  - ✓ 应对计划：讨论可能妨碍运动的因素，并商讨相应的应对计划

9. 提供书面的运动方案、行动计划和应对计划

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Appendix 3.5

Training Plan for Nurse Case Managers

(The effects of a nurse-led case management program on home exercise training for hemodialysis patients)

Teaching hours: 12 hours

Nurse case managers: 1. Attained at least a Bachelor's degree (or its equivalent) in nursing. 2. Has at least three years of experience working in HD units. 3. Able to provide genuine care through nurse-patient communication. 4. Is attentive and responsive to patients' diverse needs.	Learning objectives: Nurses should have the following competencies after participating in the training program. 1. Ability to provide exercise suggestions to hemodialysis patients 2. Ability to assist patients in leading an active lifestyle. 3. Ability to incorporate case management into clinical practice.

Training content	**Learning objectives**	**Hours**	**Teaching approaches**	**Assessment approaches**
1. Overview of research project 1.1 Background 1.2 Objectives and significance of the study 1.3 Conceptual framework and interventions 2. Role and responsibilities of case managers 3. Ethics 3.1 Ethical principles of nursing research 3.2 Data management	1. Understanding the study frame 2. State the aims and objectives of the project 3. State the significance of the exercise program for hemodialysis patients 4. Describe the project's research procedures 5. Clarify the role and responsibilities he or she is to undertake 6. Demonstrate required research ethics during the entire research process	1	Lecture Discussion	Written examination

Training content	Learning objectives	Hours	Teaching approaches	Assessment approaches
1. Exercise guides for dialysis patients 1.1 Definitions 1.2 Physical activity levels of hemodialysis patients 1.2 Benefits of exercise for hemodialysis patients 1.3 Exercise recommendations for hemodialysis patients 1.4 Types of exercise 1.5 Assessment of exercise intensity 1.6 Development of exercise plans	1. Differentiate the concepts of physical activity and exercise 2. Explain the benefits of exercise 3. State the exercise recommendations for dialysis patients 4. Describe the assessment of exercise intensity 5. Describe different exercise types and their corresponding effects 6. Demonstrate ability to develop exercise plans	1.5	Lecture Discussion Demonstration Practice	Written examination Case scenario
2. Instruct patients to develop flexibility and strength 2.1 Developing flexibility 2.1.1 Why perform flexibility exercise? 2.1.2 Simple rules 2.1.3 Demonstrate flexibility exercise 2.2 Developing strength 2.2.1 Why perform strength exercise? 2.2.2 Simple rules 2.2.3 Demonstrate strength exercise 2.3 Developing endurance 2.3.1 Why perform aerobic exercise? 2.3.2 Discuss the selection of aerobic exercise 2.3.3 Simple rules	1. Explain the benefits of flexibility exercise 2. State the rules of flexibility exercise 3. Identify the stretching area for each movement 4. Demonstrate flexibility exercise for patients 5. Demonstrate ability to develop flexibility exercise plan for patients 6. Explain the benefits of strength exercise 7. State the rules of strength exercise 8. Identify the major muscle group for each movement 9. Demonstrate strength exercise for patients 10. Demonstrate ability to develop strength exercise plan for patients 11. Explain the benefits of aerobic exercise 12. Demonstrate the ability to help patients safely select types of aerobic exercise	1	Lecture Discussion Demonstration Practice	Written examination Case scenario

	13. State the rules of aerobic exercise			
3. Self-monitoring during exercise 3.1 Exercise precautions 3.2 Interventions to reduce risks of exercise-related injuries 3.2 Exercise-related problem identification and coping mechanisms 3.3 Record exercise log 4. Developing individualized exercise goals and plans	1. State exercise precautions 2. Explain ways to reduce exercise risks 3. Instruct patients to self-monitor exercise intensity 4. Instruct patients to identify and handle exercise-related symptoms 5. Instruct patients to keep exercise log 6. Negotiate exercise goals and plans with patients	1	Lecture Discussion	Case scenario

Training content	Learning objectives	Hours	Teaching approaches	Assessment approaches
1. Interview content 1.1 Concept of health education and provision of health information 1.2. Pender Health Promotion Model (HPM) 1.3. Apply HPM and corresponding behavioral change strategies in project 1.4 Interview process 1.4.1 Evaluation 1.4.2 Advice 1.4.3 Negotiation 1.4.4. Follow-ups	1. Describe the differences between health education and the provision of health information 2. Discuss implementation of HPM in the project 3. Illustrate behavioral change strategies adopted in current project	1.5	Lecture Discussion Practice	Written examination Case scenario
2. Interview skills 2.1 Establish nurse-patient relationship 2.2 Express acceptance and understanding 2.3 Information exchange 2.4 Explore internal motivation for change 2.5 Evaluate importance and confidence 2.6 Develop action plans and coping plans	1. Apply interview skills: Open questions, active listening, and affirmation 2. Apply behavioral strategies to strengthen behavioral change motivation and confidence 3. Implement action plans and coping plans	1	Lecture Discussion Practice	Written examination Case scenario

Training content	**Learning objectives**	**Hours**	**Teaching approaches**	**Assessment approaches**
1. Introduction of case management 1.1 Definition of case management 1.2 Case management models 1.3 Role transition: Clinical nurses to case managers 1.4 Application of case management in clinical practice	1. Discuss definition of case management 2. Analyze different case management models 3. Describe application of case management in clinical practice	1	Lecturing Discussion	Written examination Case scenario
2. Application of nurse case management in current program	Apply nurse case management to promote exercise program in dialysis practice	4	Case scenario	Case scenario

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个案护士培训计划
----『护士主导的血液透析患者居家运动个案管理项目』

课程学时：12 小时

培训对象：1. 具有大专/本科或者以上学历； 2. 3 年或以上血透室工作经验； 3. 能够真诚地与患者沟通，善于聆听； 4. 善于聆听，能够积极回应患者需求。	培训目标：参加者在完成本次培训后将具备以下能力： 1. 为透析患者提供运动指导； 2. 协助患者改变静坐不动的生活习惯； 3. 将护理个案管理模式结合至临床实践中。

教学内容	学习目标	课时	教学活动	考核方式
1. 『护士主导的血液透析患者居家运动个案管理项目』介绍 1.1 研究背景 1.2 研究目的和意义 1.3 理论构架与干预内容 2. 个案护士的角色和责任 3. 研究过程中的伦理问题 3.1 护理研究的伦理原则 3.2 研究数据管理和使用	1. 了解研究项目的整体构架； 2. 说出『护士主导的血液透析患者居家运动个案管理项目』的目的； 3. 阐述运动在透析患者管理中的重要性； 4. 描述研究的基本步骤； 5. 说出自己在研究过程中的责任和角色； 6.处理基本的研究伦理情境，如研究参与者退出研究，访谈中研究参与者出现情绪波动等； 8. 存放各种表格或档案。	1	讲授 讨论	理论考核

教学内容	学习目标	课时	教学活动	考核方式
1. 透析患者的运动指引 1.1 概念简述 1.2 血液透析患者的体力活动现状 1.3 运动对透析患者的益处 1.4 透析患者的运动推荐量 1.5 运动的种类 1.6 运动强度的评估 1.7 运动量的评估	1. 区分以下概念：体力活动，运动； 2. 解释透析患者运动的获益； 3. 说出透析患者的体力活动推荐量； 4. 列出运动强度的评估方法； 5. 描述不同种类的运动以及作用； 6. 实施体力活动水平的评估。	1.5	讲授 讨论 演示 练习	理论考核 技能考核
2. 指导患者进行柔韧性和肌力训练 2.1 训练灵活性 2.1.1 训练灵活性的意义 2.1.2 简单的规则 2.1.3 柔韧性训练示教 2.2 训练肌肉力量 2.2.1 训练肌肉力量的意义 2.2.2 简单的规则 2.2.3 肌肉力量训练示教 2.3 训练心肺功能 2.3.1 训练心肺功能的意义 2.3.2 讨论居家心肺功能训练选择	1. 解释柔韧性训练的意义； 2. 说出在柔韧性训练过程中的原则； 3. 识别每个动作的拉伸部位； 4. 示范指导患者进行柔韧性锻炼； 5. 指导患者安全调整柔韧性运动量； 6. 解释肌肉力量训练的意义； 7. 说出在肌肉力量训练过程中的原则； 8. 识别每个动作的肌力训练部位； 9. 示范指导患者进行肌肉力量锻炼； 10. 指导患者安全调整肌肉力量运动量； 11. 解释心肺功能训练的意义； 12. 选择安全的居家心肺功能训练方法； 13. 说出在心肺功能训练过程中的原则。	1	讲授 示教 练习 回示	

2.3.3 简单的规则				
3. 运动中的自我监测 3.1 运动中的注意事项 3.2 降低运动风险的措施 3.2 问题的识别和应对 3.3 运动日志的记录 4. 个体化运动目标和计划的制定	1. 说出运动中的注意事项； 2. 解释防范运动风险的措施； 3. 指导患者自我监测运动强度； 4. 指导患者识别应对运动中出现的问题； 5. 指导患者记录运动日志。 6. 协商制定个体化的运动计划和目标	1	讲授 讨论	

教学内容	学习目标	课时	教学活动	考核方式
1. 访谈内容 1.1 健康教育的概念 1.2 健康教育理论 ----Pender’s 健康促进模式 1.3 Pender’s 健康促进模式在『护士主导的血液透析患者居家运动个案管理项目』中的运用 1.4 访谈内容介绍 1.2.1 评估 1.2.2 建议 1.2.3 协议 1.2.4 随访	1. 描述健康教育与健康信息提供的区别； 2. 讨论 Pender’s 健康促进模式在本项目中的运用； 3. 阐述促进行为改变的策略；	1.5	讲授 讨论 练习	理论考核 技能考核
2. 访谈技巧 2.1 护患关系建立：伙伴、合作关系 2.2 表达接受和理解：信任、给予肯定 2.3 信息交换：开放式提问 2.4 发掘改变的内在动机：决策平衡 2.5 评估重要性和信心 2.6 建立行动计划和应对计划	1. 运用访谈技巧：开放式提问、反应式聆听、给予肯定等； 2. 运用理论技巧引导患者强化行为改变的动机和信心。 3. 与患者协商建立行动计划和应对计划。	1	讲授 讨论 练习	理论考核 技能考核

教学内容	学习目标	课时	教学活动	考核方式
1. 个案管理护理模式简介 1.1 个案管理的定义 1.2 个案管理模式 1.3 角色转化：照顾者-个案护士 1.4 个案管理的临床运用	1. 讨论护理个案管理的定义； 2. 分析各类个案管理模式； 3. 简述个案管理的临床运用。	1	讲授 讨论	理论考核 技能考核
2. 个案管理在『护士主导的血液透析患者居家运动个案管理项目』中的运用	运用护理个案管理的模式促进透析患者提高体力活动水平	4	病案模拟	

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Interview record	Dialysis center	**1st interview**
	□ First Affiliated Hospital of Nanjing Medical University □ Second Affiliated Hospital of Nanjing Medical University	From ___/____/____ to ___/____/____ (Month/Day/ Year)

General information

Research code: ________________ Date of interview: ______________

Participant: ________________ Time of interview: _____________

Case manager: _________________

Home exercise suggestions

Part 1: Flexibility exercise		Part 2: Strength exercise	
1. □Neck stretch 3.□Shoulder shrug & rotation 5. □Side stretch 7. □Leg stretch	2.□Arm/hand stretch 4.□Chest & upper back strength 6.□Single knee pull 8. □Calf stretch	1.□ Arm curl 3.□Lower leg extension 5.□Seated marching 7.□ Heel raise	2.□ Arm extension 4.□Straight leg extension 6.□ Back leg swing 8.□ Side leg lift

Type	Frequency	Intensity/duration	Movement
Flexibility	□ Time(s)/week	________Repetition(s) __________Set(s)	Movement(s)1-□
Strength	□ Time(s)/week	________Repetition(s) __________Set(s)	Movement(s)1-□

Interview Summary
Please tick "√" before the item(s) that you have discussed or evaluated.

1. Attitude to exercise

The importance of physical activity and/or exercise
0 1 2 3 4 5 6 7 8 9 10
Not important at all Extremely important

2. Current physical activity level

How often do you exercise at a moderate intensity level for 30 minutes per week?
□ 0 □ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7+

3. Provision of exercise-related information
   - □ Recommended levels of physical activity for dialysis patients
   - □ Types of exercise and how to exercise
   - □ Benefits of exercise for hemodialysis patients
   - □ How to monitor exercise intensity
   - □ Exercise precautions

4. Exercise benefits—Decision balance

What are the most important benefits of exercise for you? Why?

1. ____
2. ____
3. ____
4. ____

5. Intention to exercise
   - □ Not exercising now, and will not initiate exercise
   - □ Not exercising now, but will consider starting exercise slowly
   - □ Exercise irregularly, and do not plan to increase exercise activity
   - □ Exercise irregularly, but plan to increase exercise level

6. Emphasis on self-monitoring
   - □ Exercise environment, facilities, clothing, and timing
   - □ Self-monitoring and coping
   - □ Body weight and blood pressure management
   - □ Exercise log record

Goals and plans

1. **Goal for aerobic exercise**: I will exercise_______days/week on_______(list days). I will do_____(list activity) starting with___________minutes, and adding _ ______minutes to reach my goal of _________minutes over the next ____ week(s).

Expected exercise benefits: ____

2. **Goal for strength exercise**: I will exercise____________days/week on_ ______(list days). I will do_____(list movement) starting with_____ ______repetition(s)/_____ set(s) and then adding ________repetition(s)/_____ set(s) to reach my goal of _________ repetition(s)/_____ set(s) over the next ____ week(s).

Expected exercise benefits: ____

To achieve the aforementioned goals, I am planning to perform … this week

1. Aerobic exercise

Frequency: ________time(s)/week

Intensity: □ low □ moderate □ intense

Time: _____________minutes/day

Type: _________(list activity, e.g., walking, jogging)_

I will maintain this exercise plan for________week(s), and gradually increase the exercise dosage.

2. Strength exercise

Frequency: ______time(s)/week

Type: movement(s) #______to #___________

Intensity: ___repetition(s)/___set(s)

I will maintain this exercise plan for________week(s), and gradually increase the exercise dosage.

Coping plan

Some of the reasons for not being able to exercise		Negotiated coping plan(s)
□ Exercise is hard work □I do not have anyone to exercise with □There is no convenient place to exercise □I do not enjoy exercise □ Exercise is boring □ I am too old Other reasons________	□I am usually too tired □The weather is too bad □I do not know how to exercise □I am afraid of being hurt □I do not have the time □ I am too overweight ___________	1. ________________________ 2. ________________________ 3. ________________________ 4. ________________________

Confidence

Level of confidence in ability to implement the established exercise plans
0 1 2 3 4 5 6 7 8 9 10
Not confident at all Extremely confident

Case manager: ______________________ Date: ______________________

Duration of interview: ___________________

<table>
<tr><td rowspan="2">Interview record</td><td>Dialysis center</td><td>□2nd □3rd □4th □5th □6th □7th □8th □9th interview</td></tr>
<tr><td>□ First Affiliated Hospital of Nanjing Medical University
□ Second Affiliated Hospital of Nanjing Medical University</td><td>From ___/____/____ to ___/____/____ (Month/Day/Year)</td></tr>
</table>

General information

Research code: ________________ Date of interview: ______________

Participant: ________________ Time of interview: _____________

Case manager: _________________

Home exercise suggestions

Part 1: Flexibility exercise		Part 2: Strength exercise	
1.□Neck stretch 3.□Shoulder shrug & rotation 5.□Side stretch 7.□Leg stretch	2.□Arm/hand stretch 4.□Chest & upper back strength 6.□Single knee pull 8.□Calf stretch	1.□Arm curl 3.□Lower leg extension 5.□Seated marching 7.□Heel raise	2.□Arm extension 4.□Straight leg extension 6.□Back leg swing 8.□Side leg lift

Type	Frequency	Intensity/duration	Movement
Flexibility	□ Time(s)/week	________Repetition(s) __________Set(s)	Movement(s)1-□
Strength	□ Time(s)/week	________Repetition(s) __________Set(s)	Movement(s)1-□

Interview Summary
Please tick "√" before the item(s) that you have discussed or evaluated.

1. Evaluate exercise performed in the past week: did the patient experience exercise-related symptoms or signs?
□ No
□ Yes. Details:__________

2. Evaluate referral needs
□ No
□ Yes. Details: ______________

3. Exercise attitude

The importance of physical activity and/or exercise
0 1 2 3 4 5 6 7 8 9 10 Not important at all Extremely important

4. Exercise performed in past week
1. Aerobic exercise

Frequency: ______time(s)/week

Intensity: □ low □ moderate □ intense

Time: ____________minutes/day

Type: _____________(list activity, e.g., walking, jogging)_

2. Strength exercise

Frequency: _______time(s)/week

Type: movement(s) #_to #____________

Intensity ___repetition(s)/___set(s)

5. Knowledge and skills for self-monitoring
□ The patient has adequate exercise self-monitoring knowledge and skills.
□ The patient lacks self-monitoring knowledge or skills. Details: _________
□ The patients needs more health education.

Goals and plans

1. **Goal for aerobic exercise**: I will exercise_______days/week on_______(list days). I will do_____(list activity) starting with___________minutes and adding _ _______minutes to reach my goal of _________minutes over the next ____ week(s).

Expected exercise benefits: ____

2. **Goal for strength exercise**: I will exercise_____________days/week on_ _______(list days). I will do_____(list movement) starting with_____ _______repetition(s)/_____ set(s) and adding _____________repetition(s)/_____ set(s) to a reach my goal of _________ repetition(s)/_____ set(s) over the next ____ week(s).

Expected exercise benefits: ____

Coping plan

Some of the reasons for not being able to exercise		Negotiated coping plan(s)
□ Exercise is hard work □ I do not have anyone to exercise with □ There is no convenient place to exercise □ I do not enjoy exercise □ Exercise is boring □ I am too old Other reasons________ _______	□ I am usually too tired □ The weather is too bad □ I do not know how to exercise □ I am afraid of being hurt □ I do not have the time □ I am too overweight ___________	1. ________________________ _______ 2. ________________________ _______ 3. ________________________ _______ 4. ________________________ _______

Confidence

Level of confidence in ability to implement established exercise plans
0 1 2 3 4 5 6 7 8 9 10 Not confident at all Extremely confident

Case manager: ____________________ Date: ______
Duration of interview: _________________

<table>
<tr><td rowspan="2">访谈记录</td><td>透析中心</td><td>第 _1__ 次访谈</td></tr>
<tr><td>☐ 南京医科大学第一附属医院
☐ 南京医科大学第二附属医院</td><td>从 ___/____/____ 至 ___/____/____</td></tr>
</table>

一般信息

研究编号：____________________ 访谈日期：____________________

参加者姓名：____________________ 访谈时间：____________________

个案护士：____________________

居家运动建议 （研究人员根据小组运动情况填写）

Part 1: 柔韧性运动		Part 2: 肌肉运动	
1. ☐颈部伸展	2. ☐手臂伸展	1. ☐臂部弯曲	2. ☐臂部伸展
3. ☐耸肩&旋转	4. ☐胸部和上背伸展	3. ☐小腿伸展	4. ☐直腿伸展
5. ☐侧伸展	6. ☐单膝拉伸	5. ☐坐位步行	6. ☐后腿摆动
7. ☐腿部伸展	8. ☐小腿伸展	7. ☐提踵	8. ☐侧腿抬举

类型	频率	强度/时间	种类
柔韧	☐次/周	每个动作重复_______次 做 _________组	动作 1-☐
肌力	☐次/周	每个动作重复_______次 做 _________组	动作 1-☐

访谈小结

请在已经讨论或者评估的条目前打“√”

1. 参与运动锻炼的态度

参与者认为体力活动/运动对健康的重要性
0　1　2　3　4　5　6　7　8　9　10 完全不重要　　　　　　　　　　　　非常重要

2. 当前身体活动水平

通常每周做 30 分钟以上中等体力活动多少次？
☐0　☐1　☐2　☐3　☐4　☐5　☐6　☐7+

3. 提供运动相关健康资讯
   - ☐接受血液透析治疗的慢性肾脏疾病患者的推荐体力活动水平
   - ☐运动的方式
   - ☐运动锻炼对透析患者的益处
   - ☐每次运动锻炼持续的时间及强度
   - ☐参与运动锻炼的注意事项

4. 运动的益处----决策平衡

各种锻炼的益处，对患者来说，最重要的是什么？为什么要锻炼？

1. ____
2. ____
3. ____
4. ____

5. 运动锻炼的意向
   - ☐现阶段没有运动，也不想开始运动锻炼
   - ☐现阶段没有运动，但是正考虑开始慢慢运动
   - ☐间或有运动锻炼，现在不准备增加运动量
   - ☐间或有运动锻炼，且考虑增加运动量

6. 运动自我监测指导
   - ☐安全的运动环境、设施、衣着和时间
   - ☐自我监测及应对
   - ☐体液和血压的控制
   - ☐运动日志的记录

目标与计划

1. **耐力锻炼目标**：我将在未来_________周内，计划________（如，散步，打太极拳）；每周做____次，每次_________分钟，累计________分钟。

期望获得的益处：____

2. **肌力锻炼目标**：我将在未来_________周内，计划_______（如，肌力训练）；每周做____次，每个动作重复____次，做____________组。

期望获得的益处：____

为达到上述运动目标，我**本周计划**如下：

1. 耐力锻炼

频率 Frequency：F ___________次/周

强度 Intensity：I _______强度；活动时，□能说话 □能唱歌

时间 Time: T ____________分钟/天

种类 Type：T ____________什么运动（如散步、跳舞、打太极拳）_

我将持续__________周这样的活动水平，然后增加缓慢地增加运动量。

每隔□1/□2 周调整活动计划达到另一层级水平。

2. 肌力锻炼

频率 Frequency：F ___________次/周

种类 Type：T 动作#_____至#____________

强度 Intensity：每个动作重复____次；做______组

我将持续__________周这样的活动水平，然后增加缓慢地增加动作的重复数量或者组数。

每隔□1/□2 周调整活动计划达到另一层级水平。

应对计划

可能不做运动的理由		协议应对方案
☐运动很难 ☐没人和我一起运动 ☐没有方便的运动场所 ☐我不喜欢运动 ☐运动太无聊 ☐我年龄太大 其他________	☐我经常感到累 ☐天气不好 ☐不知道如何运动 ☐没有家人支持 ☐我害怕受伤 ☐我体重太重了 ☐我没有时间 __________	1. ______________________________ 2. ______________________________ 3. ______________________________ 4. ______________________________

信心

患者认为实现上述设定运动计划的信心
0　　1　　2　　3　　4　　5　　6　　7　　8　　9　　10 根本没有　　　　　　　　　　　　　　　　非常有信心

个案护士签名：____________________　　　　　　　　日期：_______

访谈时长：______________

访谈记录	透析中心	第 ____ 次访谈
	☐ 南京医科大学第一附属医院 ☐ 南京医科大学第二附属医院	从 ___/____/____ 至 ___/____/____

一般信息

参加者姓名：____________________ 个案护士：____________________

访谈日期：____________________ 访谈时间：____________________

居家运动建议 （研究人员根据小组运动情况填写）

Part 1：柔韧性运动		Part 2：肌肉运动	
1. ☐颈部伸展	2. ☐手臂伸展	1. ☐臂部弯曲	2. ☐臂部伸展
3. ☐耸肩&旋转	4. ☐胸部和上背伸展	3. ☐小腿伸展	4. ☐直腿伸展
5. ☐侧伸展	6. ☐单膝拉伸	5. ☐坐位步行	6. ☐后腿摆动
7. ☐腿部伸展	8. ☐小腿伸展	7. ☐提踵	8. ☐侧腿抬举

类型	频率	强度/时间	种类
柔韧	☐次/周	—	动作 1-☐
肌力	☐次/周	每个动作重复________次 做 __________组	动作 1-☐

访谈小结

请在已经讨论或者评估的条目前打“ √ ”

1. 前一周运动情况评估：有无出现运动相关症状或体征
   ☐无
   ☐有，请注明：______________

2. 转介需要评估（参照血液透析中心护理规范）
   ☐无
   ☐有，请注明：______________

3. 参与运动锻炼的态度

参与者认为体力活动/运动对健康的重要性										
0	1	2	3	4	5	6	7	8	9	10
完全不重要										非常重要

4. 当前体力活动水平

1. 耐力锻炼

种类 Type：T ____________什么运动（如散步、跳舞、打太极拳）_

频率 Frequency：F ___________次/周

强度 Intensity：I _______强度；活动时，☐能说话 ☐能唱歌

时间 Time: T ___________分钟/天

2. 肌力锻炼

种类 Type：T 动作#_____至#____________

强度 Intensity：每个动作重复____次；做______组

频率 Frequency：F ___________次/周

5. 运动自我监测知识和技能
   ☐患者具备自我监测知识和技能
   ☐患者自我监测知识和技能不足，请注明具体内容：________________
   ☐强化健康教育

目标与计划

1. **耐力锻炼目标**：我将在未来__________周内，计划________（如，散步，打太极拳）；每周做____次，每次_________分钟，累计________分钟。

期望获得的益处：____

2. **肌力锻炼目标**：我将在未来__________周内，计划_______（如，肌力训练）；每周做____次，每个动作重复____次，做____________组。

期望获得的益处：____

为达到上述运动目标，我**本周计划**如下：

1. 耐力锻炼

频率 Frequency：F ___________次/周

强度 Intensity：I _______强度；活动时，☐能说话 ☐能唱歌

时间 Time: T ____________分钟/天

种类 Type：T ____________什么运动（如散步、跳舞、打太极拳）_

我将持续__________周这样的活动水平，然后增加缓慢地增加运动量。

每隔☐1/☐2 周调整活动计划达到另一层级水平。

2. 肌力锻炼

频率 Frequency：F ___________次/周

种类 Type：T 动作#_____至#____________

强度 Intensity：每个动作重复____次；做______组

我将持续__________周这样的活动水平，然后增加缓慢地增加动作的重复数量或者组数。

每隔☐1/☐2 周调整活动计划达到另一层级水平。

应对计划

可能不做运动的理由		协议应对方案
☐运动很难 ☐没人和我一起运动 ☐没有方便的运动场所 ☐我不喜欢运动 ☐运动太无聊 ☐我年龄太大 其他________	☐我经常感到累 ☐天气不好 ☐不知道如何运动 ☐没有家人支持 ☐我害怕受伤 ☐我体重太重了 ☐我没有时间 __________	1. ____________________ 2. ____________________ 3. ____________________ 4. ____________________

信心

患者认为实现上述设定运动计划的信心										
0	1	2	3	4	5	6	7	8	9	10
根本没有										非常有信心

个案护士签名：________________

访谈时长：______________　　　　日期：_______________

Appendix 3.7

Personal information

Patient code_______ Date___________ （Please √ the correct box）

---

1. Your name: ____________
2. Your birth date:___________Year________Month_______Day
3. Your gender: 1. ☐Male 2. ☐Female
4. Your marital status: 1.☐Single 2.☐Married 3. ☐Divorced 4.☐Widowed 5.☐Others____________
5. Your education level: 1.☐ Primary or below 2. ☐ Secondary 3.☐Tertiary or Vocational training 4.☐University or above 5. Others___________
6. Your employment status: 1.☐Full-time 2.☐Part-time 3.☐Retired 4.☐Studying 5.☐House-keeping 6.☐Others___________
7. Monthly salary（Including you, your spouse, and others who living with you）:
1. ☐500RMB or blow 2. ☐500-1000RMB
3. ☐1000-2000RMB 4. ☐2000-3000RMB
5. ☐3000-4000RMB 6. ☐4000-5000RMB
7. ☐5000-10000RMB 8. ☐10000RMB or above
8. How do you consider your financial status at present?
1. ☐Very insufficient 2. ☐Not enough for daily expenses 3. ☐Barely enough for daily expense 4. ☐Very sufficient
9. Are you the financial support of the family? 1. ☐Yes 2. ☐No
10. Your major source of medical costs 1. ☐Self-pay 2. ☐Social insurance
3. ☐Free medicare
4. ☐Self-bought medical insurance
5. ☐Others______________________
11. Whom you are living with? 1. ☐Nil 2. ☐Spouse
3. ☐Son or daughter___persons
4. ☐Others____________
12. Who takes care of you? 1. ☐Yourself 2. ☐Spouse
3. ☐Maid 4. ☐Son or daughter
5. ☐Parent(s)
6. ☐Others____________
13. The are available to you 1.☐Any time when needed
2.☐Occasionally 3. ☐At daytime only
4.☐At night only 5. ☐Others____________
14. Are you taking medications now? 1. ☐ Yes, how many ______
2. ☐No

参加者资料

研究编号：________ 日期：________________（请在适合您回答的方框内打“√”）

---

1. 您的姓名：____________
2. 您的出生日期 ：___________年________月_______日
3. 您的性别 ：1. □男 2. □女
4. 您的婚姻状况：1. □未婚 2. □已婚 3. □离婚/分居 4. □丧偶 5. □其他，请注明____________
5. 您的教育程度 ：1. □小学 2. □初中 3. □高中或中专 4. □大专或以上 5. 其他，请注明___________
6. 您的职业： 1. □全职 2. □兼职 3. □退休 4. □学生 5. □主理家务 6. □以上都不是，请注明___________
7. 您的家庭平均月收入（包括您，您的配偶及其他与您共同生活的家庭成员）：
   1. □500 元以下 2. □500-1000 元 3. □1000-2000 元
   4. □2000-3000 5. □3000-4000 元 6. □4000-5000 元
   7. □5000-10000 元 8. □10000 元 以上
8. 您觉得您的经济状况如何：
   1. □十分不足够 2. □不足够应付日常开支
   3. □刚刚足够应付日常开支 4. □足够有余
9. 您是否家庭经济支柱：1. □是 2. □否
10. 您的医疗费用主要来源： 1. □自费 2. □社会医疗保险金 3. □公费医疗 4. □自己购买的医疗保险 5. □其他，请注明_____________________
11. 您现在与哪些家庭成员居住： 1. □独居 2. □配偶 3. □子女___人 4. □其他，请注明____________
12. 什么人照顾您： 1. □无 2. □亲人 3. □朋友 4. □邻居 5. □保姆 6. □其他，请注明_____
13. 您所得的照顾是： 1. □随时的 2. □间中 3. □只有白天 4. □只有晚上 5. □其他，请注明____________
14. 您目前有没有服用处方药： 1. □有 2. □没有
    如果有的话，有____种

Clinical information

1. Primary cause of kidney disease 1. ☐Hypertension
2. ☐Diabetes mellitus
3. ☐Polycystic kidney
4. ☐Chronic glomerulonephritis
5. ☐ Lupus erythematosus
6. ☐Chronic pyelonephritis 7. ☐Unknown
8. ☐Gout 9. ☐Others________

2. Comorbidities: 1. ☐No other disease 2. ☐Diabetes mellitus
3. ☐Hypertension
4. ☐Coronary heart disease
5. ☐Congestive heart failure
6. ☐Other heart diseases
7. ☐Peripheral vascular diseases
8. ☐Cerebrovascular diseases
9. ☐Respiratory diseases 10. ☐Neurological diseases
11. ☐Hematological disorders 12. ☐Cancer
13. ☐Others________

3. Peritoneal dialysis history: 1. ☐Yes 2. ☐No

4. Kidney transplant history: 1. ☐Yes 2. ☐No

5. Current dialysis regimen: 1. ☐Hemodialysis
2. ☐Hemodialysis plus hemodiafiltration 3. ☐Others____

6. Date of starting hemodialysis: ________Years________Months
Dialysis duration________Months

7. Dry weight:________kg
Average weight gain in the past three dialysis sessions________Kg

8. Hemoglobin______g/L, Date______Year______Month______Day

9. Currently use of EPO: ☐Yes, EPO, Dose:____________ ☐No

10. Pre-dialysis blood pressure_________ /__________mmHg

Gait speed
Normal gait speed: Distance________m, Time________s, Speed________m/s
Fast gait speed: Distance________m, Time________s, Speed________m/s

10-repetition sit-to-stand ________s

Name of the investigator:_____________

Date of the investigation: __Year__Month__Day

疾病史

1. 肾病起因： 1. □高血压 2. □糖尿病 3. □多囊肾
4. □慢性肾小球肾炎 5. □ 红斑狼疮
6. □慢性肾盂肾炎
7. □不知道 8. □其他（请注明）________

2. 主要合并症： 1. □没有 2. □糖尿病
3. □高血压 4. □冠状动脉疾病
5. □充血性心力衰竭 6. □其他心脏疾病
7. □外周血管疾病 8. □脑血管疾病
9. □呼吸系统疾病 10. □神经系统疾病
11. □血液性疾病 12. □肿瘤
13. □其他（请注明）________

3. 是否接受过腹膜透析：1. □是 2. □否
4. 是否接受过肾脏移植：1. □是 2. □否
5. 目前的血液透析方案：1. □血液透析 2. □血液透析+滤过 3. □其他（请注明）____
6. 开始透析时间：________年________月；透析年限：________月
7. 干体重：________kg，过去三次透析间期体重平均增加：________公斤
8. 血红蛋白：______g/L，日期：______年______月______日
9. EPO 使用：□使用 EPO，剂量为：____________ □未使用 EPO
10. 透析前血压：_________/__________mmHg

步行速度
正常速度：距离________m， 时间________s，速度________m/s
最大速度：距离________m， 时间________s，速度________m/s

10 次起坐时间________s （凳高_______cm）

调查人员姓名：_____________

调查时间：201__年__月__日

You Health
——and——
Well-being

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. 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.

<u>Your health</u>

1. In general, would you say your health is: [Mark an ☑ in the one box that best describes your answer.]

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

The following items are about activities you might do during a typical day. <u>Does your health now limit</u> you in these activities? If so, how much?

	Yes, Limited a lot	Yes, limited a little	No, not limited at all
2. <u>Moderate activities</u>, such as moving a table, push a vacuum cleaner, bowing, or playing golf	☐ 1	☐ 2	☐ 3
3. Climbing <u>several</u> flights of stairs	☐ 1	☐ 2	☐ 3

During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?

		Yes	No
4.	**<u>Accomplished less</u> than you would like**	☐ 1	☐ 2
5.	**Were limited in the <u>kind</u> of work or other activities**	☐ 1	☐ 2

During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

		Yes	No
6.	**<u>Accomplished less</u> than you would like**	☐ 1	☐ 2
7.	**Didn't do work or other activities as <u>carefully</u> as usual**	☐ 1	☐ 2

8. **During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?**

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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 <u>past 4 weeks</u> …

		All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
9.	**Have you felt calm and peaceful?**	☐ 1	☐ 2	☐ 3.......	☐ 4.......	☐ 5	☐ 6
10.	**Did you have a lot of energy?**	☐ 1	☐ 2	☐ 3.......	☐ 4.......	☐ 5	☐ 6
11.	**Have you felt downhearted and blue?**	☐ 1	☐ 2	☐ 3.......	☐ 4.......	☐ 5	☐ 6

12. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Your Kidney Disease

How true or false is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
13. My kidney disease interferes too much with my life................	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
14. Too much of my time spend dealing with my kidney disease.............	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
15. I feel frustrated dealing with my kidney disease..........	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
16. I feel like a burden on my family...................	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

During the past 4 weeks, to what extent were you bothered by each of the following?

		Not at all bothered ▼	Somewhat bothered ▼	Moderately bothered ▼	Very much bothered ▼	Extremely bothered ▼
17.	Soreness in your muscles?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
18.	Chest pain?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
19.	Cramps?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
20.	Itchy skin?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
21.	Dry skin?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
22.	Shortness of breath?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
23.	Faintness of 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 patient 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

Effects of Kidney Disease on Your Daily Life

Some people are bothered by the effects of kidney disease on their daily life, while others are not. How much dies kidney disease bother you in each of the following areas?

		Not at all bothered	Somewhat bothered	Moderately bothered	Very much bothered	Extremely bothered
29.	Fluid restriction?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
30.	Dietary restriction? .	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
31.	Your ability to work around the house? ...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
32.	Your ability to travel?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
33.	Being dependent in doctors and other medical staff?............	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
34.	Stress or worries caused by kidney disease?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
35.	Your sex life?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
36.	Your personal appearance?..............	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Thank you for completing these questions!

您的健康

——和——

幸福

肾脏病与生活质量 (KDQOL™-36)

填写说明

此次调查是询问您对自己健康的看法。这一信息将有助于了解您的感受以及您进行平常活动的能力。这项调查包括关于您健康和生活的各种问题。我们很想了解您对每个问题的感受。

请您按照说明如实回答下列问题。如果您对某一个问题不能做出肯定的回答，请您按照您的理解选择最适合的答案。在最能描述您回答的方框内标注☑ 。

您的健康

1. 总体来讲，您认为您的健康状况：

非常好	很好	好	一般	差
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

以下各项是关于您在一天中可能进行的活动。您现在的健康状况会限制您进行这些活动吗？如果是，限制的程度如何？

	是的，有很大的限制	是的，有点儿限制	不，一点儿也不限制
2. 中等强度的活动，比如移动桌子、扫地、散步或者打太极拳	☐ 1	☐ 2	☐ 3
3. 上几段楼梯	☐ 1	☐ 2	☐ 3

在过去的四个星期，您在工作时或者日常活动中，有没有因为您的身体健康状况原因而出现以下问题？

		有	没有
4.	实际做的比想要做的要少..	☐ 1	☐ 2
5.	工作或其它活动的种类受到了限制..	☐ 1	☐ 2

在过去的四个星期，您在工作时或者日常活动中，有没有因为情绪问题（比如感到抑郁或焦虑）而出现以下问题？

		有	没有
6.	实际做的比想要做的要少..	☐ 1	☐ 2
7.	不像平常进行工作或活动那样仔细了....................................	☐ 1	☐ 2

8. 在过去的四个星期，疼痛对您的日常工作（包括在外工作和家务事）有多大程度的影响？

完全没有影响	有很少影响	有一些影响	有很大影响	有极大影响
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

这些问题与您在过去四个星期的感受和其他情况有关。对于每个问题，请给出最接近您的感受的一个回答。

在过去的四个星期，有多少时间…

		总是如此	大多数时间	相当多时间	有时候	偶尔	从不
9.	您觉得平静、安宁？..........	☐ 1	☐ 2	☐ 3.......	☐ 4.......	☐ 5	☐ 6
10.	您觉得精力充沛？...............	☐ 1	☐ 2	☐ 3.......	☐ 4.......	☐ 5	☐ 6
11.	您觉得情绪低落，闷闷不乐？.....................................	☐ 1	☐ 2	☐ 3.......	☐ 4.......	☐ 5	☐ 6

12. 在<u>过去的四个星期</u>，有多少时间因为您的<u>身体健康状况或者情绪问题</u>影响了您的社交活动（比如拜访朋友、亲戚等）？

总是如此	大多数时间	相当多时候	有时候	偶尔
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

您的肾脏病

下列各个陈述对您来说有多正确或不正确？

	完全正确	基本正确	不知道	基本不正确	完全不正确
13. 我的肾脏病对我的生活影响太大	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
14. 我用了太多时间来应付我的肾脏病	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
15. 我为应付我的肾脏病而感到沮丧灰心	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
16. 我觉得自己好像是家庭的负担	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

在过去的四个星期，以下各个情况对您的困扰程度有多大？

	毫无困扰	少许困扰	一般困扰	很大困扰	极大困扰
17. 肌肉酸痛？	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**
18. 胸痛？	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**
19. 抽筋？	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**
20. 皮肤瘙痒？	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**
21. 皮肤干燥？	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**
22. 呼吸急促？	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**
23. 头晕？	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**
24. 没胃口？	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**
25. 精疲力尽？	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**
26. 手或脚麻木？	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**
27. 呕吐或胃部不适？	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**
28[a]. （该条目仅适用于血液透析者）					
血管通路出现问题？	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**
28[b]. （该条目仅适用于腹膜透析者）					
腹透导管部位出现问题	☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**

肾脏病对您日常生活的影响

有些人会因为肾脏病的影响而使日常生活受到干扰，有些人则不会。在以下各方面，肾脏病对您造成的困扰有多大？

		毫无困扰	少许困扰	一般困扰	很大困扰	极大困扰
29.	摄入水分的限制？...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
30.	饮食限制？...............	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
31.	您做家务事的能 力？	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
32.	您旅行的能力？.........	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
33.	对医生和其他医 务人员的依赖？................	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
34.	肾脏病造成的压力或忧虑？.......................	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
35.	您的性生活？...........	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
		☐不适用				
36.	您的个人仪表？.........	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

感谢您完成这些问题！

Beck Depression Inventory (BDI-II)

Instructions: This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the **one statement** in each group that best describes the way you have been feeling during the **past two weeks, including today**. Circle the number beside the statement you have picked. If several statements in the group seem to apply equally well, circle the highest the number fro that group. Be sure that you do not choose more than one statement for any group.

A	☐0	**I do not feel sad.**
	☐1	**I feel sad much of the time.**
	☐2	**I am sad all the time.**
	☐3	**I am so sad or unhappy that I can't stand it**
B	☐0	**I am not discouraged about the future.**
	☐1	**I feel more discouraged about my future than I**
	☐2	**I do not expect things to work out for me.**
	☐3	**I feel my fure is hopeless and will only get worse.**
C	☐0	**I do not feel like a failure.**
	☐1	**I have failed more than I should have.**
	☐2	**As I look back, I see a lot of failures.**
	☐3	**I feel I am a total failure as a person.**

L	☐0	**I have not lost interest in other people or activities.**
	☐1	**I am less interested in other people or things than**
	☐2	**I have lost most of my interest in other people or**
	☐3	**It's hard to get interested in anything.**
M	☐0	**I make decisions about as well as ever.**
	☐1	**I find it more difficult to make decisions than usual.**
	☐2	**I have much greater difficulty in making**
	☐3	**I have trouble making any decisions.**
N	☐0	**I do not feel I am worthless.**
	☐1	**I don't consider myself as worthwhile and useful as I used to.**
	☐2	**I feel more worthless as compared to other people.**
	☐3	**I feel utterly worthless.**

D	☐0	**I get as much pleasure as I ever did from the things I**
	☐1	**I don't enjoy things as much as I used to.**
	☐2	**I get very little pleasure from the things I used to**

O	☐0	**I have as much energy as ever.**
	☐1	**I have less energy than I used to have.**
	☐2	**I don't have enough energy to do very much.**

	☐3	I can't get any pleasure from the things I used to
E	☐0	I don't feel particularly guilty.
	☐1	I feel guilty over many things I have done or should have done.
	☐2	I feel quite guilty most of the time.
	☐3	I feel guilty all of the time.
F	☐0	I don't feel I am being punished.
	☐1	I feel I may be punished.
	☐2	I expect to be punished.
	☐3	I feel I am being punished.
G	☐0	I feel the same about myself as ever.
	☐1	I have lost confidence in myself.
	☐2	I am disappointed in myself.
	☐3	I dislike myself.

	☐3	I don't have enough energy to do anything.
P	☐0	I have not experienced any change in my sleeping
	☐1	I sleep somewhat more than usual./I sleep somewhat less than usual.
	☐2	I sleep a lot more than usual./I sleep a lot less than
	☐3	I sleep most of the day./I wake up 1-2 hours early and can't get back to sleep.
Q	☐0	I am no more irritable than usual.
	☐1	I am more irritable than usual.
	☐2	I am much more irritable than usual.
	☐3	I am irritable all the time.
R	☐0	I have not experienced any change in my appetite.
	☐1	My appetite is somewhat less than usual./My appetite is somewhat greater than
	☐2	My appetite is much less than before./My appetite is much greater than usual.
	☐3	I have no appetite at all./I crave food all the time.

H	☐0	I don't criticize or blame myself more than usual.
	☐1	I am more critical of myself than I used to be.
	☐2	I criticize myself for all of my faults.
	☐3	I blame myself for everything bad that

S	☐0	I can concentrate as well as ever.
	☐1	I can't concentrate as well as usual.
	☐2	It's hard to keep my mind on anything for very long.
	☐3	I find I can't concentrate on anything.

I	☐0	**I don't have any thoughts of killing myself.**
	☐1	**I have thoughts of killing myself, but I would not carry them out.**
	☐2	**I would like to kill myself.**
	☐3	**I would kill myself if I had the chance.**
J	☐0	**I don't cry anymore than I used to.**
	☐1	**I cry more than I used to.**
	☐2	**I cry over every little thing.**
	☐3	**I feel like crying, but I can't.**
K	☐0	**I am no more restless or wound up than usual.**
	☐1	**I feel more restless or wound up than usual.**
	☐2	**I am so restless or agitated that it's hard to stay still.**
	☐3	**I am so restless or agitated that I have to keep moving or doing something.**

T	☐0	**I am no more tired or fatigued than usual.**
	☐1	**I get more tired or fatigued more easily than usual.**
	☐2	**I am too tired or fatigued to do a lot of the things I used**
	☐3	**I am too tired or fatigued to do most of the things I used**
U	☐0	**I have not noticed any recent change in my interest**
	☐1	**I am less interested in sex than I used to be.**
	☐2	**I am much less interested in sex now.**
	☐3	**I have lost interest in sex completely.**

贝克抑郁量表第2版

指导语: 本问卷有 21 组陈述句，请仔细阅读每个句子，然后根据您<u>近两周(包括今天)</u> 的感觉，从每一组中**选择一条**最适合您情况的项目。如果一组句子中有两条以上适合您，请选择最严重的一个。请注意，每组句子只能选择一个条目。在最能描述您回答的陈述的数字前“ √ ”。

A	☐0	我不觉得悲伤
	☐1	很多时候我都感到悲伤
	☐2	所有时间我都感到悲伤
	☐3	我太悲伤或太难过，不堪忍受
B	☐0	我没有对未来失去信心
	☐1	我比以往更加对未来没有信心
	☐2	我感到前景黯淡
	☐3	我觉得将来毫无希望，且只会变得更糟
C	☐0	我不觉得自己是个失败者
	☐1	我的失败比较多
	☐2	回首往事，我看到一大堆的失败
	☐3	我觉得自己是一个彻底的失败者

D	☐0	我和过去一样能从喜欢的事情中得到乐趣
	☐1	我不能像过去一样从喜欢的事情中得到乐趣
	☐2	我从过去喜欢的事情中获得的快乐很少
	☐3	我完全不能从过去喜欢的事情中获得快乐
E	☐0	我没有特别的内疚感

L	☐0	我对其他人或活动没有失去兴趣
	☐1	和过去相比，我对其他人或事的兴趣减少了
	☐2	我失去了对其他人或事的大部分兴趣
	☐3	任何事情都很难引起我的兴趣
M	☐0	我现在能和过去一样作决定
	☐1	我现在作决定比以前困难
	☐2	我作决定比以前困难了很多
	☐3	我作任何决定都很困难
N	☐0	我不觉得自己没有价值
	☐1	我认为自己不如过去有价值或有用了
	☐2	我觉得自己不如别人有价值
	☐3	我觉得自己毫无价值

O	☐0	我和过去一样有精力
	☐1	我不如从前有精力
	☐2	我没有精力做很多事情
	☐3	我做任何事情都没有足够的精力
P	☐0	我没觉得睡眠有什么变化

	□1	我对自己做过或该做但没做的许多事感到内疚		□1	我的睡眠比过去略少，或略多
	□2	在大部分时间里我都感到内疚		□2	我的睡眠比以前少了很多，或多了很多
	□3	我任何时候都感到内疚		□3	我根本无法睡觉，或我一直想睡觉
F	□0	我没觉得自己在受惩罚	Q	□0	我并不比过去容易发火
	□1	我觉得自己可能会受到惩罚		□1	与过去相比，我比较容易发火
	□2	我觉得自己会受到惩罚		□2	与过去相比，我非常容易发火
	□3	我觉得正在受到惩罚		□3	我现在随时都很容易发火
G	□0	我对自己的感觉同过去一样	R	□0	我没觉得食欲有什么变化
	□1	我对自己丧失了信心		□1	我的食欲比过去略差，或略好
	□2	我对自己感到失望		□2	我的食欲比去过去差了很多，或好很多
	□3	我讨厌我自己		□3	我完全没有食欲，或总是非常渴望吃东西

H	□0	与过去相比，我没有更多的责备或批评自己	S	□0	我和过去一样可以集中精神
	□1	我比过去责备自己更多		□1	我无法像过去一样集中精神
	□2	只要我有过失，我就责备自己		□2	任何事情都很难让我长时间集中精神
	□3	只要发生不好的事情，我就责备自己		□3	任何事情都无法让我集中精神
I	□0	我没有任何自杀的想法	T	□0	我没觉得比过去累或乏力
	□1	我有自杀的想法，但我不会去做		□1	我比过去更容易累或乏力
	□2	我想自杀		□2	因为太累或者太乏力，许多过去常做的事情不能做了
	□3	如果有机会我就会自杀		□3	因为太累或者太乏力，大多数过去常做的事情都不能做了

J	☐0	和过去比较，我哭的次数并没有增加
	☐1	我比过去哭的多
	☐2	现在任何小事都会让我哭
	☐3	我想哭，但哭不出来
K	☐0	我现在没有比过去更加烦躁
	☐1	我现在比过去更容易烦躁
	☐2	我非常烦躁或不安，很难保持安静
	☐3	我非常烦躁不安，必须不停走动或做事情

U	☐0	我没觉得最近对性的兴趣有什么变化
	☐1	我对性的兴趣比过去少了
	☐2	现在我对性的兴趣少多了
	☐3	我对性的兴趣已经完全丧失

多谢阁下的支持与参与！

Dialysis patient-perceived Exercise Benefits and Barriers Scale

Instructions

Please indicate the degree to which you agree or disagree with the following statements by ticking the corresponding columns for strongly agree, agree, disagree or strongly disagree.

	Strongly agree	Agree	Disagree	Strongly disagree
1. Exercise helps reduce my total medical costs.				
2. Exercise helps reduce my body pain.				
3. Exercise can postpone a decline in body function.				
4. Exercise prevents muscular atrophy.				
5. Frequent tiredness impedes my exercise participation.				
6. Exercise improves my mood.				
7. Exercise improves bone disease.				
8. Exercise is adverse to health of dialysis patients.				
9. I worry about a fall during exercise.				
10. Exercise improves my appetite.				
11. Frequent lower-extremity muscle fatigue impedes my exercise participation.				
12. I lack an understanding of the benefits of exercise.				
13. Exercise helps me lead an optimistic and active life.				
14. Exercise is not suitable for me since I have other comorbidities.				
15. Body pain impedes my exercise participation.				
16. Exercise improves my quality of life.				

17. I lack an understanding of the knowledge on how to carry out exercise.				
18. I worry that exercise may make me feel thirsty.				
19. Exercise is not suitable for me since I have kidney disease.				
20. Exercise can keep my body weight at steady level.				
21. I worry that exercise may affect my arteriovenous fistula.				
22. Exercise helps enhance my self-care abilities.				
23. Exercise will keep me from having other diseases (e.g., cold).				
24.Outdoor exercise adds burden to my family since I need their company while I am out.				

What other benefits do you think exercise has?

____

What other factors do you think can impede your exercise participation?

____

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透析患者锻炼益处／障碍量表

填写指导：请您对以下每个条目的陈述内容表明自己的看法：非常同意、同意、不同意、非常不同意，请在相应的态度栏划“√”。

	非常同意	同意	不同意	非常不同意
1.锻炼有利于减少我总的医疗费用开支。				
2.锻炼有助于减轻身体疼痛。				
3.锻炼能延缓躯体功能减退。				
4.锻炼可以防止肌肉萎缩。				
5.我常感到疲倦妨碍了我进行锻炼。				
6.锻炼能使我感到心情比较好。				
7.锻炼能改善骨病。				
8.锻炼不利于透析患者的身体健康。				
9.我担心锻炼时会跌倒。				
10.锻炼可以使我的胃口较好。				
11.我常感到下肢乏力妨碍了我进行锻炼。				
12.我缺乏对锻炼益处的了解。				
13.锻炼有助于我乐观、积极的生活。				
14.我患有其他合并症不宜锻炼。				
15.身体疼痛妨碍了我进行锻炼。				
16.锻炼能提高我的生活质量。				

17.我缺乏透析患者如何进行运动锻炼的信息。				
18.我担心锻炼引起口渴。				
19.我患有肾脏病不宜锻炼。				
20.锻炼可以使我的体重控制较平稳。				
21.我担心锻炼会影响动静脉内瘘。				
22.锻炼能提高我的生活自理能力。				
23.锻炼可以减少我患其他病**(**如感冒**)**的次数。				
24.我外出需要家人陪伴，到户外锻炼为他们增添了负担。				

您认为锻炼还能为您带来哪些方面的益处？

____

您认为还有哪些方面妨碍了您参加锻炼？

____

Appendix 3.8

Exercise Log

From ____/____ to /____/____ 2013
Exercise plan for this week: ____
Please tick "√" in the appropriate column when you have performed the corresponding exercise. If you did not perform the exercise, please mark a "×" in the corresponding column, and give the reason in the "Remarks" column. If you experienced any discomfort during exercise, please also record it in the "Remarks" column.

	Flexibility exercise	**Strength exercise**			**Aerobic exercise (e.g., walking)**			**Remarks**
			Repetitions	**Sets**		**Duration**	**Intensity**	
Example	√	√	12	3	√	15minutes	A bit hard	No discomfort
	×	×			×			No one to exercise with
Monday	□	□			□			
Tuesday	□	□			□			
Wednesday	□	□			□			
Thursday	□	□			□			
Friday	□	□			□			

运 动 日 志

从　**2013 /____ /____**　至　**2013 /____ /____**　第____周

本周运动计划：____

做完运动后，请在适当的方格内打勾“√”；如若没有做运动请在相应的方格内打“×”。如运动中出现任何不适，请将情况记录于备注栏；如无运动，请将没有运动的原因同样记录于备注栏　。

	柔韧性锻炼	肌力锻炼			有氧运动　（如：散步）			备注
			重复次数	组数		时间	强度	
例子	√	√	12	3	√	15 分钟	有点辛苦	无任何不适
	×	×			×			没人和我一起运动
星期一	□	□			□			
星期二	□	□			□			
星期三	□	□			□			
星期四	□	□			□			
星期五	□	□			□			
星期六	□	□			□			
星期天	□	□			□			

Appendix 3.9a

To Chow Ka Yee Susan (School of Nursing)
From KWONG Wai Yung, Chair, Departmental Research Committee
Email hsenid@ Date 13-Nov-2012

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 01-Dec-2012 to 04-Jul-2014:

Project Title: The effects of a nurse-led case management program on home exercise training for hemodialysis patients
Department: School of Nursing
Principal Investigator: Chow Ka Yee Susan

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, has also obtained ethical approval for the project, the Co-PI will also assume the responsibility in respect of the ethical approval (in relation to the areas of expertise of respective Co-PI in accordance with 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 separate email notification should you be required to obtain fresh approval.

KWONG Wai Yung
Chair
Departmental Research Committee

Appendix 3.9b

Clinical Access Approval for "The Effects of a Nurse-led Case Management Program on Home Exercise Training for Hemodialysis Patients"

Party A: "The effects of a nurse-led case management program on home exercise training for hemodialysis patients" Research Team, The Hong Kong Polytechnic University

Party B: First Affiliated Hospital of Nanjing Medical University

We hereby certify that the Ph.D. candidate, Tao Xingjuan, from Party A is permitted to conduct "The effects of a nurse-led case management program on home exercise training for hemodialysis patients" in the dialysis center of our hospital starting in February 2013.

The aim of the program in the above-captioned study is to determine the effects of nurse case management on home exercise for hemodialysis patients. Recruited patients will be randomly allocated into either a intervention or control group and receive the corresponding intervention. The duration of the intervention is three months. All eligible patients will be invited to participate in a questionnaire investigation, evaluation of gait speed, and 10-repetition sit-to-stand performance test at baseline and at weeks 6 and 12 of the study. Data will be collected for program evaluation only.

The program has obtained ethical approval from the ethics committee of Party A. Clinical implementation of the program will strictly comply with the research protocol approved by the ethics committee.

Signature(s) (Party A)____________________________________

Date____________________________________

Signature(s) (Party B)____________________________________

Date____________________________________

Collaborative Agreement

Role and Responsibilities of Two Parties

Party A

□ Design the study program and training plan.

□ Provide training for clinical nurses participating in the program.

□ Provide training for data collectors.

□ Perform random allocation.

□ Monitor the program process and organize regular meetings to guarantee program quality.

□ Provide booklets and exercise logs for participants.

□ Provide research support throughout program implementation.

□ Provide collaboration fee to Party B.

Party B

□ Provide research site and cases.

□ Recommended appropriate clinical nurses to participate in the program.

□ Coordinate research program if needed.

□ Implement study intervention according to the program protocol.

Ownership of research output

□ The program is the Ph.D. project of TAO Xingjuan. All research output and the copyright thereto is owned by Party A, which has priority in reporting the research findings.

□ Party B can write manuscripts only on the content Party B was involved in. The order of authorship should reflect the relative contribution of each author. Because Party A is providing financial support, Party A should always be listed as one of the authors in any publication related to the program.

□ Party B can apply for funding for projects related to the current program in mainland China only after obtaining permission from Party A. Those projects should include Party A as one of the investigators.

□ All program output should acknowledge the Hong Kong Polytechnic University.

Party A: "The effects of a nurse-led case management program on home exercise training for hemodialysis patients" Research Team, The Hong Kong Polytechnic University

Party B: First Affiliated Hospital of Nanjing Medical University

Signature(s)	____________________		Signature(s)	____________________
Date	____________________		Date	____________________

护士主导的血液透析患者居家运动个案管理项目

临床实施同意书

甲方：香港理工大学“护士主导的血液透析患者居家运动个案管理项目”课题组

乙方：南京医科大学第二附属医院

兹证明甲方博士研究生陶幸娟已获得乙方同意，于 2013 年 2 月开始在乙方血液透析中心开展护士主导的血液透析患者居家运动个案管理项目。

此项研究的目的是探讨由护士主导的透析患者居家运动个案管理的成效。研究的参与者将会随机分配到不同的护理组，分别接受相应的护理。研究将持续 12 周（3 个月），参与者将会被邀请在护理计划实施前，实施后 6 周和 12 周接受三次问卷调查及躯体功能测试（步速测试和 10 次起坐测试）。所收集资料用于评价项目的成效，从而帮助透析患者改善生活质量。

本研究已通过甲方人类实验对象操守小组委员会审批。在乙方的研究过程将遵照审批通过的研究建议书进行。

甲方课题负责人签名 ______________

甲方负责单位盖章 ______________ SCHOOL OF NURSING 香港理工大學護理學院 THE HONG KONG POLYTECHNIC UNIVERSITY

日　　期 2013年4月1日

乙方课题负责人签名 ______________

乙方负责单位盖章 ______________ 2013.4.3.

日　　期 ______________

研究双方分工与成果分配

<u>双方在研究中的分工情况</u>

甲方

- 设计研究方案，培训计划及课程。
- 培训参与研究的个案护士。
- 培训项目协调员及资料收集员。
- 对入组对象进行随机分组。
- 审核研究方案，监控研究质量，定期召开协调会议和研究人员的工作会议。
- 提供患者项目实施过程中所用的手册，日志等。
- 提供项目实施过程中的学术支持。
- 根据乙方参与项目实施的具体情况，提供本项目的研究协作费。

乙方

- 提供研究基地，研究案例。
- 组织并安排参与研究的工作人员接受培训。
- 负责本项目在研究场所实施过程中的协调。
- 组织课题实施小组 8 人按照培训内容及干预标准实施具体的研究方案
- （共 84 例个案）。

研究成果所有权和使用权

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- 乙方的研究项目参与人员经甲方同意后，可以就其负责的研究内容撰写文章；发表文章时，根据国际惯例，按照实际贡献程度的原则进行作者的排序。因为甲方为项目来源单位，乙方在发表相关论文时应将甲方列为作者之一。
- 乙方就本课题的相关内容在国内申报项目立项或研究成果奖项时，必须经过甲方同意，并为甲方署名。
- 合作双方根据合作期间所获得的成果，包括论文，专著，成果报道等均须注明香港理工大学对本项目研究的支持及项目编号。

甲方：香港理工大学“护士主导的血液透析患者居家运动个案管理项目”课题组	乙方：南京医科大学第二附属医院
课题负责人：（签名）________	课题负责人：（签名）________
日　　期：2013年4月1日	日　　期：2013年4月2日

护士主导的血液透析患者居家运动个案管理项目
临床实施同意书

甲方：香港理工大学“护士主导的血液透析患者居家运动个案管理项目”课题组

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SCHOOL OF NURSING 香港理工大學護理學院 THE HONG KONG POLYTECHNIC UNIVERSITY

甲方课题负责人签名________________

甲方盖章 ________________

日　　期 2013年4月1日

乙方护理部负责人签名________________

乙方盖章 ________________

护理部

日　　期 ________________

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- 培训参与研究的个案护士。
- 培训项目协调员及资料收集员。
- 对入组对象进行随机分组。
- 审核研究方案，监控研究质量，定期召开协调会议和研究人员的工作会议。
- 提供患者项目实施过程中所用的手册，日志等。
- 提供项目实施过程中的学术支持。
- 根据乙方参与项目实施的具体情况，提供本项目的研究协作费。

乙方

- 提供研究基地，研究案例。
- 组织并安排参与研究的工作人员接受培训。
- 负责本项目在研究场所实施过程中的协调。
- 按照培训内容及干预标准实施具体的研究方案。

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- 乙方的研究项目参与人员经甲方同意后，可以就其负责的研究内容撰写文章；发表文章时，根据国际惯例，按照实际贡献程度的原则进行作者的排序。因为甲方为项目来源单位，乙方在发表相关论文时应将甲方列为作者之一。
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- 合作双方根据合作期间所获得的成果，包括论文，专著，成果报道等均须注明香港理工大学对本项目研究的支持及项目编号。

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香港理工大學 SCHOOL OF NURSING THE HONG KONG POLYTECHNIC UNIVERSITY	江苏省人民医院 护理部
课题负责人：（签名） ________	护理部负责人：（签名） ________
日　　期：2013年4月1日	日　　期：2013.4.10

INFORMATION SHEET

The effects of a nurse-led case management program on home exercise training for hemodialysis patients

You are invited to participate in a study supervised by Dr. Susan Chow and Prof. Frances Wong and conducted by TAO Xing-Juan, who is a student of the School of Nursing in The Hong Kong Polytechnic University.

The objective of this research is to examine the effects of the nurse-led case management program on home exercise for hemodialysis patients. You will be randomly assigned to different treatment group and receive nursing interventions accordingly. The research will last for 12 weeks. You are invited to participant in the interviews and walking tests before the program, at 12 and 16 weeks after commencement the program. The interview and walk tests will take about 30-40 minutes. The interviews and tests will discontinue if you feel discomfort during the intervention period or at data collection time.

You have every right to withdraw from the study at any time. Your withdrawal will not affect the care and treatment you usually received in the Hospital. All information related to you will remain confidential, and will be identifiable by codes known only to the researcher.

If you have any complaints about the conduct of this research study, please do not hesitate to contact Dr Virginia Cheng, Secretary of the Human Subjects Ethics Sub-Committee of The Hong Kong Polytechnic University in writing (c/o Research Office of the University) stating clearly the responsible person and department of this study.

If you would like more information about this study, please contact TAO Xing-Juan at telephone number (852) 3400 8164 or her supervisor Dr. Susan Chow at telephone number (852) 2766 6775.

Thank you for your interest in participating in this study.

Principal Investigator

Dr. Susan Chow

有关资料

护士主导的血液透析患者居家运动个案管理项目

诚邀您参加由香港理工大学护理学院周家仪博士、黄金月教授负责监督，香港理工大学护理学院博士研究生陶幸娟负责执行的研究计划。该计划由香港理工大学护理学院与南京医科大学第一附属医院（江苏省人民医院）共同负责执行。

这项研究的目的是探讨由护士主导的透析患者居家运动个案管理的成效。根据随机分配的原则，您可能会分配至不同的护理组，分别接受相应的护理。本研究在不影响您现在所接受治疗和护理的基础上，为您提供每周一次的透析治疗前的中心小组运动（6 次，每次 20-30 分钟），以及随机提供规律护士随访。研究将持续 12 周（3 个月）。所有参与者将在护理计划实施前，实施后 6 周和 12 周接受三次问卷调查，步行测试和 10 次起坐测试。希望您的参与及所提供的资料能有助于评价护理服务的成效，从而帮助透析患者改善生活质量。

规律运动对接受血液透析治疗的肾脏病患者的益处已经获得研究证实。本研究通过教授并指导透析治疗患者运动将会对参与本研究的患者带来益处。在运动过程中，您可能会出现肌肉酸痛或者轻微的胸部不适。为减少这些不适感出现的可能性，我们将会根据您目前的身体状况，为您提供个体化的运动剂量和运动进展。如果您在运动过程中有任何不适，可随时与陶幸娟联系。

您享有充分权利在研究开始之前或之后决定退出该项研究，而不会受到任何对您不正常的待遇或被追究责任。凡有关您的资料将会保密，一切资料的编码只有研究人员得悉。

如果您对这项研究有任何不满，可随时与香港理工大学人类实验对象操守小组委员会秘书郑小姐联系（地址：香港理工大学研究事务处转交）。

如果您想获得更多有关这项研究的资料，请与香港理工大学护理学院研究生陶幸娟，电话 13505 联系，或联络她的导师香港理工大学护理学院周家仪博士，电话（00852）3400 6775 联系。
感谢您有兴趣参与这项研究。

主要研究员（PI）
周家仪

有关资料

护士主导的血液透析患者居家运动个案管理项目

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这项研究的目的是探讨由护士主导的透析患者居家运动个案管理的成效。根据随机分配的原则，您可能会分配至不同的护理组，分别接受相应的护理。本研究在不影响您现在所接受治疗和护理的基础上，为您提供每周一次的透析治疗前的中心小组运动（6 次，每次 20-30 分钟），以及随机提供规律护士随访。研究将持续 12 周（3 个月）。所有参与者将在护理计划实施前，实施后 6 周和 12 周接受三次问卷调查，步行测试和 10 次起坐测试。希望您的参与及所提供的资料能有助于评价护理服务的成效，从而帮助透析患者改善生活质量。

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感谢您有兴趣参与这项研究。

主要研究员（PI）
周家仪

Appendix 3.11

CONSENT FORM

The effects of a nurse-led case management program on home exercise training for hemodialysis patients

I ________________________________ hereby consent to participate in the captioned research conducted by the School of Nursing, The Hong Kong Polytechnic University, Jiang-Su Province Hospital, and the Second Affiliated Hospital of Nanjing Medical University.

The research procedures described in the attached information sheet has been fully explained. My participation in the research is voluntary. I understand the information obtained from this research may be used in future research and published. However, my right to privacy will be retained, as my personal information will not be revealed.

I acknowledge that I have the right to question any part of the procedure. I understand that I am not obliged to take part and can withdraw at any time without penalty of any kind.

Name of participant ____

Signature participant____

Name of researcher_CHOW K.Y. Susan, WONG K.Y. France, TAO Xing-Juan___

Signature of researcher____

Data ____ _______

参与研究同意书

护士主导的血液透析患者居家运动个案管理项目

本人 ________________同意参加由香港理工大学护理学院周家仪博士、黄金月教授负责监督，香港理工大学护理学院博士研究生陶幸娟负责执行的研究计划；香港理工大学护理学院与南京医科大学第一附属医院（江苏省人民医院）共同负责执行的研究项目。

我理解此研究所获得的资料仅用于研究和学术交流。然而，我有权保护自己的隐私，我的个人资料将不能泄露。

我已获得对所附有关资料中的研究步骤的充分解释。我理解可能会出现的风险。我是自愿参与这项研究。

我理解我有权在研究过程中提出问题，在任何时候决定退出研究将不会受到任何不正常的待遇或被追究责任。

参加者姓名 ________________________________

参加者签名 ________________________________

研究人员姓名 周家仪、黄金月、陶幸娟________________

研究人员签名________________________________

日期 ________________________________

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参加者姓名 ____

参加者签名 ____

研究人员姓名 周家仪、黄金月、陶幸娟________________________

研究人员签名 ____

日期 ____

1. Results of ITT analysis

Table 1.1 Post hoc analyses for the two groups on fast gait speed

Group	df1	df2	*F* ratio	*p-value*
Intervention	1.660 [a]	92.946	8.083	0.001*
Control	2	110	0.264	0.768

[a]. The degree of freedom of F ratio is evaluated by Greenhouse-Geisser correction as estimates of adjustment (epsilon), if Mauchly's sphericity is not assumed.
Significant level for Bonferroni adjusted t-test was set at 0.025 (0.05/2).

Table 1.2 Post hoc analyses for the two groups on 10-STS

Group	df1	df2	*F* ratio	*p-value*
Intervention	2	112	101.989	<0.001*
Control	1.468 [a]	80.762	21.224	<0.001*

[a]. The degree of freedom of F ratio is evaluated by Greenhouse-Geisser correction as estimates of adjustment (epsilon), if Mauchly's sphericity is not assumed.
Significant level for Bonferroni adjusted t-test was set at 0.025 (0.05/2).

Table 1.3 Post-hoc pairwise comparisons between times for the control group on 10-STS

Group	Time	Mean difference	*P value*
Control	T0 & T1	3.554	<0.001*
	T0 & T2	4.929	<0.001*
	T1 & T2	1.375	0.096

Significant level for Bonferroni adjusted t-test was set at 0.0167 (0.05/3).

Table 1.4 Within-group analyses on the subscale scores of the KDQOL-36™

Group	Subscales	df	*n*	χ^2	*p-value*
Intervention	BKD	2	57	9.310	*0.010
	EKD	2	57	11.078	*0.004
	SPL	2	57	7.916	*0.019
	PCS	2	57	7.251	0.027
	MCS	2	57	4.291	0.117
Control	BKD	2	56	1.66	0.436
	EKD	2	56	1.594	0.451
	SPL	2	56	0.198	0.906
	PCS	2	56	0.250	0.882
	MCS	2	56	1.750	0.417

Significant level for Bonferroni adjusted t-test was set at 0.025 (0.05/2).

Table 1.5 Post-hoc pairwise comparisons between times

Group		Time	Mean rank	z-score	*P value*
Intervention	BKD	T0 & T1	21.85	-1.755	0.079
		T0 & T2	26.50	-2.508	0.012*
		T1 & T2	21.90	-1.550	0.121
	EKD	T0 & T1	24.05	-2.289	0.022
		T0 & T2	24.20	-2.813	0.005*
		T1 & T2	19.58	-2.055	0.040
	SPL	T0 & T1	28.50	-0.259	0.796
		T0 & T2	27.11	-2.311	0.021
		T1 & T2	20.31	-2.532	0.011
	PCS	T0 & T1	25.21	-0.957	0.338
		T0 & T2	23.37	-2.888	0.004*
		T1 & T2	26.69	-2.113	0.035
	MCS	T0 & T1	26.00	-1.609	0.108
		T0 & T2	23.36	-2.317	0.021
		T1 & T2	29.57	-1.164	0.244

Significant level for Bonferroni adjusted t-test was set at 0.0167 (0.05/3).

Table 1.6 Comparison between groups at the three time intervals

Subscales		Intervention mean rank	Control mean rank	Z-score	p-value
BKD	T0	54.29	59.76	-0.890	0.374
	T1	57.11	56.89	-0.035	0.972
	T2	56.64	57.37	-0.118	0.906
EKD	T0	52.34	61.74	-1.526	0.127
	T1	54.98	59.05	-0.661	0.509
	T2	57.79	56.20	-0.259	0.796
SPL	T0	59.58	54.38	-0.845	0.398
	T1	61.00	52.93	-1.311	0.190
	T2	64.18	49.69	-2.355	0.019*
PCS	T0	55.26	58.77	-0.569	0.570
	T1	57.53	56.46	-0.172	0.863
	T2	60.57	53.19	-1.226	0.220
MCS	T0	57.79	56.20	-0.258	0.796
	T1	59.04	54.92	-0.669	0.503
	T2	61.27	52.65	-1.398	0.162

Mann-Whitney U-tests were performed on the non-abnormally distributed data. Significant level for Bonferroni adjusted t-test was set at 0.025 (0.05/2).

Table 1.7 Comparison between groups at the three time intervals on SRH

		Intervention mean rank	Control mean rank	Z-score	p-value
SRH	T1	61.15	52.78	-01.507	0.132
	T2	59.30	54.66	-0.790	0.430

Mann-Whitney U-tests were performed on the non-abnormally distributed data. Significant level for Bonferroni adjusted t-test was set at 0.025 (0.05/2).

Table 1.8 Comparison between groups at the three time intervals on BDI

		Intervention mean rank	Control mean rank	Z-score	p-value
BDI-II	T0	61.90	52.01	-1.606	0.108
	T1	58.89	55.07	-0.621	0.535
	T2	55.27	58.76	-0.566	0.571

Mann-Whitney U-tests were performed on the non-abnormally distributed data. Significant level for Bonferroni adjusted t-test was set at 0.025 (0.05/2).

Table 1.9 Post hoc analyses for the two groups on DPEBBS

Group	df1	df2	*F* ratio	*p-value*
Intervention	2	112	19.791	<0.001*
Control	1.807[a]	99.396	10.930	<0.001*

[a]. The degree of freedom of F ratio is evaluated by Greenhouse-Geisser correction as estimates of adjustment (epsilon), if Mauchly's sphericity is not assumed.
Significant level for Bonferroni adjusted t-test was set at 0.025 (0.05/2).

2. Results of PP analysis

Table 2.1: Comparisons of physical performance tests by group over time

Physical performance tests		Baseline	At 6 weeks	At 12 weeks	Between Groups	Within Groups	Interaction Effect
	n	Mean (SD)	Mean (SD)	Mean (SD)	F (p-value)	F (p-value) [A,B,C]	F (p-value)
Normal gait speed (cm/s)					4.93 (*0.029)	7.47 (*0.001)	3.30 (*0.043)
Intervention	56	121.56 (25.17)	129.48 (22.91)	133.43 (27.84)		9.27 (*<0.001) [*0.006,*0.001,0.516]	
Control	51	116.78 (28.74)	119.01 (24.35)	119.03 (24.13)		0.55 (0.55)	
F (p-value)		0.84 (0.362)	5.24 (*0.024)	8.11 (*0.005)			
Fast gait speed (cm/s)					4.35 (*0.039)	4.42 (*0.016)	3.34 (*0.042)
Intervention	56	168.66 (37.36)	175.29 (35.41)	179.49 (37.46)		7.48 (*0.002) [*0.055,*0.007,0.208]	
Control	51	159.22 (41.89)	160.76 (38.84)	159.82 (36.63)		0.16 (0.854)	
F (p-value)		1.52 (0.221)	4.09 (0.046)	7.52 (*0.007)			
10-repetition sit-to-stand test (seconds)					3.18 (0.077)	91.80 (*<0.001)	5.10 (*0.011)
Intervention	56	19.66 (6.56)	13.97 (4.99)	15.52 (5.87)		98.03 (*<0.001) [*<0.001,*<0.001,*<0.001]	
Control	51	21.78 (17.23)	16.74 (6.49)	18.15 (10.03)		20.10 (*<0.001) [*<0.001,*<0.001,0.117]	
F (p-value)		0.73 (0.395)	2.79 (0.098)	6.15 (*0.015)			

*A: baseline versus at 6 weeks; B: baseline versus at 12 weeks; C: at 6 weeks versus at 12 weeks. * p< 0.05 for two way RM-ANOVA results; 0.25 for one way RM-ANOVA & between-group comparison at each time point, 0.017 for pairwise comparisons for each group among the three time points*

Table 2.2: Comparison of quality of life by group over time point

Kidney Disease Quality of life (KDQOL-36^{TM})	Baseline		After 6 weeks	After 12 weeks	Within Groups
	n	Median (25^{th} – 75^{th})	Median (25^{th} – 75^{th})	Median (25^{th} – 75^{th})	Chi-square (p-value) [A,B,C]
Symptoms and problems list					5.47 (0.065)
Intervention	56	79.17 (66.67 – 89.58)	79.17 (67.71 – 89.58)	83.33 (75.00 – 91.67)	7.27 (0.026)
Control	51	77.08 (64.58 – 89.58)	77.08 (64.58 – 87.50)	77.08 (64.58 – 87.50)	0.32 (0.851)
Z (p-value)		-0.86 (0.390)	-1.10 (0.273)	-2.27 (0.024*)	
Burden of kidney disease					8.06 (*0.018)
Intervention	56	37.50 (18.75 – 60.94)	43.75 (31.25 – 62.50)	50 (20.31 – 79.69)	8.89 (*0.012) [0.103,*0.013,0.090]
Control	51	50.00 (25 – 62.50)	43.75 (2.00 – 62.50)	43.75 (25.00 – 75.00)	1.33 (0.513)
Z (p-value)		-1.10 (0.271)	-0.14 (0.891)	-0.02 (0.988)	
Effects of kidney disease on daily life					7.71 (*0.021)
Intervention	56	58.26 (41.19 – 70.76)	60.61 (46.88 – 75.00)	65.63 (45.09 – 83.26)	10.018 (*0.007) [0.031,*0.007,0.058]
Control	51	62.5 (46.88 – 75)	64.29 (50.00 – 75.00)	62.96 (44.42 – 83.82)	0.64 (0.728)
Z (p-value)		-1.63 (0.103)	-0.65 (0.514)	-0.17 (0.866)	
PCS					4.36 (0.113)
Intervention	56	41.45 (33.84 – 46.73)	41.86 (34.86 – 50.14)	44.89 (39.66 – 50.89)	7.33 (0.026)
Control	51	42.90 (31.55 – 48.75)	41.63 (36.01 – 47.56)	43.01 (35.43 – 47.29)	0.12 (0.943)
Z (p-value)		-0.42 (0.671)	-0.11 (0.916)	-1.31 (0.189)	
MCS					6.64 (0.036)
Intervention	56	45.15 (38.51 – 53.70)	49.10 (41.36 – 57.81)	52.89 (40.59 – 59.69)	4.74 (0.093)
Control	51	46.60 (38.72 – 54.00)	48.76 (41.19 – 55.36)	46.97 (41.86 – 55.28)	2.39 (0.302)
Z (p-value)		-0.012 (0.990)	-0.37 (0.715)	-1.08 (0.282)	

A: baseline versus at 6 weeks, B: baseline versus at 12 weeks; C: 6 weeks versus at 12 weeks.

** p< 0.25 for Friedman test & Mann-Whitney test results, 0.017 for pairwise comparisons for each group among the three time points*

Table 2.3: Comparison of self-rated health by group over time

Self-perceived health	Baseline		After 6 weeks	After 12 weeks	Within Groups
	n	Median (25th – 75th)	Median (25th – 75th)	Median (25th – 75th)	Chi-square (p-value) [A,B,C]
Self-rated Health					29.01 (*0.000)
Intervention	56	25.00 (25.00 – 50.00)	25.00 (25.00 – 50.00)	50.00 (25.00 – 75.00)	19.78 (*0.000) [0.040,*0.000,*0.002]
Control	51	25.00 (25.00 – 50.00)	25.00 (25.00 – 50.00)	50.00 (25.00 – 50.00)	10.29 (*0.006) [0.212,*0.003,0.023]
Z (p-value)		-1.217 (0.224)	-1.47 (0.142)	-0.97 (0.331)	

A: baseline versus at 6 weeks, B: baseline versus at 12 weeks; C: 6 weeks versus at 12 weeks.
** p< 0.25 for Friedman test & Mann-Whitney test results, 0.017 for pairwise comparisons for each group among the three time points*

Table 2.4: Comparison of depressive symptoms by group over time

Beck Depressive Inventory (BDI)	Baseline		After 6 weeks	After 12 weeks	Within Groups
	n	Median (25th – 75th)	Median (25th – 75th)	Median (25th – 75th)	Chi-square (p-value) [A,B,C]
BDI score					12.15 (*0.002)
Intervention	56	13.50 (6.00 – 23.25)	9.00 (6.00 – 14.75)	7.67 (2.25 – 17.25)	15.51 (*<0.001) [0.017,*0.001,0.273]
Control	51	10.50 (5.00 – 17.00)	10.00 (5.00 – 15.00)	10.00 (4.00 – 20.00)	2.13 (0.345)
Z (p-value)		-1.29 (0.196)	-0.40 (0.687)	-0.83 (0.406)	

A: baseline versus at 6 weeks, B: baseline versus at 12 weeks; C: 6 weeks versus at 12 weeks.
** p< 0.25 for Friedman test & Mann-Whitney test results, 0.017 for pairwise comparisons for each group among the three time points*

Table 2.5: Comparison of physical activity level by group over time

Physical activity level	After 6 weeks		After 12 weeks	Within Groups
	n	Median (25th – 75th)	Median (25th – 75th)	Z (p-value)
Intervention	56	85.00 (60.00 – 155.00)	90.00 (80.00 – 175.00)	-1.90 (0.058)
Control	51	60.00 (0.00 – 120.00)	40.00 (0.00 – 90.00)	-3.04 (*0.002)
Z (p-value)		-1.82 (0.069)	-4.58 (*0.000)	

** p < 0.05.*

Table 2.6: Comparison of patient-perceived exercise benefits and barriers scores by group over time

Dialysis Patient-perceived Exercise Benefits and Barriers Scale (DPEBBS)	Baseline		At 6 weeks	At 12 weeks	Between Groups	Within Groups	Interaction Effect
	n	Mean (SD)	Mean (SD)	Mean (SD)	F (p-value)	F (p-value) [A,B,C]	F (p-value)
DPEBBS score					4.103 (*0.045)	25.48 (*<0.001)	1.41 (0.247)
Intervention	56	68.21 (6.08)	71.73 (6.80)	73.39 (6.88)		18.39 (*<0.001) [*<0.001,*<0.001,0.148]	
Control	51	67.02 (5.85)	70.00 (7.29)	70.14 (6.76)		8.54 (*0.001) [*0.005,*0.005,1.000]	
F (p-value)		1.20 (0.276)	2.29 (0.133)	6.57 (*0.012)			

*A: baseline versus at 6 weeks; B: baseline versus at 12 weeks; C: at 6 weeks versus at 12 weeks. * p< 0.05 for two way RM-ANOVA results; 0.25 for one way RM-ANOVA & between-group comparison at each time point, 0.017 for pairwise comparisons for each group among the three time points*

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