EFFECTIVENESS OF A NURSE-LED SELF-MANAGEMENT SUPPORT PROGRAM ON KNOWLEDGE, SELF-MANAGEMENT BEHAVIOR, SELF-EFFICACY AND QUALITY OF LIFE AMONG KIDNEY PATIENTS

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Thesis Submitted to the School of Graduate Studies, Universiti Putra Malaysia in Fulfilment of the Requirements for the Degree of Doctor of Philosophy

July 2022

FPSK (p) 2022 49

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July 2022

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Background: The complexity of chronic kidney disease (CKD) and its treatments have made self-management behavior inevitably challenging. Evidence indicates that providing education with self-management skills may improve numerous health outcomes in patients with pre-dialysis CKD. Aim: This PhD thesis aims to examine the effectiveness of a locally developed nurse-led self-management support program (CKD-NLSM) for patients with CKD stages 3-4. Methods: Three phases were planned to achieve the study aims. In Phase 1, three instruments namely the Kidney Disease Knowledge Survey [KiKS], the CKD Self-Management [CKD-SM], and the Self-Efficacy for Managing Chronic Disease [SEMCD] were translated, culturally adapted, and validated to be used in Phase 3. In Phase 2, a co-design approach was used to develop the CKD-NLSM intervention for patients with CKD stages 3-4 based on the Social Cognitive Theory. In Phase 3, the CKD-NLSM was evaluated in a randomized controlled trial (RCT) of its effectiveness compared to standard usual care on kidney disease knowledge, CKD self-management behavior, self-efficacy, quality of life, blood pressure control, and adherence to CKD diet estimated by dietary protein intake, dietary sodium intake, and dietary acid load. The parallel RCT was conducted in adult with CKD stages 3–4, aged 18 years and above in a tertiary teaching hospital. The CKD-NLSM intervention comprises 6-week program in addition to standard usual care, while the control group received standard usual care. All outcomes were measured at baseline and 26 weeks post-baseline (modified due to the social restrictions caused by the COVID-19 pandemic). The between- and within-group intervention effects were estimated using two-way repeated measure ANOVA/ANCOVA for normally distributed variables while Generalized Estimating Equation (GEE) for non-normal distributed variables. The group effects were tested as Time*Group. Results: A total of 130 patients with CKD stages 3-4 participated in the parallel RCT with 66 randomized to the CKD-NLSM and 64 to control group. Baseline characteristics between the control and intervention patients were comparable except education, age, and CKD-stages. The mean (SD) for age was 61.7 (12.02) years (intervention), and 68.1 (10.13) (control). The majority in the intervention

group (57.6%) were at stage 3b while in control group were at stages 3a and 3b in equally proportion totaled at 75%. CKD-NLSM improved participants' total kidney disease knowledge (24.6±0.36 versus 14.5±0.54, $p<0.001$), total CKD self- management behavior (81.0±1.24 versus 65.4±1.67, $p<0.001$) and self-efficacy (44.9±0.84 versus 30.1±1.33, $p<0.001$). Within-group improvement was also observed, except in quality of life. There were no significant differences in systolic blood pressure control and adherence to diets estimated by dietary protein intake, dietary sodium intake, and dietary acid load. Conclusion: CKD-NLSM is effective in improving kidney-specific knowledge, CKD self-management behavior and self-efficacy in patients with CKD stages 3-4. A larger and longer study is needed to examine the effect of CKD-NLSM on dietary protein intake, dietary sodium intake, and dietary acid load (adherence to diet control), quality of life, kidney functions and progression.

Abstrak tesis yang dikemukakan kepada Senat Universiti Putra Malaysia sebagai memenuhi keperluan untuk ijazah Doktor Falsafah

KEBERKESANAN PROGRAM SOKONGAN PENGURUSAN KENDIRI JURURAWAT TERHADAP PENGETAHUAN, TINGKAHLAKU PENGURUSAN KENDIRI, EFFIKASI KENDIRI DAN KUALITI HIDUP PESAKIT BUAH PINGGANG

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Latar Belakang: Kerumitan penyakit buah pinggang kronik (CKD) dan rawatannya telah menjadikan tingkah laku pengurusan diri sememangnya mencabar. Bukti menunjukkan bahawa menyediakan pendidikan dengan kemahiran pengurusan diri boleh meningkatkan banyak kesihatan hasil pada pesakit dengan CKD pra-dialisis. Matlamat: Tesis PhD ini bertujuan untuk meneliti keberkesanan program sokongan pengurusan diri yang diterajui jururawat yang dibangunkan tempatan (CKD-NLSM) untuk pesakit CKD peringkat 3-4. Kaedah: Tiga fasa telah dirancang untuk mencapai matlamat kajian. Dalam Fasa 1, tiga instrumen iaitu Buah Pinggang Tinjauan Pengetahuan Penyakit [KiKS], Pengurusan Kendiri CKD [CKD-SM], dan Keberkesanan Diri untuk Mengurus Penyakit Kronik [SEMCD] telah diterjemahkan, secara budaya disesuaikan, dan disahkan untuk digunakan dalam Fasa 3. Dalam Fasa 2, pendekatan reka bentuk bersama ialah digunakan untuk membangunkan campur tangan CKD-NLSM untuk pesakit dengan peringkat CKD 3-4 berdasarkan Teori Kognitif Sosial. Dalam Fasa 3, CKD-NLSM telah dinilai dalam percubaan terkawal rawak (RCT) keberkesanannya berbanding standard biasa mengambil berat tentang pengetahuan penyakit buah pinggang, tingkah laku pengurusan diri CKD, keberkesanan diri, kualiti hidup, kawalan tekanan darah, dan pematuhan diet CKD dianggarkan oleh pengambilan protein diet, pengambilan natrium diet, dan beban asid diet. RCT selari telah dijalankan pada orang dewasa dengan peringkat CKD 3-4, berumur 18 tahun dan ke atas di peringkat pengajian tinggi hospital mengajar. Intervensi CKD-NLSM terdiri daripada program 6 minggu sebagai tambahan kepada penjagaan biasa standard, manakala kumpulan kawalan menerima penjagaan biasa standard. Semua hasil diukur pada garis dasar dan selepas 26 minggu garis dasar (diubah suai kerana kepada sekatan sosial yang disebabkan oleh pandemik COVID-19). Kesan intervensi Antara- dan Dalam Kumpulan dianggarkan menggunakan ukuran berulang dua hala ANOVA/ANCOVA untuk pembolehubah taburan normal manakala Anggaran Umum Persamaan (GEE) untuk pembolehubah teragih bukan normal. Kesan kumpulan telah diuji sebagai *Time*Group*. Keputusan:

Sebanyak 130 pesakit dengan CKD peringkat 3-4 mengambil bahagian RCT selari dengan 66 rawak kepada CKD-NLSM dan 64 untuk kumpulan kawalan. Ciri garis dasar adalah setanding kecuali pendidikan, umur dan peringkat CKD. Purata (SD) untuk umur ialah 61.7 (12.02) tahun (campur tangan), dan 68.1 (10.13) (kawalan). Majoriti dalam kumpulan intervensi (57.6%) berada pada tahap 3b semasa dalam kumpulan kawalan berada pada peringkat 3a dan 3b dalam perkadaran yang sama berjumlah 75%. CKD-NLSM meningkatkan jumlah pengetahuan penyakit buah pinggang peserta (24.6±0.36 berbanding 14.5±0.54, p<0.001), jumlah tingkah laku pengurusan diri CKD (81.0±1.24 berbanding 65.4±1.67, p<0.001) dan efikasi kendiri (44.9±0.84 berbanding 30.1±1.33, p<0.001). Peningkatan dalam kumpulan juga diperhatikan, kecuali dalam kualiti hidup. Tiada perbezaan ketara didapati dalam kawalan tekanan darah dan pematuhan diet yang dianggarkan oleh pengambilan diet protein, pengambilan diet natrium, dan diet beban asid. Kesimpulan: CKD-NLSM berkesan dalam meningkatkan pengetahuan khusus buah pinggang, tingkah laku pengurusan sendiri CKD dan efikasi kendiri pada pesakit CKD peringkat 3-4. Kajian yang lebih besar dan yang lebih lama diperlukan untuk mengkaji kesan CKD-NLSM terhadap pengambilan diet protein, pengambilan diet natrium, dan diet beban asid (pematuhan kepada kawalan diet), kualiti hidup, fungsi dan perkembangan buah pinggang.

ACKNOWLEDGEMENTS

I thank the Almighty Allah for providing me the opportunity and strength to pursue this study.

A special thanks to my mother and father; words cannot express how grateful I am, for their encouragement, support and for all the sacrifice they have made to help my pursuit of a higher education degree. I would like to thank my husband, Mr. Hazza, for his unwavering support over the years, and to my beautiful daughters Fatimah and Zainab who have lived and breathed my studying. I hope that I will inspire you in learning and your success soon.

I would like to express my sincere gratitude to my main supervisor Professor Dr. Chew Boon-How, who has been a great mentor to me. Your continuous support, patience, motivation, and immense knowledge have been priceless. I feel highly indebted to my supervisory committee members, Professor Dr. Lim Soo Kun, Dr. Tang Li Yoong and Dr. Aneesa Abdul Rashid for your kind assistance, advice, guidance, and insightful comments. A special thanks to the CKD nurse-educators Miss. Karina Binti Abdul Wahid Pereira and Miss. Fatimah Hasanah Binti Mohd Radzi for their assistance in delivering the support program. Sincere appreciation to The National Kidney Foundation of Malaysia (NKF), Malaysia for their collaboration in designing and printing the CKD-Booklet.

Finally, I would like to thank the management and patients at the Universiti Malaya Medical Centre, for their support and cooperation during this study.

This thesis was submitted to the Senate of Universiti Putra Malaysia and has been accepted as fulfilment of the requirement for the degree of Doctor of Philosophy. The members of the Supervisory Committee were as follows:

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CKD	Chronic Kidney Disease
eGFR	Glomerular Filtration Rate
ESKD	End Stage Renal Disease
QoL	Quality Of Life
HRQoL	Health-Related QoL
BP	Blood Pressure
RRT	Renal Replacement Therapy
KEEP	The National Kidney Foundation Kidney Early Evaluation Program
ISN-KDDC	The International Society of Nephrology's Kidney Disease Data Centre
SEEK	The Screening and Early Evaluation Of Kidney Disease Project
MDRD	Modification of Diet in Renal Disease
CKD-EPI	Chronic Kidney Disease Epidemiology Collaboration
AKI	Acute Kidney Injury
GN	Glomerulonephritis
DN	Diabetic Nephropathy
HD	Haemodialysis
PD	Peritoneal Dialysis
HbA1c	Glycosylated Haemoglobin
RCTs	Randomised Controlled Trials
SCT	Social Cognitive Theory
EBP	Evidence-Based Practice
CKD-NLSM	CKD nurse-led self-management
KiKS	Kidney Disease Knowledge Survey
CKD-SM	CKD self-management

SEMCD	Self-efficacy for Managing Chronic Disease
IPOS-Renal	Integrated Palliative Care Outcome Scale-Renal
ESAS	Edmonton Symptom Assessment System
SMBQ	Self-Management Behavior Questionnaire
KDQ	Kidney Disease Questionnaire
PiKS	Perceived Kidney Disease Knowledge is 9-item Survey
CKD-SE	Chronic Kidney Disease Self-Efficacy
U.S.	United States
KDQ	Kidney Disease Questionnaire
KTQ	Kidney Transplant Questionnaire
KDQOL-36	Kidney Disease Quality of Life-36
BPV	Blood Pressure Variability
SPRINT	Systolic Blood Pressure Intervention Trial
LPDs	Low Protein Diets
PLADO	Plant-Dominant Low Protein Diets
KA	Ketoacid
EAAs	Essential Amino Acids
CVD	Cardiovascular Disease
NRS	Non-Randomized Study
PRISMA	Preferred Reporting Items for Systematic Reviews And Meta-Analyses
DVDs	Digital Versatile Discs
CRP	C-Reactive Protein
U.K.	United Kingdom
RPK	Renal Protection Knowledge
HPLP-IIC	Health Promoting Lifestyle Profile-II Chinese Version
SDSCA	Summary Of Diabetes Self-Care Activities

BMI	Body Mass Index
T2DM	Type 2 Diabetes
COSMIN	COnsensus-Based Standards for The Selection Of Health Status Measurement Instruments
PCS	Physical Component Summaries
MCS	Mental Component Summaries
HPD	High Protein Diet
EPI	Estimated Protein Intake
UUN	Urine Urea Nitrogen
NEAP	High Net Endogenous Acid Production
EFA	Exploratory Factor Analysis
SPSS	Statistical Package for Social Science
PCA	Principal Component Analysis
KMO	Kaiser Meyer Olkin
KR-20	Kuder Richardson 20
ICC	Intra Class Correlation Coefficient
K	Cohen's Kappa Coefficient
M	Mean Score
SD	Standard Deviation
RAS	Renin-Angiotensin-System
ITT	Intention To Treat
GEE	Generalised Estimating Equation
DF	Degrees Of Freedom
Mdn	Median
SRD	Sodium Restricted Diet

CHAPTER 1

INTRODUCTION

1.1 Background of the Study

The two most common chronic diseases that leading to chronic kidney disease (CKD) are diabetes and hypertension (Ghaderian & Beladi-Mousavi, 2014). The CKD is characterized by slow progression of renal dysfunction and can be classified into five stages based on estimated glomerular filtration rate (eGFR) (Webster et al., 2017). Moderate kidney problems (29-59 mL min/1.73 m2) and severe kidney problems (15-29 mL min/1.73 m2) are classified as stages three and four, respectively. The progression of CKD can lead to stage five CKD, also known as end stage renal disease (ESKD) if untreated (Evans et al., 2004) and a huge economic burden is incurred by many countries due to the dialysis therapy associated with ESKD. In Malaysia, the growth of ESKD patients on dialysis can be expected to continue at an alarming rate. Effective steps to address and curb further increase in new patients requiring dialysis are urgently needed, in order to mitigate the expected financial and health catastrophes associated with the projected increase of such patients (Bujang et al., 2017) due to low public awareness of the issue.

Patients with CKD must be able to self-manage their disease in order to delay or prevent its deterioration (Tong et al., 2015). A person's ability to manage symptoms, treatment, physical and psychological consequences and changes in lifestyle associated with a chronic condition is known as self-management (Barlow et al., 2002). It is important that a patient can monitor his or her condition and maintain a satisfactory quality of life (QoL) by controlling his or her cognitive, behavioral, and emotional responses. In this way, a dynamic and continuous self-regulation process is established. In addition, to become self-reliant, the patient must be vigilant about identifying (potential) complications and to seek medical attention when necessary. Thus, those diagnosed with pre-dialysis CKD, as well as their caregivers, should be identified to develop effective strategies in facilitating their health management to hinder their ailment from getting worse.

According to (Qaseem et al., 2014), more than 90% of patients with CKD have early stage (stages 1-3) disease and most are asymptomatic until late stages 4-5 (Qaseem et al., 2014). However, there is growing evidence that self-management interventions and programs mainly at CKD stages 3-4 improve healthcare outcomes for CKD patients, which translates into a better health-related QoL (HRQoL), higher self-efficacy, improved kidney disease knowledge and CKD self-management (Havas et al., 2016; Havas et al., 2018; Nguyen et al., 2019a), improved physiological results (eGFR & blood pressure (BP)) (Havas et al., 2018) as well as delay renal replacement therapy (RRT) requirement (median: 17 months), and extended survival (pre-dialysis median: 2.25 years), in comparison to typical care (Devins et al., 2003; Devins et al., 2005). Yet, many patients fail to respond to or comply with intervention related to CKD self-management (Byrne et al., 2011; Chen et al., 2011; Richard, 2006), and it appears that self-

management interventions aren't 'one size fits all' based on the differences seen in effect sizes between patients.

It may be possible to delay the progression of chronic diseases such as CKD as well as enable patients with CKD to cope with the psychological burden of this condition if renal healthcare personnel can help them control their chronic conditions. There are studies on CKD that use self-management education to facilitates compliance with treatment regimens and self-management plan (Havas et al., 2016; Havas et al., 2018; Nguyen et al., 2019a). However, the education provided was often limited to the provision of disease-specific information or uses a non-interactive educational approach due to time and manpower restraints in clinical settings (Bonner et al., 2014). Thus, nurses play a pivotal role in the management of patients with CKD. Helping and enabling people to be aware of their condition, and educating them to make informed decisions about long-term treatment is thought to be beneficial.

Our study aimed to investigate CKD patients' support needs and their caregivers (family physicians, renal nurses, & nephrologists) in order to propose an effective CKD self-management intervention by embedding cultural values of CKD patients and their psychological demands in light of the behavioral change theory. As CKD self-management is far from being a personal issue, those close to CKD patients should be aware of some essential aspects, including the nature of the disease and its related treatment, doctor appointments, and other significant details (Phillips et al., 2015). Involvement of family ties who function as facilitators should aid CKD patients in maintaining a positive perspective towards CKD self-management, including medication, physical activity, and nutrition intake. Printed materials and other beneficial resources should be made available to caregivers during CKD self-management educational intervention. In fact, CKD patients would be motivated to join such intervention programs with support given by family members.

In this chapter, all aspects revolving around CKD (e.g., definition, risk factors, prevalence, & management) are discussed. Next, the research significance, objectives, and questions are presented. This chapter ends with a summary of the thesis.

1.2 Chronic Kidney Disease (CKD)

1.2.1 Definition and Classification

The internationally accepted definition of CKD is kidney damage marker (three-month albuminuria) or eGFR < 60 ml/min/1.73m2 (Levin et al., 2013). Deterioration of kidney function is reflected in the five stages of CKD based on eGFR or other kidney damage marker(s), whereas kidney failure due to CKD is irreversible (Webster et al., 2017) (see Table 1.1). Normal eGFR or ≥ 90 mL/min/1.73m² indicates the initial stage. Next, eGFR that ranges at 60-89 mL/min/1.73m² signifies the second stage. Moving on, stage 3 is composed of 3a (mild-moderate dysfunction) and 3b (moderate-severe dysfunction)

(eGFR ranges at 45-59 mL/min/1.73m² & 30-44 mL/min/1.73m², respectively). Lastly, eGFR ranges at 15-29 mL/min/1.73m² and < 15 mL/min/1.73m² reflect stages 4 and 5, respectively. Stage 5 or ESKD demands RRT (e.g., dialysis or kidney transplantation), or conservative care (also known palliative care or non-dialysis) (Webster et al., 2017).

Table 1.1: Stages of Chronic Kidney Disease (CKD)

CKD Stage	eGFR (mL/min/1.73m^2)	Description
Stage 1	≥90	Normal or increased eGFR
Stage 2	60-89	Slightly decreased eGFR
Stage 3a	45-59	Mild-moderate decrease eGFR
Stage 3b	30-44	Moderate-severe decrease eGFR
Stage 4	15-29	Severe decrease eGFR
Stage 5	<15	ESKD-no dialysis
Stage 5D and 5T		ESKD-dialysis and Kidney transplantation

[Adapted from: Johnson et al., 2013; Webster et al., 2017]
Abbreviations: CKD, Chronic Kidney Disease; eGFR, estimated glomerular filtration rate; ESKD, end-stage kidney disease; D, dialysis; T, transplantation.

1.2.2 Prevalence

1.2.2.1 Global

Notably, CKD has become a health concern across developing and developed countries due to high rates of premature death and deteriorated QoL as its consequence (Tsai et al., 2010). The CKD is on the rise globally, with 11-13% of patients at stage 3 of the disease (Hill et al., 2016). The substantial variation in CKD prevalence stems from the diagnosis of CKD and national data collection techniques for registry reports. As CKD is becoming one of the leading causes of mortality (Jha et al., 2013), the healthcare resources may face greater strain and countries with low and middle income may be adversely affected due to restriction in their resources.

According to The National Kidney Foundation Kidney Early Evaluation Program (KEEP) report, KEEP Mexico City showed 22% prevalence of CKD, which is comparable to the 26% prevalence in KEEP US (Obrador et al., 2010). Recently, the U.S. Centers for Disease Control and Prevention estimated that 37 million adults (15%) in U.S. were likely to suffer from CKD (Centers for Disease Control Prevention, 2021). Similarly, upon assessing CKD prevalence and chronic liver disease markers in England based on biological measure and self-report in 2016, 15% of adults (age: 35 and above) suffered from any of the five CKD stages while 7% were diagnosed with CKD stages 3-5 (Fat et al., 2017). Meanwhile, the prevalence of CKD in Canadian primary care at a national level was 71.9 per 1000 individuals (Bello et al., 2019). In Australia, ~ 1.7

million Australians aged 18 years and above (~ 1 in 10) displayed CKD symptoms, whereas 1.8 million cases of hospitalization were related to CKD in 2017-2018 (Zhang et al., 2021).

1.2.2.2 Asia

The Asian region has been witnessing a hike in CKD prevalence (Abraham et al., 2016; Khan et al., 2018). The International Society of Nephrology's Kidney Disease Data Centre (ISN-KDDC) reported that CKD prevalence in China was 29.9%, 18.0% in Mongolia, 16.8% in India, and 20.1% in Nepal (Ene-Iordache et al., 2016). According to Singh et al. (2013), Screening and Early Evaluation of Kidney Disease Project (SEEK) found the overall CKD prevalent in -India at 17.2%, with ~ 6% suffering from stage 3 or worse. In Saudi Arabia, the over-all prevalence was 5.7% and 5.3% using the Modification of Diet in Renal Disease (MDRD) and Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation, respectively (Alsuwaida et al., 2010). The prevalence of CKD was found to be 11.4%, 18.6%, and 17.6%, respectively, among those diagnosed with CKD in a multi-ethnic Asian population in Singapore (Sabanayagam et al., 2010).

1.2.2.3 Malaysia

According to National Diabetes Registry Report, 2013-2019 (Ministry of Health Malaysia, 2020), it is estimated that 3.9 million (18.3%) of the Malaysian adult population had raised blood sugar in 2019. These numbers are expected to grow. The report also found that the overall trend for comorbidities, including hypertension and dyslipidemia, increased from 2013 to 2019. Based on audited patients for 2019, 80.4% had hypertension, and 74.3% had dyslipidemia. As for total complications reported in 2019, 14.6% of patients had diagnosed nephropathy, 10.6% had presence of retinopathy and 5.9% were reported to have Ischemic Heart Disease. Further, the national prevalence of hypertension among Malaysian adults was 30.3% with rates increasing with age as reported by National Health and Morbidity Survey (NHMS) in 2015 (Institute for Public Health, 2015). This figure risen to 49.39% for the year 2018 (Zaki et al., 2021).

Meanwhile, Malaysians diagnosed with CKD are increasing in number as a consequence of the increasing prevalence of diabetes, and hypertension in the middle age population (Bujang et al., 2017). According to Hooi et al. (2013), West Malaysia had a prevalence of 9.07% of CKD in 2011; this figure had risen to 15.5% for the year 2018 (Saminathan, Hooi, Yusoff, et al., 2020). The increasing number of CKD patients has caused a strain in the healthcare segment (Bujang et al., 2017).

1.2.3 Risk Factors and Attributable Causes of CKD in Adults

Evidently, obesity, diabetes, and hypertension have been known as risk factors that cause CKD (Luyckx et al., 2017). Non-traditional CKD risk factors, including kidney stones, nephrotoxins (prescription medicines & alternative remedies), maternal and fetal exposure, acute kidney injury (AKI), infections, and environmental exposure are progressively being marked as main threats to kidney function (Luyckx et al., 2017). In Asia, factors linked with CKD in other studies include age, diabetes, hypertension, metabolic syndrome, traditional medicines, and non-steroidal anti-inflammatory drugs (LI et al., 2011). However, diabetes, increasing age, and hypertension were identified as significant risk factors in Malaysia (Saminathan, Hooi, Mohd Yusoff, et al., 2020). Comprehending these risk factors may facilitate medical practitioners and nurses in reducing risks for developing CKD and in establishing effective CKD self-management programs.

Causes of CKD vary, especially between developed and developing countries. In developing countries, unsanitary conditions, poorer medical care, and high rates of infectious diseases contribute significantly to CKD development (Ayodele & Alebiosu, 2010). In developed countries, risk of infectious disease is lower, whereas diabetes types I and II, as well as hypertension, are the most common causes of CKD (Jager & Fraser, 2017). Prevalence of diabetes and hypertension has been escalating in recent decades (Guariguata et al., 2014; Mills et al., 2016), and largely contributing to higher rates of CKD, which is predicted to worsen as time passes (Guariguata et al., 2014).

In Asia, chronic glomerulonephritis (GN), diabetic nephropathy (DN), chronic interstitial nephropathy, and nephrolithiasis are the leading causes of ESKD (Tsukamoto et al., 2009). However, Asia is experiencing a changing trend in ESKD etiology. There has been an increase in DN-related ESKD in Japan (43.4% in 2007) and Malaysia (52.2% in 2005) (Tsukamoto et al., 2009). A reduction in the prevalence of GN and nephrolithiasis has been noted in Malaysia although the latter has remained an integral cause of CKD in Macau (Tsukamoto et al., 2009). Salman et al. (2015) showed that DN (44,9%) and hypertension (24,2%) were the most common causes of CKD among Malaysian patients treated at a tertiary care hospital in the northeast of Peninsula Malaysia.

1.2.4 The CKD Management and Treatment

Previous studies have suggested that early intervention for managing CKD through the use of suitable therapies is crucial for minimizing the progression and the effect of CKD (El Din et al., 2016; Johnson et al., 2013). The two techniques for managing early CKD stages are pharmacological and nonpharmacological (Johnson et al., 2013). Nonetheless, as eGFR hits below 15 mL/min/1.73m², RRT (i.e., hemodialysis (HD), peritoneal dialysis (PD), & kidney transplant) becomes a requirement (Webster et al., 2017).

Lifestyle alteration, weight management, and dietary modification are some techniques applied in non-pharmacological therapy to manage early CKD stages (Johnson et al., 2013). The goal of weight management is to maintain a stable, healthy weight and to lose weight without pharmacological intervention if possible. Dietary modification refers to the adoption of a healthy diet that restricts fat, sodium, and protein. Meanwhile, low alcohol intake, regular exercise, and stop smoking are some efforts related to lifestyle alteration (Johnson et al., 2013). Such intervention efforts are bound to prevent CKD consequences and delay CKD progression mainly by controlling blood glucose, BP, and cholesterol level (Johnson et al., 2013).

Meanwhile, pharmacological treatment involves controlling cholesterol, BP, and blood glucose levels to hinder mortality and morbidity due to CKD (Johnson et al., 2013; Nicholas et al., 2013; Norris & Nicholas, 2015). Some of the related aims are listed as follows: BP < 140/90 mmHg but when albuminuria exceeds > 300 mg/day, BP must be < 130/80 mmHg (Nicholas et al., 2013; Norris & Nicholas, 2015); and glycosylated hemoglobin (HbA1c) < 7.0% (American Diabetes Association, 2015; Johnson et al., 2013).

This study investigated stages 3-4 CKD patients who did not require RRT. Hence, effective interventions should delay CKD from progressing among them, which include healthy lifestyle, balanced diet, and adherence to medication. This is because; many appear to be indifferent towards kidney dysfunction. Plantinga et al. (2008) discovered that < 6% of stage 3 CKD patients and < 30% of stages 4-5 CKD patients had never consulted a nephrologist. This highlights the need to improve knowledge related to kidney disease and CKD self-management behavior among patients with pre-dialysis CKD.

1.2.5 Nursing in Malaysia

Healthcare organizations worldwide face challenges in maintaining high-quality care, given severely constrained human resources (Lu et al., 2012). This phenomenon is no different in Malaysia, which faces a shortage of qualified and experienced nurses, especially in hospitals (Kanchanachitra et al., 2011). The demand for nurses has increased mainly due to the rapid development of the nation's healthcare sector and the changing demographic patterns of the population (Kanchanachitra et al., 2011).

The nursing workforce in Malaysia has grown over the last few decades (Barnett et al., 2010), but it is still considered insufficient to adequately serve the entire population. Furthermore, the nursing shortage is not solely due to the lack of qualified nurses available in the profession, but also due to a dearth of nurses willing to work under the present conditions (Buchan & Aiken, 2008). To address the shortage and to build health care capacity, Malaysia has more than doubled its nursing workforce over the past decade, primarily through an increase in the domestic supply of new graduates (Barnett et al., 2010). Hirschmann (2022) revealed that the number of registered nurses in the country has shown an upward trend since 2016, and there were around 110 thousand

registered nurses in 2020. According to 24th Report of the Malaysian Dialysis and Transplant Registry, the number of registered dialysis nurses/medical technicians in Malaysia increased from 1808 in 2011 to 3920 in 2016 (Wong & Bak, 2018). Furthermore, (Bujang et al., 2017) reported that there shall be a minimum ratio of trained staff nurse (or equivalent) for every 6 patients on hemodialysis in the same treatment shift (MOH Malaysia, 2010).

According to (Ramoo et al., 2013), Malaysian nurses feel that they do not have enough say in decisions related to management policies and the practices that affected them. This may be partly due to Asian cultures, where bureaucrats are given considerable power and subordinates are expected to be passive (Sriratanaprapat & Songwathana, 2011). However, Barnett et al. (2008) found that patients suffering from difficulties adhering to fluid and dietary restrictions may benefit from ongoing education and encouragement from nephrology nurses. Based on a recent clinic-based randomized controlled trials (RCTs) by Chew et al. (2018), it was found that the interventions delivered by Malay health clinic nurses decreased diabetes distress significantly.

1.3 Problem Statement

The global prevalence and burden of CKD is high (Webster et al., 2017) and is continually increasing. Not only is CKD a major economic burden (Wyld et al., 2015), it is also a physical (Murtagh et al., 2007), psychological (Lee et al., 2013), and social (Finnegan-John & Thomas, 2013) burden. Those suffering from CKD would normally experience non-specific symptoms at the early stage (Webster et al., 2017) with many are uninformed of the disease or only have a limited understanding of it. Hence, CKD is typically diagnosed upon reaching stages 3b and above as the patients begin experiencing several complications, including uremia, anemia, and fluid overload (Bello et al., 2017; Thomas et al., 2008).

The current study is needed to be conducted because there was a lack of knowledge related to CKD (Alobaidi, 2021; Bonner et al., 2014; Okoro et al., 2020). A study reported by Wright et al. (2011), "35 percent of patients reported knowing little or nothing about their own CKD diagnosis and nearly half reported they did not have any knowledge about treatment options if their kidneys failed" (p. 338). In addition, despite the fact that patient education is an important part of CKD treatment, it has been reported by Young et al. (2011) that "patient's perceived and actual knowledge about CKD care and treatments are less than desirable" (p. 381). Blickem et al. (2013) concluded that "Professionals have expressed concerns that disclosing asymptomatic stage III CKD to patients may create anxiety, therefore associated risks are considered difficult for patients to understand" (p. 2).

Furthermore, in a nephrology clinic where the patients observed for BP, electrolyte imbalances, and fluid management, CKD patients seemed to have poor knowledge related to their disease (Ng et al., 2016) and weak self-management behavior (Phua et al., 2017). Besides, concerning comments by numerous patients that newly diagnosed

with CKD and not aware about the disease include: "No one ever told me that I had kidney problems," "What do you mean I have kidney problems?" and "I am only here for my blood pressure and swelling of the legs." This consistent with that of research assessing the knowledge level of CKD among patients Malaysia (Ng et al., 2016), which depicted that the "Malaysian population is still inadequately informed on CKD, especially those who are at risk of developing CKD and its complications" (p. 103). As well, poor knowledge related to CKD is significantly correlated with various demographic characteristics, especially among those with lower socioeconomic status (Ng et al., 2016). In addition, Phua et al. (2017) also stated that "Malaysian patients at late stage of CKD had poorer CKD self-management when compared to those at early stage of CKD" (p. 186). Thus, CKD patients, particularly diabetic nephropathy patients, those who are low educated and have multiple co-morbidities should receive special attention to ensure self-management.

In a review of 19 RCTs involving CKD self-management intervention on pre-dialysis patients, methodological and theoretical limitations were found in the literature on these interventions (Peng et al., 2019). Thus, it is crucial to assess the needs of those diagnosed with CKD to receive adequate support for CKD self-management, so that an effective intervention may be proposed to enhance CKD self-management considering behavior change theory. In this current study, the site principal investigator, who is a nephrologist, upholds that evidence-based structured CKD self-management support program that involves patients' education and psychosocial support led by CKD nurse-educators may bridge the gap in knowledge and self-efficacy of the disease for better understanding and CKD self-management. Hence, the following question is posed, "Is lack of kidney disease knowledge and self-efficacy related to suboptimal patient education and psychosocial support?" CKD education and psychosocial support is crucial to foster effective CKD self-management. From the stance of Social Cognitive Theory (SCT), an intervention effort should essentially overcome shortcomings of self-efficacy and knowledge lurking in the community (Nguyen et al., 2019a). The literature depicts the efficacy of SCT in improving CKD self-management by enhancing both knowledge and self-efficacy related to kidney disease (Havas et al., 2018; Nguyen et al., 2019a). Therefore, the current intervention built based on behavioral change theory to empower Malaysian patients suffering from stages 3-4 CKD by equipping them with adequate disease-related knowledge, enhancing their confidence for better CKD self-management behavior and QoL.

1.4 Research's Objectives

Despite the vast studies on CKD early detection and treatment, more evaluation of early education and psychosocial support is required to enhance kidney disease knowledge, self-efficacy, and CKD self-management behavior that not only can enhance one's overall well-being, but also delay CKD progression.

The main objective of this project of evidence-based practice (EBP) is to evaluate the effectiveness of a nurse-led self-management support program on kidney disease

knowledge, CKD self-management behavior, self-efficacy, and HRQoL among patients with chronic kidney disease stages 3-4.

The study's specific objectives are as follows:

Primary objectives:

1. To assess the effect of a structured nurse-led self-management support program for patients with CKD stages 3-4 (the CKD-NLSM) in comparison to standard usual care on kidney disease knowledge.

2. To assess the effect of a structured nurse-led self-management support program for patients with CKD stages 3-4 (the CKD-NLSM) in comparison to standard usual care on CKD self-management behavior.

Secondary objectives:

1. To assess the effect of a structured nurse-led self-management support program for patients with CKD stages 3-4 (the CKD-NLSM) in comparison to standard usual care on self-efficacy.

2. To assess the effect of a structured nurse-led self-management support program for patients with CKD stages 3-4 (the CKD-NLSM) in comparison to standard usual care on HRQoL.

3. To assess the effect of a structured nurse-led self-management support program for patients with CKD stages 3-4 (the CKD-NLSM) in comparison to standard usual care on BP control.

4. To assess the effect of a structured nurse-led self-management support program for patients with CKD stages 3-4 (the CKD-NLSM) in comparison to standard usual care on CKD diet adherence estimated by dietary protein intake, dietary sodium intake and dietary acid load.

1.5 Research's Questions

Typically, EBP projects employ PICO for stating the related hypotheses, with PICO meaning as follows: Population/Disease (P), Intervention/Issue of Interest (I), Comparison group/Current Practice (C), and Outcome (O) (Melnyk & Fineout-Overholt, 2011). After conducting a needs assessment via literature review and observation, the emerging PICO question is: Does implementing the CKD-NLSM support program for stages 3-4 CKD patients improve the gap in kidney disease knowledge and CKD self-management behavior?" The following lists the statements based on PICO.

- P: Adults (18 years old and above) referred to nephrology with stages 3-4 CKD diagnosis.

- I: Implementing the CKD-NLSM support program involved three group-based sessions on CKD-SM, three follow-up phone calls, and CKD-Booklet.

- C: Compare the outcomes between two randomized groups (one group exposed to CKD-NLSM support program and the other group received the standard usual care).

- O: Improvement in gaps related to kidney disease knowledge, CKD self-management behavior, self-efficacy, HRQoL, BP control and CKD dietary adherence. The outcomes were assessed through baseline (T0) and post-program assessment (T1).

The research questions are as follows:

1. Did participants enrolled in a structured nurse-led self-management support program for patients with CKD stages 3-4 (the CKD-NLSM) show significant improvements on their kidney disease knowledge, and CKD self-management behavior than those who received standard usual care?

2. Did participants enrolled in a structured nurse-led self-management support program for patients with CKD stages 3-4 (the CKD-NLSM) show significant improvements on their CKD self-management behavior than those who received standard usual care?

3. Did participants enrolled in a structured nurse-led self-management support program for patients with CKD stages 3-4 (the CKD-NLSM) show significant improvements on their self-efficacy than those who received standard usual care?

4. Did participants enrolled in a structured nurse-led self-management support program for patients with CKD stages 3-4 (the CKD-NLSM) show significant improvements on their HRQoL than those who received standard usual care?

5. Did participants enrolled in a structured nurse-led self-management support program for patients with CKD stages 3-4 (the CKD-NLSM) show significant improvements on their, BP control than those who received standard usual care?

6. Did participants enrolled in a structured nurse-led self-management support program for patients with CKD stages 3-4 (the CKD-NLSM) show significant improvements on their CKD diet adherence estimated by (dietary protein intake, dietary sodium intake and dietary acid load) than those who received standard usual care?

1.6 Research's Hypothesis

The study's hypothesized that the participants enrolled in a structured nurse-led self-management support program for patients with CKD stages 3-4 (the CKD-NLSM) show significant improvements on their kidney disease knowledge, CKD self-management behavior, self-efficacy, and HRQoL than those who received standard usual care.

The study's specific hypothesis are as follows:

1. The participants enrolled in a structured nurse-led self-management support program for patients with CKD stages 3-4 (the CKD-NLSM) show significant improvements on their kidney disease knowledge than those who received standard usual care.

2. The participants enrolled in a structured nurse-led self-management support program for patients with CKD stages 3-4 (the CKD-NLSM) show significant improvements on their CKD self-management behavior than those who received standard usual care.

3. The participants enrolled in a structured nurse-led self-management support program for patients with CKD stages 3-4 (the CKD-NLSM) show significant improvements on their self-efficacy than those who received standard usual care.

4. The participants enrolled in a structured nurse-led self-management support program for patients with CKD stages 3-4 (the CKD-NLSM) show significant improvements on their HRQoL than those who received standard usual care.

5. The participants enrolled in a structured nurse-led self-management support program for patients with CKD stages 3-4 (the CKD-NLSM) show significant improvements on their BP control than those who received standard usual care.

6. The participants enrolled in a structured nurse-led self-management support program for patients with CKD stages 3-4 (the CKD-NLSM) show significant improvements on their CKD diet adherence estimated by (dietary protein intake, dietary sodium intake and dietary acid load) than those who received standard usual care.

1.7 The Significance of the Project

The significance of this EBP project is explained by the following three reasons: First, the prevalence of CKD has been escalating across developing countries, including in Malaysia. The CKD prevalence in 2018 was 15.48% (Saminathan, Hooi, Yusoff, et al., 2020), an increase from 9.07% in 2011 (Hooi et al., 2013). Based on the latest Malaysian's Forecasting (Bujang et al., 2017), the incidence and prevalence of ESKD have been increasing since the past two decades with an alarming trend. Worsening CKD

can result in expensive RRT requirement for life sustenance, which is burdensome to those patients, their families, and the community. Delaying CKD progression to hinder dialysis and mortality demands attention in the Malaysian context to avoid straining the healthcare system.

Second, evidence denotes those patients who receive adequate psychosocial support and CKD self-management information can effectively manage CKD and delay its development. Ultimately, self-management revolves around taking care of oneself to avoid worsening impacts of the disease. Provision of adequate support to effectively engage in CKD self-management is warranted to enhance one's well-being.

Third, although studies have examined ESKD patients with RRT requirement with better treatment adherence due to CKD self-management (Lin et al., 2017; Mason et al., 2008), only a handful of studies have looked into psychosocial and education support to enhance CKD self-management behavior, kidney disease knowledge, and self-efficacy at stages 3-4 of CKD (Mason et al., 2008). Although (Peng et al., 2019) had identified 19 RCTs that attempted to improve self-management in patients with early CKD stages, those studies portrayed significant methodological limitations, extremely varied interventions, and mostly not based upon validated theories of behavior change.

As such, this is the initial RCT for the Malaysian context that bridges the listed literature gaps. The study outcomes may substantially facilitate in enhancing psychosocial and educational support for improved CKD self-management among CKD patients.

1.8 Research's Phases

Three phases were deployed in this study: development, implementation, and evaluation. In phase 1, the following three instruments: the Kidney Disease Knowledge Survey (KiKS) (Wright et al., 2011), the CKD Self-Management (CKD-SM) (Lin et al., 2013), and the Self-efficacy for Managing Chronic Disease (SEMCD) (Lorig et al., 2001) translated, culturally adapted, and psychometrically evaluated in the Malay language. The instruments are required to evaluate key outcomes (kidney disease knowledge, CKD self-management behavior and self-efficacy) in Phase 3. In the development phase (Phase 2), patients with stages 3-4 CKD and their families were involved to co-design, develop, and pilot test the theory-based intervention for CKD-self-management. In phase 3, parallel RCT was executed to assess the effectiveness of the proposed theory-driven CKD-NLSM, in comparison to the standard usual care. Data retrieved from both trial baseline and final evaluation were deployed to examine the level of responsiveness for the three questionnaires. Due to the unavailability of suitable validated instruments in the Malay language, we combined the questionnaire validation process in the RCT.

1.9 Operational Definitions

The terms given below are deployed for the purpose of this study:

Chronic kidney disease (CKD): eGFR of <60 mL/min per 1.73 m^2, kidney damage markers, or both, for three months regardless of the cause (Levin et al., 2013).

Knowledge: Information, comprehension, and skills acquired via experience or education (Oxford Learner's Dictionaries, 2015).

Self-efficacy: One's belief or confidence in his/her capability to attain a present goal (Bandura, 1977).

Self-management: Effectively managing life with a chronic illness, including: making important lifestyle modifications; handling physical and mental symptoms and changes; as well as managing treatment (Barlow et al., 2002).

Health-related quality of life (HRQoL): A patient's subjective perception of his/her ailment and treatment with regard to physical, psychological, and social-well-being (Juczyński, 2006).

Social Cognitive Theory (SCT): Behavioral theory that explains the interactions among behavior, personal factors, and individual environment (Bandura, 1977).

1.10 Thesis Overview

This thesis is composed of six chapters. This initial chapter presents the aspects of CKD, as well as the research significance, objectives, and questions. The second chapter depicts the literature review regarding the deleterious effect of CKD, CKD self-management, earlier studies on self-management of CKD, and substantial gaps within the CKD self-management studies. The chapter also evaluates SCT as the theoretical foundation for CKD self-management intervention. Chapter 3 is comprised of three phases to describe the methodology undertaken in this study, the result of the questionnaires translation and validation (Phase 1) as well as the result of intervention pilot testing (Phase 2). Chapter 4 presents the study outcomes of the trial (Phase 3). In Chapter 5, the reported findings are discussed and compared with the recent literature. Finally, Chapter 6 presents the research contributions, drawbacks, implications and recommendations, as well as concluding remarks.

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