EFFECTIVENESS OF SELF-AND FAMILY MANAGEMENT SUPPORT COMBINED WITH THE MOBILE HEALTH APPLICATION PROGRAM AMONG PERSONS WITH CHRONIC KIDNEY DISEASE STAGE 3: A RANDOMIZED CONTROLLED TRIAL

SANGRAWEE MANEESRI

A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF

THE REQUIREMENTS FOR THE DOCTOR DEGREE OF PHILOSOPHY

(INTERNATIONAL PROGRAM)

IN NURSING SCIENCE

FACULTY OF NURSING

BURAPHA UNIVERSITY

2022

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ดุษฎีนิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปรัชญาดุษฎีบัณฑิต (หลักสูตรนานาชาติ)

สาขาวิชาพยาบาลศาสตร์

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The Dissertation of Sangrawee Maneesri has been approved by the examining committee to be partial fulfillment of the requirements for the Doctor Degree of Philosophy (International Program) in Nursing Science of Burapha University

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SANGRAWEE MANEESRI : EFFECTIVENESS OF SELF-AND FAMILY MANAGEMENT SUPPORT COMBINED WITH THE MOBILE HEALTH APPLICATION PROGRAM AMONG PERSONS WITH CHRONIC KIDNEY DISEASE STAGE 3: A RANDOMIZED CONTROLLED TRIAL. ADVISORY COMMITTEE: KHEMARADEE MASINGBOON, D.S.N., NUJJAREE CHAIMONGKOL, Ph.D. 2022.

The increasing prevalence of chronic kidney disease (CKD) is a public health burden in the world, as well as in Thailand. Self-management strategies can effective prevent the progression of chronic diseases. This randomized controlled experimental study examined the effectiveness of self-management and family management support in combination with the mHealth application program in persons with stage 3 CKD.

The 40 patients with stage 3 CKD and their family members were recruited between November 2020 and 2021. They were randomly allocated into either the experimental (n = 20) or control group (n = 20). The control group received the usual care, while the experimental group received the program in addition to the usual care. Four sessions of the program were carried out over four weeks, including pre-intervention (week 1), post-intervention (week 4), and follow-up (week 16) periods. Two-way repeated measures ANOVA and an independent t-test were used.

According to the results, there were statistically significant differences in the interaction effects (time*group) as evidenced by the mean score for self-management behaviors, SBP, and DBP. The participants in the experimental group had better self-management behaviors and DBP than those in the control group at the follow-up ($F(1, 38) = 6.276$, $p < .05$; $F(1, 38) = 7.521$, $p < .05$, respectively).

Furthermore, there was a significant improvement of both self-management behaviors and SBP in the experimental group across pre-intervention and follow-up ($M_{diff} = -13.550$, $p < .05$; $M_{diff} = 10.350$, $p < .05$, respectively).

This program has shown a statistically significant increase in self-management behavior and a decrease in BP over time, particularly in week 16. Consequently, the mHealth application should be integrated into current nursing practice to improve outcomes for those with stage 3 CKD. Long-term studies should be carried out to test the sustainability of the findings.

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CHAPTER 1
INTRODUCTION

Background and significance

Chronic kidney disease (CKD) is a non-communicable disease (NCD) with growing prevalence as a global public health problem, including Thailand. CKD is defined as abnormalities of kidney structure or function. It may be with or without decreased glomerular filtration rate (GFR) [GFR < 60 ml/min/1.73 m^2 for ≥ 3 months], and with or without kidney damage (KDIGO, 2013). CKD can be classified into 5 stages, follow the value of eGFR. It is a significant risk factor for cardiovascular disease, which causes premature death. The global prevalence of CKD at all stages are 11% to 13%, and most cases (approximately 7.6%) are in stage 3 (eGFR 30-59 ml/min/1.73 m^2) (Hill et al., 2016). In Thailand, a high prevalence of adult patients with CKD is reported (17.5%), and most of them (7.5%) are in stage 3 (Ingsathit et al., 2010). CKD stage 3 can rapidly progress to end-stage renal disease (ESRD) if patients continue to perform unhealthy behaviors and fail to adhere to therapeutic regimens.

Currently, there are 170,774 ESRD cases treated with renal replacement therapy (RRT) or accounted for 2,580 cases per million populations (The Nephrology Society of Thailand, 2020). Its incidence continuously increases by 15%-20% per year. (The Nephrology Society of Thailand, 2015). The predicted numbers of patients on RRT corresponded to an annual growth rate of 7.2%-7.4% for continuous ambulatory peritoneal dialysis (CAPD) and hemodialysis (HD) and 4.8% for a kidney transplant (KT) (Thammatacharee & Suphanchaimat, 2020). The rapid increase of number of ESRD patients is considered a major public health problem that affects not only physical, mental, social, economic aspect of patients but also health insurance system of Thailand.

The cost of dialysis rapidly increases from 160 to 3,900 million Thai Baht within five years (2008 to 2012), and continues to rise to 7,529 million Thai Baht in the fiscal year 2017 of National Health Security Office (NHSO, 2017). This is the highest budget for specific disease treatment in universal health coverage scheme (UCS) in Thailand (Tangcharoensathien et al., 2015; Tantivess et al., 2013). In addition, patients with ESRD who receive dialysis as a treatment are suffered either from physical symptoms, namely, excessive tiredness, sleep disturbance, and pain in bones/joints (Brown et al., 2017; Senanayake, 2017) or from psychological problems including anxiety and depression (Schouten et al., 2019; Vasilopoulou et al., 2015). This leads to a diminished quality of life (Ishiwatari et al., 2020; Joshi et al., 2017) and is associated with an increased risk for future hospitalization (Hickson et al., 2018; Molnar et al., 2018) and mortality rate (Chongthanakorn, 2018; Sanyang & Sambou, 2020).

The prevalence of CKD and its effects on health outcomes and economic impact have made a national concern. In 2013, Ministry of Public Health (MOPH) has formulated a policy of service plan for kidney disease 2013 to 2017 for preventing and delaying the progression of CKD (MOPH, 2013). The strategy related to self-management has been frequently used to achieve this goal. Self-management is not only a concept broadly adopted in many countries as a key action but also an essential strategy for improving chronic care at all ages (Wagner, 1998; Wagner et al., 1996). Self-management is also a dynamic, interactive, and daily decision-making process in which individuals engage in activities that help them manage and control chronic illness (Barlow et al., 2002; Lorig & Holman, 2003). It has a procedure to make certain behavioral changes over a prolonged period of time supported by health care providers to control and monitor their chronic disease in daily life (Creer, 2000).

According the Individual and Family Self-Management Theory (IFSMT) of Ryan and Sawin (2009), individuals and family members with self-management behaviors tend to improve their health outcomes. They also assume responsibility of self-management of chronic conditions or engage in healthy behaviors by purposefully performing a cluster of learned behaviors. Living with a condition or engagement in healthy behaviors is complex and requires integration of self-management behaviors with lifestyles of individuals and family members. For CKD patients, self-management is defined as their positive efforts to oversee and participate in their health care that aims not only to optimize health and prevent complications but also to control symptoms. It also encourages them to change towards healthy lifestyles and to maintain their health condition (Curtin & Mapes, 2001). Five components of self-management behaviors in CKD patients to be measured include (1) self-care activities,

(2) medication adherence, (3) communication with health care providers, (4) self-advocacy, and (5) partnership in care (Curtin et al., 2008).

Self-management in CKD patients have revealed positive outcomes, which are classified into the following four groups: 1) clinical outcomes such as blood pressure (BP), estimate glomerular filtration rate (eGFR), serum creatinine, urine protein, body weight, body mass index (BMI), and hemoglobin A1C (Chen et al., 2018; Lin et al., 2013; Timmerman et al., 2017); 2) behavioral outcomes e.g., self-care activity, self-management behaviors, medication adherence, communication between patient and providers (Chen et al., 2018; Havas et al., 2018; Lin et al., 2013; Walker et al., 2013); 3) cognitive outcomes including knowledge, and perceived self-efficacy (Donald et al., 2018); and 4) quality of life (Blakeman et al., 2014; He et al., 2017; Lee et al., 2016).

However, for patients with CKD stage 3, the essential outcomes that need to be improved in order to prevent the progression of the disease are self-management behaviors, kidney function or eGFR, and BP (González et al., 2020; Peng et al., 2019; Zimbudzi et al., 2018). From the literature review, the problem of patients with early-stage CKD was a low level of self-management behavior (Sritarapipat et al., 2012) to a moderate level (Photharos, 2017). The lowest scores of self-management behaviors are in the components of self-advocacy, partnership in care, and communication with health providers, respectively (Curtin et al., 2008; Krajachan et al., 2018; Sritarapipat et al., 2012). Furthermore, 15% of CKD patients had a low level of medication adherence (Cedillo-Couvert et al., 2018). It is a very important factor that causes disease progression that is reflected by the decline of eGFR.

eGFR is the best test to measure the level of kidney function and determines the stage of kidney disease, which can be calculated from results of serum creatinine, age, body size, and gender. Thus, eGFR is recommended for routine use for kidney function assessment in clinical practice (KDIGO, 2013). The purpose of slowing the deterioration of kidney function is to prevent the loss of eGFR over 4 ml/min/1.73 m^2/year (MOPH, 2013; Thanakitjaru, 2015). Achievement of this goal can delay the need for dialysis in CKD patients for approximately 7 to 14 years (Jiamjariyapon et al., 2017; Leesmidt, 2016). However, the research in Thailand found that 45.1%

of patients with stage 1-3b CKD have a rapid progress (Srina et al., 2018). The factors that predict the rapid kidney function decline are previous cardiovascular disease, low serum albumin, high proteinuria, low and high BMI, and high systolic BP (Srina et al., 2018; Vigil et al., 2015).

High BP is a vital factor damaging glomerulus and nephron. It causes protein leak in urine and reduces eGFR. Therefore, control of BP within the criteria (less than 130/80 mmHg) is important to slow progression of disease. Moreover, the reduction of cardiovascular disease risk which is the leading cause of premature death in CKD patients can delay the disease progress (ACC/AHA, 2017; KDIGO, 2012), The study on BP control in CKD stage 3 (Schneider et al., 2018) has found that the prevalence of hypertension in CKD patients is 96.2%. However, only 49.3% of them successfully control their BP. Thus, BP control in CKD patients remains a challenging issue even in the setting of nephrology specialist care.

A review of the literature shows that healthcare providers have developed a program to improve self-management behaviors and clinical outcomes for early-stage CKD. It usually has the following components: (1) use of theory related behavior modification to guide study designs and program development such as self-regulation, health literacy, person-centered care, social-cognitive theory, and individual and family self-management theory, (2) a multidisciplinary team approaches to provide comprehensive care, and (3) delivery of interventions by face-to-face interaction integrated with IT devices to transfer knowledge and encourage patients to perform self-management behaviors continuing especially mobile phone (Blakeman et al., 2014; Havas et al., 2018; Jiamjariyapon et al., 2017; Lin et al., 2013; Seephom et al., 2014; Walker et al., 2013).

Moreover, key self-management processes that maintain self-management behaviors include social facilitation (e.g., social influence and social support). The social influence is a message in which respectful persons in positions with authority and expert in advising and encouraging patients to engage in healthy behaviors and maintain health management. These respectful persons might be family members with indirect effects on self-management behaviors (Photharos et al., 2018). Furthermore, social support, which is considered crucial in providing instrumental or information support to a person or family, has the explicit goal of assisting or facilitating the engagement in health behaviors (Ryan & Sawin, 2009). Although the family member is a key person assisting patient with CKD to engage and maintain self-management behaviors, the lack of their involvement during intervention delivery has been reported (Welch, 2015).

The majority of the management of chronic conditions takes place in the everyday home setting; therefore, family can be highly influential on individual behaviors (Ory et al., 2013). A good family functioning can lead to improved self-care confidence and autonomous motivation for medications and diet adherence (Stamp et al., 2016). Also, the family is the key in constructing the conductive environment for family engagement and support. Adaptation within the family includes maintenance of cohesion between family members, normalization and contextualization of the chronic condition (Whitehead et al., 2017). Therefore, the participation of family members in self-management support program for persons with CKD is imperative.

IFSMT guides intervention because it is a dynamic phenomenon consisting of three dimensions: context, process, outcomes. Factors in contextual dimension influence individual and family engagement in self-management process resulting in more positive outcomes for chronic disease patients (Ryan & Sawin, 2009). According to an experimental research review based on this theory, it was found that, after receiving self-management program, participants with chronic diseases had significantly better health behaviors and clinical outcomes (Kaewsongk et al., 2018; Seephom et al., 2014).

Currently, health services have changed rapidly with the adoption of information communication technology (ICT) to support health care practice. According to Thailand 4.0 Policy that focuses on innovation-driven economy, Health 4.0 is adapted by health care sector as well (MOPH, 2018). From Thailand 4.0 to Health 4.0, it is essential to integrate electronic health (eHealth) strategy with a framework in the same direction towards a long-term success. eHealth is a health care practice supported by electronic processes and communications, and encompasses a range of services or systems that are at the edge of medicine/health care and information technology. It consists of eight components (MOPH, 2017), one of which is mobile health (mHealth).

mHealth is defined by WHO as a medical and public health practice supported by mobile devices such as mobile/smartphones, patient monitoring devices, personal digital assistants (PDAs) and other wireless devices. It is increasingly used in health care and public health practice for communication, data collection, patient monitoring, and education. It facilitates adherence to chronic disease management (WHO, 2011). The results of previous systematic reviews showed that mHealth interventions were effective for improving self-management behaviors, treatment adherence, and disease-specific clinical outcomes for patients with chronic diseases such as diabetes mellitus, hypertension, stroke, asthma, and CKD (Hamine et al., 2015; Kosa et al., 2019; Nakhornriab et al., 2017; Yi et al., 2018).

Ong and colleagues have developed a smartphone-based system to boost self-management for patients with advanced-stage CKD and integrated its use with usual care (Ong et al., 2016). The system comprises four functions, namely, BP monitoring, medication management, symptom assessment, and laboratory result tracking. The prebuilt customizable algorithms provide real-time personalized feedbacks and alerts of patients to providers when pre-defined treatment thresholds are crossed; or critical changes have occurred. The results showed that there was a high number of patients' adherence to sustainable smartphone use. The smartphone program is able to reduce BP at a statistically significant level and to detect medication errors. Patients said that they felt more confident in controlling their conditions, while clinicians perceived patients to be better informed and more engaged (Ong et al., 2016). In addition, the study of Chen et al. (2018) developed mHealth for communications between the nephrologist and early-stage CKD patients. In spite of its results showing a significant correlation between average daily usage and physician-patient conversation, there was no statistical significance in light of improved clinical outcomes such as urine protein, BMI, BP, and eGFR.

A previous study found that various effective self-management programs could improve self-management behaviors of early-stage CKD patients after completing the program. However, they were unable to maintain long-term self-management behaviors (Lin et al., 2013). The lack of family member's involvement in self-management program (Welch, 2015) was also reported as the remaining problem. Although mHealth application was used in self-management program, it had few impacts on outcomes and had no function to monitor self-management behaviors of patients with early-stage CKD (Chen et al., 2018). It is a challenge for health care providers to effectively develop and implement such program in era of IT advancement in line with electronic health (eHealth) strategy of Thailand's Ministry of Public Health 2017 to 2026 (MOPH, 2017).

According to literature review, there is a limit number of a randomized controlled trial (RCT) studies integrated with IT devices to support self-management in CKD patients (Lee et al., 2018), mainly in stage 3. At this stage, patients have no symptoms which affect their daily life resulting in their unawareness of changes in self-management behaviors. Also, most patients with CKD stage 3 may develop into ESRD patients if they live without effective self-management behaviors. Therefore, the researcher will conduct RCT study that aims to develop and examine the effectiveness of self-and family management support combined with the mHealth application among patients with CKD stage 3. This program is created from the synthesis of evidence-based practice and supported by IFSMT of Ryan and Sawin (2009). Family members are invited to participate in program activities, help patients use mHealth application, and support self-management in daily life. The research activities will be carried out in conjunction with multidisciplinary approach, which is the usual care. The researcher expects that this program will generate good outcomes for patients with CKD stage 3. They will be able to improve self-management behaviors, control BP, and prevent the decline of eGFR.

Research Objectives

The effectiveness of self-and family management support combined with the mHealth application among persons with CKD stage 3 is examined as follows:

1. To compare mean scores of self-management behaviors and BP between the experimental and control groups at pre-intervention (week 1), post-intervention (week 4), and follow-up (week 16).

2. To compare mean scores of eGFR between the experimental and control groups at pre-intervention (week 1) and follow-up (week 16).

3. To compare mean scores of self-management behaviors and BP within the experimental group at pre-intervention (week 1), post-intervention (week 4), and follow-up (week 16).

Research Hypotheses

1. The participants in the experimental group have significantly higher mean scores of self-management behaviors than those in the control group in post-intervention (week 4) and follow-up (week 16) periods.

2. The participants in the experimental group have significantly lower mean scores of SBP and DBP than those in the control group in post-intervention (week 4) and follow-up (week 16) periods.

3. The participants in the experimental group have a significantly higher mean score of eGFR than those in the control group in follow-up (week 16) periods.

4. For the experimental group, mean scores of self-management behaviors in post-intervention (week 4) and follow-up (week 16) sessions are significantly higher than those in pre-intervention (week 1) periods.

5. For the experimental group, mean scores of SBP and DBP in post-intervention (week 4) and follow-up (week 16) are significantly lower than those in pre-intervention (week 1) periods.

Conceptual Framework of the Study

This research conceptual framework was developed based on the theory of Individual and Family Self-Management Theory (IFSMT) of Ryan and Sawin (2009) and reviewed related literatures. According to Ryan and Sawin (2009), individual and family self-management includes purposeful incorporation of health-related behaviors into daily functioning of an individual or family. The family unit is not limited to biological families. Individual and family self-management prevents or attenuates illness and facilitates the management of complex health regimens in many aspects that reflect individual and family values as well as beliefs in a personally meaningful way. The individual or family assumes responsibility for individual and family self-management, which is likely in collaboration with health care professionals.

IFSMT has three major concepts, namely, context, process, and outcomes, which dynamically affect each other. The context refers to risks or protective factors and includes condition-specific factors, physical and social environments, and individual and family characteristics. Condition-specific factors are those physiological, structural or functional characteristics of the condition. This also includes its treatment or prevention of the condition that affects the amount, type, and nature of behaviors needed for self-management. Self-management processes of enhancing knowledge and beliefs (e.g., self-efficacy), regulation of skills and abilities (e.g., self-monitoring), and social facilitation (e.g., family support, instrumental support) are identified. Self-management processes affect chronic disease management, both proximal outcomes (e.g., self-management behaviors specific to a condition) and distal outcomes (e.g., health status, quality of life, and cost of health).

Also, this theory focuses on patients and their family members on the belief that the family and the patient are the same units (family as a unit). When a change occurs in any one member of the family, it leads to a change in the family system. The families' characteristics of closeness, caregiver's coping skills, mutually supportive family relationships, clear family organization, and direct communication about the illness and its management are related to better family and individual outcomes (Grey et al., 2006). Therefore, the family is the center of care enabling patients to have proper self-management behaviors and continuous practice. Moreover, receiving of family support and collaboration with health care professionals promote the awareness of health conditions or actual health behaviors. This will develop knowledge and self-regulation skills and abilities including higher self-efficacy leading to the ability to practice those behaviors and constant engagement in self-management.

Thus, the researcher will apply this theory to patients with CKD stage 3, which needs to manage their conditions for three months. The research framework consists of context and processes of self-management and is integrated with mHealth application, which is the instrument supported by health care providers. The intervention comprises four sessions over four weeks as follows: (1) identifying and measuring risks and protective factors, (2) providing knowledge and caring beliefs, (3) developing self-regulation skills and providing family support and mHealth application, and

(4) developing abilities in self-evaluation and management of responses associated with health behavioral change. Also, the empirical evidence is collected in order to establish a program by modifying self-regulation activities (Lin et al., 2013), self-efficacy activities (Nguyen et al., 2019), and mHealth application for CKD patients (Ong et al., 2016). The improvement of self-management behaviors, BP, and eGFR are the expected outcomes. The research framework of the study is presented in Figure 1.

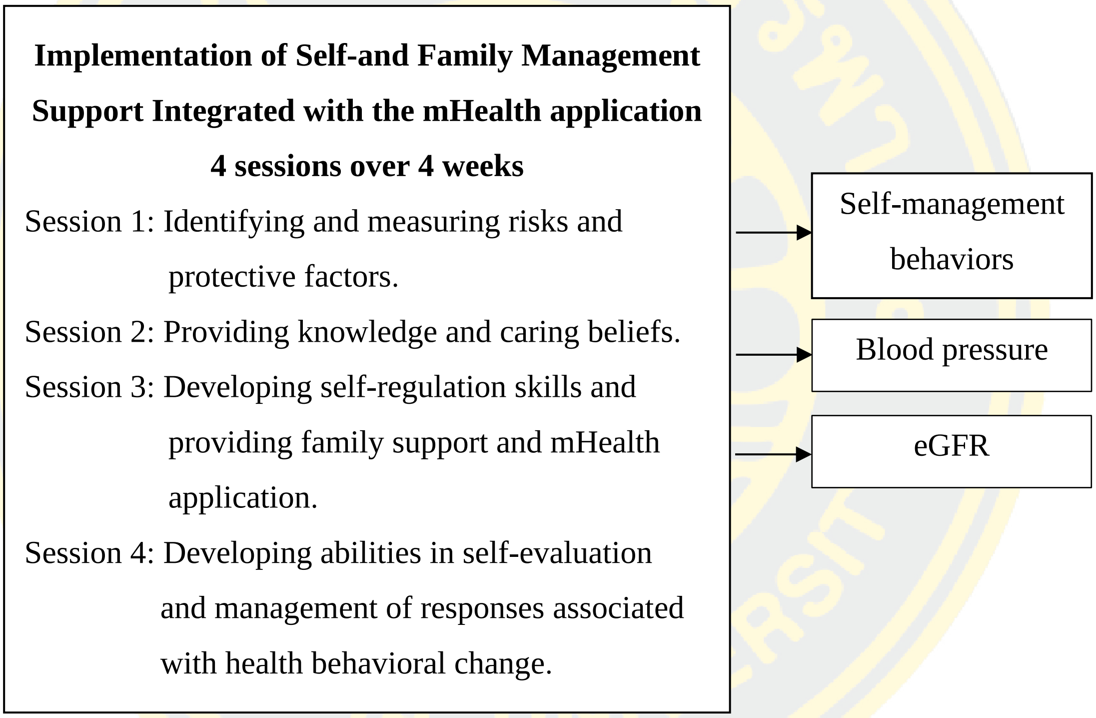


Figure 1 Research Framework of the Study

Scope of the Research

A randomized controlled trial (RCT) was employed in this study to evaluate the effectiveness of self-and family management support combined with the mHealth application. The participants were CKD stage 3 and aged $\geq$ 18 years who received treatment and follow-up at Samut Prakan Hospital's CKD clinic between November 2020 and November 2021. A total of 40 participants were randomly assigned to the experimental and control groups of 20 each.

Definition of Terms

1. Self-and family management support combined with the mHealth application refers to a set of activities provided for participants in the experimental group. The researcher uses this intervention in preparing persons and families to assume responsibility of managing or engaging in healthy behaviors. The self-and family management support combined with the mHealth application was developed based on IFSMT of Ryan and Sawin (2009) and implemented in four sessions over four weeks. mHealth application, run on mobile device with six interactive functions to support health care practices, was specifically designed for persons with CKD stage 3.

2. Self-management behaviors is defined as activities performed by patients with CKD stage 3 to prevent the progression of disease by engaging in health care in daily life. Self-management behaviors consist of five components: (1) self-care activities, (2) medication adherence, (3) communication, (4) self-advocacy, and (5) partnership in care. They are measured by Self-Management Behaviors Questionnaire (SMBQ) of Curtin et al. (2008) and translated in Thai by Sritarapipat et al. (2012).

3. Blood pressure (BP) is a unit that reflects the amount of pressure exerted on artery wall when blood flows through it. BP has two values, namely, systolic blood pressure (SBP) or peak blood pressure during active cardiac contraction, and diastolic blood pressure (DBP) or pressure in the period of cardiac ventricles relax. In this study, it is measured by Home Blood Pressure Monitoring (HBPM), Omron Hem-7120 brand. The blood pressure measurement method follows the guidelines of Thai Hypertension Society (2019).

4. Estimated Glomerular Filtration Rate (eGFR) is a unit of plasma that flows from glomerulus into Bowman's space over a specific period. It represents kidney function and determines the stage of CKD. In this study, eGFR is calculated by CKD-EPI creatinine equation. eGFR value is obtained from medical records of participants at Samut Prakan Hospital's CKD clinic.

CHAPTER 2
LITERATURE REVIEW

The literature reviews are presented in seven parts to provide an understanding of the relevant context in the present study. The first part describes chronic kidney disease. The second part focuses on the concept of self-management. The third part describes the theoretical framework of the Individual and Family Self-Management Theory (IFSMT). The fourth part describes family support enhancing CKD patient self-management. The fifth part describes mHealth applications for CKD management. The sixth part presents the outcomes of this study. The last part presents self-and family management support combined with the mHealth application program among persons with CKD stage 3.

Chronic kidney disease

Chronic kidney disease (CKD) is a global public health problem, including in Thailand, which causes premature death and progression to ESRD that requires treatment by dialysis or a kidney transplant (Thanakitjaru et al., 2014). Currently, the tendency of disease incidence is increasing rapidly. Patients with CKD have a higher chance of encountering many diseases, particularly cardiovascular disease and other complications that occur from the permanent loss of kidney function. As a result, health care providers must understand the definitions, classifications, etiology, pathophysiology, signs and symptoms, risk factors for disease progression, and management to effectively prevent CKD progression.

1. Definition of CKD

The Kidney Disease: Improving Global Outcomes (KDIGO) has recently published an updated guideline to clarify the definition and classification of CKD 2012. The definition covers the updated recommendations for the evaluation and management of individuals with CKD based on new evidence published in 2002 (KDIGO, 2013). The definitions of CKD describe abnormalities of kidney structure or function that have been present for > 3 months, with implications for health as follows:

1) Markers of kidney damage (one or more)

- Albuminuria (albumin excretion rate [AER] ≥ 30 mg/24 hours; albumin-to-creatinine ratio [ACR] ≥ 30 mg/g [≥ 3 mg/mmol]).

- Anomalies in urine sediment.

- Electrolyte and other abnormalities due to tubular disorders.

- Histology detects abnormalities.

- Imaging detects structural abnormalities.

- Kidney transplantation history.

2) Decreased glomerular filtration rate (GFR) < 60 ml/min/1.73 m^2 (GFR categories G3a–G5).

2. Classification of CKD

The KDIGO (2012) recommends that CKD be classified based on the cause, GFR category (Table 1), and albuminuria category (Table 2). A low glomerular filtration rate and a high urine albumin value indicated a worsening of CKD. The severity of a CKD classification helps a health care provider to provide care and manage specifically with the disease and achieve an effective health outcome for a patient with CKD.

Tables 1 GFR categories in CKD

GFR Category	**GFR (ml/min/1.73m^2)**	**Terms**
G1	> 90	Normal or high
G2	60-89	Mildly decreased*
G3a	45-59	Mildly to moderate decrease
G3b	30-44	Moderately to severely decrease
G4	15-29	Severely decreased
G5	< 15	Kidney failure

* Relative to young adult level. In the absence of evidence of kidney damage, neither GFR category G1 nor G2 fulfill the criteria for CKD (KDIGO, 2013, p. 27)

Tables 2 Albuminuria categories in CKD

Category	AER (mg/24 hr)	ACR (approximate equivalent)		
		(mg/mmol)	(mg/g)	Terms
A1	< 30	< 3	< 30	Normal to mildly increased
A2	30-300	3-30	30-300	Moderately increased*
A3	> 300	> 30	> 300	Severely increase**

*Relative to young adult level. **Including nephrotic syndrome (albumin excretion usually > 2200 mg/24 hours [ACR > 2220 mg/g; > 220 mg/mmol]) (KDIGO, 2013, p. 28)

3. Etiology

The two main causes of CKD are diabetes and hypertension, which are responsible for up to two-thirds of the cases (NKF, 2019). Genetics, male gender, African American ethnicity, elderly people, obesity, dyslipidemia, low birth weight, exposure to nephrotoxic agents such as alcohol, analgesic drugs, and heavy metals, acute kidney injury, low socioeconomic status, smoking, and obstructive sleep apnea are all risk factors for CKD (Kazancioglu, 2013; KDIGO, 2012).

In Thailand, it is found that the most common cause of CKD is diabetes (36.30%), followed by hypertension (23.30%), obstructive nephropathy (4.79%), and chronic glomerulonephritis (2.43%) (Thanakitjaru et al., 2014). In addition, there are other causes such as chronic pyelonephritis, polycystic kidney disease, lupus nephritis, and analgesic drugs.

4. Pathophysiology

Pathophysiology of CKD occurs when glomerular, tubular, and vascular cells are abnormal. The causes of renal injury are based on immunologic reactions (initiated by immune complexes or immune cells), tissue hypoxia and ischemia, exogenic agents such as drugs, endogenous substances (e.g., glucose or paraproteins, and others), and genetic defects. Irrespective of the underlying cause, glomerulosclerosis and tubulointerstitial fibrosis are common in CKD (Matovinović, 2009).

4.1 Mechanism of glomerular impairment

Hereditary defects account for a minority of glomerular diseases. A prototype of inherited glomerular disease is Alport's syndrome, or hereditary nephritis, usually transmitted through an X-linked dominant trait, although autosomal dominant and recessive forms have been reported as well. In its classical X-linked form, there is a mutation in the COL4A5 gene that encodes the α5 chain of type IV collagen located on the X chromosome.

Immunologic glomerular injury. Most acquired glomerular diseases are triggered by immune-mediated injury, and metabolic and mechanical stress. Based on pathological and pathogenetic aspects, it can be classified into three groups, including

(1) non-proliferative (without cell proliferation) glomerular diseases without glomerular inflammation and deposition of immunoglobulins, (2) proliferative glomerular diseases with deposition of immunoglobulins leading to increased cellularity (proliferative glomerulonephritis, e.g., lupus nephritis, IgA nephropathy, anti-GBM, postinfectious GN), and (3) heterogenous group of glomerular diseases in systemic diseases such as glomerular disease in diabetes, amyloidosis, and paraproteinemia.

Non-immunologic glomerular injury. Hemodynamic, metabolic, and toxic injuries can induce glomerular impairment. The important factors are systemic hypertension, glomerular hypertension, and metabolic injury (e.g., diabetes mellitus).

1) Systemic hypertension can cause glomeruli and glomerular hypertension, resulting in local changes in glomerular hemodynamic that may cause glomerular injury. The kidney is normally protected from systemic hypertension by autoregulation, which can be overwhelmed by high blood pressure, meaning that systemic hypertension is translated directly into the glomerular filtration barrier, causing glomerular injury. Chronic hypertension leads to arteriolar vasoconstriction and sclerosis, with consequent secondary sclerosis and glomerular and tubulointerstitial atrophy. Different growth factors such as angiotensin II, EGF, PDGF, and CSGF, TGF-ß cytokine, activation of stretch-activated ion channels, and early response genes are involved in coupling high blood pressure to myointimal proliferation and vessel wall sclerosis.

2) Glomerular hypertension is normally an adaptive mechanism in remaining nephrons to increase workload caused by nephron loss, regardless of the cause. This sustained intraglomerular hypertension increases mesangial matrix production and leads to glomerulosclerosis by ECM accumulation. The process is mediated by TGF-ß in the first place, with a contribution from angiotensin II, PDGF, CSGF, and endothelins. Systemic and glomerular hypertension are not necessarily associated; as glomerular hypertension may precede systemic hypertension in glomerular disease.

4.2 Mechanism of tubulointerstitial impairment

Regardless of the etiology, CKD is characterized by renal fibrosis, glomerulosclerosis, and tubulointerstitial fibrosis. The impairment of the tubulointerstitium (tubulointerstitial fibrosis and tubular atrophy) is at least as important as that of the glomeruli (glomerulosclerosis). There is a common consensus that the severity of tubulointerstitial injury correlates closely with long-term impairment of renal function. The current study focuses on explaining the pathophysiology of hypertension and diabetes, which are the main causes of CKD, with the following details:

Hypertension is a common disease in patients with CKD. The prevalence ranges from 60% to 90%, depending on the stage of CKD and its cause. CKD is closely linked to pathophysiologic states such that sustained hypertension can lead to worsening kidney function and a progressive decline in kidney function can conversely lead to worsening blood pressure control. The pathophysiology of hypertension in CKD is complex and it is a sequela of multiple factors, including reduced nephron mass, increased sodium retention and extracellular volume expansion, sympathetic nervous system overactivity, and activation of hormones including the renin-angiotensin-aldosterone system (RAAS), and endothelial dysfunction.

CKD is associated with increased activity of the RAAS. There is a reduction in blood flow in peritubular capillaries downstream of sclerosed glomeruli. As a result of this reduced effective (perceived) blood flow, glomeruli in these regions secrete excessive renin, thereby increasing circulating angiotensin II levels.

Angiotensin II has a direct vasoconstrictor effect, which increases systemic vascular resistance and blood pressure. Because there are fewer functioning glomeruli in CKD, each remaining glomerulus must increase its glomerular filtration rate (GFR). Increasing systemic arterial pressure helps bolster perfusion pressure and GFR (Ku et al., 2019).

Angiotensin II also promotes sodium reabsorption in the proximal tubule and (through aldosterone) in the collecting duct. Moreover, the net loss of overall GFR impairs sodium excretion, which also leads to sodium retention. Sodium retention causes hypertension through volume-dependent and volume-independent mechanisms. Excess extracellular volume leads to increased perfusion of peripheral tissues, which stimulates vasoconstriction, increases peripheral vascular resistance, and therefore increases BP. Extracellular volume expansion also leads to the production of ouabain-like steroids that induce vasoconstriction and therefore increase peripheral vascular resistance. Volume-independent mechanisms include increased vascular stiffness and increased central sympathetic outflow (a direct sequela of increased extracellular sodium) (Ku et al., 2019).

Overactivity of the sympathetic nervous system (SNS) in CKD stimulates renin production by the renal juxtaglomerular cells. Beyond SNS activation by sodium retention, renal ischemia also leads to renal afferent nerve excitation through adenosine. Finally, experimental and clinical studies suggest that angiotensin II levels (which are higher in patients with CKD as detailed above) directly stimulate SNS activity. Endothelial dysfunction (including impaired nitrous oxide production), oxidative stress, and elevated endothelin levels are also implicated in the pathogenesis of hypertension in patients with CKD (Ku et al., 2019).

Thus, HT leads to high intraglomerular pressure, impairing glomerular filtration and finally damaging the glomeruli, leading to an increase in protein filtration, resulting in abnormally increased amounts of protein in the urine (microalbuminuria or proteinuria). Microalbuminuria is the presence of small amounts of albumin in the urine and is often found as the first sign of CKD. Proteinuria (protein-to-creatinine ratio ≥ 200 mg/g) is present when CKD progresses, and it is associated with a poor prognosis for both kidney disease and CVD (Buffet & Ricchetti, 2012). While hypertension contributes to the development of CKD, CKD is also a major factor in the progression of hypertension. Thus, patients with CKD need to control blood pressure, which has the benefit of slowing the progression of CKD, and hypertension, and preventing CVD risk.

Diabetic kidney disease (DKD) develops in approximately 40% of patients who have diabetes types 1 and 2. Risk factors for DKD can be conceptually classified as susceptibility factors (e.g., age, sex, race/ethnicity, and family history), initiation factors (e.g., hyperglycemia and acute kidney injury), and progression factors (e.g., hypertension, dietary factors, and obesity). The most prominent established risk factors are hyperglycemia and hypertension (Alicic et al., 2017).

The normal healthy glomerulus includes afferent arterioles, capillary loops, endothelial cells, basement membrane, podocytes, parietal epithelial cells, and tubule epithelial cells and is impermeable to albumin. In contrast, the structure of the kidneys will be changed by DKD. The earliest consistent change is the thickening of the glomerular basement membrane, which is apparent within 1.5–2 years of the DM type 1 diagnosis. It is paralleled by capillary and tubular basement membrane thickening. Other glomerular changes include loss of endothelial fenestrations, mesangial matrix expansion, and loss of podocytes with effacement of foot processes. Within 5–7 years after DM type 1 diagnosis, mesangial volume expansion is detectable (Alicic et al., 2017; Reidy et al., 2014). In later stages of diabetes, interstitial changes and glomerulopathy coalesce into segmental and global sclerosis. Renal structure changes in patients with DM2 are similar to those seen in DM1, but they are more heterogeneous and less predictably associated with clinical presentations (Alicic et al., 2017). Changes in kidney structure allow plasma proteins to escape into the urine, causing proteinuria and the hypoproteinemia, edema, and other signs of impaired kidney function.

Furthermore, critical metabolic changes from hyperglycemia-induced alters kidney hemodynamics and promotes inflammation and fibrosis in early diabetes leading to several abnormalities, including hyperaminoacidemia, hyperperfusion, and high intraglomerular pressure (Alicic et al., 2017). However, systemic and glomerular hypertension causes the nephron to be permanently destroyed, causing the glomerular filtration rate to decrease. Therefore, controlling blood sugar levels together with controlling blood pressure, especially with medications that inhibit the angiotensin system, is an effective way to slow DKD progression.

5. Signs and symptoms

The clinical manifestations of CKD are initiated by an increase in nitrogenous waste, causing a condition known as "uremia," which induces other complications. The uremia state includes signs and symptoms of altered fluid, electrolytes, and acid-base balance; alterations in regulatory functions (e.g., blood pressure control, production of red blood cells, and impaired vitamin D synthesis); and the effects of uremia on body function (e.g., uremia encephalopathy, peripheral neuropathy, and pruritus). At this stage, many organs and structures in the body are virtually affected. The symptoms at the onset of uremia (e.g., weakness, fatigue, nausea, apathy) are often subtle. More severe symptoms include extreme weakness, frequent vomiting, lethargy, and confusion. Without treatment of dialysis or a renal transplant, coma and death can follow (Grossman & Porth, 2014).

A person with CKD stage 3 has moderate kidney damage. They are more likely to develop kidney disease complications, but they may not experience any severe symptoms until their kidneys fail. Patients may notice symptoms such as feeling tired and having less energy, difficulty concentrating, poor appetite, difficulty sleeping, muscle cramping at night, swollen feet and ankles, puffiness around their eyes, especially in the morning, dry and itchy skin, and the need to urinate more frequently, especially at night (NKF, 2019). Furthermore, the symptoms of the early stages of CKD are bone and joint pain, lack of energy, and difficult sleep (Brown et al., 2017; Senanayake et al., 2017).

Bone and joint pain

In 2012, the NKF subdivided stage 3 CKD (eGFR 30-59 ml/min/1.73 m^2) into 2 subtypes, which are stage 3a (eGFR 45-59 ml/min/1.73 m^2) and 3b (eGFR 30-44 ml/min/1.73 m^2). The purpose of this division is to acknowledge that stage 3 CKD encompasses a broad range of renal functions and that there may be clear biological distinctions among the renal–bone–vascular calcification pathophysiology (e.g., CKD–MBD) between 3a and 3b CKD. Derangements in the biochemical regulatory process that accompany CKD become more severe as the disease progresses. Early CKD is associated with a progressive rise in osteocyte-derived fibroblast growth factor 23

(FGF-23) and, later, a progressive rise in endogenous parathyroid hormone production (PTH) that is higher in stage 3a than in stage 3b CKD (Miller, 2014).

Bone disease can happen in the early stages of CKD. However, most patients with early-stage CKD may have no symptoms or feelings of bone disease but may present in late-stage CKD. The regulation of serum phosphate levels requires a daily urinary excretion of an amount equal to that ingested in the diet. With deteriorating renal function, phosphate excretion is impaired, resulting in risen serum phosphate levels. At the same time, serum calcium levels, which are inversely regulated to serum phosphate levels, fall. The drop in serum calcium stimulates releasing of parathyroid hormone (PTH) causing increased calcium resorption from bone. Vitamin D synthesis is also impaired in CKD. The kidney regulates vitamin D activity by converting the inactive form of vitamin D (25[OH] vitamin D3) to calcitriol (1,25 [OH] vitamin D3), the active form of vitamin D (Grossman & Porth, 2014). Therefore, resulting in subsequent bone disease which usually causes bone pain, joint pain, bone deformation, poor mobility, and bone fractures.

Lack of energy or Fatigue

Lack of energy or fatigue usually occurs from anemia. In CKD anemia may occur at an early stage (CKD stage 2 and 3), in which the threshold values for making the diagnosis of anemia, and the need for treatment is Hb < 13 g/dl in men, Hb < 12 g/dl in women (Cases et al., 2018). Among patients with CKD, there is a relative deficiency in erythropoietin production, and this is the main reason for anemia in CKD patients. Other factors that may contribute to anemia include iron deficiency, blood loss, inflammation, hemolysis, and nutritional deficits (Fishbane & Spinowitz, 2018). Anemia results in reduced oxygen delivery to the body's organs and tissues, making symptoms such as fatigue, shortness of breath, insomnia, headaches, and reduced mental acuity common. Fatigue may develop slowly as anemia progresses, and patients may not be fully aware of how their lives have been affected.

Anemia can affect cardiovascular function. Anemia-related renal failure causes a decrease in blood viscosity and a compensatory increase in heart rate. The decreased blood viscosity also exacerbates peripheral vasodilation and contributes to decreased vascular resistance. Cardiac output increases in a compensatory fashion to maintain adequate perfusion. Anemia also limits myocardial oxygen supply, particularly in people with coronary heart disease, leading to angina pectoris and other ischemic events (Grossman & Porth, 2014).

Difficult sleep or Insomnia

Insomnia is defined as "a repeated difficulty with sleep initiation, duration, consolidation, or quality that occurs despite adequate opportunity and circumstances for sleep, and results in some form of daytime impairment." Insomnia patients typically have difficulty falling and staying asleep, as well as unwanted prolonged periods of wakefulness during normal sleep periods (Nigam et al., 2018). Previous studies have identified physiological and psychological risk factors for insomnia. There is a direct link between orexin or hypocretin levels and insomnia. Orexin has been linked to arousal, wakefulness, and appetite. In patients with CKD or ESRD, a lack of orexin (hypocretin) leads to increased periods of wakefulness that can be associated with insomnia. Also, kidney dysfunction leads to hypercalcemia, generating psychiatric overtones typically associated with hypercalcemia, such as anxiety, depression, psychosis, and insomnia (Nigam et al., 2018).

However, the cause of sleep disorders is complicated includes psychological disorders (depression, anxiety), lifestyle factors (coffee/nicotine use, daytime napping, sleep hygiene), as well as intrinsic, CKD-specific factors (anemia, bone/joints pain, uremia, alterations in neurotransmitter production). Thus, the way to manage insomnia must be to preserve kidney function and manage other problems together.

6. Factors predicting the progression of CKD

KDIGO (2012) has defined CKD progression based on one or more of the following: (1) GFR decline (90 [G1], 60–89 [G2], 45–59 [G3a], 30–44 [G3b], 15–29 [G4], 15 [G5] ml/min/1.73 m^2). A certain drop in eGFR is defined as a drop in GFR category accompanied by a 25% or greater drop in eGFR from baseline; (2) rapid progression is defined as a sustained decline in eGFR of more than 5 ml/min/1.73 m^2/year; and (3) increasing the number of serum creatinine measurements and duration of follow-up increases confidence in assessing progression. The prediction of the progression of CKD depends on many factors, especially the eGFR and albuminuria categories (Figure 2).

Prognosis of CKD by GFR and Albuminuria Categories				**Persistent albuminuria categories Description and range**		
				A1	A2	A3
				Normal to mildly increased	Moderately increased	Severely increased
				< 30 mg/g < 3mg/mmol	30-300 mg/g 3-30 mg/mmol	> 300 mg/g > 30 mg/mmol
GFR categories (ml/min/1.73m^2) Description and range	G1	Normal or high	≥ 90			
	G2	Mildly decreased	60-90			
	G3a	Mildly to moderately decreased	45-59			
	G3b	Moderately to severely decreased	30-44			
	G4	Severely decreased	15-29			
	G5	Kidney failure	< 15			

Note: GFR and albuminuria grid to reflect the risk of progression by intensity of coloring by Green: low risk (if no other markers of kidney disease, no CKD); Yellow: moderately increased risk; Orange: high risk; Red, very high risk (KDIGO, 2013, p. 34).

Figure 2 Prognosis of CKD by GFR and albuminuria category

The CKD patients with progression are recommended to meet a specialist to examine for reversible causes of progression. The factors associated with CKD progression including cause of CKD, level of GFR, level of albuminuria, age, sex, race/ethnicity, elevated BP, hyperglycaemia, dyslipidaemia, smoking, obesity, history of cardiovascular disease, ongoing exposure to nephrotoxic agents, and others.

According to the report of CKD progression in Thailand from the Thai-SEEK project 2 (The Nephrology Society of Thailand, 2015) during eight years' follow-up, the overall incidence of CKD was 28 percent, and abnormal albuminuria was the major contributor for CKD diagnosis. The main abnormality that a nephrologist provides a diagnosis of CKD was hypertensive nephropathy and glomerular disease, which contributed about 50 percent of diagnosis. The rate of eGFR declines in average of 1.58 ml/min/1.73m^2 per year. The incidence rate of CKD progression was 23 percent. The factors associated with CKD progression are diabetes mellitus and hyperuricemia. Moreover, the factors related to death, including age > 45 years, male gender, low income, hypertension, work involve significant physical activity and CKD status which the ESRD showed the highest incidence rate of death.

7. Management for slowing CKD progression

Although CKD is generally progressive and irreversible, there are guidelines for providers and patients to slow the progression, enabling patients to live longer without complications or the need for renal replacement therapy. Treatment strategies to slow progression and reduce cardiovascular risk are 1) nutritional management, 2) lifestyle modification, and 3) medical management to control blood pressure and blood glucose, and reduce albuminuria (KDIGO, 2013; The Nephrology Society of Thailand, 2015).

1) Nutritional management

CKD causes the accumulation of waste produced by protein metabolism and induces uremia, leading to various complications. It also induces electrolytes and acid-base imbalance causing life-threatening conditions such as hyperkalemia and metabolic acidosis. Thus, nutrition management for patients with CKD is important to reduce the risk of CKD progression and complications, especially by reducing the intake of protein, sodium, potassium, and phosphate.

Protein restriction

High protein intake may lead to increased intraglomerular pressure and glomerular hyperfiltration. This can cause damage to the glomerular structure, leading to aggravating CKD. Hence, a low protein diet of 0.6–0.8 g/kg/day is often recommended for the management of patients with non-dialysis-dependent CKD. In addition, patients with CKD should avoid a high protein diet of more than 1.2 g/kg/day, because it can induce alterations in renal function (Kalantar-Zadeh et al., 2016). Patients with CKD should consume at least 60% protein as a high biological value protein or protein containing all essential amino acids, such as meat protein or egg white. Besides, they should get enough energy from the diet as follows: those aged under 60 years should receive 35 kcal/kg of ideal body weight. Blood albumin levels should be checked every 3-6 months, with albumin levels greater than 3.5 g/dl (The Nephrology Society of Thailand, 2015).

Sodium restriction

In CKD, the kidneys' inability to excrete sodium is a major cause of hypertension and albuminuria and can lead to the progression of the disease. Thus, dietary sodium restrictions for CKD have become an important practice to control blood pressure and albuminuria. KDIGO (2012) recommended lowering salt intake to < 90 mmol (< 2 g) per day (corresponding to 5 g of sodium chloride) in adults with CKD unless contraindicated. The result of a meta-analysis of RCTs in adult patients with non-dialysis CKD (stages 1-4) showed a moderate dietary sodium restriction can reduce BP and proteinuria/albuminuria significantly (Garofalo et al., 2018). Thus, they should avoid high sodium intake (> 4.6 g/day) because it is associated with adverse outcomes such as a decline in both creatinine-based measures of renal function (GFR) and an increase in proteinuria (Smyth et al., 2014).

Potassium restriction

Hyperkalemia is a life-threatening complication for CKD patients. Serum potassium concentration is a key determinant of the resting cell membrane potential of neurons and muscle fibers. Consequently, hyperkalemia is associated with a variety of neuromuscular complications, including abdominal cramping, weakness, and cardiac arrhythmias. Approximately 90% of potassium is excreted through the kidneys. In CKD, the ability of potassium excretion is decreased while potassium excretion in the gastrointestinal tract is increased, resulting in hyperkalemia. Hyperkalemia often results from failure to follow dietary potassium restrictions, leading to constipation, acute acidosis that causes the release of intracellular potassium into the extracellular fluid, trauma or infection that causes the release of potassium from body tissues, or exposure to medications that contain potassium, prevent its entry into cells or block its secretion in distal nephrons (Grossman & Porth, 2014).

The assumption is that dietary potassium intake is an important element of serum potassium concentrations in CKD patients. Therefore, the recommendation to avoid high-potassium foods is fundamental to preventing hyperkalemia. The Nephrology Society of Thailand (2015) recommends eating foods with low potassium such as vegetables: cucumbers, zucchini, raw papaya, green beans, onion, cabbage, and fruit: pineapple, watermelon, grapefruit, mangosteen, rambutan, and apple.

Phosphate restriction

Levels of serum phosphorus in patients with CKD remain within the normal range or may even be modestly below the normal range until the GFR declines to 20 to 30 mL/min/1.73 m^2 (stage 4 of CKD). Thus, it may appear that restriction of rich-phosphate foods is not necessary for patients with Stages 1, 2, and 3 of CKD. However, phosphate retention occurs in stage 3a and such phosphate retention participates in the genesis of secondary hyperparathyroidism (KDIGO, 2017). Indeed, the blood levels of PTH are elevated when GFR falls to 60 mL/min/1.73 m^2, even though serum phosphorus levels are not elevated. Thus, controlling serum phosphate is important for patients with CKD to reduce the risk of cardiovascular disease and mortality rate.

Reducing phosphate and protein intake is a widely accepted strategy to aid in the control of hyperphosphatemia. It is a essential part of the recommendations issued by both the KDIGO and KDOQI guidelines, with a daily phosphate intake of 800 to 1,000 mg/d and a daily protein intake (as the major source of phosphate) of 1.2 g/kg body weight (Barreto et al., 2019). In addition, phosphate binders are provided to reduce the absorption of dietary phosphate in the gastrointestinal tract. Patients with CKD stage 3b-5 with hyperparathyroidism should maintain normal levels of calcium and phosphate in combination with the treatment of vitamin D deficiency. If the parathyroid hormone level tends to increase, calcitriol (active vitamin D) or alfacalcidol (vitamin D analog) is considered to provide for tracking calcium levels and periodic serum phosphate (The Nephrology Society of Thailand, 2015).

2) Lifestyle modification

Much evidence shows that lifestyle may have an impact on the risk of developing CKD and the risk of CKD progression. Meanwhile, the management of CKD patients focuses on physical activity and quitting smoking.

Physical activity

There is evidence showing that higher physical activity levels are associated with slower rates of eGFR loss in CKD patients. Participants who performed physical; activity > 150 minutes per week had the lowest rate of eGFR cystatin C loss (mean, 26.2% per year compared with 29.6% per year among inactive participants). Each 60-minute increase in weekly physical activity duration was associated with a 0.5% slower decline in eGFR (95% confidence interval, 0.02 to 0.98; $p < .05$) in adjusted analyses (Robinson-Cohen et al., 2014). KDIGO (2012) has also recommended and encouraged people with CKD to perform physical activity compatible with cardiovascular health and tolerance (aiming for at least 30 minutes, 5 times per week), to achieve a healthy weight (BMI of 20 to 25, according to country-specific demographics).

Stop smoking

Smoking is a risk factor for the onset and progression of CKD in the general population; the risk increases with an increase in smoking duration, several cigarettes smoked daily, and packs/year (Choi et al., 2019; Hallan & Orth, 2011). The result of a systematic review found that the consumption of ≥ 15 packs per year increases the risk of progression of CKD (Elihimas Júnior et al., 2014).

Two mechanisms might explain the relationship between smoking and CKD onset and progression. The first is related to conditions that predispose to CKD, such as DM and HT. Smoking can cause further endothelial damage in patients with HT or DM, resulting in CKD onset or progression. The second category is a shared feature of smoking and CKD, specifically, oxidative stress. As a result, oxidative stress is already increased during the early stages of CKD as a result of enhanced oxidant production and a compromised antioxidant mechanism (Nagasawa et al., 2012). Thus, advice to stop smoking is a benefit for CKD patients.

3) Medical management

Controlling the progression of CKD requires treatment with medication, especially antihypertensive and hypoglycaemic drugs, to control blood pressure, and blood glucose levels, and reduce albuminuria. Patients with CKD must have effective medication management by meeting the goals of CKD management guidelines (KDIGO, 2012; The Nephrology Society of Thailand, 2015) and concordance with HT (ACC/AHA, 2017) and DM (ADA, 2020) guidelines in follows:

Blood pressure control

Hypertension is one of the leading factors that contribute to the progressive decline of renal function, leading to ESRD, and thus has become an important target in the treatment of CKD. Currently, the treatment target for patients with CKD is a clinic systolic BP < 130 mmHg (ACC/AHA, 2017; KDIGO, 2012). Uncontrolled hypertension can lead to significant cardiovascular morbidity and mortality and accelerate progression to ESRD. Although intensive blood pressure control has not been shown in clinical trials to slow the progression of CKD, it reduces the risk of adverse cardiovascular outcomes and mortality (Ku et al., 2019).

The main approaches to hypertension management in CKD include dietary (salt) restriction, exercise, stopping smoking, and initiation of treatment with angiotensin-converting enzyme inhibitors (ACE-I) or angiotensin receptor blockers (ARB) and diuretic therapy. Support CKD patients' exercise, control weight, and have a body mass index (BMI) value of between 20 and 25 kg/m^2. The limitation of sodium intake to less than 2,000 mg/day and quitting smoking (The Nephrology Society of Thailand, 2015). An ACE-I, or ARB, is a medication that is recommended for controlling blood pressure in CKD patients. The KDIGO (2012) suggests using ARB or ACE-I for diabetic adults with CKD and urine albumin excretion of 30–300 mg/24 hours (or equivalent) and non-diabetic adults with CKD and urine albumin excretion > 300 mg/24 hours (or equivalent). There is sufficient evidence to recommend combining an ACE-I with an ARB to prevent the progression of CKD.

Blood glucose control

Hyperglycemia, the defining feature of diabetes, is a fundamental cause of vascular target organ complications, including DKD. Intensive treatment of hyperglycemia prevents elevated albuminuria or delays its progression, but patients may be at an increased risk of severe hypoglycemia.

Evidence that intensive treatment affects the loss of GFR is sparse. There are three recommendations related to assessing for hyperglycemia, including 1) a target HbA1c of 7% to prevent or delay the progression of the microvascular complications of diabetes, including DKD; 2) untreated diabetes and HbA1c target of < 7% in patients at risk of hypoglycemia; and 3) target HbA1c be extended above 7% in individuals with co-morbidities or limited life expectancy and risk of hypoglycemia (ADA, 2020; NKF, 2012). Moreover, the patients should control their pre-prandial capillary plasma glucose to a normal level of 80–130 mg/dL (4.4–7.2 mmol/L). This is recommended for diabetic patients with stage 1-3 CKD with an AER of less than 300 mg/day and without the risk of hypoglycemia, which may control blood sugar levels to be close to the recommended low level. The maximal acceptable postprandial capillary plasma glucose level should be less than 180 mg/dL (less than 10 mmol/L) (The Nephrology Society of Thailand, 2015).

In conclusion, CKD is a complex disease, both in its cause and pathology, that affects all systems of the body. Therefore, it must require comprehensive management of CKD and co-morbidity together. CKD management focuses on nutrition and medication management as well as lifestyle modification. Furthermore, the co-morbidity can be prevented by controlling blood pressure and blood glucose levels to continue to slow the progression of CKD effectively.

Self-management concept

Chronic diseases are health problems that require ongoing management over years or decades. Self-management is the key to approaching this issue and improving health outcomes, which embraces a range of indicators such as knowledge, skills, and bio-psychosocial markers of health (Boger et al., 2015). Self-management support is an essential aspect of the integrated care program for the prevention and management of the chronic disease. It is key to deliver person-centered care in which patients are empowered to participate in the management of their condition actively. In this session, the definition, and attributes of self-management for a person with chronic disease related to CKD are described.

1. Definitions of Self-management

Although self-management is often used interchangeably with terms such as self-care, self-regulation, and disease management, the different tasks are performed. Many authors interpret self-care as consisting of those performed at home by healthy people to prevent illness, rather than merely managing an existing illness. At the same time, self-regulation is more distantly related, referring to the capacity to control and manage thoughts, emotions, or behavior (Grady & Gough, 2014). Self-management emphasizes an individual’s involvement in defining health. Self-management is the intention and “involves the use of specific processes, can be affected by specific programs and interventions, and result in specific types of outcomes” (Ryan & Sawin, 2009). Disease management is a group of coherent interventions designed to prevent or manage one or more chronic conditions using a systematic, multidisciplinary approach and potentially employing multiple treatment modalities. The goal of disease management is to promote self-management by patients and to address the illnesses or conditions with maximum clinical outcome, effectiveness, and efficiency (Schrijvers, 2009).

Based on the concept, self-management has been described and considered for more than 40 years, with the term first used by Creer (2000), who defined self-management of chronic illness as a procedure where patients change some aspect of their behavior. It involves processes including goal selection, information collection, information processing and evaluation, decision making, action, and self-reaction. Self-management is also described by WHO as one of the critical components in improving chronic care by focusing on supporting behavioral skills to manage conditions at home and includes having the necessary medications and medical equipment, self-monitoring tools, and self-management skills as part of integrated care (Nuño et al., 2012).

For CKD, Curtin & Mapes (2001) defined self-management as the patients’ positive efforts to oversee and participate in their health care to optimize health, prevent complications, control symptoms, manipulate medical resources, and minimize the intrusion of the disease into their preferred lifestyles.

2. Attributes of self-management

According to the literature reviews, self-management is categorized into three characteristics: self-management processes, self-management tasks, and self-management skills. These terms are used interchangeably in the literature, but they have different meanings and practices. The self-management process specifies the work of patients living with a chronic illness that underlies tasks and skills. Both tasks and skills are viewed as behaviors, but tasks as the essential work of self-management, while skills describe the specific ways an individual accomplishes tasks (Schulman-Green et al., 2012).

Self-management process

Individuals actively manage chronic illnesses through self-management, which is a dynamic process. It involves processes including (a) goal selection, (b) information collection, (c) information processing and evaluation, (d) decision making, (e) action, and (f) self-reactions. Successful mastery and performance of self-management skills result in the following outcomes, including (a) changes in mortality and morbidity indices of the disease, (b) improvement in the quality of life experienced by patients and those around them; and (c) the development of self-efficacy, patients' beliefs in what they can contribute to the management of their disorder, in part through their becoming partners with their physicians and other health care providers to control the chronic disease or disorder (Creer, 2000).

Grey et al. (2006) depicted self and family management processes as being influenced by risk and protective factors and as contributing to outcomes but did not specify these processes. Ryan and Sawin (2009) described the self-management processes of enhancing knowledge and beliefs (i.e., self-efficacy, outcome expectancy, goal congruence), regulation of skills and abilities (i.e., goal-setting, self-monitoring, reflective thinking, decision making, planning and action, self-evaluation, emotional control), and social facilitation (i.e., influence, support, collaboration). These processes of self-management have higher specificity than previous conceptualizations. However, they do not address the emotional or existential challenges of living with a chronic illness.

Self-management tasks and skills

Corbin and Strauss conducted a qualitative study on people with chronic conditions (Corbin & Strauss, 1988). They found three sets of self-management tasks. The first set of tasks involves the medical management of the condition, such as taking medication, adhering to a special diet, or using an inhaler. The second set of tasks consists of maintaining, changing, and creating new meaningful behaviors or life roles. For example, people with back pain may need to change the way they garden or participate in favorite sports. The final task requires an individual to deal with the emotional sequel of having a chronic condition, which alters one's view of the future. Someone with chronic disease commonly experiences emotions such as anger, fear, frustration, and depression.

Therefore, learning to manage these emotions becomes a part of the work that is required to maintain the condition. Lorig and Holman (2003) defined self-management as a common term in health education, and its name is attached to many health promotions and patient education programs. It presents three self-management tasks, which are medical management, role management, and emotional management. It comprises six self-management skills for chronic disease, including problem-solving, decision making, resource utilization, the formation of a patient-provider partnership, action planning, and self-tailoring (Lorig, & Holman, 2003). In addition, self-management for CKD patients in the pre-dialysis stage comprises five skills or behaviors, including communication with health care providers, partnership in care, self-care activities, self-advocacy, and medication adherence (Curtin et al., 2008)

The above literature review reveals that the definition and attribute of self-management vary according to the context of each chronic disease, most of which do not specify all three attributes together. However, Schulman-Green et al. (2012) explain that self-management consists of three processes as follows (1) focusing on illness needs, (2) activating resources, and (3) living with a chronic illness, in which the tasks and skills are delineated for each category.

1) Focusing on illness needs reflects the tasks and skills that are necessary for the physical management of chronic conditions. As a part of this process, individuals learn about chronic illness, take ownership of their health needs, and perform health promotion activities. Tasks and skills of learning about self-management include acquiring information about the disease and learning requisite regimens, skills, and strategies to manage daily illness needs. Taking ownership of health needs involves the tasks and skills of learning about and managing body responses, completing health tasks (e.g., keeping appointments, taking medications), and becoming an expert (e.g., goal setting, decision making, problem-solving, planning, and evaluation) (Schulman-Green et al., 2012).

2) Activating resources that are integral to optimum self-management include individuals (e.g., family members, friends, healthcare providers) and community resources and services (e.g., spiritual resources, social and transportation services). Such community resources assist individuals in managing various aspects of their illness, including medical, psychosocial, spiritual, and financial facets. Self-

management tasks and skills related to activating resources include communicating with healthcare providers, coordinating services, identifying and benefiting from psychological resources, being part of a spiritual community, obtaining and managing social support, and addressing social or environmental challenges (Schulman-Green et al., 2012).

3) Living with a chronic illness is a self-management process that includes tasks and skills related to coping with the disease and growing as a person, as well as transitioning from a focus on the illness needs to integrating the illness into the context of the individual's life. Four tasks are identified: processing emotions, adjusting, integrating illness into daily life, and meaning-making (Schulman-Green et al., 2012).

In conclusion, the characteristics of self-management are defined in different ways by the objective of practice. Self-management of chronic illness combines the elements of the process, tasks, and skills to encourage them to be active agents in managing their health, which effects on normalizing of the chronic condition. Most of the self-management definitions, skills, and tasks focus on individual self-management but do not involve family. The researcher realizes the importance of family in supporting and helping patients with chronic diseases to have better self-management behaviors. Therefore, the theory of individual and family self-management of Ryan and Sawin (2009) was used as a guideline for the program's activities among persons with CKD stage 3.

The Individual and Family Self-Management Theory

Individual and family self-management theory (IFSMT) by Ryan and Sawin (2009) is a middle-range descriptive theory based on deductive and inductive processes. This theory is established from different sources of conceptual perspectives, including three types of literature. (1) Articles focus on theoretical constructs, including risk and protective factors and complementary outcomes, processes of self-regulation, and common tasks across chronic conditions. (2) Articles describe theoretically based self-management interventions and programs. (3) Articles examining the efficacy of theoretically based self-management research reviews.

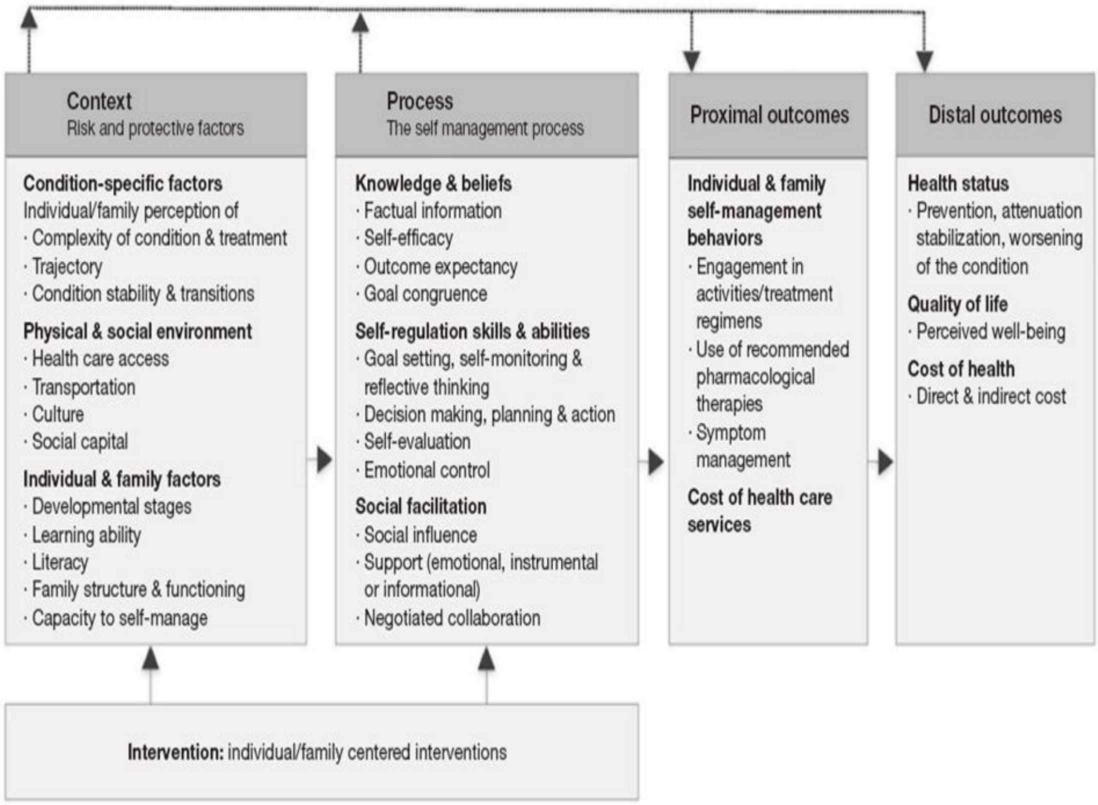


Figure 3 The individual and family self-management theory was modified with the permission of the authors (Ryan & Sawin, 2014).

Self-management is used to manage chronic conditions as well as to engage in health promotion behaviors (Ryan & Sawin, 2009). It is a multidimensional, complex phenomenon that is conceptualized as affecting individuals, dyads, or families across all developmental stages. It includes condition-specific risk and protective factors, the physical and social environment, and the unique characteristics of individuals and family members. Furthermore, it consists of self-management processes, specifically, facilitation of knowledge and beliefs, improvement of self-regulation skills and abilities, and social facilitation. It affects several outcomes, both short and long term (Figure 3).

1. Context dimension

The contextual factors are risks or protective factors that refer to (1) condition-specific factors, (2) physical and social environments, and (3) individual and family characteristics. Condition-specific factors are the physiological, structural, or functional aspects of the condition, its treatment, or prevention that influence the amount, type, and nature of behaviors required for self-management. Examples of condition-specific factors are the complexity of the condition or treatment, trajectory, physiological stability, or physiological transitions. Environmental factors are physical or social aspects such as accessibility to health care, the transition from one health care provider or setting to another, transportation, neighbourhood, work, school, culture, or social capital. Individual family factors are those characteristics that affect the individual and family directly (Ryan & Sawin, 2009; 2014).

In the current research, the researchers emphasize family factors, because whether children or adults have a chronic illness, affects the family in every aspect. Thus, if a person has proper family functioning, it will also positively affect the self-management behavior of those with chronic disease or illness. The family includes parents, siblings, spouse/ partner, and friends, which has a significant potential to influence patients' chronic illness self-management (Lee et al., 2017). Moreover, the family function has an indirect effect on self-management behavior among persons with early-stage CKD (Photharos et al., 2018). Thus, the engagement of family members (defined here as any family member or friend providing unpaid support for health care) who provide care for a person with chronic disease in the management programs may lead to the improvement of effective patient self-management sustainably.

The models of programs that aim to increase effective family support for chronic illness management and self-care among adult patients should have three domains consisting of 1) Programs that guide family members in setting goals for supporting patient self-care behaviors, leading to improved implementation of family support roles, mixed success, and enhanced patient outcomes. 2) Programs that train the family in supportive communication techniques, such as prompting patients coping techniques or use of autonomy-supportive statements, cause successfully improved patient symptom management and health behaviors. 3) Programs that give families the tools and infrastructure they need to track clinical symptoms and medications (Rosland & Piette, 2010). Although proper family functioning leads to better self-management behaviors among chronic disease patients, there is a lack of family involvement during intervention delivery for early-stage CKD (Welch et al., 2015), which needs to be improved in research and practice.

2. Process dimension

The model is influenced by theories of health behavior change, including; 1) self-regulation theory, 2) social support theory, and 3) research related to SM of chronic illnesses. According to this descriptive theory, persons will be more likely to engage in the recommended health behaviors if they have been informed about and embrace health beliefs consistent with their behavior if they develop self-regulation abilities to change their health behaviors, and if they experience social facilitation that positively influences and supports them to engage in preventative health behaviors (Ryan & Sawin, 2009; 2014).

Knowledge and beliefs have an impact on behavior, specifically on self-efficacy, outcome expectancy, and goal congruence. Self-regulation is the process that is used to change health behavior and consists of activities such as goal-setting, self-monitoring, reflective thinking, decision making, planning, self-evaluation, and the management responses associated with health behavior change. Social facilitation includes the concepts of social influence, social support, and negotiated collaboration between individuals, families, and health care professionals. All three processes of self-management were developed as a program to improve the self-management behaviors and clinical outcomes of patients with stage 3 CKD.

Self-regulation is an iterative process that people engage in to achieve changes in health behaviors. Self-regulation comprises skills and abilities including 1) goal setting, 2) self-monitoring and reflective thinking, 3) decision making, 4) planning and action, 5) self-evaluation, and 6) management of responses (Ryan & Sawin, 2009). Lin et al. (2013) have developed a self-management education program based on self-regulation theory to evaluate its effectiveness on self-efficacy and self-management behavior and CKD progression among patients with early-stage of CKD. In this single group, pre-test and post-test, repeated-measures, longitudinal study, participants underwent baseline pre-testing (T0) and post-testing at 3 (T1), 6 (T2), and 12 months (T3) after the self-management program was completed. The results showed self-efficacy increased significantly at T2 ($\chi 2 = 8.97$, $p < .05$) and T3

($\chi2 = 10.71$, $p < .05$) compared with T0, but it did not improve for self-management behavior. However, eGFR rates remained stable throughout the 12 months.

Self-efficacy is a behavior-specific concept and refers to the degree of an individual's confidence and ability to successfully engage in behavior in normal and stressful situations (Ryan & Sawin, 2009). Nguyen et al. (2019) conducted a study about the effectiveness of self-management programs in people with CKD stage 3-5 focused on self-management, knowledge, self-efficacy, health-related quality of life, and blood pressure. The intervention was guided by a social cognitive theory and included a face-to-face educational session followed by telephone support. Both groups followed for 16 weeks. At week 16, compared with the control group, large effect sizes for improved self-management, knowledge, and self-efficacy were detected. In terms of health-related quality of life, the physical and mental health components significantly improved. However, there were no significant differences in either systolic or diastolic blood pressures.

Social influence is a message or dialogue in which respected persons in positions of perceived authority with expert knowledge advise and encourage individuals and families to engage in specific health behaviors. These respected persons may be health care providers, family, friends, neighbors, work colleagues, and members of community groups or printed or electronic mediums such as magazines, television, or the internet (Ryan & Sawin, 2009). Social influence, which is used most frequently, is to encourage and facilitate behavior change through advice and recommendations from medical experts and health professionals, as well as to provide reminders to improve medication or treatment adherence.

Support (emotional, instrumental, or informational) consists of emotional, instrumental, or informational support provided for a person or family with the explicit goal of assisting or facilitating their engagement in health behaviors (Ryan & Sawin, 2009). The mHealth application is an instrument supported by health care providers and widely used for caring for patients with various chronic diseases. However, there is a lack of understanding of how to use mHealth applications to maintain CKD patients' self-management continuity.

3. Outcome dimension

This theory has proximal and distal outcomes. The proximal outcome is an individual/family's actual engagement in self-management behaviors specific to a condition, risk, or transition, in addition to managing symptoms and pharmacological therapies. The cost associated with health care services is referred to as a proximal outcome. Distal outcomes are related, in part, to the achievement of proximal outcomes. These outcomes fall into three primary categories: health status, quality of life, or perceived well-being, and cost of health-both direct and indirect (Ryan & Sawin, 2009; 2014). In the current study, the self-management behaviors among persons with stage 3 CKD were measured as a proximal outcome and blood pressure and eGFR were measured as distal outcomes.

Family support enhancing CKD patient self-management

Traditionally self-management focused on individuals or families. Self-management is defined uniquely combines these parallel theories, integrating individual and family self-management. From the perspective of systems theory, a change in one component of a system, i.e., a family member leads to changes in the system (family) and all of its members. An individual’s capacity and needs affect the success or failure of the individual or the family in self-management (Ryan & Sawin, 2009). Chronic kidney diseases are illnesses that require attention throughout life and they require people to make major changes to adapt their lives to these conditions both for the people who suffer from the disease and /or their families. In Thailand, most patients will rely on their family members to take care of them when they are ill or getting old. When one person in a family is diagnosed with a chronic disease, everyone in the family must help him or her, especially with physical, emotional, instrumental, and financial support. Thus, the family considers an important social support source for the individual with chronic disease.

The majority of the management of chronic disease takes place in the everyday home setting and family can be highly influential on individual behaviors (Ory et al., 2013). The family is key to constructing a conducive environment for engagement and support. Adaptation within the family included maintaining cohesion between family members, normalization, and contextualization of the chronic condition (Whitehead et al., 2017). Besides, the patients with good family functioning can lead improved self-care confidence and autonomous motivation for medications and diet adherence (Stamp et al., 2016) which is consistent with the research of Peñarrieta et al. (2015). They study self-management and family support in chronic diseases. The result shows percentages of the relationship of the group with good self-management and good family functioning represented 84% of the sample against 16% of the group with good self-management and poor family functioning. The results of Spearman showed a significant correlation ($r_s = 0.327$, $p < .001$) between self-management and family function. The analysis of the Kendall Tau correlation coefficient showed a significant correlation between self-management and family functionality of 0.24 ($p < .001$).

Moreover, family participation in self-management support programs was also beneficial in delaying the progression of chronic disease. Thojampa (2017) studied the effects of self-management support and family participation enhancing programs on the delayed progression of diabetic nephropathy in Thai adults with type 2 diabetes. The results show that there was a significant difference in self-management activities among three points of time (week 1, week 8, and week 12), $p < .05$. Also, after attending the program (week 12), the experimental group had a higher score on self-management activities and self-efficacy than their baseline values (week 1). The mean HbA1c level, serum creatinine level, and glomerular filtration rate between the experimental and control groups had significant differences.
It showed that after attending the self-management support and family participation enhancing program (week 12), the results of the experimental group had significantly changed and showed better outcomes than those of the control group.

Support from family and other social groups has been cited as a key factor in changing diet patterns (e.g., sodium reduction) and increasing physical activity. However, research shows that caregivers report feeling unprepared, having insufficient knowledge, and receiving inadequate support from clinicians. Thus, allowing the family and other caregivers to get involved in CKD patient education may better equip them to support the patients they care for and ultimately yield improved patient outcomes (Narva et al., 2016). There is also a need for patients to involve their families in self-management interventions. Both patients and caregivers identified and appreciated support from family due to family members' helping them with very practical tasks, finding information and resources (e.g., websites), and assisting with driving, cooking, and medication management (Donald et al., 2019). Therefore, it is imperative to promote family involvement in self-management support programs to improve and maintain health outcomes for CKD patients.

The mHealth applications for CKD management

Currently, technology has become more advanced, and integrating information technology into health care is a challenge. Therefore, health service providers must develop their capabilities to use technology and create innovative health services, especially mHealth, which is gaining popularity due to its ease of use. Thus, before the development of mHealth for CKD management, it is necessary to know the definitions and applications of mHealth, the support of the Thai government to use mHealth, and mHealth applications that are used in the literature on chronic diseases, including CKD, as follows:

1. Definition of mHealth

There are various definitions of mHealth. For example, mHealth is defined as "mobile computing, medical sensors, and communication technologies for healthcare" (Istepanian et al., 2004). The Global Observatory for eHealth (2011) defines mHealth, or mobile health, as medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices. mHealth involves the use and capitalization of a mobile phone’s core utility of voice and short messaging service (SMS) as well as more complex functionalities and applications including general packet radio service (GPRS), third and fourth generation mobile telecommunications (3G and 4G systems), global positioning system (GPS), and Bluetooth technology. Alternatively, mHealth may mean the use of mobile devices to monitor or detect biological changes in the human body while device management entities, such as hospitals, clinics, or service providers, collect data and use them for healthcare and health status improvement (Park, 2016).

Although mHealth has many meanings, it has the same purpose in that people can access health information and health care services equally. Also, to promote good health and well-being. For this research, mobile health refers to mobile devices such as mobile phones or tablets with interactive functions that support the self-management of patients with CKD stage 3.

2. The application of mHealth

The use of mobile and wireless technologies has the potential to transform health care service delivery with multiple functions. From the survey of WHO (2011), fourteen categories of mobile applications were found as follows: health call centers, emergency toll-free telephone services, managing emergencies and disasters, mobile telemedicine, appointment reminders, community mobilization and health promotion, treatment compliance, mobile patient records, information access, patient monitoring, health surveys, and data collection, surveillance, health awareness-raising, and decision support systems.

Presently, there are a growing number of mobile applications for chronic illness patients. The most commonly used applications for CKD patients are CKD information and CKD self-management (57%), e-consultation (25%), CKD nutrition education (24%), and eGFR calculators (19%). The most commonly used applications among health care professionals are comprehensive clinical calculators (including eGFR; 45%), CKD medical professional information (24%), stand-alone eGFR calculators (21%), and CKD clinical decision support (21%). In the aspects of patient care, the applications are intended to support self-management for CKD patients by encouraging patients to participate actively in health care activities (83.6%), recognize and effectively respond to symptoms (50.9%), and disease-specific knowledge (48.2%) (Lee et al., 2018).

The previous study identified two general weaknesses in the existing applications: In essence, the applications fell short of accommodating advanced interactive features such as providing motivational feedback and promoting family member and caregiver participation in the applications' utilization (Siddique et al., 2019). Therefore, the development of the application should increase the interactive function between the patients and the health care providers so that effective communication can deal with the problem directly. Besides, the family should participate in application utilization to encourage patients to have proper self-management behavior continuously.

3. The support of the Thai government to use mHealth

The policy of Thailand 4.0, aims to change for a value-based economy, which is driven by innovation. As a result, the health care sector will adapt to Health 4.0 as well (MOPH, 2018). It is essential to integrate the eHealth strategy into a framework for moving in the same direction to be successful in the long term. eHealth is a healthcare practice supported by electronic processes and communication and encompasses a range of services or systems that are at the edge of medicine, healthcare, and information technology (MOPH, 2017). Also, the technology driving Health 4.0 and eHealth comprises (1) social web and networking; (2) telehealth; (3) electronic health records; (4) mobile applications; (5) eLearning; (6) internet of things; (7) cloud computing; (8) big data and health analytics; (9) robotics; and (10) artificial intelligence (MOPH, 2017; Paoin, 2017).

mHealth is considered the most popular technology used to test, but it has both benefits and barriers. The benefits of using mHealth for people to be more involved in their health care are those people who care about their health with enthusiasm. People will also receive services from hospitals that are convenient, faster, and of higher quality. The barriers to using mHealth are still lack of a policy framework, uncertainty about cost-effectiveness, people's lack of knowledge of applications, and lack of technical expertise (MOPH, 2017).

4. mHealth applications that have been used in the literature on chronic disease, including CKD.

Previous evidence showed that using mHealth applications leads to effectively improving outcomes for chronic diseases such as stroke, diabetes, psychotic disorders, lung disease, and cardiovascular disease. Nakhornriab and colleagues (2017) tested the effectiveness of a mobile application on medication adherence in patients with stroke. The mHealth application consists of 7 main functions, including personal information, medicine boxes, medication information, medication statistics, appointments, settings, and contact staff. The results showed that medication adherence was statistically significantly higher in the experimental group than in the control group ($p < .05$). The mobile application can improve patient adherence to medication by 42.85%.

Triantafyllidis et al. (2019) conducted a systematic review of mHealth in chronic disease management by showing the features and outcomes of mHealth interventions. The results showed the highest percentage of the interventions targeted patients with diabetes (63%), followed by patients with psychotic disorders (23%), lung diseases (10%), and cardiovascular disease (3%). The studies showed significant positive outcomes in glucose concentration, physical activity, lung function parameters, mental health interventions assessing N-back performance, medication adherence, and hospitalizations.

For CKD, the mHealth application was developed and tested for effectiveness to improve self-care and self-management. It has several functions, which are as follows: (1) documentation, including personal information, medical history, blood test results, weight, and current medication; (2) monitoring or tracking, including blood pressure, laboratory results, and exercise (3) provides information on CKD, diet, medicine, and exercise. (4) symptom assessment and management, (5) communication with healthcare providers, (6) reminders, and (7) Real-time personalized patient feedback and alerts to providers when predefined treatment thresholds are crossed or critical changes occur (Chen et al., 2018; Doyle et al., 2019; Ong et al., 2016). Outcomes that were significantly improved using the mobile application for CKD patients can be classified into two groups, including (1) self-management behavior; communication, exercise, and medication management, and (2) clinical outcomes: blood pressure control, six-minute walking test, total cholesterol, LDL cholesterol, waist circumference, and body fat (Chen et al., 2018; Doyle et al., 2019; Ong et al., 2016). Data from the interview showed that after using the mobile application, patients indicated feeling more confident and in control of their condition, and clinicians perceived patients to be better informed and more engaged (Ong et al., 2016).

In conclusion, the mHealth application helps to improve self-management behaviors, clinical parameters, and outcomes specific to CKD. The mHealth application is a tool with an excellent solution to collect and provide various health information on patient health, including maintenance of patient medical records and medication adherence. It also contributes to the decision of healthcare providers to provide treatment to patients.

Outcomes of a self-management program among persons with CKD

Improved health, prevention of complications, and worsening of chronic illness are critical measures of effective self-management. In several pieces of evidence, self-management programs among patients with CKD are effective in improving health outcomes in self-management behaviors and clinical outcomes, which include blood pressure and estimated glomerular filtration rate.

1. Self-management behaviors

Self-management behaviors are the behaviors that are used to manage chronic conditions as well as engage in health promotion behaviors (Ryan & Sawin, 2009). For CKD patients, self-management is applied to an individual to promote positive attempts to control and participate in health care in daily life and to embrace tasks in the medical, role, and emotional management to optimize health, prevent complications, control symptoms, organize medical resources, and minimize the intrusion of the disease into the person's preferred lifestyle (Curtin & Mapes, 2001).

For this study, self-management behaviors were measured among people with CKD stage 3 by the Self-Management Behaviors Questionnaire (SMBQ), which was modified by the researcher from the SMBQ for people with CKD at the pre-dialysis stage by Curtin et al. (2008). They comprise five attributes, self-care activities, medication adherence, communication, self-advocacy, and partnership in care (Curtin et al., 2008).

Self-care activities

Self-care activities represent the "action" dimension of self-management and are based on the premise that the best outcomes in health care result when patients are actively involved in their care. Self-care entails performing some aspects of physical care and also includes behaviors such as tracking treatment progress, monitoring symptoms and side effects and pursuing positive wellness-related behaviors in their daily lives, such as a healthy diet and regular exercise (Curtin et al., 2005; Curtin et al., 2008).

Medication adherence

WHO defines adherence as "the extent to which a person's behaviors-taking medication, following a diet, and/or executing lifestyle changes-correspond with agreed recommendations from a health care provider." (Sabaté, WHO, NMH, & CCH, 2001). In most cases, medications constitute a critical part of care, and clinicians must encourage patients to take medications as prescribed. The interdependence of the various dimensions of self-management becomes clear in the context of the adherence component. That is, if communication is effective and a working partnership is present, there should be, in turn, a greater likelihood of adherence. (Curtin et al., 2008).

The literature review found that patients with early-stage CKD had a low level of self-management behaviors, which accounted for 58.8 percent. The lowest scores of self-management behaviors are in the domains of self-advocacy, partnership in care, and communication with health providers, respectively (Curtin et al., 2008; Krajachan et al., 2018; Sritarapipat et al., 2012). The self-management program has significantly improved self-management behaviors and activities compared with usual care (Suwanwaha et al., 2016; Zimbudzi et al., 2018).

Communication

Communication is essential because disease self-management is neither safe nor feasible unless patients provide their clinicians with information about their symptoms, ask questions that promote independent problem solving, and receive relevant information and guidance from their clinicians in return (Curtin et al., 2008). Effective patient-provider communication is of particular importance for CKD patients. Patients' capacity to slow the progression of CKD may be limited by their lack of knowledge about the disease, its co-morbidities, psychosocial influences, and their ability to interact and communicate effectively with their health care provider (Lopez-Vargas et al., 2014). Ineffective communication can result in inadequate CKD knowledge, poor self-management adherence, and worse health outcomes.

Self-advocacy

Self-advocacy in self-management represents patients' willingness to act positively in their self-interest, make decisions for themselves, negotiate with health care professionals, and exercise control over their care and treatment. Examples of self-advocacy behaviors include seeking second opinions, changing doctors, offering suggestions regarding care and treatment, and using treatments other than or in addition to what is suggested by the physician (Curtin et al., 2008).

Partnership in care

A partnership is a dynamic relationship among diverse actors based on mutually agreed objectives and pursued through a shared understanding of the most rational division of labor based on the respective comparative advantages of each partner. The partnership encompasses mutual influence, with a careful balance between synergy and respective autonomy, which incorporates mutual respect, equal participation in decision-making, mutual accountability, and transparency (Brinkerhoff, 2002). Partnership in care is crucial to self-management. It is interdependent with the communication dimension of self-management because a true partnership with the healthcare team is only possible when patients can effectively communicate with them. A successful partnership includes behaviors related to patients' pursuit of improved communication with clinicians as well as independent and proactive information seeking from sources other than the clinicians, such as articles, books, or health websites (Curtin et al., 2008).

2. Blood pressure (BP)

BP is the value that reflects the amount of pressure exerted on the walls of the arteries as the blood moves through them. It is measured in millimeters of mercury (mmHg). Both the systolic and diastolic pressure are measured, and these figures are usually represented with the systolic pressure first, followed by the diastolic pressure. Normal BP values are systolic pressure between 120-129 mmHg and diastolic pressure between 80-84 mmHg (Thai Hypertension Society, 2019). If BP is high or if someone is diagnosed with hypertension, it is the most significant risk factor for the development and progression of CKD. BP typically rises with declines in kidney function, and sustained elevations in BP hasten the progression of kidney disease (Judd & Calhoun, 2015). The interaction between hypertension and CKD is complicated and increases the risk of adverse cardiovascular events, especially systolic BP elevation (Flint et al., 2019). Thus, BP monitoring is essential in the management of hypertension in CKD patients. For CKD management, the optimal blood pressure level was less than 130/80 mmHg (ACC/AHA, 2017; KDIGO, 2012). When blood pressure rises, factors such as sodium and potassium intake, physical fitness, alcohol, smoking, amphetamine, obesity, corticosteroid, non-steroidal anti-inflammatory drugs (NSAIDs), and herbs should be considered (Thai Hypertension Society, 2019; Whelton et al., 2017).

From the literature review, it was found that the prevalence of hypertension in patients with CKD stage 3 is 96.2 percent. Only 49.3 percent had undergone blood pressure control, according to studies (Schneider et al., 2018). have shown that self-management programs for people with CKD have significantly improved BP compared to usual care (Peng et al., 2019; Suwanwaha et al., 2016; Zimbudzi et al., 2018). There are a few studies that found no significant improvement in blood pressure levels (Seephom et al., 2014).

3. Estimated Glomerular Filtration Rate (eGFR)

eGFR is a value of the plasma flow from the glomerulus into Bowman's space over a specified period. It represents kidney function and determines the stage of chronic kidney disease. GFR cannot be measured directly. The urinary or plasma clearance of an ideal filtration marker, such as inulin, iothalamate, or iohexol, is the gold standard for the measurement of GFR. However, this is cumbersome and not used in clinical practice. Instead, serum levels of endogenous filtration markers, such as creatinine, have traditionally been used to estimate GFR (NKF, 2014). The main factors affecting creatinine generation are muscle mass (e.g., increased muscle mass, malnutrition/muscle wasting) and diet (e.g., restriction of dietary protein and ingestion of cooked meats). However, serum creatinine alone is not an adequate marker of kidney function. There are various methods to calculate eGFR. For this study, eGFR calculated by the CKD-EPI equation is expected to perform better than the Modification of Diet in Renal Disease (MDRD) Study equation, especially at higher GFR, with less bias, improved precision, and greater accuracy. (Levey et al., 2009). This equation comprises four parameters, including serum creatinine, age, gender, and ethnicity.

The normal value for eGFR is 90 ml/min/1.73 m^2 and it is considered the best test to measure kidney function and determine the stage of kidney disease (NKF, 2019). The level of eGFR and its magnitude of change over time is vital to the detection of kidney disease, understanding its severity, making decisions about diagnosis, prognosis, and treatment, and screening of CKD progression. One year is a proper period to measure an eGFR decline rate, and it is a good predictor of CKD prognosis (Nojima et al., 2017). However, an eGFR is a standard outcome to measure the progression of CKD. Thus, it is necessary to measure eGFR between the experimental and control groups after receiving an intervention in the current study.

A Self-and family management support combined with the mHealth application program among persons with CKD stage 3

Although there are many self-management programs for CKD patients, there are still limited programs that integrate IT tools into the program. Thus, the researcher needs to review all the literature that uses IT tools to support self-management among persons with CKD stage 3. The literature review found eight experimental studies, two systematic reviews and two meta-analyses that were associated with the self-management support integrated mHealth application program among persons with CKD stage 3 (Blakeman et al., 2014; Chen et al., 2018; Doyle et al., 2019; Havas et al., 2018; He et al., 2017; Jeddi et al., 2017; Lee et al., 2016; Lin et al., 2013; Seephom et al., 2014; Timmerman et al., 2017; Walker et al., 2013; Zimbudzi et al., 2018), which has the following three components:

1. Elements and components of self-management support interventions

All the included studies had a theoretical underpinning for their self-management elements. Key elements of these interventions are derived from self-regulation (Lin et al., 2013), social cognitive (Timmerman et al., 2017), and individual and family self-management theory (Seephom et al., 2014). Standardized education and training (e.g., dietary control and exercise, blood pressure management, blood sugar control, and emotional distress reduction), peer contact, multidisciplinary team, goal setting, problem-solving, and social support are among these elements.

2. Delivery characteristics

Most of the studies had more than one delivery element that utilized face-to-face delivery and integrated IT tools, such as VDO media (Lin et al., 2013), telephone support and consultation (Havas et al., 2018; Seephom et al., 2014), interactive websites (Blakeman et al., 2014), mobile applications (Chen et al., 2018; Doyle et al., 2019), and the nutrition data system for research software (Timmerman et al., 2017). All studies had members of the multidisciplinary team facilitating the delivery of self-management support interventions. A diversity of providers included nurses, nephrologists, dietitians, social workers, general practitioners, and lay health workers, among whom nurses are the most common health professional group.

3. Duration of intervention delivery

The study duration varied and ranged from three weeks to three years, with at least four weeks required to achieve clinically meaningful outcomes and a three-month follow-up effect (He et al., 2017; Jeddi et al., 2017; Lee et al., 2016; Zimbudzi et al., 2018). Also, the duration of the face-to-face session was between 20 minutes and 2 hours, and the telephone phone session lasted 5–60 minutes (Havas et al., 2018; Timmerman et al., 2017).

From the above literature review, there is still a gap in research, which is a lack of systematic involvement of the family in self-management programs. The family has a crucial person for chronic disease management. The majority of the management of chronic conditions takes place in the everyday home setting, and family can be highly influential on individual behavior (Ory et al., 2013). Proper family functioning can lead to improved self-care confidence and autonomous motivation for medication and diet adherence (Stamp et al., 2016). Also, families were essential in constructing an environment that was conducive to family engagement and support. Adaptation within the family included maintaining cohesion between family members, normalization, and contextualization of the chronic condition (Whitehead et al., 2017).

Also, there is a limit to the interactive IT tools that have an interactive function to transfer knowledge, communication, and trigger patients to have effective and sustainable self-management behaviors. The IT tools that are integrated into the self-management support program consists of telephones, mobile applications, telemedicine, video conferencing, computerized systems (websites), and the internet. The mobile application was often used to transfer data or knowledge and to communicate with healthcare providers or researchers (Blakeman et al., 2014) because it was easier to use and access than computerized systems (Jeddi et al., 2017). Moreover, 49.6 million Thai people (79.3%) use a mobile phone (National Statistical Office, 2015). Thus, integrating mHealth into the self-management program for Thai people is suitable.

CKD stage 3 is considered a critical problem because it has the highest number of all stages of CKD which further develop into a massive number of ESRD if they live without effective self-management programs. Therefore, the researcher conducted an RCT study that aimed to develop and examine the effectiveness of self- and family management support combined with the mHealth application program among persons with CKD stage 3. This program was created from the synthesis of evidence-based practice and is supported by the IFSMT of Ryan and Sawin (2009). Family members were invited to participate in program activities to help patients using the mHealth application and support self-management in daily life.

The program implementation consisted of four sessions over four weeks. The delivery intervention comprised: (1) identifying and measuring risks and protective factors, (2) providing knowledge and caring beliefs, (3) developing self-regulation skills and providing support from family and mHealth applications, and (4) developing abilities in self-evaluation and management of responses associated with health behavior change. The outcomes were measured three times: pre-intervention (week 1), post-intervention (week 4), and follow-up (week 16). The mHealth application was designed by researchers and created by experts who developed the mHealth application. It was used for Android operating systems and working online. This application consisted of six functionalities that were proper for self-management among patients with CKD stage 3, as follows: (1) personal information; (2) eGFR calculation; (3) laboratory result record and BP monitoring; (4) trend graph; (5) CKD management; and (6) communication with the healthcare provider. We expected that the program might show good outcomes for patients with CKD stage 3, were able to improve self-management behaviors, control BP, and prevent the decline of eGFR.

CHAPTER 3
RESEARCH METHODOLOGY

The objective of this study was to examine the effectiveness of self-and family management support combined with the mHealth application program on self-management behaviors, BP, and eGFR among persons with CKD stage 3. This chapter describes the research design, population and sample, research setting, instrumentation, protection of human subjects, data collection procedures, and data analysis.

Research Design

A randomized controlled trial (RCT), pre-post intervention, and follow-up design were applied in this study. It is considered the goal standard of experimental research. RCT design is made up of three properties, which are as follows:

1) Manipulation: The manipulation in this study was the self-and family management support combined with the mHealth application program plus usual care, which was provided for the participants in the experimental group.

2) Control: This study controlled threats and prevented confounding factors by controlling the individual characteristics, setting, and dose of intervention. The experimental group received self-and family management support combined with the mHealth application program plus usual care, whereas the control group received only usual care. Internal validity was controlled by performing a double-blind technique (blinding the participants and outcomes assessor) until allocation concealment was completed.

3) Randomization: Controlled external validity was performed by randomly assigning participants into either a control or experimental group using simple random sampling without replacement.

Thus, the RCT design was appropriate for a research design to test the effectiveness of the self-and family management support combined with the mHealth application program for persons with CKD stage 3.

Population and Sample

Target populations refer to Thai people with CKD stage 3 who had been diagnosed by a nephrologist with an eGFR of 30-59 ml/min/1.73m^2 for ≥ 3 months and followed up at the CKD clinic at Samut Prakan Hospital in 2020.

Participants refer to the target population who had met inclusion criteria.

Inclusion criteria for the participants were:

1) Aged ≥ 18 years.

2) CKD stage 3a (eGFR = 45–59 ml/min/1.73 m^2) or 3b (eGFR = 30-44 ml/min/1.73 m^2).

3) Controllable co-morbidity diseases (based on clinical parameters from the medical history). HT with BP < 180/110 mmHg without symptoms of hypertensive crisis. DM with FBS ≤ 250 mg/dl and without symptoms of diabetic crisis.

4) Free from a cognitive impairment which was screened by the Thai mental state examination (TMSE). The cutoff point for TMSE was ≥ 23 scores.

5) The participants or family members possessed the Android smart mobile phones and were able to use mobile phone applications fluently and were feasible to access the internet.

6) Full ability to read and write in Thai.

7) Living in the province of Samut Prakan.

Inclusion criteria for family members were:

1) Aged ≥ 18 years.

2) Living with the participants.

3) Take responsibility and role of the main caregiver, overseeing the patient's diet, medication, and follow-up visits.

Exclusion criteria:

1) The participants with advanced CKD or who received hemodialysis during program activities

2) The participants who had adjusted to increasing their antihypertensive drug dose during program activities.

Discontinuation criteria:

Termination criteria:

1) The participants who had a severe illness or were in a critical phase and needed to be hospitalized during program activities.

2) The participants who died during the program activities.

Withdrawal criteria:

1) The participants who requested to withdraw because they were inconvenient to participate in the program activities as scheduled.

Sample Size

The sample size was calculated by using a power calculation with the G*power program (Version 3.1.9.2; Faul, Erdfelder, Buchner & Lang, 2009). Power analysis involved the F test for ANOVA repeated measure within-between factors with a power of .80, a significance level of .05, and an effect size of .56, all of which were obtained from a previous study on self-management intervention for CKD (Zimbudzi et al., 2019). The effect size was then transformed into F tests by the converting effect size program, which was equal to .28 (Lenhard & Lenhard, 2016). These measures were repeated three times with a total minimum sample size of 32 participants and a 25% attrition rate (Suresh & Chandrashekara, 2012). Therefore, a total of 40 participants were finally recruited, and 20 of them were randomly assigned to each group.

Recruitment Procedures

Recruitment procedures were performed at the CKD clinic of Samut Prakan Hospital in the following steps:

Step 1: Potential participants were randomly assigned to the experimental and control groups by lottery for the week of CKD clinic service. The experimental group was recruited in the second week of the month and the control group was recruited in the fourth week of the month.

Step 2: The 1st research assistant (RA_1) checked the name list of CKD patients who had made appointments with the nephrologist at the CKD clinic the day before the meeting. Then, RA_1 verified medical history records to recruit the potential participants who were in line with inclusion criteria.

Step 3: Potential participants arrive at the CKD clinic. The RA_1 approached them to screen for cognitive impairment by the TMSE. If the score of TMSE $\geq$ 23 points, it meant that the participants had no cognitive impairment. Then, assessing the ability to use mobile phone applications and internet access was performed, and family members who were taking the role of the main caregiver and could participate in the program were asked to participate.

Step 4: The researcher explained the research objectives, processes, benefits, and potential risks of the study to the eligible participants. If the participants were willing to participate, they received a consent form to sign.

Randomization Procedures

Simple random sampling was used for this study. Initially, the researcher prepared 2 slips, each of which was written with the symbol "E" meaning the experimental group, and "C" meaning the control group. Then the head nurse of the CKD clinic drew out a slip from a box on which the first draw was randomly assigned in the second week of the month, and the second draw was randomly assigned in the fourth week of the month. As a result, the participants following up at the CKD clinic in the second week of the month were assigned to the experimental group, and the participants following up at the CKD clinic in the fourth week of the month were assigned to the control group.

Research Setting

Samut Prakan Hospital is a tertiary hospital with more than 500 beds where there were specialists in every department, including the nephrology department. The nephrology department is responsible for 570 patients with ESRD, including 348 undergoing peritoneal dialysis, 180 undergoing hemodialysis, and 42 receiving supportive care. The CKD clinic is an outpatient department that provided medical services for patients with CKD at stages 3 to 5 to promote prevention, slowing the deterioration of the kidneys, and treatment of kidney replacement therapy. The number of patients with CKD who followed up at the CKD clinic was 121, divided into stage 2 of 6 cases, stage 3 of 67 cases, stage 4 of 44 cases, and stage 5 of 4 cases. The clinic is open on the second and fourth Thursday of each month from 13.00 to 16.00 hrs.

A treatment protocol for CKD clinics following the service plan (kidney disease) of the MOPH (2013) consists of three parts: a multidisciplinary team, educational programs, and data management systems for CKD patients. The multidisciplinary team refers to healthcare providers who have been working at the CKD clinic comprising of nephrologists, RRT nurse practitioners, dietitians, pharmacists, and physiotherapists. The educational program consists of medication use, dietary control, and health care practices. The data management system of CKD patients was beneficial for the analysis of outcomes indicators based on the criteria of the Nephrology Society of Thailand. The activities of the CKD clinic are: (1) measuring vital signs and blood and urine testing before meeting the nephrologist; (2) meeting the nephrologist to receive treatment and medication; (3) meeting other health care providers to obtain knowledge about medication use, dietary control, self-care activity, and exercise; and (4) receiving the next follow-up appointment, which CKD stage 3 often follows-up at 4 months.

In the CKD clinic, nurses play an important role in the care of patients with CKD by educating and assisting them to be aware of their disease and make informed decisions about long-term therapy. Keep track of the eGFR, BP, and blood sugar in the diaries of CKD patients. Educating patients on the importance of BP control ensures they are aware that reducing raised BP and maintaining good glycemic control is a key factor in preventing the progression of CKD.

Research Instruments

Three types of research instruments were used to collect the data in this study. The details of each instrument were described as followed:

1. Screening Instruments

1.1 The Thai Mental State Examination (TMSE)

This form was developed by the Train the Brain Forum Committee in Thailand (1993). It is intended to be used as a screening test for dementia in the elderly. It was used to screen for cognitive impairment among the elderly with stage 3 CKD in this study. The total score for TMSE comprised 30 points, containing six basic sub-tests; orientation (6 points), registration (3 points), attention (5 points), the calculation (3 points), language (10 points), and recall (3 points). The cut-off points for screening normal people without cognitive impairment for the TMSE was ≥ 23 points.

2. Data Collection Instruments

2.1 The Demographic Data Record Form

This form was developed by the researchers to gather demographic data from the participants, consisting of three parts: general information for the participants, general information for the family, and health information for the participants. Part 1: Participants' general information included their gender, age, religion, marital status, education level, occupation, medical care entitlements, income, and use of technological devices. Part 2: Families' general information, such as the number of family members, their ages and relationships, and the family's income. Part 3: Health Information for the participants included the current stage of CKD, duration of diagnosis with CKD, weight, height, BMI, serum creatinine, serum albumin, urine protein, urine creatinine, hemoglobin, hematocrit, blood glucose, HbA1C, lipid profile, comorbidities, current medications, and history of hospital admission.

2.2 The Clinical Outcomes Record Form

This form was developed by the researchers to gather the values for BP and eGFR. The value of BP was measured by the RA_1 at the CKD clinic, Samut Prakan Hospital, using a sphygmomanometer brand Omron Hem-7120. BP was measured as a baseline after immediately completing the intervention and follow-up period. The value of eGFR was also obtained from the medical record at the baseline and follow-up period.

2.3 The Self-Management Behaviors Questionnaire (SMBQ)

It was developed by Curtin et al. (2008) based on Curtin and Mapes's self-management concept (Curtin & Mapes, 2001), and it has been used to measure self-management behaviors for patients with CKD at the pre-dialysis stage.
The SMBQ consisted of five dimensions of self-management behaviors with 37 items, including self-care activities (11 items), medication adherence (1 item), communication (8 items), self-advocacy (10 items), and partnership in care (7 items). This instrument had five-point Likert-type scales ranging from 1 (never) to 5 (all the time) as a scoring system. Scores ranged from 37 to 185, obtained by summarizing the response values across all items. The total score indicates the level of self-management behaviors, with 37–85.9 being considered low, 86–135.9 was considered moderate, and 136–185 was considered high. The scale's internal consistency reliability showed a good value, with coefficients (alpha) for the subscales ranging from 0.70 to 0.84 (Curtin et al., 2008).

This instrument was translated into Thai by Sritarapipat et al. (2012) using the back-translation technique and was used in research on the causal model of elderly Thais' self-management behaviors of pre-dialysis CKD. Cronbach's alpha for the SMBQ was 0.95. Moreover, the instrument was used in research on the effectiveness of self-management enhancement programs for Thais with CKD at pre-dialysis stages by Suwanwaha et al. (2016). Cronbach's alpha for the Thai version SMBQ was 0.92. For this research, the instrument was modified regarding the time to assess self-management behaviors from six months to one month, which was appropriately considered for the program activities.

3. Intervention Instruments

3.1 The protocol of self-and family management supports combined with the mHealth application program for persons with CKD stage 3

This protocol was adopted from two constructs of the individual and family self-management theory of Ryan & Sawin (2009; 2014), related to context and process. Furthermore, the activities of self-regulation (Lin et al., 2013) and self-efficacy (Nguyen et al., 2019) were also applied to the protocol. This protocol consisted of four sessions over four weeks with the delivery interventions by the researchers and the 2nd research assistant (RA_2) (Table 3).

3.2 Worksheets

Seven worksheets were used in conducting research activities as follows: 1) Identifies risk and protective factors, 2) Assess the self-management knowledge, 3) Assess the self-efficacy, 4) Self-management planning, 5) Assess the self-management behavior modification, 6) Assess the benefits and problems of participating in the program, and 7) Assess the satisfaction with the mHealth application.

3.3 CKD Handbook

There were two handbooks provided for the participants. The title of a CKD handbook was "Tips and tricks to preventing renal failure." The content was appropriate for general people and patients with CKD. It was produced by the Nephrology Society of Thailand, the National Health Security Office, and the Food and Drug Administration (2015). This handbook included necessary information and knowledge regarding self-management such as kidney function, the effect of CKD, signs and symptoms, hypertension and diabetes mellitus management, diet and lifestyle changes, and tips and tricks for preventing renal failure. CKD’s nutrition handbook title was "How to eat when kidneys start to deteriorate." It contained the main principles of diet planning for people with chronic kidney diseases, food menus, and food exchange categories.

3.4 VDO's media

The VDO media regarding CKD knowledge could be downloaded from the YouTube of the Rama Channel. Two parts and six episodes of VDO contained a variety of talks with the expertise of a nephrologist, lasting about 10 minutes per episode. The content featured in the VDO included causes of CKD, risk factors, signs and symptoms, complications, medical treatment, nutritional management, and medication use for CKD stages 1-3.

3.5 PowerPoint Handout

The researcher created ten PowerPoint handouts on the following topics: 1) Kidney anatomy and functions, 2) Causes of CKD, 3) Symptoms of CKD, 4) Stage and prognosis of CKD, 5) Lifestyle changes to protect the kidneys, 6) Diet for CKD patients, 7) BP and blood sugar control, 8) Medicines, supplements, herbs, and nephrotoxic substances, 9) Therapeutic therapy for renal replacement, and 10) the mHealth applications for CKD management.

3.6 Home Blood Pressure Monitor (HBPM)

HBPM was an effective self-monitoring tool for hypertensive patients. It helped to improve the diagnosis of white-coat hypertension and the prediction of cardiovascular risk. Furthermore, HBPM was less expensive and simpler to implement (George & MacDonald, 2015). For this research, BP was measured using the Omron brand Hem-7120 and verified for accuracy equal to ± 5 mmHg by the medical equipment center at Samut Prakan Hospital. The researchers gave 20 HBPM devices to the participants in the experimental group. They were asked to monitor BP at home by following the standard procedures and taking two measurements on each occasion after 5 minutes of sitting rest and 1 minute between measurements. Then recorded the average BP in the mHealth application 1-2 times a week (Thai Hypertension Society, 2019; Whelton et al., 2017; Unger et al., 2020).

3.7 The mHealth Application

The mHealth application was called "Kidney Healthy," and was designed by researchers and created by experts who developed the mHealth application. It was used for Android operating systems and working online. This application consisted of six functionalities that were proper for supporting self-management among persons with CKD stage 3, as follows:

1) Personal information: This function was used to record code names and personal data, both general and health-related data.

2) eGFR Calculator: The calculator was used to calculate eGFR by using the CKD-EPI creatinine 2009 equation (Levey et al., 2009). This equation included four variables comprised of serum creatinine, age, gender, and ethnicity.

3) BP monitoring and laboratory result recording: This function was used to record laboratory results such as eGFR, urine protein, serum albumin, serum creatinine, and HbA1C, as well as to monitor BP at home at least 1-2 times per week. The evaluation results were shown at the bottom of the screen, representing simple alerts and feedback when predefined treatment thresholds were crossed or critical changes occurred.

4) Trend graph: This function showed trend graphs of laboratory results such as eGFR, urine albumin, BP, and HbA1c that represented the progression of CKD and co-morbidity.

5) CKD management: This function adds CKD handbooks and VDO's media to provide knowledge of the disease, medication, nutrition, and exercise for patients with stage 3 CKD, as well as management when the patients had problems controlling their BP and the progression of their CKD.

6) Communication: This function was an interactive function that provided a channel of communication or consultation between patients and healthcare providers when serious problems occurred.

Tables 3 Summary of four sessions of the research protocol

Week/Time	Session	Activity/Training	Instrument	Method
Week 1 (30 minutes)	Session 1: Identifying and measuring risks and protective factors	- Explore and identify risks and protective factors	- Worksheet 1	- Individual assessment
Week 2 (60 minutes)	Session 2: Providing CKD knowledge and caring beliefs	- Provide knowledge - Self-efficacy enhancement	- Power point - Worksheet 2 and 3	- Group-based education and discussion
Week 2 (120 minutes)	Session 3: Developing of self-regulation skills and providing support from family and mHealth application	- Self-regulation skills training (i.e., goal setting, self-monitoring and reflective thinking, decision making, planning and action) - mHealth application skills training	- Worksheet 4 - HBPM - mHealth application	- Group-based discussion - Demonstration - Return-demonstration
Week 4 (30 minutes)	Session 4: Developing abilities in self-evaluation and management of responses associated with health behaviors change	- Self-regulation skill training (i.e., self-evaluation, reflective thinking)	- Worksheet 5, 6, and 7	- Individual assessment

Psychometric Properties of Research Instruments

Content Validity

The content validity of SMBQ, the research protocol, and the mHealth application were tested by five experts, including one nephrologist, three specialist professors in internal medicine nursing and care for CKD patients, and one nurse practitioner in renal replacement therapy and CKD care. The experts were asked to assess the content validity of the instruments based on consideration of content, language suitability, and arrangement. The instruments were then revised according to the recommendations of the experts. The result of the Content Validity Index (CVI) of the SMBQ was .95.

Reliability

The reliability of the SMBQ was tried out on 15 participants who had similar characteristics to the participants in the study at the CKD clinic of Samut Prakan Hospital. The internal consistency reliability of the SMBQ was good with the Cronbach's alpha value of.84. The actual reliability for the SMBQ among the three times measured were .86, .87, and .89, respectively.

Inter-rater reliability

During the training phase for the research assistant to collect data, the researchers and the RA_1 independently marked the answers from five participants in all of the questionnaires at the same time. Then, the inter-rater reliability was tested using the percentage of the agreement to examine the confirmatory understanding of each item between the researchers and the RA_1. The value of inter-rater reliability was .92.

Protection of Human Subjects

Protection of the rights of participants in this study complied with the Declaration of Helsinki (World Medical Association, 2013). This research was registered as a randomized trial by the Thai Clinical Trial Registry (project code TCTR20200928004). After approval from the research ethics committee of Burapha University (project code G-HS 064/2563) and the human research review boards of Samut Prakan Hospital (project code Oq05463), the data collection started. The researchers provided information about the research study either verbally or via an information sheet to potential participants individually. The information included research objectives, benefits, potential risks, types of questionnaires, time involved, and tasks to be completed. The participant's right to withdraw from the study at any time was also explained. After that, informed consent was signed by the participants before providing the questionnaires. The confidentiality of participants was ensured by using a code number to ensure their privacy.

Pilot Study

The pilot study was conducted to test the feasibility of the self-and family management support combined with the mHealth application program. The inclusion criteria recruited stage 3 CKD patients and family members to install the mHealth app called "Kidney Healthy" for CKD management for four months. The outcome was initially evaluated following the completion of the program in weeks 4 and 16.

Five families were interested in participating in this research. Most of the participants were female (60%). The age level of participants was adult, with an average age of 57.46 years (SD = 18.58), and the CKD was at stage 3b (60%). Most caregivers were healthy, with an average age of 43.32 (SD = 16.31). Self-management behaviors were much higher in week 4 (M_{diff} = -13.80, $p < .05$), and slightly increase at week 16 without any intervention. The results of the pilot study showed that this intervention possibly increased self-management behaviors even in the short term. Therefore, the researcher must find ways to enable participants and family members to maintain self-management behaviors by boosting, encouraging, and empowering them via mHealth applications. After the intervention period, systolic blood pressure (SBP) drops significantly ($F_{3,12}$ = 6.69, $p < .05$). The number of times BP was recorded in the application, 2.04 times per week (r = -.90, $p < .05$), was one factor correlated with the decrease in SBP. Whereas, there was no significant decrease in diastolic blood pressure (DBP).

After participating in the pilot study program, the participants and family members reported the behavioral changes. The participation in dietary control, exercise, stress relief, kidney function monitoring, BP monitoring, and taking more strict medication. The adoption of mHealth applications has made it easier for people to take care of themselves. The ten items of overall satisfaction with mHealth application usage were 4.6 out of 5 scores (high level). The highest score was for the topic "Content presentation is clearly formatted, not confusing, and easy to understand." The lowest score was for the topic "Application menu use language that is easy to understand and implement." After that, the mobile health application was improved based on user evaluations and recommendations.

The problem of participation in the program among the participants and family members was the number of sessions in the program were too many times, making it impossible to participate every time. Therefore, the researchers merged two and three sessions together for the convenience of the participants and family members. It was also beneficial to the participants and family members to be able to try the mHealth application longer and more proficiently. Therefore, this study provided preliminary feasibility for the mHealth and family involvement program to improve self-management behaviors and reduce BP.

Data Collection Procedures

The procedures for data collection consisted of three phases as followed:

1. Research Assistant Training and Preparation Phase

Two research assistants (RA) in this study were practitioner nurses. They were trained to collect data and to help researchers implement the program. Firstly, the researchers recruited two RA who were nurse practitioners and had at least five years of work experience caring for CKD patients and were currently working at the CKD clinic at Samut Prakan Hospital. The researcher then provided information on the study, including objectives, inclusion criteria for recruiting participants, consent forms, and the role of RA_1. The RA_1 was formally trained to recruit the participants and collect the data. If there were any questions or concerns raised during the training sessions, they were addressed and declared. A pilot study was conducted after the RA_1 had fully understood the study details and procedures. Then five participants who had the same characteristics as the potential participants were interviewed by the researcher and RA_1 to test the inter-rater reliability of the research instrument.

Thereafter, the training of RA_2 was formally provided to an intervenor that helped researchers conduct the program at sessions 2 and 3. The researcher explained the details of the program objectives and activities for each session. In the pilot study, the researcher demonstrated how to conduct each session and the solutions to solve the problem when it occurred. After having a full understanding of the study details and procedures, RA_2 was then returned to demonstrate how to conduct each session with five participants who had the same characteristics as the potential participants and finally provided constructive feedback at the end of each program session.

2. Implementation Phase

2.1 The permission letters for data collection from Burapha University were sent to the directors of Samut Prakan Hospital.

2.2 After obtaining IRB approval from Samut Prakan Hospital, the researchers contacted the head nurse, head nurse of the ODP, and staff of the CKD clinic at Samut Prakan Hospital to describe the study plans and provide essential information about the research study and data collection procedures to obtain their permission to assess the setting for conducting the research study.

2.3 After being authorized to collect the data, the head nurse of the CKD clinic randomly recruited the participants into the experimental and control groups by drawing a weekly lottery. To reduce the potential contamination between the two groups, the experimental group was recruited in the second week of the month. The control group was recruited in the fourth week of the month.

2.4 After permission was granted from the CKD clinic at Samut Prakan Hospital. When the potential participants came to the CKD clinic, the researcher introduced themselves and informed the potential participants about the study's objectives, the process of data collection, the human rights protection issues, and ethical considerations, as well as the time requirement for participating in the study. Afterward, they were given time to review and decide before signing consent form. If the potential participants wanted to participate, they received a consent form to sign. On the other hand, the potential participants who did not wish to participate were then selected as the next number on the recruitment list.

2.5 After signing the document of consent to take part in the research project, the RA_1 started to collect the participants' demographic data. The participants were asked to fill in the parts of general information about the participant and family, and the RA_1 filled in the data gained from the medical record in the parts of health information. Also, measuring BP, obtaining the value of eGFR from the medical record, and filling in the data on the clinical outcomes record form was conducted.

2.6 Then, RA_1 gave the self-management behavior questionnaires with 37 items to the participants, which took approximately 45 minutes to complete. Before answering the self-management behavior questionnaire, RA_1 provided additional information to the participants that, during the survey, if they were uncomfortable answering a specific question, they could refrain from answering that question.

2.7 The RA_1 verified the completeness of the data in all questionnaires immediately after finishing the interview/data collection and thanked the participants for their participation. Then the researcher made an appointment for the next implementation phase.

2.8 During program implementation, twenty participants in the control group received usual care from the CKD clinic at Samut Prakan Hospital. The usual care of the CKD clinic provided essential knowledge to manage CKD from a multidisciplinary team including a nephrologist, RRT nurse practitioner, a dietitian, a pharmacist, and a physiotherapist. Furthermore, the CKD nutrition booklet and a notebook to record information about risk factors for CKD were provided. The progression of treatment was recorded via a graph showing eGFR levels and a record of treatment.

2.9 In the experimental group, twenty participants received self-and family management support combined with the mHealth application program plus usual care from the CKD clinic at Samut Prakan Hospital. The researchers and RA_2 delivered the program following the protocol. The program consisted of four sessions over four weeks, as followed:

Session 1 (week 1): Identifying and measuring risk and protective factors, which aimed to identify condition-specific factors, physical/social environment, and individual/family factors that could be a possible risk or protective factor. The researchers conducted the program by themselves individually in the first week, spending approximately 30 minutes in a private room at the CKD clinic, Samut Prakan Hospital.

Session 2 (week 2): Providing knowledge and caring beliefs for the participants and family members. This session aimed to provide and improve their knowledge to increase understanding and self-confidence to manage CKD. The researchers and RA_2 conducted the program on a small group of 10-12 persons/group (participants of 5-6 persons and family members of 5-6 persons) in the second week, spending approximately 60 minutes in a private room at the CKD clinic, Samut Prakan Hospital. The essential topics for CKD knowledge consisted of causes, signs and symptoms, complications, treatment, and self-management guidelines to delay renal degeneration (The Nephrology Society of Thailand, 2015).

The self-efficacy activity of Nguyen et al. (2019) was used in the program to increase self-confidence to manage CKD. The self-confident encouraging program included (1) providing feedback from patients by identifying problems of concern for CKD knowledge and self-management, identifying priority goals related to self-management behavior, and sharing experiences of managing their health such as choosing healthy food, exercising, and taking medication; (2) assisting the participants in developing achievable goals and identifying strategies to manage their current condition related to kidney disease; and (3) positive reinforcement in responding to participants' concerns.

Session 3 (week 2): This session consisted of two activities, including (1) developing self-regulation skills and (2) providing support from family and the mHealth application. The researchers, RA_2, and IT experts conducted the program in a workshop for 10–12 persons/group (participants 5–6 persons and family members 5-6 persons) in the third week, spending approximately 120 minutes in a private room at the CKD clinic, Samut Prakan Hospital.

Activity 1: Developing self-regulation skills aimed at encouraging collaboration between participants and healthcare providers in order to learn and establish self-regulation skills. The self-regulation activities of Lin et al. (2013) were selected to apply in the program, including (1) proposing personal target problems to be addressed in disease management; (2) observing and judging causes producing problems; (3) setting up workable personal goals; (4) developing specific strategies to achieve goals; (5) self-evaluating the effectiveness of strategies to achieve the goal; and (6) recognizing one's outcome performance.

Activity 2: Providing support from family and mHealth application. This session aimed to provide a better understanding of the importance of CKD self-management and instruction on how to use the mHealth application to support self-management. This session comprised three activities, including (1) demonstrating how to install the mHealth application named "Kidney Healthy" and filling in the username and password for registration and also how to use six functions of the mHealth application; (2) allowing the participants and their family members to try it out by recording their laboratory results and BP in the application, communication with healthcare provider via line official; (3) return-demonstration of how to use the mHealth application to the researchers, RA_2, and IT experts, after they had been using the mHealth at home.

Session 4 (week 4): Developing abilities in self-evaluation and management of responses associated with health behavior change. This session aimed to encourage the participants to evaluate their change in self-management behaviors and clinical outcomes. The researcher conducted the program by themselves individually in the fourth week, spending approximately 30 minutes in a private room at the CKD clinic, Samut Prakan Hospital. This session encouraged the participants to evaluate their change in each domain of self-management behavior and change in laboratory results, especially BP level and eGFR from the mHealth application. They also explained how the management of physical, emotional, and cognitive responses associated with self-management behavior changed. Finally, inquiring about benefits, problems, and obstacles of involving a family to participate in the program activities and using the mHealth application to support self-management were performed as well as assessing the satisfaction of mHealth application.

3. Evaluation Phase

3.1 After all four sessions of the program completed in week 4, the researchers thanked the participants and their family members for participating in the program. Then, the RA_1 assessed outcomes of self-management behaviors and BP immediately after completing the program (week 4). Meanwhile, the outcomes of the participants in the control group were assessed at the same time.

3.2 For the follow-up period, the RA_1 made an appointment with the participants in the experimental group in the next three months after completing the program (week 16) for assessing the sustainability of self-management behaviors, BP, and eGFR at the CKD clinic, Samut Prakan Hospital. Simultaneously, the control group received the appointment to complete a questionnaire at the CKD clinic.

3.3 After the follow-up period was completed, services provided for the participants in the control group were the CKD handbook, HBPM brand Omron Hem-7120, and accessibility to use the mHealth application.

To comply with the guidelines for preventing the spread of new coronavirus disease 2019 (COVID-19) at every phase of the research project. The researcher adjusted the data collection pattern according to the social distancing guidelines and maintained cleanliness according to the policy of Samut Prakan Hospital. Before entering the CKD clinic, the participants', RAs', and researchers' body temperature must be checked. Furthermore, a facemask was asked to be used at all times of the program activity and data collection, using alcohol, hand sanitizers, and disinfectants to clean the device, including the location used for data collection.

Data Analyses

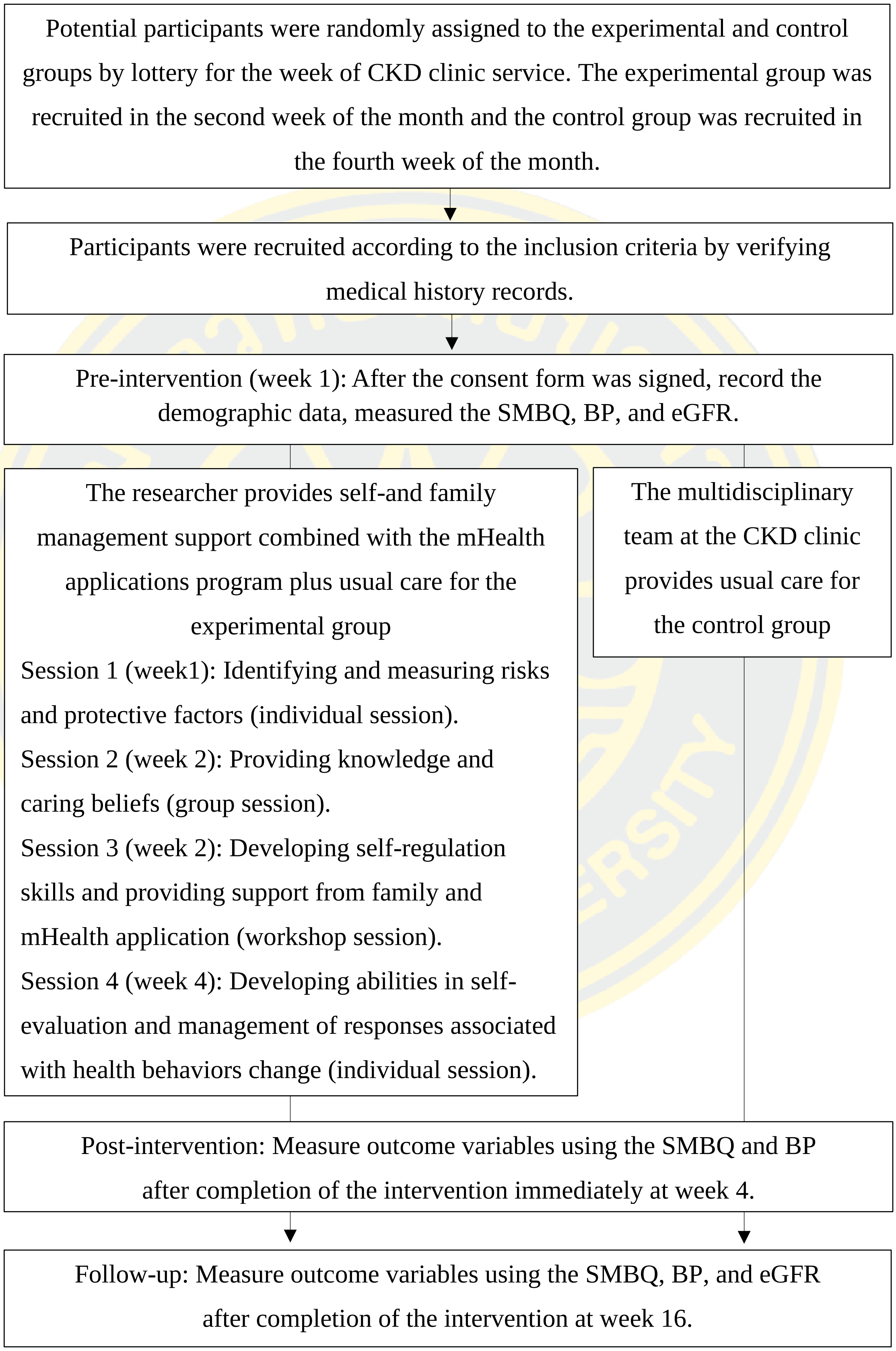
The statistical analysis of the data was performed using a statistical software program. The level of significance was set at .05 as followed:

1. Descriptive statistics, including frequency, percentage, mean, and standard deviation, were used to analyze and describe the demographic characteristics of the participants.

2. Chi-square test, Fisher's exact test, and independent t-test was used to evaluate the differences in the demographic characteristics between the experimental and control groups.

3. Independent t-test was used to examine the changes in mean scores of eGFR between the experimental and control groups at pre-intervention (week 1) and follow-up (week 16).

4. Two-Way Repeated Measures ANOVA (one within-one between) was employed to test for changes in mean scores of self-management behaviors, SBP, and DBP comparing the experimental and control groups at pre-intervention (week 1), post-intervention (week 4), and follow-up (week 16).



Figures 4 Flow diagram of study processes and interventions

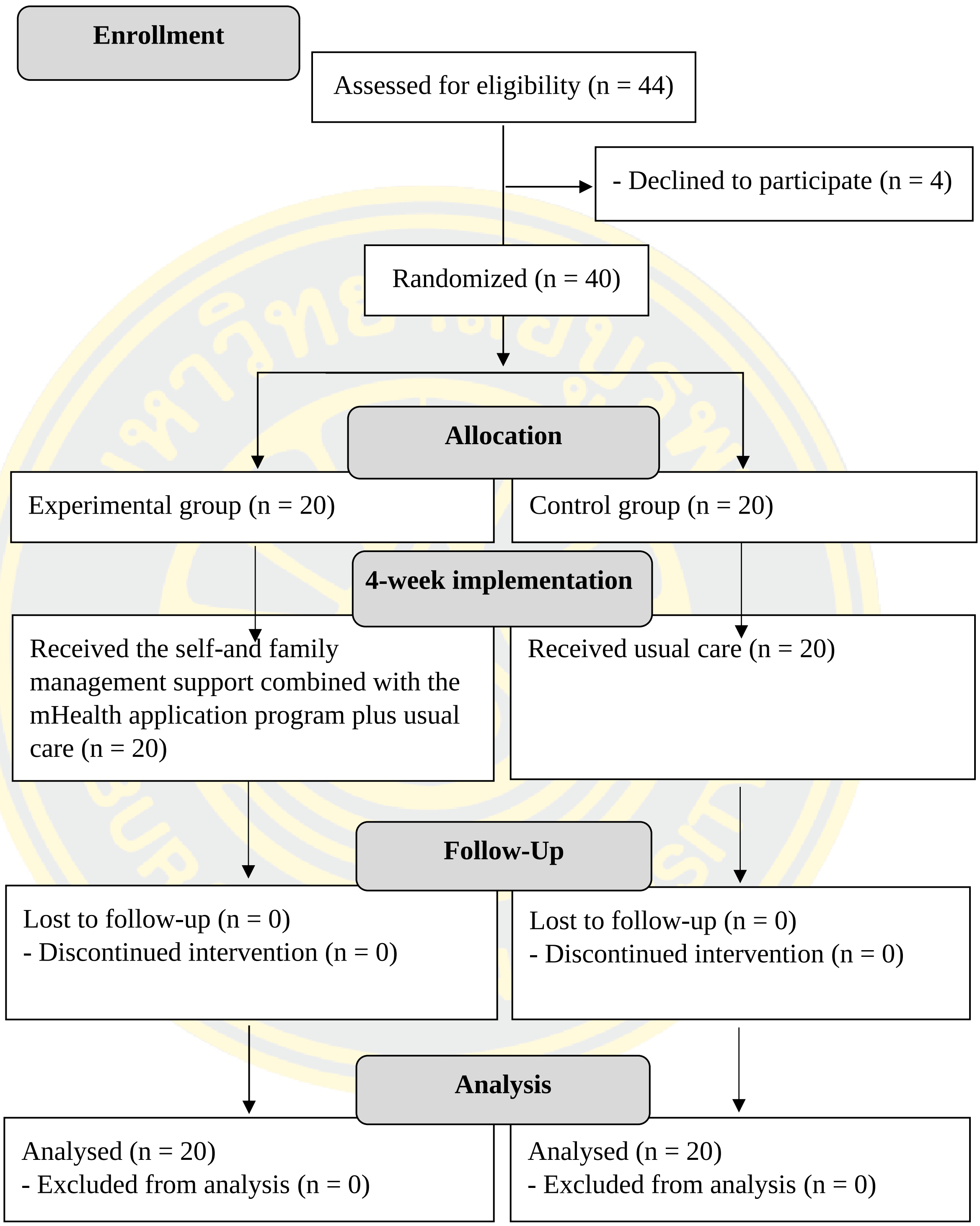
CHAPTER 4
RESULTS

This chapter presented the results of this study in seven-part parts. The first part revealed the CONSORT Flow Diagram. The second part described the demographic characteristics of the participants and their families. The third part reported the evaluation of statistical assumptions for the dependent variables. The fourth part reported descriptive statistics of the outcome variables. The fifth part reported the comparisons of pre-intervention scores of outcome variables. The sixth part showed the study's hypotheses testing. The final part described the conclusion of the findings.

CONSORT Flow Diagram

The number of patients with CKD who followed up at the CKD clinic was 121 cases. Sixty-seven participants were assessed for eligibility criteria, and 44 were invited to participate in the research project. However, 4 of them declined to participate in the research project, eventually leaving only 40 participants who were willing to participate in the research project. Forty participants were randomly assigned to the experimental group (20 cases) and the control group (20 cases).

The experimental group received the program. In the period of post-intervention and follow-up, there was no drop-out rate among the participants in the experimental group. Therefore, the analysis of the results was performed for both experimental group (n = 20) and a control group (n = 20), as shown in Figure 5.



Figures 5 CONSORT flow diagram of the progress through the phases of a parallel randomized trial of two groups (Schulz et al., 2010)

The demographic characteristics of the participants

The demographic data of the participants consisted of three parts: general information, health information, and family information. Part 1 described the participants' general information, such as gender, age, religion, marital status, education level, occupation, payment scheme, income, smoking, alcohol consumption, use of technological devices, and use of mobile phone applications. Part 2 described the health information of the participants, including the current stage of CKD, duration of diagnosis with CKD, body mass index (BMI), serum creatinine, urine protein, urine creatinine, hemoglobin, hematocrit, fasting blood sugar, hemoglobin A1C (HbA1C), lipid profile, comorbidities, current antihypertensive medications, and history of hospital admission. Part 3 described the family's general information, including the number of family members, the relative and age of the main caregiver, the family income, and the health of the main caregiver. These demographic characteristics were analyzed using descriptive statistics including frequency, percentage, mean, and standard deviations. The differences in demographic characteristics between the experimental and control groups were analyzed by the chi-square test, Fisher's exact test, and independent t-test statistics as shown in tables 4 to 6.

In the experimental group, 75% of the participants were males. The majority age group was elderly (70%) and the mean age was 63.70 years (SD = 11.63, range 43-87). All participants were Buddhist (100%) and 90% were married. The level of education was lower than a bachelor's degree (80%) among employees, merchants, and business owners (55%). They had incomes < 5,000 baht per month (50%) and used the universal coverage (100%) for their healthcare scheme to access health care. The majority of them (65%) did not smoke and drank alcohol (55%). Regarding technological devices, they mostly used mobile telephones 5-7 days/week (95%) and used mobile applications 5-7 days/week (60%).

As shown in Table 4, most of the individual characteristics in the control group were like those in the experimental group. Most of them were males (65%). The major age group was the elderly (75%), with a mean age of 66.25 years (SD = 10, range 47-85). The religion was Buddhism (95%), and they were mostly married (70%). The level of education was lower than a bachelor's degree (95%) for employees, merchants, and business owners (55%). They had incomes < 5,000 baht per month (50%) and used the universal coverage (100%) for their healthcare scheme to access health care (80%). Most of the participants had never smoked (65%) or drank alcohol (60%). They mostly used a mobile telephone 5-7 days/week (70%) and a mobile application 5-7 days/week (70%).

The information between the experimental and control groups was compared by using an independent t-test for continuous data, a chi-square, and Fisher's exact tests for categorical data to determine their differences. The statistics showed no significant differences in the participants' general information between the two groups (*p* >.05). The details are shown in Table 4.

Tables 4 Description of the general information of participants

Characteristics	**Experimental group (n = 20)**		**Control group (n = 20)**		**Test**	***p*-value**
	n	**%**	**n**	**%**		
Gender					$\chi2$ = .476	.490
Male	15	75	13	65		
Female	5	25	7	35		
Age (years)					$\chi2$ = .125	.723
43-59	6	30	5	25		
≥ 60	14	70	15	75		
Average	63.70 ± 11.63		66.25 ± 10.00		*t* = -.744	.462
Range	43-87		47-85			
Religion					Fisher's	1.00
Buddhism	20	100	19	95	exact	
Christianity	0	0	1	5	= 1.026	

Tables 4 (Continued)

Characteristics	**Experimental group (n = 20)**		**Control group (n = 20)**		**Test**	***p*-value**
	n	**%**	**n**	**%**		
Marital status					Fisher's	.235
Married	18	90	14	70	exact	
Single, Separated, and Widow	2	10	6	30	= 2.500	
Education					Fisher's	.342
< Bachelor's Degree	16	80	19	95	exact	
≥ Bachelor's Degree	4	20	1	5	= 2.057	
Occupation					$\chi2 < .001$	1.000
Unemployed	7	35	7	35		
Employee, Merchant, Business owner	11	55	11	55		
State enterprise, Government officer, Retired civil servant	2	10	2	10		
Income/Month (Baht)					$\chi2 < .001$	1.000
< 5,000	10	50	10	50		
5,000-50,000	8	40	8	40		
> 50,000	2	10	2	10		
Payment scheme					Fisher's	1.000
Universal coverage	17	85	16	80	exact	
Social insurance, State enterprise, Government welfare	3	15	4	20	= .173	

Tables 4 (Continued)

Characteristics	**Experimental group (n = 20)**		**Control group (n = 20)**		**Test**	***p*-value**
	n	**%**	**n**	**%**		
Smoking					χ2 < .001	1.000
No	13	65	13	65		
Yes, ever	7	35	7	35		
Alcohol drinking					χ2 = .102	.749
No	11	55	12	60		
Yes, ever	9	45	8	40		
Use of technology device						
Mobile phone					Fisher's	.091
1-4 days/week	1	5	6	30	exact	
5-7 days/week	19	95	14	70	= 4.329	
Use of mobile phone application					χ2 = 3.636	.057
1-4 days/week	8	40	14	70		
5-7 days/week	12	60	6	30		
Tablet / iPad					Fisher's	.342
Never	19	90	16	80	exact	
Ever	1	5	4	20	= 2.057	
Computer					Fisher's	1.000
Never	16	80	17	85	exact	
Ever	4	20	3	15	= .173	

Sixty percent of the participants in the experimental group had CKD stage 3b, with a mean duration of CKD diagnosis of 5.75 years (*SD* = 4.98, range 1–19). Hypertension was the most common comorbidity disease (40%). There has been no history of hospitalization due to CKD in the previous year (75%). Most of them had overweight (50%) with BMI = 25-29.9 kg/m^2, average 25.00 kg/m^2 (*SD* = 2.89, range 18.36–30.51). The high HbA1C of 9.10% (*SD* = 3.84, range 5–12.60). The normal values of laboratory tests were reported, including serum albumin, hematocrit, hemoglobin, fasting blood sugar, and lipid profile. Abnormal laboratory results showed an average serum creatinine of 1.64 mg/dl (*SD* = 0.32, range 1.04–2.21), urine protein of 49.26 mg/mmol (*SD* = 141.68, range 4-631).

In the control group, 52.4% were diagnosed with CKD stage 3b. The mean duration of CKD diagnosis was 5.46 years (*SD* = 5.40, range 0.25-20). Hypertension with dyslipidemia was the most common comorbid disease (30%). No history of hospitalization related to CKD in the past 1 year (80%). Most of them had normal weight (55%) with BMI = 18.5-24.9 kg/m^2, average 26.94 kg/m^2 (*SD* = 4.54, range 21.54-36.79). The normal values of laboratory tests were reported, including serum albumin, hematocrit, hemoglobin, fasting blood sugar, HbA1c, cholesterol, and high-density lipoprotein cholesterol (HDL-C). Abnormal laboratory results showed the average serum creatinine was 1.47 mg/dl (*SD* = 0.33, range 0.98–2.11), triglyceride was 158.46 mg/dl (*SD* = 66.33, range 87–326), and low-density lipoprotein cholesterol (LDL-C) was 101.94 mg/dl (*SD* = 48.21, range 35-230).

The health information of participants between experimental and control groups in the pre-intervention period was compared using an independent t-test, a chi-squared, and Fisher's exact tests. The result showed no difference, except for triglyceride level where the control group was significantly higher than the experimental group (t = - 2.921, p < .05) (Table 5).

Tables 5 Descriptions of health information of the participants

Characteristics	Experimental group (n = 20)		Control group (n = 20)		Test	*p*-value
	n	%	n	%		
The current stage of CKD					$\chi 2$ = .102	.749
Stage 3a	8	40	9	45		
Stage 3b	12	60	11	55		

Tables 5 (Continued)

Characteristics	**Experimental group (n = 20)**		**Control group (n = 20)**		**Test**	***p*-value**
	n	**%**	**n**	**%**		
HT					$\chi 2$ = 1.026	.311
Yes	8	40	5	25		
No	12	60	15	75		
HT and DM					Fisher's	1.000
Yes	2	10	3	15	exact	
No	18	90	17	85	= .229	
HT and DLP					$\chi 2$ = .125	.723
Yes	5	25	6	30		
No	15	75	14	70		
HT and DM and DLP					Fisher's	1.000
Yes	1	5	2	10	exact	
No	19	95	18	90	= .360	
HT and DM and DLP and CVD					Fisher's	.487
Yes	0	0	2	10	exact	
No	0	0	18	90	= 2.105	
History of hospital admission related CKD 1 year ago					Fisher's	1.000
No	15	75	16	80	exact	
≥ 1 time	5	25	4	20	= .143	
BMI (kg/m^2)					$\chi 2$ = 4.940	.176
< 18.5	1	5	0	0		
18.5-24.9	8	40	11	55		
25-29.9	10	50	5	25		
≥ 30	1	5	4	20		
Average	25.00 ± 2.89		26.94 ± 4.54		*t* = -1.606	.116
Range	18.36-30.51		21.54- 36.79			

Tables 5 (Continued)

Characteristics	**Experimental group (n = 20)**	**Control group (n = 20)**	**Test**	***p*-value**
	M (SD)	***M (SD)***		
Duration of diagnosis CKD (years)			*t* = .175	.862
Average	5.75 ± 4.98	5.46 ± 5.40		
Range	1-19	0.25-20		
Number of antihypertensive drugs			*t* = - 1.085	.285
Average	1.50 ± .76	1.85 ± 1.23		
Range	1-3	0-4		
Serum creatinine (mg/dl)			*t* = 1.570	.125
Average	1.64 ± 0.32	1.47 ± 0.33		
Range	1.04-2.21	0.98-2.11		
Serum albumin (mg/dl)			*t* = -1.102	.279
Average	3.71 ± 0.92	3.97 ± 0.40		
Range	2-4.60	2.70-4.40		
Hematocrit (%)			*t* = -.407	.686
Average	40.09 ± 3.25	40.65 ± 5.28		
Range	34.50–48.10	32.70-49.80		
Hemoglobin (g/dl)				
Average	12.65 ± 1.12	13.10 ± 1.75	*t* = -.959	.344
Range	10.50-14.80	10.30-16.00		
Fasting Blood Sugar (mg/dl)			*t* = -.704	.488
Average	111.30 ± 48.41	123.31 ± 38.19		
Range	77-243	84-218		
HbA1C (%)			*t* = 1.793	.100
Average	9.10 ± 3.84	6.93 ± 0.93		
Range	5-12.60	5.90-8.30		

Tables 5 (Continued)

Characteristics	**Experimental group (n = 20)**	**Control group (n = 20)**	**Test**	***p*-value**
	M (SD)	***M (SD)***		
Total cholesterol (mg/dl)			*t* = .477	.641
Average	169.71 ± 43.38	159.44 ± 42.25		
Range	138-258	71-206		
Triglycerides (mg/dl)			*t* = -2.921	.007*
Average	97.23 ± 36.23	158.46 ± 66.33		
Range	49-161	87-326		
LDL-C (mg/dl)			*t* = .292	.772
Average	97.60 ± 33.32	101.94 ± 48.21		
Range	59-194	35-230		
HDL-C (mg/dl)			*t* = .959	.366
Average	53.00 ± 21.21	41.25 ± 14.51		
Range	38-68	14-59		

All families in the experimental group had more than two members, with an average of four. The main caregivers of the participants were their husbands or wives (55%), and they were healthy (70%). The majority of primary caregivers were adults (70%), with a mean age of 50.25 years (SD = 14.41, range 20–74). Families had incomes of between 10,001 and 50,000 baht per month (40%).

For the control group, most families had a family member more than two people (85%), with an average of four. The main caregivers of the participants were their husbands or wives (60%), and healthy (60%). The main caregiver's age was reported to be adult (65%), with a mean age of 53.10 years (*SD* = 14.45, range 26–73). They had an income of between 10,001 and 50,000 baht per month (55%). The general information of family members between experimental and control groups in the pre-intervention period was compared with an independent t-test and a chi-squared test. There were no significant differences in general information of family members between the two groups ($p > .05$). The details are shown in Table 6.

Tables 6 Descriptions of the general information of family members

Characteristics	**Experimental group (n = 20)**		**Control group (n = 20)**		**Test**	***p*-value**
	n	**%**	**n**	**%**		
Number of family members					Fisher's exact = 3.243	.231
1-2	0	0	3	15		
> 2	20	100	17	85		
Average	3.80 ± 1.32		3.95 ± 1.54		*t* = -.331	.743
Range	2-7		2-8			
Main caregiver					χ2 = .102	.749
Husband or Wife	11	55	12	60		
Child or Grandchild	9	45	8	40		
Age of main caregiver (years)					χ2 = .114	.736
20-59	14	70	13	65		
≥ 60	6	30	7	35		
Average	50.25 ± 14.41		53.10 ± 14.45		*t* = -.625	.536
Range	20-74		26-73			
Health of main caregiver					χ2 = .440	.507
Healthy	14	70	12	60		
Having illness	6	30	8	40		
Family income/Month (Baht)					χ2 = .918	.632
≤ 10,000	7	35	5	25		
10,001-50,000	8	40	11	55		
> 50,000	5	25	4	20		

Evaluations of statistical assumptions for the dependent variables

Multivariate techniques and their univariate counterparts were based on a fundamental set of assumptions representing the requirements of the underlying statistical theory. Assumptions testing for repeated measures ANOVA comprised 1) outliers, 2) normality, 3) homogeneity of variance, and 4) compound symmetry.

1. Test for outliers

The univariate outliers of the variables were tested using a box plot, which revealed that the experimental group had two cases outliers (Case No. 17 for SMBQ data at Time 3, Case No. 20 for SBP data at Time 2 and Time 3, and Case No. 20 for DBP data at Time 2 and Time 3). The control group had no outliers. The multivariate outliers of variables were tested by Mahalanobis distance with chi-square. There were no multivariate outliers in terms of probability of values (Mahalanobis values < .001). Thus, the total sample size was 20 cases for the intervention group and 20 cases for the control group.

2. Normality testing

The scores of self-management behaviors, SBP, and DBP were tested for univariate normality, a Kolmogorov-Smirnov (p >.05), and by visual inspection of the participants' histograms and normal Q-Q plots. A z value of skewness and kurtosis was calculated by dividing the skewness or kurtosis value by their standard error. Values were between ±1.96, which corresponded to a .05 error level. These results indicated that the self-management behaviors, SBP, and DBP were within the normal distribution for both the intervention and control groups.

3. Homogeneity of variance (between-subject)

Levene's statistic was used to test the assumption of homogeneity of variances for the between-subject design. The test of homogeneity of variances for the between-subject comparison showed no significance (p >.05). This indicated that the variances of the dependent variables between groups were equal. Then the homogeneity of variances assumption was met. All of the error variances of the subscale were equal across groups.

4. Mauchly's test of sphericity (within-subject)

Mauchly's test of sphericity was used to test the assumption of sphericity. The total score of self-management behaviors showed no significant

(p >.05) indicated that the homogeneity of variance-covariance matrices was equal and the sphericity assumptions were met. Therefore, Sphericity Assumed was selected to report the results of repeated measure ANOVA in these aspects. In contrast, the value of SBP and DBP were significant ($p < .05$) indicating the homogeneity of variance-covariance matrices was not equal, and the sphericity assumptions were not met. Therefore, Greenhouse-Geisser was selected to report the results of the repeated measure ANOVA in these aspects.

Descriptive statistics of the outcome variables

In this study, outcome variables were total score self-management behaviors, SBP, and DBP. They were measured at pre-intervention (week 1), post-intervention (week 4), and follow-up (week 16) as illustrated in table 7.

For the experimental group, the mean scores of self-management behaviors were at a moderate level for all three time periods but gradually increased. The mean score of SBP at pre-intervention was 131.30 mmHg (*SD* = 22.98), which exceeded the SBP treatment standard of less than 130 mmHg. However, BP levels gradually continued to decrease after receiving the program. The mean scores of DBP were normal and continued to decrease after receiving the program.

For the control group, the mean scores of self-management behaviors were at a moderate level for all three time periods but increased in the post-intervention period and decreased at follow-up. SBP and DBP mean scores decreased in the post-intervention period but increased at follow-up. An estimated glomerular filtration rate (eGFR) was measured at pre-intervention (week 1) and follow-up (week 16). During the follow-up period, the mean eGFR scores in the experimental group were higher. In contrast, the mean eGFR scores in the control group were lower during the follow-up period (Table 7).

Tables 7 Means and standard deviations of self-management behaviors scores, SBP, and DBP, and eGFR at pre-intervention (week 1), post-intervention (week 4), and follow-up (week 16) for the experimental and control group

Variable	**Week**	**Experimental group (n = 20)**		**Control group (n = 20)**	
		M	***SD***	***M***	***SD***
Total score of self-management behaviors	1	112.20	20.23	113.35	19.54
	4	121.00	20.46	115.30	15.75
	16	125.75	18.45	111.00	18.79
Subscale score					
Self-care activities	1	42.90	10.80	40.90	7.84
	4	46.30	7.06	45.45	6.56
	16	48.10	6.53	44.00	7.66
Medication adherence	1	5.00	0.00	4.90	7.66
	4	5.00	0.00	5.00	0.00
	16	5.00	0.00	5.00	0.00
Communication	1	24.65	6.80	26.35	7.07
	4	26.05	6.98	25.00	7.36
	16	27.05	6.43	23.00	7.48
Self-advocacy	1	25.25	4.08	25.50	4.67
	4	27.20	4.90	25.35	3.25
	16	27.85	5.95	25.25	4.55
Partnership in care	1	14.40	6.08	15.70	4.50
	4	16.45	6.95	14.50	6.02
	16	17.75	6.42	13.75	5.98
SBP	1	131.30	22.98	127.50	14.55
	4	126.80	18.90	126.30	12.97
	16	120.95	16.40	129.70	11.47

Tables 7 (Continued)

Variable	Week	Experimental group (n = 20)		Control group (n = 20)	
		M	***SD***	***M***	***SD***
DBP	1	79.35	13.07	79.80	13.76
	4	78.50	11.30	79.40	12.16
	16	74.60	9.82	82.60	8.59
eGFR	1	42.47	9.18	42.28	9.86
	16	44.27	11.04	43.48	10.62

Comparisons of the pre-intervention score of outcome variables

During pre-intervention (week 1), the scores of all outcome variables were compared between the experimental and control groups. These outcomes were conducted to examine their differences before implementing the intervention by using an independent t-test. The results showed no significant differences (p > .05) in mean scores of self-management behaviors, SBP, DBP, and eGFR between the experimental and control groups at pre-intervention (Table 8).

Tables 8 Comparisons of the mean scores of outcome variables between the experimental and control group measured at the pre-intervention (week 1)

Variable	Experimental group (n = 20)		Control group (n = 20)		***t***	***p*-value**
	M	***SD***	***M***	***SD***		
Self-management behaviors	112.20	20.23	113.35	19.54	-.183	.856
SBP	131.30	22.98	127.50	14.55	.625	.536
DBP	79.35	13.07	79.80	13.76	-.106	.916
eGFR	42.47	9.18	42.28	9.86	-.932	.357

Testing of research hypotheses

This study aimed to examine the effectiveness of self-and family management support combined with the mHealth application program among persons with CKD stage 3. Research hypotheses were to compare the study outcomes of self-management behaviors, SPB, DBP, and eGFR of the participants between the experimental and control groups during three-time measures.

1. Comparisons of self-management behavior scores obtained from three-time measures in the experimental and control groups, as well as three-time measures within the experimental group

Two-Way Repeated Measures ANOVA (one within-one between) was used to determine a mean difference in total scores of self-management behaviors between the experimental and control groups at the pre-intervention (week 1), post-intervention (week 4), and follow-up (week 16). Bonferroni-corrected pairwise t-tests were used to compare the differences between each pair of times. The result showed that there was a significant difference in the interaction effect (time*group) ($F(2, 76) = 3.233$, $p < .05$, $\eta^2_p = .078$) (Table 9). Although the main effects of group (between-subjects) and time (within-subjects) were not a significant difference.

The line graph connecting each time point of self-management behaviors scores in the experimental group showed a dramatic increase over time, whereas

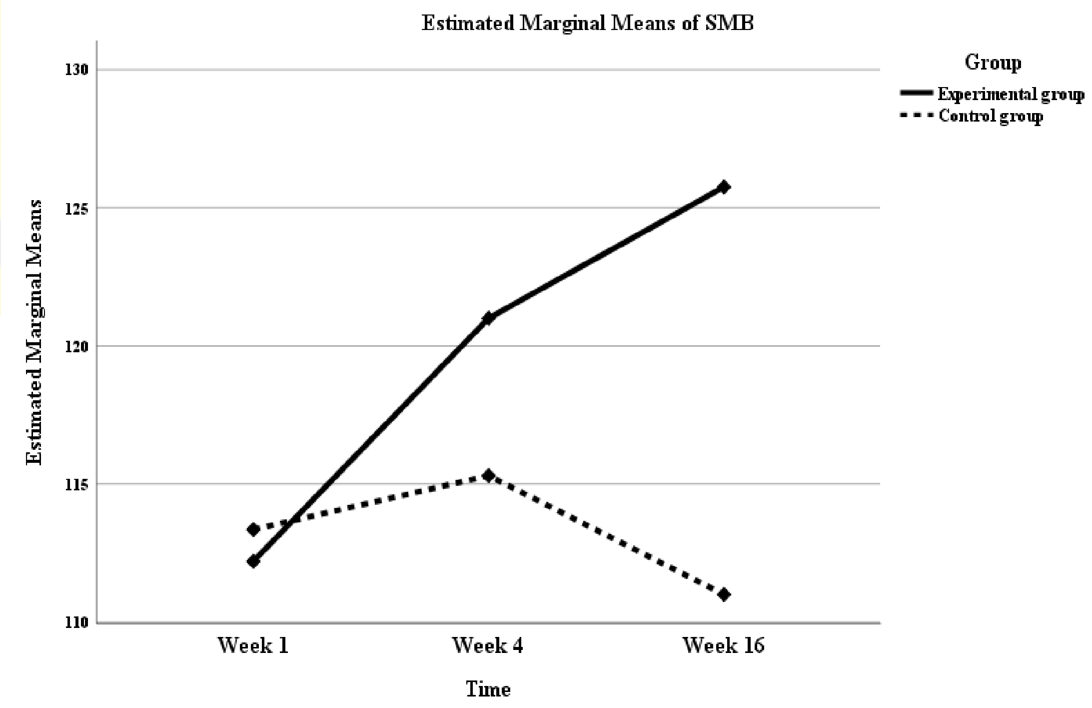
those in the control group showed an increase at week 4 and a decrease at week 16. The details are shown in Figure 6.

The finding indicated that persons with CKD stage 3 who received self-and family management support combined with the mHealth application program and those who did not receive had mean self-management behavior scores that changed over time.

Tables 9 Repeated measure ANOVA for self-management behaviors scores

Source variation	***SS***	***df***	***MS***	***F***	***p*-value**	η^2_p
Between subjects						
Group	1241.633	1	1241.633	1.820	.185	.046
Error	25921.167	38	682.136			
Within subjects						
Time	804.017	2	402.008	2.043	.137	.051
Time*Group	1272.117	2	636.058	3.233	.045*	.078
Error time	14952.533	76	196.744			

η^2_p = Partial Eta Squared



Figures 6 Comparisons of self-management behaviors scores between experimental and control group among 3 times measures

After the interaction effects showed significance, the simple effects were later tested to determine the effects of each group at each point of time (between-subjects). At the follow-up (week 16), the simple effects of groups revealed a significant difference (F (1, 38) = 6.276, p < .05, η^2_p = .142) (Table 10). This finding presented that the self-management behaviors of the participants in the experimental group were better than those in the control group during the follow-up period.

Tables 10 Simple effect of groups on self-management behaviors scores between experimental and control groups at each point of times

Source	***df***	***SS***	***MS***	***F***	***p*-value**	η^2_p
Pre-intervention (week 1)						
Group	1	13.225	13.225	.033	.856	.001
Error	38	15029.750	395.520			
Post-intervention (week 4)						
Group	1	324.900	324.900	.974	.330	.025
Error	38	12670.200	333.426			
Follow-up (week 16)						
Group	1	2175.625	2175.625	6.276	.017*	.142
Error	38	13173.750	346.678			

η^2_p = Partial Eta Squared

For the simple effect of time (within-subjects), there were statistically significant differences in the experimental group for at least one pair of times (F(2, 38) = 5.094, p <. 05, η^2_p = .211) (Table 11). At the follow-up (week 16), the mean scores of self-management behaviors in the experimental group were significantly higher than in the pre-intervention (week 1) (M_{diff} = 13.550, p < .05) (Tab1e 12). These findings indicated that patients with CKD stage 3 who received self-and family management support combined with the mHealth application program at follow-up (week 16) had better self-management behaviors than in the pre-interventions (week 1). When the time changed, self-management behaviors improved.

Tables 11 Simple effect of time on self-management behaviors scores in the experimental and control groups

Source	*df*	*SS*	*MS*	*F*	*p*-value	η^2_p
Experimental group						
Between subject	19	15144.317				
Interval	2	1890.700	945.350	5.094	.011*	.211
Error	38	7052.633	185.596			
Total	59	24087.65				
Control group						
Between subject	19	10776.850				
Interval	2	185.433	92.717	.446	.644	.023
Error	38	7899.900	207.892			
Total	59	18862.183	0.446			

η^2_p = Partial Eta Squared

Tables 12 Comparisons of mean difference of total scores of self-management behaviors between each pair of times within the experimental and control groups by using Bonferroni-corrected pairwise t-tests

Time	Time	M_{diff}	*SE*	*p*-value	95% CI for Difference	
					Lower	Upper
Experimental group						
Week 1	Week 4	-8.800	4.258	.137	-19.465	1.865
Week 1	Week 16	-13.550*	4.467	.013*	-24.739	-2.361
Week 4	Week 16	-4.750	4.575	.917	-16.210	6.710
Control group						
Week 1	Week 4	-1.950	4.258	1.000	-12.615	8.715
Week 1	Week 16	2.350	4.467	1.000	-8.839	13.539
Week 4	Week 16	4.300	4.575	1.000	-7.160	15.760

2. Comparisons of SBP and DBP scores obtained from three-time measures in the experimental and control groups, as well as three-time measures within the experimental group

Two-Way Repeated Measures ANOVA (one within-one between) was used to determine a mean difference in total scores of SBP and DBP between the experimental and control groups in the pre-intervention (week 1), post-intervention (week 4), and follow-up (week 16). Bonferroni-corrected pairwise t-tests were used for comparisons of the differences between each pair of times.

For SBP, the result showed that there was a significant difference in the interaction effect (time*group) (F(1.654, 62.866) = 4.260, $p < .05$, $\eta^2_p = .101$). For DBP, the result showed that there was a significant difference in the interaction effect (time*group) F(1.682, 63.899) = 3.550, $p < .05$, $\eta^2_p = .085$). Both SBP and DBP found no significant difference in their main effects (Table 13). The line graph connecting each time point of SBP and DBP in the experimental group showed a dramatic decrease over time, whereas those in the control group showed a decrease at week 4 and an increase at week 16. The details are shown in Figures 7 and 8.

The finding indicated that patients with CKD stage 3 who received self-and family management support combined with the mHealth application program and those who did not receive had mean SBP and DBP scores that changed over time.

Tables 13 Repeated measure ANOVA of the SBP and DBP scores

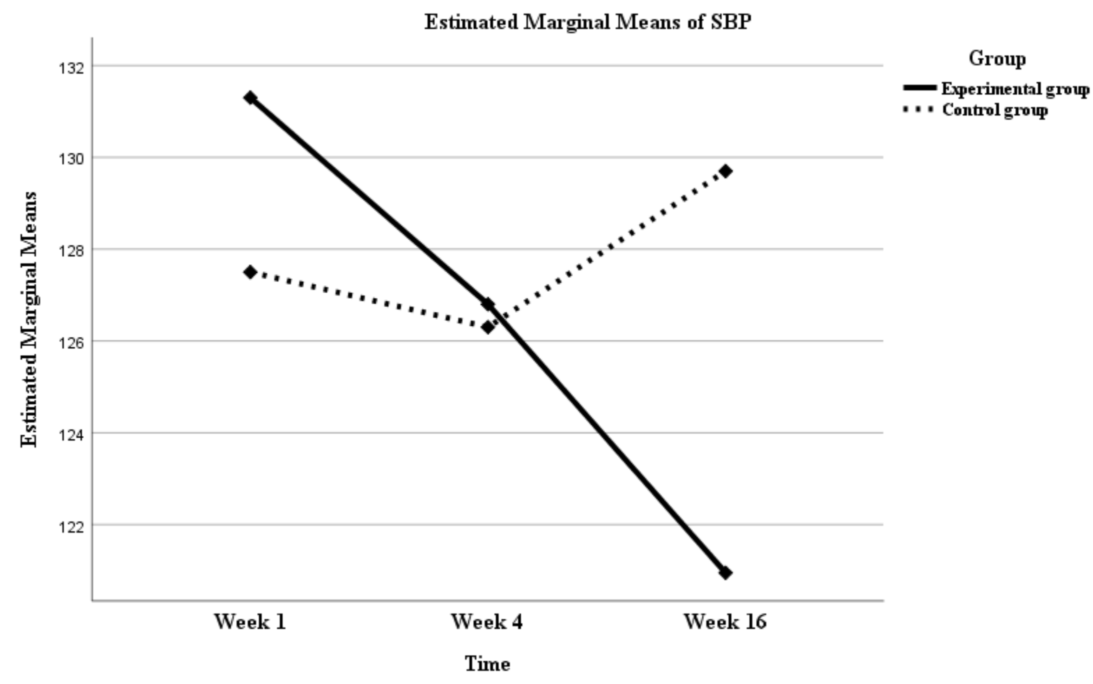
Source variation	***SS***	***df***	***MS***	***F***	***p*-value**	η^2_p
SBP						
Between subjects						
Group	66.008	1	66.008	.104	.749	.003
Error	24095.317	38	634.087			
Within subjects						
Time	349.717	1.654	211.389	1.760	.185	.044
Time*Group	846.517	1.654	511.683	4.260	.025*	.101
Error time	7550.433	62.866	120.103			

η^2_p = Partial Eta Squared

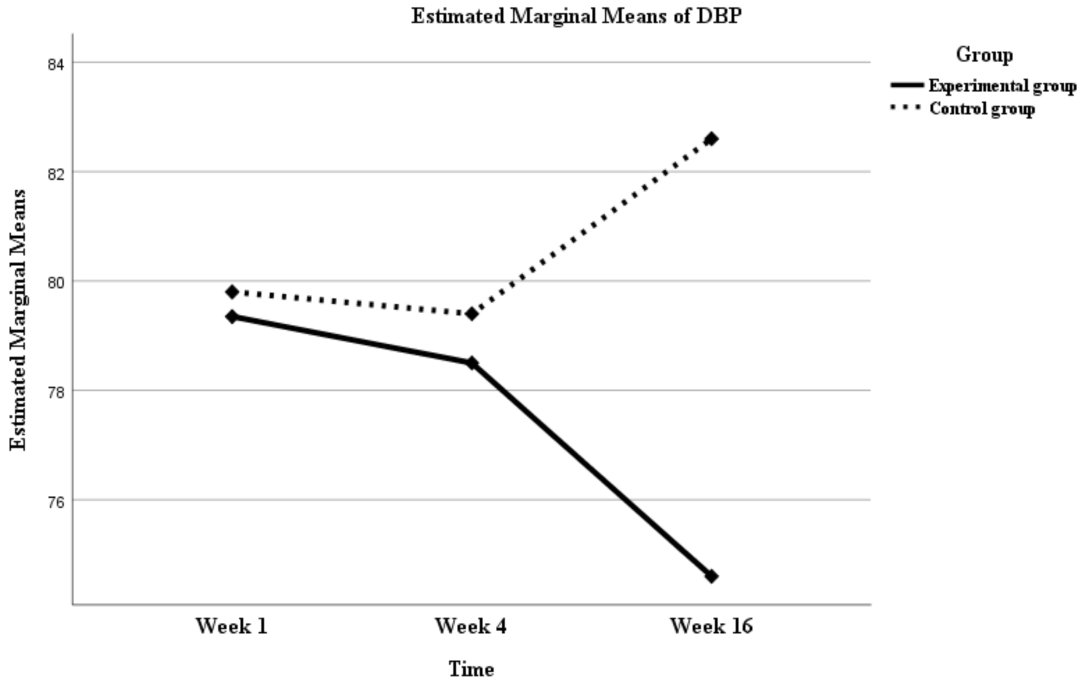
Table 13 (Continued)

Source variation	***SS***	***df***	***MS***	***F***	***p*-value**	η^2_p
DBP						
Between subjects						
Group	291.408	1	291.408	.965	.332	.025
Error	11471.383	38	301.879			
Within subjects						
Time	19.517	1.682	11.606	.193	.787	.005
Time*Group	358.717	1.682	213.323	3.550	.042*	.085
Error time	3839.767	63.899	60.091			

η^2_p = Partial Eta Squared



Figures 7 Comparisons of estimated marginal means of SBP between experimental and control group among 3 times measures



Figures 8 Comparisons of estimated marginal means of DBP between experimental and control group among 3 times measures

After the interaction effects showed significance, the simple effects were later tested to determine the effects of each group at each point in time. For SBP, there was no difference in the mean scores of self-management behaviors between the experimental and control groups at the 3-times point (Table 14). However, there was a significant difference in mean DBP scores between the experimental and control groups at the follow-up (week 16) ($F(1, 38) = 7.521$, $p < .05$, $\eta^2_p = .165$) (Table 15). This finding demonstrated that the DBP of the participants in the experimental group was better than the control group during the follow-up period.

Tables 14 Simple effect of groups on SBP scores at each point of times

Source	***df***	***SS***	***MS***	***F***	***p*-value**	η^2_p
Pre-intervention (week 1)						
Group	1	144.400	144.400	.390	.536	.010
Error	38	14053.200	369.821			
Post-intervention (week 4)						
Group	1	2.500	2.500	.010	.923	< .001
Error	38	9981.400	262.668			
Follow-up (week 16)						
Group	1	765.625	765.625	3.823	.058	.091
Error	38	7611.150	200.293			

η^2_p = Partial Eta Squared

Tables 15 Simple effect of groups on DBP scores at each point of times

Source	***df***	***SS***	***MS***	***F***	***p*-value**	η^2_p
Pre-intervention (week 1)						
Group	1	2.025	2.025	.011	.916	< .001
Error	38	6841.750	180.046			
Post-intervention (week 4)						
Between subject	1	8.100	8.100	.059	.810	.002
Error	38	5235.800	137.784			
Follow-up (week 16)						
Between subject	1	640.000	640.000	7.521	.009*	.165
Error	38	3233.600	85.095			

η^2_p = Partial Eta Squared

For the simple effect of time (within-subjects), there were statistically significant differences in mean SBP scores in the experimental group at least one pair of times ($F(2, 38) = 4.445$, $p < .05$, $\eta^2_p = .190$ (Table 16). The mean SBP scores in the experimental group were significantly lower at the follow-up (week 16) than at the pre-intervention (week 1) ($M_{diff} = -10.350$, $p < .05$) (Tab1e 18). While none of the time pairs in the mean scores of DBP were statistically different (Table 17 and 19). These findings indicated that patients with CKD stage 3 who received self-and family management support combined with the mHealth application program at follow-up (week 16) had better SBP than in the pre-intervention (week 1). When the time changed, SBP improved.

Tables 16 Simple effect of time on SBP scores in the experimental and control groups

Source	***df***	***SS***	***MS***	***F***	***p*-value**	η^2_p
Experimental group						
Between subject	19	17325.650				
Interval	2	1077.300	538.650	4.445	.018*	.190
Error	38	4604.700	121.176			
Total	59	23007.650				
Control group						
Between subject	19	6769.667				
Interval	2	118.933	59.467	.767	.471	.039
Error	38	2945.733	77.519			
Total	59	9834.333				

η^2_p = Partial Eta Squared

Tables 17 Simple effect of time on DBP scores in the experimental and control groups

Source	*df*	*SS*	*MS*	*F*	*p*-value	η^2_p
Experimental group						
Between subject	19	5850.983				
Interval	2	256.633	128.317	2.956	.064	.135
Error	38	1649.367	43.404			
Total	59	7756.983				
Control group						
Between subject	19	5620.400				
Interval	2	121.600	60.800	1.055	.358	.053
Error	38	2190.400	57.642			
Total	59	7932.400				

η^2_p = Partial Eta Squared

Tables 18 Comparisons of mean difference of SBP scores between each pair of time differences within the experimental group and control group by using Bonferroni-corrected pairwise t-tests

Time	Time	M_{diff}	*SE*	*p*-value	95% CI for Difference	
					Lower	Upper
Experimental group						
Week 1	Week 4	4.500	3.367	.568	-3.932	12.932
Week 1	Week 16	10.350*	3.602	.020*	1.328	19.372
Week 4	Week 16	5.850	2.344	.051	-.021	11.721
Control group						
Week 1	Week 4	1.200	3.367	1.000	-7.232	9.632
Week 1	Week 16	-2.200	3.602	1.000	-11.222	6.822
Week 4	Week 16	-3.400	2.344	.465	-9.271	2.471

Tables 19 Comparisons of mean difference of DBP scores between each pair of time differences within the experimental group and control group by using Bonferroni-corrected pairwise t-test

Time	**Time**	M_{diff}	***SE***	***p*-value**	**95% CI for Difference**	
					Lower	**Upper**
Experimental group						
Week 1	Week 4	.850	2.421	1.000	-5.213	6.913
Week 1	Week 16	4.750	2.534	.206	-1.596	11.096
Week 4	Week 16	3.900	1.696	.081	-.349	8.149
Control group						
Week 1	Week 4	.400	2.421	1.000	-5.663	6.463
Week 1	Week 16	-2.800	2.534	.828	-9.146	3.546
Week 4	Week 16	-3.200	1.696	.201	-7.449	1.049

3. Comparisons of eGFR scores obtained from two-time measures in the experimental and control groups

An independent t-test was used to examine the changes in mean scores of eGFR between the participants in the experimental and control groups in the pre-intervention (week 1) and follow-up (week 16).

During the follow-up period (week 16), the mean eGFR scores in the experimental group were higher than in the control group (M_{diff} =.80, *SD* = 3.43), as shown in Table 20. However, there was no significant difference in the mean score of eGFR between the experimental and control groups (*t* = .232, *p* = .818).

The result indicated that patients with CKD stage 3 who received self-and family management support combined with the mHealth application program plus usual care and those who received only usual care had no difference found in mean scores of eGFR.

Tables 20 Comparison of an eGFR at follow-up (week 16) between the experimental group and control groups

Variable	Experimental group (n = 20)	Control group (n = 20)	Mean difference	*t*	*p*-value
	M (SD)	***M (SD)***	***M (SD)***		
eGFR	44.27(11.04)	43.48(10.62)	.80(3.43)	.232	.818

Conclusion of the findings

In a three-time measurement, self-management behaviors, SBP, DBP, and eGFR were used to determine the effectiveness of self-management and family management support in combination with the mHealth application program in people with stage 3 CKD. The results of the research can be concluded as follows:

Two-Way Repeated Measures ANOVA was used to test the mean difference in self-management behaviors, SBP, and DBP scores between the experimental and control groups at pre-intervention (week 1), post-intervention (week 4), and follow-up (week 16). We found self-management behaviors, SBP, and DBP in the experimental group presented continuous improvements, and there was a significant change at the sixteenth week of the follow-up period. In the control group, it improved after the experiment at the fourth week but worsened at the sixteenth week follow-up.

According to the findings, the mean score for self-management behaviors, SBP, and DBP revealed statistically significant differences in the interaction effects (time*group). The participants in the experimental group had better self-management behaviors and DBP than those in the control group at the follow-up ($F(1, 38) = 6.276$, $p < .05$; $F(1, 38) = 7.521$, $p < .05$, respectively). Additionally, there was a significant improvement of both self-management behaviors and SBP in the experimental group across pre-intervention and follow-up ($M_{diff} = -13.550$, $p < .05$; $M_{diff} = 10.350$, $p < .05$, respectively).

Lastly, an independent t-test was used to test the mean difference in eGFR between the experimental and control groups during pre-intervention (week 1) and follow-up (week 16). The result revealed that during the follow-up period (week 16), the mean eGFR scores in the experimental group were higher than in the control groups. Nevertheless, there was no significant difference in the mean score of eGFR between the two groups (t = .232, p = .818). Based on the findings, it can be concluded that four of the five research hypotheses are supported, demonstrating the effectiveness of this research program.

CHAPTER 5
DISCUSSION

This chapter was presented in five parts, namely, a summary of the study, discussion of the research findings, strengths and limitations, suggestions and recommendations, and, finally, conclusion.

Summary of the study

A randomized controlled trial (RCT), pre- and post-intervention, and follow-up designs were conducted to examine the effectiveness of self-and family management support combined with the mHealth application on self-management behaviors, BP, and eGFR among persons with CKD stage 3. Self-and family management support combined with the mHealth application was developed based on IFSMT of Ryan and Sawin (2009). This selected theory was applied in this study and implemented with CKD stage 3 patients, who need to manage their condition for four months. The research framework consisted of context and processes of self-management integrated with mHealth application based on the support from family members and healthcare providers. The intervention comprised four sessions over four weeks as follows: (1) identifying and measuring risks and protective factors, (2) providing knowledge and caring beliefs, (3) developing self-regulation skills and providing family support and mHealth application, and (4) developing abilities in self-evaluation and management of responses associated with health behavioral change. The empirical evidence was also collected to establish a program by modifying self-regulation activities of Lin et al. (2013), self-efficacy activities of Nguyen et al. (2019), and mHealth application for CKD patients (Ong et al., 2016).

The data collection was conducted at CKD clinic in Samut Prakan Hospital, Thailand from November 2020 to November 2021. Forty participants with CKD stage 3a (eGFR = 45-59 ml/min/1.73 m^2) or 3b (eGFR = 30-44 ml/min/1.73 m^2) were recruited into this study using inclusion criteria. To prevent bias and contamination between the two groups, the lotto drawing method was used in randomly assigning potential participants to experimental and control groups (20 each) in different weeks of CKD clinic service. In other words, the experimental and control groups were recruited in the second and fourth week of the month, respectively. In post-intervention period, there was no dropout from the study. The outcome variables, including self-management behaviors, SBP, DBP, and eGFR, were gathered before receiving the program (week 1). After four sessions of the program were completed in week 4, the outcomes were measured immediately. They were then reexamined in week 16 to assess the sustainability after program completion. Meanwhile, only eGFR was measured in week 1 and 16. The data were analyzed with descriptive statistics, chi-square, Fisher's exact test, independent t-test, and Two-Way Repeated Measures ANOVA.

The results revealed no differences in general information of participants and family members in both intervention and control groups. However, for health information, participants had a significant difference in mean scores of triglycerides. In pre-intervention session, there was no significant difference of self-management behavior scores, SBP, DBP, and eGFR in both groups.

Two-Way Repeated Measures ANOVA (one within-one between) was used to determine the mean difference of self-management behaviors, SBP, and DBP obtained from three-time measures. The results indicated statistically significant differences in the interaction effects (time*group) as evidenced by the mean score of self-management behaviors, SBP, and DBP. In the follow-up (week 16) period, the simple effect of group-presented self-management behavior and DBP was significantly different. The mean scores of self-management behaviors and SBP in the experimental group were significantly higher than those in the pre-intervention (week 1) period. In addition, an independent t-test was used to determine the mean difference in eGFR between the experimental and control groups obtained from two-time measures. However, there was no significant difference in the mean score of eGFR in the two groups during the follow-up period.

Discussion of the research findings

The overall results of the current study indicated that self-and family management support combined with the mHealth application partially support hypotheses. The program was able to improve self-management behaviors and significantly reduce SBP and DBP among stage 3 CKD patients. However, the intervention had no significant effect on their eGFR. The discussion of the effectiveness of a self-and-family management support combined with the mHealth application in the experimental and control groups across three-time measurement period was consistent with the following findings:

Self-management behaviors

Hypothesis 1: The participants in the experimental group have significantly higher mean scores of self-management behaviors than those in the control group in post-intervention (week 4) and follow-up (week 16) periods.

The first hypothesis was supported by the statistical result of Time*Group interaction effect on self-management behavior scores, which revealed a statistical significance ($F(2, 76) = 3.233$, $p < .05$, $\eta^2_p = .078$). Also, there was a significant difference in mean scores of self-management behaviors between experimental and control groups in follow-up (week 16) period ($F(1, 38) = 6.276$, $p < .05$, $\eta^2_p = .142$). The research findings indicated that, in week 16, persons with CKD stage 3 who received usual care together with self-and family management support combined with the mHealth application had significant higher mean scores of self-management behaviors than those who received only usual care.

Hypothesis 4: For the experimental group, mean scores of self-management behaviors in post-intervention (week 4) and follow-up (week 16) sessions are significantly higher than those in pre-intervention (week 1) periods.

This hypothesis was supported by the difference in the mean score of self-management behaviors in week 16 in comparison to week 1. A statistical significance was found ($M_{diff} = 13.550$, $p < .05$). The findings indicated that, in follow-up (week 16) period, persons with CKD stage 3 who received usual care together with self-and family management support combined with the mHealth application had significantly higher mean scores of self-management behaviors than those in pre-intervention (week 1) session.

The significant increase in self-management behaviors scores was due to the component characteristics of program and intervention that integrated with several methods. Firstly, the program development was fundamentally based on individual and family self-management theory (IFSMT) and a literature review. IFSMT illustrates the complexity of self-management process and provides a framework for demonstrating how contextual risk and protective factors, as well as components of self-management process contribute to patient outcomes. Self-management behaviors and health status are consistent with the "process by which individuals and families use knowledge and beliefs, self-regulation skills and abilities, and social facilitation to achieve health-related outcomes" (Ryan & Sawin, 2009). Therefore, patients and family members are expected to engage in promoting health behaviors and modifying lifestyles.

Secondly, the participants' increased self-management behaviors are also explained by the trainings of self-regulation skills, namely, goal setting, self-monitoring and reflective thinking, decision making, planning and action, and self-evaluation. Self-regulation is frequently studied in relation to the processes of selection, goal pursuit, and behavioral change. The stages of behavior change process consist of (1) initial response, (2) continued response, (3) maintenance, and (4) habit (Weinstein et al., 1998). The strength of self-regulatory seems to be more important in the initial response and continued response phases when compared to the maintenance and habit phases. During the initial response phase, individuals are likely to have a difficulty in successfully initiating the new pattern of behavior if they are in a situation involving other significant self-regulatory demands. Given that the threat passed by lapses and relapses is predicted to occur during the continued response phase, self-regulatory strength should be an important determinant in whether individuals are able to complete this phase of behavior change process (Rothman et al., 2004).

Thirdly, another explanation was that increased self-management behaviors might be because of informational support and more self-efficacy. Knowledge was delivered in the second session of intervention through VDO presentation regarding CKD together with the distribution of Power Point Handout and self-management booklets entitled "Tips and tricks to preventing renal failure" and "How to eat when kidneys start to deteriorate". Despite the fact that the knowledge was the elementary intervention that improved a range of outcomes among patients with CKD, it alone was insufficient to promote and sustain health behavioral change, particularly where there is such a complex regimen.

Previous studies have shown that knowledge of CKD and self-efficacy has positive relationships with self-management (Chuang et al., 2021; Moktan et al., 2019). Self-efficacy was the most significant predictor for self-management and explained 49% of total variance (Chuang et al., 2021). Thus, self-efficacy could be seen as a mediator and predictor of self-management. In the social cognitive theory (SCT), self-efficacy could be improved through performance accomplishment, vicarious experience, verbal persuasion, and self-appraisal as strategies to support self-management behavior (Bandura, 1997). Performance accomplishment was a sense of confidence derived from within individuals when they felt a sense of success, particularly when they believed that they have mastered such behavior. Performance accomplishment was the most important strategy to assist participants to actually perform self-management behavior. According to Nguyen et al. (2019) who conducted a self-management program based on social cognitive theory (SCT) in patients with CKD, large effect sizes for improved self-management were found in week 16 when compared to the control group.

These findings were consistent in some parts with previous studies that showed the effectiveness of self-management enhancement programs for Thais with CKD at pre-dialysis stage (Suwanwaha et al., 2016). Self-management enhancement program aimed to train participants with nine skills of self-management; enhance their perceived self-efficacy; and provide them with information regarding CKD and self-management concepts. Results revealed that, after the completion of 4-week program, the experimental group had significantly better self-management behaviors in comparison to the control group. The program could successfully modify self-management behaviors in a short period of time. No difference was found in a longer term (4 months), self-management behavior scores were higher when compared to pre-intervention period.

Fourthly, social support has been shown to be a significant predictor for self-management behaviors (Chen et al., 2018). In this study, family support was the most important for participants. Healthcare providers play a different role in helping patients to carry out disease management tasks, while family caregivers provide more hands-on and day-to-day care than any other individual. As such, they need not only access to information but also ability to process and take action in order to provide the best quality care. Therefore, family caregivers are expected to be helpful in encouraging self-management behaviors and thereby ensuring better health outcomes (Sperber et al., 2013; Vaccaro et al., 2014). In Thai culture, family involvement in providing care cannot be ignored, especially for the elderly and persons with disabilities/chronic diseases. Therefore, family participation programs were also effective for health behaviors and health outcomes of patients with CKD stage 3.

The maintenance of self-management behaviors for chronic disease needed the family caregiver’s support. A chronic disease could occur and cycle in recurrence throughout a lifetime. It affected the patient’s symptoms and mood so emotional and physical supports were needed. Additionally, family members influenced the patient’s psychological adjustment and illness management, adoption of behaviors influencing recovery, functioning, and adherence to treatments (Goldberg & Rickler, 2011). In this study, after the caregiver was involved in the program, they were more knowledgeable about CKD including its pathology, diet, exercise, stress relief, and medication. They were more confident in providing care for their family member with CKD and involved in setting goals, planning, implementing, self-monitoring, and evaluating their performance. Besides, the results showed that goals of most patients and caregivers were to improve kidney function so that they needed no dialysis. Consequently, they were encouraged to stick to the plan by the time the assessment was done.

Finally, the integration of mHealth application supported patients' decision-making and improved healthcare delivery. The study results corresponded to several studies that integrated mobile phone self-management system with usual care. The functions of mHealth provided educational contents, namely, CKD handbook and VDO media, CKD medication, renal diet, self-monitoring, and communication with healthcare providers (Doyle et al., 2019; Fakih El Khoury et al., 2020; Ong et al., 2016; St-Jules et al., 2021; Yang et al., 2020). It ensured efficacy of health outcome improvement and behavior modification in patients with CKD. Moreover, the continuity of patient-centered care for CKD provided by mHealth application could support patients' self-management. The value of a novel mHealth approach for individualized medication and health management is demonstrated (Hsieh et al., 2018). mHealth system had the potentials to optimize personalized care into existing clinical services and might help hospitals and health authorities to perform continuous quality improvement and policy development.

Blood pressure (BP)

Hypothesis 2: The participants in the experimental group have significantly lower mean scores of SBP and DBP than those in the control group in post-intervention (week 4) and follow-up (week 16) periods.

This hypothesis was supported by the statistical result of the Time*Group interaction effect on SPB and DBP, which revealed a statistical significance ($F(1.654, 62.866) = 4.260$, $p <.05$, $\eta^2_p = .101$; $F(1.682, 63.899) = 3.550$, $p <.05$, $\eta^2_p = .085$, respectively). Moreover, there was a significant difference between the experimental and control groups in terms of mean scores of DBP in the follow-up (week 16) period ($F(1, 38) = 7.521$, $p < .05$, $\eta^2_p = .165$). The research findings indicated that in week 16, persons with CKD stage 3 who received usual care together with self-and family management support combined with the mHealth application had lower mean scores of DBP than those who received only usual care.

Hypothesis 5: For the experimental group, mean scores of SBP and DBP in post-intervention (week 4) and follow-up (week 16) are significantly lower than those in pre-intervention (week 1) periods.

This hypothesis was partially supported by the difference in the mean score of SBP in week 16 when compared to week 1. A statistically significance was found ($M_{diff} = -10.350$, $p < .05$). The findings indicated that, in follow-up (week 16) period, persons with CKD stage 3 who received usual care together with self-and family management support combined with the mHealth application had significantly lower mean scores of SBP than those in pre-intervention (week 1) period.

The significant decrease in SBP and DBP was due to the component characteristics of program and intervention that integrated with three methods. Firstly, mHealth application was able to record BP. The recorded data were analyzed and a trend graph of BP was displayed. The upward trend graph indicated behavioral modifications that caused the increase in BP. On the other hand, the graph with a downward trend implied that participants had good BP control. In addition, interactive feedback and counseling by the researcher via mHealth application might help participants to identify factors contributing to a high BP so that problems could be resolved efficiently and rapidly. Therefore, interactive mHealth intervention might be useful for improving BP control in adults, especially those with inadequate BP control (Lu et al., 2019).

With the ongoing development of mobile technologies and scarcity of healthcare resources, mHealth–based self-management has emerged as a useful treatment for hypertension. Its efficacy was evaluated in numerous studies. According to the meta-analysis, mHealth intervention groups had a greater reduction in both SBP and DBP when compared to the control groups, - 3.78 mmHg ($p < .001$; 95% CI -4.67 to -2.89) and -1.57 mmHg ($p < .001$; 95% CI -2.28 to -0.86), respectively. Subgroup analyses showed consistent reductions in SBP and DBP across different frequencies of reminders, interactive patterns, intervention functions, and study duration subgroups. A total of 16 studies reported better medication adherence and behavioral change in the intervention groups, while the other 8 showed no significant change (Li et al., 2020).

Secondly, BP monitoring was essential for managing hypertension in patients with CKD. The optimal BP for CKD management is less than 130/80 mmHg (KDIGO, 2021; Whelton et al., 2017). The researcher provided accurate HBPM to all participants in the experimental group to measure BP daily or 1-2 times a week following standard guidelines (Thai Hypertension Society, 2019; Whelton et al., 2017; Unger et al., 2020). HBPM plays an important role in monitoring hypertensive patients. Self-measured BP monitoring was associated with a reduction in BP, and the benefits of self-measured BP monitoring were at the greatest when it was done along with cointerventions (Shimbo et al., 2020). There were numerous international guidelines on hypertension management that supports the use of self-monitoring as an adjunct to home-based BP assessments. The effect of self-blood pressure monitoring (SBPM) is associated with the decreased BP ($p < 0.001$) (Jo et al., 2019; Sheppard et al., 2020). The increase in the frequency of SBPM ≥ once a week and better drug compliance (Jo et al., 2019) resulted in the reduction of BP. A nurse-led training program was an effective strategy to improve patients' adherence to correct guidelines and techniques of SBPM at home (Simonetti et al., 2021).

Finally, the effective reduction of BP needed lifestyle modification. The components of the intervention that reduced BP were composed of four main activities: exercising (at least 30 minutes, 5 days per week), eating of low-saturated fat and low sodium diet, medication adherence, and stress relief. The control of SBP and DBP levels was associated with a lower risk of composite kidney outcome that reflected CKD progression. SBP had a greater association with adverse kidney outcomes than DBP (Lee et al., 2021). This program was more effective than DBP in reducing SBP because it was related to the participants' health factors such as BMI and blood lipids.

For this study, BMI, triglyceride, and LDL-C of the control group were higher than normal level. This made it difficult and time-consuming to control DBP. BMI influenced long-term BP variability. As BMI increased, the mean value of the average real variability of systolic blood pressure (ARVSBP) gradually rose too. ARVSBP increased by 0.077 for every one-unit increase in BMI. Multiple logistic regression analysis indicated that, when compared to normal weight, the obesity or being overweight was a risk factor for the increase in ARVSBP. The corresponding odds ratios for being obese or overweight were 1.23 (1.15–1.37) and 1.10 (1.04–1.15), respectively (Chen et al., 2018). Also, there was a significantly positive correlation among DBP, triglyceride, and LDL-C (Anika et al., 2015; Behradmanesh & Nasri, 2012). Therefore, to achieve DBP reduction goal, the decrease of BMI, triglyceride, and LDL-C had to be emphasized.

Estimated glomerular filtration rate (eGFR)

Hypothesis 3: The participants in the experimental group have a significantly higher mean score of eGFR than those in the control group in follow-up (week 16) periods.

The mean scores of eGFR in the experimental group were higher than the ones in the control group during the follow-up period (week 16) (M_{diff} = .80, SD = 3.43). However, there was no significant difference of the mean scores of eGFR between the experimental and control groups (t = .232, p = .818). The result indicated that patients with CKD stage 3 who received usual care together with self-and family management support combined with the mHealth application and those who received only usual care had no different mean scores of eGFR. Therefore, these findings failed to support research hypothesis.

This corresponded to the findings of a systematic review and meta-analysis, which found that self-management intervention programs had no significant effect on eGFR change (Lee et al., 2016; Peng et al., 2019). However, it has been shown that this program can increase eGFR, which exceeds care goals of CKD patients. The goal of preventing renal impairment was to keep eGFR from a rapid decrease over 4 ml/min/1.73 m2/year (MOPH, 2013; Thanakitjaru, 2015).

The increase in eGFR in both experimental and control groups might be the impact of multidisciplinary care. The previous study showed the effectiveness of multidisciplinary care in increasing eGFR. Trisirichok et al. (2019) studied the effects of self-management supported by multidisciplinary teams to delay CKD progression in patients with CKD stage 2-4. In month 12 after the program, participants had a significant increase of mean score of eGFR to the level of $p < .05$. According to 2-year study of Jiamjariyapon et al. (2017) who investigated the effectiveness of comprehensive multidisciplinary health care program (Integrated CKD Care) in delaying the progression of stage 3–4 CKD in rural Thai communities, the difference of mean score of eGFR over time in the intervention group was significantly lower than the one in the control group at 2.74 ml/min/1.73 m^2 (95%CI 0.60 - 4.50, $p < .05$).

The integration of mHealth with CKD patient care was found both effective and ineffective in improving eGFR. Chen et al. (2018) developed mHealth application for communication between the nephrologist and early-stage CKD patients. The results showed a significant correlation between average daily usage and physician-patient conversation. However, there was no statistical significance in improving clinical outcomes such as BMI, BP, urine protein, and eGFR. Li et al. (2020) studied the effectiveness of mHealth application and social media in supporting self-management of patients with CKD stage 1-4. After the completion of intervention, eGFR of the experimental group was higher than the one of the control groups (M = 72.47, SD = 24.28 vs M = 59.69, SD = 22.25 ml/min/1.73m^2, $p < .05$). The decline in eGFR was significantly slower in the intervention group (- 0.56 vs - 4.58 ml/min/1.73 m^2) too.

Another reason why results reflected no statistically significant was that participants in the experimental group had a high level of HbA1c (M = 9.10, SD = 3.84). A relationship between HbA1C variability and renal progression in type 2 diabetes patients with CKD stages 3-4 was found. The results indicated that a greater HbA1C variability and a decrease of HbA1C, which might be related to the intensive diabetes control, was associated with a lower risk of progression to dialysis in patients with stages 3-4 CKD and poor glycemic control (HbA1c ≥ 7%) (Lee et al., 2018).

Therefore, program activities integrated with social media or other platforms could be an additional avenue for monitoring health behaviors, namely, walk step count, distance, and consumed calories. This could effectively increase eGFR and slow CKD progression. There are strategies for a more rigorous controlling of HbA1c levels. In addition, the appropriate timing of eGFR measure should be up to one year (Nojima et al., 2017) for reliably predicting CKD progression.

Strength and limitation

The strengths of the study should be acknowledged according to the following three essential points: First, this research was guided by the Individual and Family Self-Management Theory (IFSMT) of Ryan and Sawin (2009). It was widely used for improving self-management behaviors and health status in patients with chronic diseases. IFSMT consisted of three major concepts, which dynamically affect each other, including context, process, and outcomes. The context of participants and their families were assessed as follows: 1) condition-specific factors, 2) physical and social environments, and 3) individual and family characteristics. After that, the factors that supported and hindered self-management behaviors were identified in order to devise individualized care plans.

Theoretical processes that are effective for improving research outcomes include knowledge, self-efficacy, self-regulation, and social support. The comprehensive education on all aspects of CKD and changes in care beliefs was provided to enhance greater confidence in self-management. The development of self-regulation skills were essential in self-management process, which consisted of identifying problems, setting goals, planning clear actions, strengthening self-discipline and self-monitoring, and evaluating performance. When plan implementation generated a concrete effect, its consequence was maintained change in self-management behaviors. Inviting family members to participate in program activities was also found to be very important. Because family members play a role in supporting the self-management of CKD patients in their daily lives, such as managing diet and medications, encouraging exercise, observing and monitoring abnormalities in symptoms, and attending medical appointments on a regular basis.

Second, eHealth strategy relied on the use of mobile phone technology for health care of patients with CKD. It was the beginning for adjusting service model of CKD Clinic in the 21st century. It was also coherent with the Ministry of Public Health's policy, which stated that the application was a powerful and effective health care devise that was accessible at anytime and anywhere. It was found that mHealth intervention may not play a major role in improving clinical outcomes when compared with conventional care. More importantly, this study also found that clinical outcomes could be ameliorated even further by combining mHealth with support by a family caregiver rather than using mHealth intervention exclusively. According to the analytical results, mHealth intervention could be used as a treatment strategy to optimize the effective management of hypertension and CKD.

Finally, participants in the experiment group received HBPM to monitor their BP daily and record it in mHealth application. HBPM had various advantages as follows. It could take multiple readings over an extended period of time and avoids white-coat reaction to BP measurement. It was reproducible and able to make a better prediction of cardiovascular morbidity and mortality than office BP. Patients could better understand hypertension management, while telemonitoring allowed healthcare professionals to oversee remote monitoring and detects increased BP variability (George & MacDonald, 2015). HBPM use was common in patients with hypertension and CKD. HBPM users were more likely to follow lifestyle and dietary modifications for the effective controlling of BP and CKD progression.

Three following limitations to this study should be addressed: First, this research was conducted only in one setting; therefore, it has limitations on its generalizability in other settings with different contexts. Second, as this research stored BP data in mHealth application, limitations in mobile application skills and internet connections might hinder the registration of BP and use of other functions of mHealth application. In comparison to older patients, younger patients and family members were more likely to use mHealth intensively and interactively. Therefore, technology literacy of patients should be thoroughly assessed by renal teams before its implementation in practice. Finally, COVID-19 pandemic has made it difficult to conduct research and to closely follow the plan. The number of participants in the group session was reduced due to location and individual restrictions. For this reason, the researcher modified research activities to suit this pandemic situation so that the research could be carried out.

Suggestions and recommendations

The results of this study provide evidence for healthcare providers to improve self-management behaviors and BP in CKD stage 3 patients. Moreover, this intervention offers an increased scope of practice for health professionals, nurses, or caregivers who can apply the evidence to support the use of the individual and family self-management theory (IFSM). The integration of mobile phone technology with CKD patient care is consistent with the Thai Ministry of Public Health's eHealth strategy and essential in COVID-19 pandemic situation. It allows patients to receive continuing and equal care and stay safe from COVID-19. The identified gaps in this study are the introduction of health policies and organizational supports for mHealth and HBPM implementation in CKD stage 3 patients. The findings may reflect the necessary development of a comprehensive service model that utilizes mHealth technologies for home monitoring and self-management of CKD stage 3 patients.

Self-directed mHealth programs may be a useful adjunct to usual care with multidisciplinary approach. As most CKD patients are the elderly, the use of technology might be problematic, especially among Thai elderly. Therefore, it is important to allow family members who are competent in technology use to participate in CKD care program. Nurses should hold sessions with rigorous hands-on training for both participants and their health care providers to ensure they have the full set of skills to leverage mHealth application.

Future research should focus on other health care settings to confirm the effectiveness of integrating mHealth application regarding regular services, to assess long-term sustainability of self-management behavior change, and to determine the quality of life and overall cost-effectiveness. mHealth application functionality should be developed to cover all aspects of CKD patient care. The information technology (IT) Experts should be invited to review application's design, usability, and reliability prior to deployment. In addition, other platforms and technologies should be considered such as IOS system, telehealth, and social media, to improve the quality of CKD patient care.

Conclusion

Self-and family management support combined with the mHealth application was developed based on Individual and Family Self-Management Theory (IFSMT) by Ryan and Sawin (2009) and a literature review. In follow-up (week 16) session, it was found to enhance self-management behaviors and reduce SBP and DBP when compared to usual care. This program took family as a "unit of care" and incorporated IT technology to enhance health literacy about CKD for individual patients and family members; improve their self-management skills at home; promote self-monitoring to trigger any clinical changes (BP, eGFR); and provide more effective long-distance communication for client-providers. Moreover, it was found to be an effective approach for patients with CKD and their family members in developing knowledge, confidence, and self-regulation skills to manage their illness. Therefore, professional nurses should integrate this program into clinical practice for better patient outcomes.

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APPENDICES

APPENDIX A

Inviting documents of experts

รายนามผู้ทรงคุณวุฒิ

1. รองศาสตราจารย์ ดร.อรวมน ศรียุกตศุทธ	ภาควิชาการพยาบาลอายุรศาสตร์ คณะพยาบาลศาสตร์ มหาวิทยาลัยมหิดล
2. รองศาสตราจารย์ ดร.ดวงรัตน์ วัฒนกิจไกรเลิศ	ภาควิชาการพยาบาลอายุรศาสตร์ คณะพยาบาลศาสตร์ มหาวิทยาลัยมหิดล
3. ผู้ช่วยศาสตราจารย์ ดร.มนพร ชาติชำนิ	กลุ่มวิชาการพยาบาลผู้ใหญ่และผู้สูงอายุ คณะพยาบาลศาสตร์ มหาวิทยาลัยรังสิต
4. นายแพทย์ ชัยวัฒน์ พิสุทธิ์ไพศาล	อายุรแพทย์โรคไต โรงพยาบาลสมุทรปราการ
5. พยาบาลวิชาชีพ สุนทรี เพิ่มพูนสวัสดิ์	หัวหน้าหน่วยไต โรงพยาบาลสมุทรปราการ

ที่ อว ๘๑๓๗/ ๓๖๕

มหาวิทยาลัยบูรพา
๑๖๙ ถ.ลงหาดบางแสน ต.แสนสุข
อ.เมือง จ.ชลบุรี ๒๐๑๓๑

๑๐ กรกฎาคม พ.ศ. ๒๕๖๓

เรื่อง ขอเชิญเป็นผู้ตรวจสอบความตรงตามเนื้อหาของเครื่องมือการวิจัย

เรียน คณบดีคณะพยาบาลศาสตร์ มหาวิทยาลัยมหิดล

สิ่งที่ส่งมาด้วย ๑. เค้าโครงดุษฎีนิพนธ์
๒. เครื่องมือวิจัย

ด้วย นางสาวแสงระวี มณีศรี รหัสประจำตัวนิสิต ๖๑๘๑๐๐๒๔ หลักสูตรปรัชญาดุษฎีบัณฑิต สาขาวิชาพยาบาลศาสตร์ (หลักสูตรนานาชาติ) คณะพยาบาลศาสตร์ มหาวิทยาลัยบูรพา ได้รับอนุมัติเค้าโครงดุษฎีนิพนธ์ เรื่อง "Effectiveness of a Self-Management Support Integrated with the Mobile Health Application Program on Self-Management Behaviors, Blood Pressure, and Estimated Glomerular Filtration Rate among Persons with Chronic Kidney Disease Stage ๓: A Randomized Controlled Trial" โดยมี ผู้ช่วยศาสตราจารย์ ดร.เขมารดี มาสิงบุญ เป็นประธานกรรมการควบคุมดุษฎีนิพนธ์ ซึ่งอยู่ในขั้นตอนการเตรียมเครื่องมือการวิจัย นั้น

เนื่องจากท่านเป็นผู้มีความเชี่ยวชาญเกี่ยวกับการวิจัยดังกล่าวอย่างดียิ่ง ในการนี้ บัณฑิตวิทยาลัย มหาวิทยาลัยบูรพา จึงขอเชิญเป็นผู้ตรวจสอบความตรงตามเนื้อหาของเครื่องมือการวิจัยของนิสิต ดังเอกสารสิ่งที่ส่งมาด้วย

จึงเรียนมาเพื่อโปรดพิจารณา จะเป็นพระคุณยิ่ง

ขอแสดงความนับถือ

(รองศาสตราจารย์ ดร.นุจรี ไชยมงคล)
คณบดีบัณฑิตวิทยาลัย ปฏิบัติการแทน
อธิการบดีมหาวิทยาลัยบูรพา

สำเนาเรียน ๑. รองศาสตราจารย์ ดร.อรวมน ศรียุกตศุทธ
๒. รองศาสตราจารย์ ดร.ดวงรัตน์ วัฒนกิจไกรเลิศ

บัณฑิตวิทยาลัย มหาวิทยาลัยบูรพา
โทร ๐๓๘ ๒๗๐ ๐๐๐ ต่อ ๗๐๗, ๗๐๕
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๒. เครื่องมือวิจัย

ด้วย นางสาวแสงระวี มณีศรี รหัสประจำตัวนิสิต ๖๑๘๑๐๐๒๔ หลักสูตรปรัชญาดุษฎีบัณฑิต สาขาวิชาพยาบาลศาสตร์ (หลักสูตรนานาชาติ) คณะพยาบาลศาสตร์ มหาวิทยาลัยบูรพา ได้รับอนุมัติเค้าโครงดุษฎีนิพนธ์ เรื่อง "Effectiveness of a Self-Management Support Integrated with the Mobile Health Application Program on Self-Management Behaviors, Blood Pressure, and Estimated Glomerular Filtration Rate among Persons with Chronic Kidney Disease Stage ๓: A Randomized Controlled Trial" โดยมี ผู้ช่วยศาสตราจารย์ ดร.เขมารดี มาสิงบุญ เป็นประธานกรรมการควบคุมดุษฎีนิพนธ์ ซึ่งอยู่ในขั้นตอนการเตรียมเครื่องมือการวิจัย นั้น

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คณบดีบัณฑิตวิทยาลัย ปฏิบัติการแทน
อธิการบดีมหาวิทยาลัยบูรพา

(สำเนาเรียน ผู้ช่วยศาสตราจารย์ ดร.มนพร ชาติชำนิ)

บัณฑิตวิทยาลัย มหาวิทยาลัยบูรพา
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๑๐ กรกฎาคม พ.ศ. ๒๕๖๓

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เรียน ผู้อำนวยการโรงพยาบาลสมุทรปราการ

สิ่งที่ส่งมาด้วย ๑. เค้าโครงดุษฎีนิพนธ์
๒. เครื่องมือวิจัย

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จึงเรียนมาเพื่อโปรดพิจารณา จะเป็นพระคุณยิ่ง

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คณบดีบัณฑิตวิทยาลัย ปฏิบัติการแทน
อธิการบดีมหาวิทยาลัยบูรพา

สำเนาเรียน ๑. นายแพทย์ชัยวัฒน์ พิสุทธิ์ไพศาล
๒. พว.สุนทรี เพิ่มพูนสวัสดิ์

บัณฑิตวิทยาลัย มหาวิทยาลัยบูรพา
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APPENDIX B

Instruments

ที่ อว ๘๑๓๗/ ๑๘๔

บัณฑิตวิทยาลัย มหาวิทยาลัยบูรพา
๑๖๙ ถ.ลงหาดบางแสน ต.แสนสุข
อ.เมือง จ.ชลบุรี ๒๐๑๓๑

๒๘ พฤษภาคม พ.ศ. ๒๕๖๓

เรื่อง ขออนุญาตให้นิสิตใช้เครื่องมือวิจัยในการทำวิทยานิพนธ์

เรียน คณบดีบัณฑิตวิทยาลัย มหาวิทยาลัยเชียงใหม่

ด้วยนางสาวแสงรวี มณีศรี รหัสประจำตัว ๖๑๘๑๐๐๒๔ นิสิตหลักสูตรปรัชญาดุษฎีบัณฑิต สาขาวิชาพยาบาลศาสตร์ คณะพยาบาลศาสตร์ ได้รับอนุมัติเค้าโครงวิทยานิพนธ์ เรื่อง ประสิทธิผลของโปรแกรมสนับสนุนการจัดการตนเองร่วมกับแอพลิเคชั่นสุขภาพมือถือต่อพฤติกรรมการจัดการตนเอง ความดันโลหิตและอัตราการกรองของไตของผู้ที่มีโรคไตเรื้อรังระยะที่ ๓: การทดลองแบบสุ่มและมีกลุ่มควบคุม โดยมี ผู้ช่วยศาสตราจารย์ ดร.เขมารดี มาสิงบุญ เป็นประธานกรรมการควบคุมดุษฎีนิพนธ์ มีความประสงค์ขออนุญาตใช้เครื่องมือวิจัยในการทำดุษฎีนิพนธ์ คือ "แบบสอบถามพฤติกรรมการจัดการตนเอง (The Self-Management Behavior Questionnaire)" จากดุษฎีนิพนธ์ เรื่อง แบบจำลองเชิงสาเหตุของการจัดการตนเองของผู้สูงอายุที่เป็นโรคไตเรื้อรังระยะก่อนการบำบัดทดแทนไต ของคุณปริญดา ศรีธราพิพัฒน์ หลักสูตรปรัชญาดุษฎีบัณฑิต สาขาวิชาพยาบาลศาสตร์ คณะพยาบาลศาสตร์ พ.ศ. ๒๕๕๕ ซึ่งมี รองศาสตราจารย์ ดร.ลินจง โปธิบาล เป็นอาจารย์ที่ปรึกษาหลัก

ในการนี้ บัณฑิตวิทยาลัย มหาวิทยาลัยบูรพา จึงขออนุญาตให้นางสาวแสงรวี มณีศรี ใช้เครื่องมือวิจัยในการทำดุษฎีนิพนธ์ ทั้งนี้ สามารถติดต่อนิสิตได้ที่เบอร์โทรศัพท์ ๐๘-๐๒๒๑-๕๒๒๙ หรือที่ E-mail: sangrawee.m@rsu.ac.th

จึงเรียนมาเพื่อโปรดทราบและพิจารณาอนุญาต จักขอบพระคุณยิ่ง

ขอแสดงความนับถือ

(รองศาสตราจารย์ ดร.นุจรี ไชยมงคล)
คณบดีบัณฑิตวิทยาลัย ปฏิบัติการแทน
ผู้รักษาการแทนอธิการบดีมหาวิทยาลัยบูรพา

บัณฑิตวิทยาลัย มหาวิทยาลัยบูรพา
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ที่ อว ๘๑๓๗/ว ๒๒

บัณฑิตวิทยาลัย มหาวิทยาลัยบูรพา
๑๖๙ ถ.ลงหาดบางแสน ต.แสนสุข
อ.เมือง จ.ชลบุรี ๒๐๑๓๑

๑๐ กันยายน พ.ศ. ๒๕๖๓

เรื่อง ขออนุญาตให้นิสิตใช้เครื่องมือวิจัยในการทำวิทยานิพนธ์

เรียน คณบดีคณะแพทยศาสตร์ โรงพยาบาลรามาธิบดี มหาวิทยาลัยมหิดล

ด้วยนางสาวแสงรวี มณีศรี รหัสประจำตัว ๖๑๘๑๐๐๒๔ นิสิตหลักสูตรปรัชญาดุษฎีบัณฑิต สาขาวิชาพยาบาลศาสตร์ คณะพยาบาลศาสตร์ ได้รับอนุมัติเค้าโครงวิทยานิพนธ์ เรื่อง ประสิทธิผลของโปรแกรมสนับสนุนการจัดการตนเองร่วมกับแอพลิเคชั่นสุขภาพมือถือต่อพฤติกรรมการจัดการตนเอง ความดันโลหิตและอัตราการกรองของไตของผู้ที่มีโรคไตเรื้อรังระยะที่ ๓: การทดลองแบบสุ่มและมีกลุ่มควบคุม โดยมี ผู้ช่วยศาสตราจารย์ ดร.เขมารดี มาสิงบุญ เป็นประธานกรรมการควบคุมดุษฎีนิพนธ์ มีความประสงค์ขออนุญาตใช้เครื่องมือวิจัยในการทำดุษฎีนิพนธ์ คือ “สื่อวิดีโอจาก Rama Channel รายการวาไรตี้ (Kidney Variety) EP.1 รู้จักกับ “ไต” part 1-3, part 2-3, part 3-3 และ EP.4 ไตวายเรื้อรังในระยะเริ่มต้น-ระยะปานกลาง part 1-3, part 2-3, part 3-3”

ในการนี้ บัณฑิตวิทยาลัย มหาวิทยาลัยบูรพา จึงขออนุญาตให้นางสาวแสงรวี มณีศรี ใช้เครื่องมือดังกล่าวในการทำดุษฎีนิพนธ์ ทั้งนี้ สามารถติดต่อนิสิตได้ที่เบอร์โทรศัพท์ ๐๘-๑๒๒๑-๕๒๒๙ หรือที่ E-mail: sangrawee.m@rsu.ac.th

จึงเรียนมาเพื่อโปรดทราบและพิจารณาอนุญาต จักขอบพระคุณยิ่ง

ขอแสดงความนับถือ

(รองศาสตราจารย์ ดร.นุจรี ไชยมงคล)
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อธิการบดีมหาวิทยาลัยบูรพา

บัณฑิตวิทยาลัย มหาวิทยาลัยบูรพา
โทร ๐๓๘ ๑๐๒ ๗๐๐ ต่อ ๗๐๗, ๗๐๕
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สำเนาเรียน รองคณบดีฝ่ายสื่อสารองค์กร คณะแพทยศาสตร์ โรงพยาบาลรามาธิบดี มหาวิทยาลัยมหิดล

แบบทดสอบสมรรถภาพทางสมองของไทย

The Thai mental state examination (TMSE)

คำชี้แจง: แบบทดสอบสมรรถภาพทางสมองของไทย ใช้เพื่อทดสอบความรู้และความเข้าใจในการทำงานของสมองซึ่งใช้กันอย่างแพร่หลายในการคัดกรองภาวะสมองเสื่อมและความบกพร่องทางสติปัญญาในผู้สูงอายุ การทดสอบแบบคัดกรองนี้มีคะแนนเต็ม 30 คะแนน หากคะแนน ≤ 23 คะแนน ก็หมายความว่ามีภาวะสมองเสื่อมหรือมีความบกพร่องทางสติปัญญาในผู้สูงอายุ

คำถาม	คะแนนเต็ม	คะแนนที่ได้
1. Orientation (6 คะแนน)		
วัน, วันที่, เดือน, ช่วงของวัน	4	
ที่นี่ที่ไหน	1	
คนที่เห็นในภาพนี้มีอาชีพอะไร 	1	
2. Registration (3 คะแนน) บอกของ 3 อย่างแล้วให้พูดตาม ต้นไม้ รถยนต์ มือ	3	
3. Attention (5 คะแนน) บอกวันย้อนหลัง อาทิตย์ เสาร์ ศุกร์ พฤหัสบดี พุธ อังคาร จันทร์	5	
…………………………………………………………………		
…………………………………………………………………		
…………………………………………………………………		
6. Recall (3 คะแนน) ถามของ 3 อย่างที่ให้จำตามข้อ 2 ต้นไม้ รถยนต์ มือ	3	
คะแนนรวม	30	

แบบสอบถามข้อมูลส่วนบุคคล
The demographic data record form

ตอนที่ 1: ข้อมูลทั่วไปของกลุ่มตัวอย่าง

คำชี้แจง: โปรดทำเครื่องหมาย ✓ ลงในช่อง [ ] หรือใส่ข้อความในช่องว่างให้ตรงกับความเป็นจริงของตัวท่านมากที่สุด

1. เพศ [ ] ชาย [ ] หญิง
2. อายุ ....ปี...................เดือน
3. ศาสนา [ ] พุทธ [ ] คริสต์ [ ] อิสลาม [ ] อื่นๆ..........
4. สถานภาพสมรส [ ] โสด [ ] สมรส [ ] แยกกันอยู่ [ ] อย่างร้าง [ ] หม้าย
5. ระดับการศึกษา [ ] ประถมศึกษา [ ] มัธยมศึกษา [ ] อนุปริญญา [ ] ปริญญาตรี [ ] ปริญญาโท [ ] ปริญญาเอก

....

....

11. การใช้อุปกรณ์เทคโนโลยี
    โทรศัพท์มือถือ [ ] ไม่เคยใช้ [ ] 1-2 วัน/สัปดาห์ [ ] 3-4 วัน/สัปดาห์ [ ] 5-7 วัน/สัปดาห์
12. การใช้แอพพลิเคชั่นโทรศัพท์มือถือ
    [ ] ไม่เคยใช้ [ ] 1-2 วัน/สัปดาห์ [ ] 3-4 วัน/สัปดาห์ [ ] 5-7 วัน/สัปดาห์

ตอนที่ 2: ข้อมูลทั่วไปของครอบครัว

1. จำนวนสมาชิกในครอบครัว ....คน
2. ผู้ดูแลหลัก [ ] บิดา [ ] มารดา [ ] สามี [ ] ภรรยา [ ] บุตรชาย [ ] บุตรสาว [ ] อื่นๆ.....................

....

....

....

5. สุขภาพของผู้ดูแลหลัก [ ] สุขภาพแข็งแรง [ ] มีโรคประจำตัว

ตอนที่ 3: ข้อมูลสุขภาพของผู้เข้าร่วม (บันทึกโดยนักวิจัย)

1. ระยะของโรคไตเรื้อรัง [ ] ระยะ 3a [ ] ระยะ 3b

2. ระยะเวลาการเจ็บป่วยด้วยโรคไตเรื้อรัง ………………..ปี………..........เดือน

3. น้ำหนัก…………กิโลกรัม ส่วนสูง………เซ็นติเมตร ดัชนีมวลกาย………กิโลกรัม/ตารางเมตร

4. Serum creatinine……………….mg/dl (วันที่………/………../……....)

……………………………………………………………………………………………
…..…………………………………………………………………………………………
……….
……………………………………………………………………………………………
…..

10. โรคร่วม [ ] ความดันโลหิตสูง [ ] เบาหวาน [ ] ไขมันในเลือดสูง
[ ] โรคหัวใจ [ ] โรคเก๊าท์ [ ] โรคอื่นๆ……………

11. ยาที่ได้รับ [ ] ยาความดันโลหิตสูง ระบุชื่อยา...
[ ] โรคหัวใจ [ ] เบาหวาน [ ] ไขมันในเลือดสูง
[ ] โรคเก๊าท์ [ ] สมุนไพร [ ] ยาแก้ปวด
[ ] อาหารเสริม/วิตามิน [ ] อื่นๆ………………………………………

12. กาประวัติการนอนโรงพยาบาล 1 ปีที่ผ่านมา………………ครั้ง

การวินิจฉัยโรค…………………………………………………………………….....................

แบบสอบถามพฤติกรรมการจัดการตนเอง

The Self-Management Behaviors Questionnaire (SMBQ)

คำชี้แจง แบบสอบถามส่วนนี้เป็นแบบประเมินในการปฏิบัติพฤติกรรมการจัดการตนเองของผู้ที่มีโรคไตเรื้อรังระยะที่ 3 ขอให้ท่านโปรดตอบข้อคำถามทีละข้อ โดยเลือกตอบเพียงคำตอบเดียวในแต่ละข้อ ซึ่งคำตอบของท่านไม่มีถูกหรือผิด และขอความกรุณาตอบคำถามให้ครบทุกข้อ โดยทำเครื่องหมาย ✓ ลงในช่องที่ตรงกับพฤติกรรมที่ท่านได้ปฏิบัติเกี่ยวกับการจัดการตนเองขณะป่วยเป็นโรคไตเรื้อรังในช่วง 1 เดือนที่ผ่านมา ซึ่งได้กระทำตามความเป็นจริงที่สุดใน 5 ระดับ คือ

5 หมายถึง ท่านมีพฤติกรรมหรือกระทำกิจกรรมตามข้อความนั้น**เป็นประจำอย่างสม่ำเสมอ**

4 หมายถึง ท่านมีพฤติกรรมหรือกระทำกิจกรรมตามข้อความนั้น**บ่อยครั้งแต่ไม่สม่ำเสมอ**

3 หมายถึง ท่านมีพฤติกรรมหรือกระทำกิจกรรมตามข้อความนั้น**นาน ๆ ครั้ง**

2 หมายถึง ท่านมีพฤติกรรมหรือกระทำกิจกรรมตามข้อความนั้น**น้อยมาก**

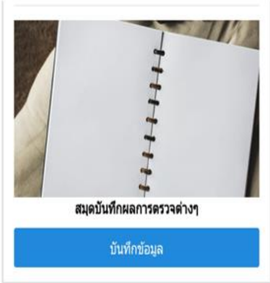
1 หมายถึง ท่าน**ไม่มี**พฤติกรรมหรือ**ไม่ได้กระทำ**กิจกรรมตามข้อความนั้น

ข้อความ	5	4	3	2	1
Self-care (กิจกรรมการดูแลตนเอง)					
1. ควบคุมระดับน้ำตาลในเลือดของตนเองให้อยู่ในระดับปกติ					
2. ได้ไปตรวจตามกำหนดเวลานัดของโรงพยาบาล					
3. ควบคุมระดับความดันโลหิตของตนเองให้อยู่ในระดับปกติ					
....					
....					
....					
35. ท่านได้เข้าฟังการบรรยายหรือการสอนการให้ความรู้โรคไตเรื้อรัง					
36. ท่านได้ค้นหาวิธีการรักษาอื่น ๆ เพื่อแก้ไขปัญหาความเจ็บป่วย อาการหรือผลข้างเคียงที่เกิดขึ้นจากการรักษาโรคไตเรื้อรัง					
37. ท่านได้เขียนหรือเตรียมคำถามเกี่ยวกับโรคไตเรื้อรังหรือการรักษาไว้สอบถามแพทย์/พยาบาลก่อนเข้าพบ					
คะแนนรวม...........................					

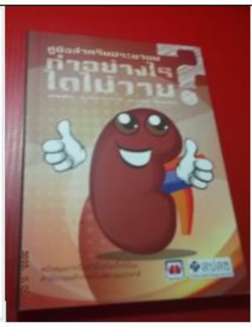
แอพพลิเคชั่นสุขภาพมือถือ

Mobile Health Application

เมนูหลัก



เมนูหลัก



โปรแกรมสนับสนุนการจัดการตนเองร่วมกับแอพพลิเคชั่นสุขภาพมือถือ ต่อพฤติกรรมการจัดการตนเอง ความดันโลหิต และอัตราการกรองของไต ของผู้ที่มีโรคไตเรื้อรังระยะที่ 3: การทดลองแบบสุ่มและมีกลุ่มควบควบคุม

ประกอบด้วย 4 ระยะคือ ระยะก่อนการทดลอง ระยะทดลอง ระยะหลังการทดลอง และระยะติดตามผล โดยระยะทดลองประกอบด้วย 4 Session ใช้เวลา 4 สัปดาห์ ซึ่งมีกิจกรรมดังตารางที่ 1

ตารางที่ 1 กิจกรรมของโปรแกรมสนับสนุนการจัดการตนเองร่วมกับแอพพลิเคชั่นสุขภาพมือถือ ของผู้ที่มีโรคไตเรื้อรังระยะที่ 3

กิจกรรม	สัปดาห์	ครั้งที่	ผู้ดำเนินการ	รูปแบบ	เวลา
Session 1: ระบุและประเมินปัจจัยเสี่ยงและปัจจัยป้องกัน (Identifying and measuring risks and protective factors)	1	1	ผู้วิจัย	รายบุคคล	30 นาที
Session 2: ให้ความรู้และความเชื่อด้านการดูแล (Providing knowledge and caring beliefs)	2	2	ผู้วิจัยและผู้ช่วยวิจัย	กลุ่มย่อย	60 นาที
Session 3: พัฒนาทักษะการควบคุมตนเองและสนับสนุนการจัดการตนเองโดยสมาชิกในครอบครัวและแอพพลิเคชั่นสุขภาพมือถือ (Developing self-regulation skills and providing support from family and mHealth application)	2	2	ผู้วิจัย ผู้ช่วยวิจัย และผู้เชี่ยวชาญด้านเทคโนโลยีการสื่อสาร	อบรมเชิงปฏิบัติการ	120 นาที
Session 4: พัฒนาความสามารถในการประเมินตนเองและจัดการการตอบสนองที่เกิดจากการเปลี่ยนแปลงพฤติกรรมสุขภาพ (Developing abilities in self-evaluation and management of responses associated with health behaviors change)	4	3	ผู้วิจัย	รายบุคคล	30 นาที

ระยะทดลอง:

สัปดาห์ที่ 1 Session 1 ระบุและประเมินปัจจัยเสี่ยงและปัจจัยป้องกัน (Identifying and measuring risk and protective factors) ดำเนินกิจกรรมการวิจัย ณ ห้องประชุมคลินิกชะลอไตเสื่อม โรงพยาบาลสมุทรปราการ ใช้เวลา 30 นาที ทำกิจกรรมเป็นรายบุคคล

วัตถุประสงค์	กิจกรรมผู้วิจัย/ผู้ช่วยวิจัย	กิจกรรมกลุ่มตัวอย่าง	เวลา	สื่อ/อุปกรณ์/เครื่องมือ
		กลุ่มทดลอง		
1. เพื่อค้นหาและระบุปัจจัยที่สนับสนุนหรือเป็นอุปสรรคต่อการจัดการตนเองเกี่ยวกับโรคไตเรื้อรัง	1.1 สอบถามเกี่ยวกับบริบทของกลุ่มตัวอย่างที่ส่งผลการจัดการตนเองเกี่ยวกับโรคไตเรื้อรัง ได้แก่ 1) ปัจจัยเฉพาะโรค 2) ปัจจัยด้านกายภาพและสิ่งแวดล้อม และ 3) ปัจจัยส่วนบุคคลและครอบครัว	1.1 อธิบายเกี่ยวกับบริบทของตนเองและครอบครัวใน 3 ปัจจัย - ปัจจัยเฉพาะโรค เช่น อาการแสดงของโรค ความรุนแรงของโรค โรคร่วม การรักษา และผลกระทบของต่อการดำเนินชีวิต - ปัจจัยด้านกายภาพและสิ่งแวดล้อม เช่น การเข้าถึงบริการสุขภาพและระบบการส่งต่อ การดูแลรักษาการทำงาน ศาสนาหรือวัฒนธรรม - ปัจจัยส่วนบุคคลและครอบครัว เช่น ความรู้และความเชื่อเกี่ยวกับโรคไตเรื้อรัง สัมพันธภาพในครอบครัว และเศรษฐานะ	30 นาที	- ใบงานที่ 1 ระบุปัจจัยที่สนับสนุนหรือเป็นอุปสรรคต่อการจัดการตนเองเกี่ยวกับโรคไตเรื้อรัง 3 ปัจจัย ได้แก่ 1) ปัจจัยเฉพาะโรค 2) ปัจจัยด้านกายภาพและสิ่งแวดล้อม 3) ปัจจัยส่วนบุคคลและครอบครัว
	1.2 ให้กลุ่มตัวอย่างระบุว่าปัจจัยใดบ้างที่ช่วยสนับสนุนหรือเป็นอุปสรรคต่อการจัดการตนเองเกี่ยวกับโรคไตเรื้อรัง	1.2 ระบุปัจจัยที่สนับสนุนและเป็นอุปสรรคต่อการจัดการตนเองเกี่ยวกับโรคไตเรื้อรัง ในใบงานที่ 1		

สัปดาห์ที่ 4 Session 4 พัฒนาความสามารถในการประเมินตนเองและจัดการการตอบสนองที่เกิดจากการเปลี่ยนแปลงพฤติกรรมสุขภาพ (Developing abilities in self-evaluation and management of responses associated with health behavior change) ดำเนินกิจกรรมการวิจัย ณ ห้องประชุมคลินิกชะลอไตเสื่อม โรงพยาบาลสมุทรปราการ ใช้เวลา 30 นาที ทำกิจกรรมเป็นรายบุคคล

วัตถุประสงค์	**กิจกรรมผู้วิจัย/ผู้ช่วยวิจัย**	**กิจกรรมกลุ่มตัวอย่างและสมาชิกในครอบครัว**	**เวลา**	**สื่อ/อุปกรณ์**
		กลุ่มทดลอง		
1. เพื่อส่งเสริมให้กลุ่มตัวอย่างสามารถประเมินผลการจัดการตนเองได้อย่างถูกต้อง	1.1 กระตุ้นให้กลุ่มตัวอย่างประเมิน ผลการจัดการตนเอง ตามปัญหาที่ตั้งไว้ในใบงานที่ 4 ใน Session ที่ 3	1.1 ประเมินผลการจัดการตนเองตามเป้าหมายที่ตั้งไว้ในใบงานที่ 4 ในSession ที่ 3	10 นาที	- ใบงานที่ 4 การตั้งเป้าหมายในการจัดการตนเอง
2. เพื่อให้กลุ่มตัวอย่างมีการจัดการการตอบสนองที่เกิดขึ้นจากการเปลี่ยน แปลงพฤติกรรมการจัดการตนเองได้อย่างเหมาะสม	2.1 ให้กลุ่มตัวอย่างวิเคราะห์การตอบสนองทางร่างกายและอารมณ์ที่เกี่ยวข้องกับการเปลี่ยนแปลงพฤติกรรมการจัดการตนเองและวิธีการจัดการ	2.1 วิเคราะห์การตอบสนองทางร่างกายและอารมณ์ที่เกี่ยวข้องกับการเปลี่ยนแปลงพฤติกรรมการจัดการตนเองและวิธีการจัดการ	10 นาที	- ใบงานที่ 5 การตอบสนองที่เกิดขึ้นจากการปรับเปลี่ยนพฤติกรรมการจัดการตนเอง
3. เพื่อให้ทราบถึงประโยชน์ ปัญหาอุปสรรคของการใช้แอพพลิเคชั่นสุขภาพมือถือและการนำสมาชิกในครอบครัวเข้าร่วมในโปรแกรมวิจัย	3.1 สอบถามเกี่ยวกับประโยชน์ ปัญหาอุปสรรคของการใช้แอพพลิเคชั่นสุขภาพมือถือและการนำสมาชิกในครอบครัวเข้าร่วมในโปรแกรมวิจัย	3.1 อธิบายประโยชน์ ปัญหาอุปสรรคของการใช้แอพพลิเคชั่นสุขภาพมือถือและการนำสมาชิกในครอบครัวเข้าร่วมในโปรแกรมวิจัย	10 นาที	- ใบงานที่ 6 ประโยชน์/อุปสรรคของโปรแกรมวิจัย - ใบงานที่ 7 ประเมินความพึงพอใจต่อ mHealth application

APPENDIX C

Ethical document

ที่ ๐๕๒/๒๕๖๓

เอกสารรับรองผลการพิจารณาจริยธรรมการวิจัยในมนุษย์
มหาวิทยาลัยบูรพา

คณะกรรมการพิจารณาจริยธรรมการวิจัยในมนุษย์ มหาวิทยาลัยบูรพา ได้พิจารณาโครงการวิจัย

รหัสโครงการวิจัย : G-HS 064/2563
โครงการวิจัยเรื่อง : ประสิทธิผลของโปรแกรมสนับสนุนการจัดการตนเองร่วมกับแอพพลิเคชั่นสุขภาพมือถือต่อพฤติกรรมการจัดการตนเอง ความดันโลหิตและอัตราการกรองของไต ของผู้ที่มีโรคไตเรื้อรังระยะที่ ๓: การทดลองแบบสุ่มและมีกลุ่มควบคุม
หัวหน้าโครงการวิจัย : นางสาวแสงรวี มณีศรี
หน่วยงานที่สังกัด : นิสิตระดับบัณฑิตศึกษา คณะพยาบาลศาสตร์

คณะกรรมการพิจารณาจริยธรรมการวิจัยในมนุษย์ มหาวิทยาลัยบูรพา ได้พิจารณาแล้วเห็นว่า โครงการวิจัยดังกล่าวเป็นไปตามหลักการของจริยธรรมการวิจัยในมนุษย์ โดยที่ผู้วิจัยเคารพสิทธิและศักดิ์ศรีในความเป็นมนุษย์ ไม่มีการล่วงละเมิดสิทธิ สวัสดิภาพ และไม่ก่อให้เกิดภยันตรายแก่ตัวอย่างการวิจัยและผู้เข้าร่วมโครงการวิจัย

จึงเห็นสมควรให้ดำเนินการวิจัยในขอบข่ายของโครงการวิจัยที่เสนอได้ (ดูตามเอกสารตรวจสอบ)

๑. แบบเสนอเพื่อขอรับการพิจารณาจริยธรรมการวิจัยในมนุษย์	ฉบับที่ ๒ วันที่ ๘ เดือน กันยายน พ.ศ. ๒๕๖๓
๒. เอกสารโครงการวิจัยฉบับภาษาไทย	ฉบับที่ ๒ วันที่ ๘ เดือน กันยายน พ.ศ. ๒๕๖๓
๓. เอกสารชี้แจงผู้เข้าร่วมโครงการวิจัย	ฉบับที่ ๒ วันที่ ๘ เดือน กันยายน พ.ศ. ๒๕๖๓
๔. เอกสารแสดงความยินยอมของผู้เข้าร่วมโครงการวิจัย	ฉบับที่ ๑ วันที่ ๒๓ เดือน กรกฎาคม พ.ศ. ๒๕๖๓
๕. เอกสารแสดงรายละเอียดเครื่องมือที่ใช้ในการวิจัยซึ่งผ่านการพิจารณาจากผู้ทรงคุณวุฒิแล้ว หรือชุดที่ใช้เก็บข้อมูลจริงจากผู้เข้าร่วมโครงการวิจัย	ฉบับที่ ๑ วันที่ ๒๓ เดือน กรกฎาคม พ.ศ. ๒๕๖๓
๖. เอกสารอื่น ๆ (ถ้ามี)	ฉบับที่ - วันที่ - เดือน - พ.ศ. -

วันที่รับรอง : วันที่ ๑๖ เดือน กันยายน พ.ศ. ๒๕๖๓
วันที่หมดอายุ : วันที่ ๑๕ เดือน กันยายน พ.ศ. ๒๕๖๔

ลงนาม
(รองศาสตราจารย์ ดร.วิทวัส แจ้งเอี่ยม)
ประธานคณะกรรมการพิจารณาจริยธรรมการวิจัยในมนุษย์ มหาวิทยาลัยบูรพา
ชุดที่ ๑ (กลุ่มคลินิก/ วิทยาศาสตร์สุขภาพ/ วิทยาศาสตร์และเทคโนโลยี)

หนังสือรับรองจริยธรรมการวิจัยในมนุษย์
โรงพยาบาลสมุทรปราการ

การวิจัยนี้และเอกสารประกอบของการวิจัยตามรายการแสดงด้านล่าง ได้รับการพิจารณาจาก คณะกรรมการพิจารณาจริยธรรมการวิจัยในมนุษย์ โรงพยาบาลสมุทรปราการแล้ว มีความเห็นว่าการวิจัยที่จะดำเนินการมีความสอดคล้องกับหลักจริยธรรมสากล ตลอดจนกฎหมายข้อบังคับและข้อกำหนดภายในประเทศ จึงเห็นสมควรให้ดำเนินการวิจัยตามข้อเสนอการวิจัยนี้ได้

ชื่อการวิจัย (ไทย) : ประสิทธิผลของโปรแกรมสนับสนุนการจัดการตนเองร่วมกับแอพพลิเคชั่นสุขภาพมือถือต่อพฤติกรรมการจัดการตนเอง ความดันโลหิต และอัตราการกรองของไต ของผู้ที่มีโรคไตเรื้อรังระยะที่ 3 : การทดลองแบบสุ่มและมีกลุ่มควบคุม

ชื่อการวิจัย (อังกฤษ) : Effectiveness of a Self-Management Support Integrated with the Mobile Health Application Program on Self-Management Behaviors, Blood Pressure, And Estimated Glomerular Filtration Rate among Persons with Chronic Kidney Disease Stage 3 : A Randomized Controlled Trial.

ผู้วิจัย : นางสาวแสงรวี มณีศรี

หน่วยงานที่สังกัด : คณะพยาบาลศาสตร์ มหาวิทยาลัยบูรพา

ลงนาม..	ลงนาม..
(นายประภากร จำนงประสาทพร)	(นางกัลยา ตีระวัฒนานนท์)
ประธานคณะกรรมการพิจารณาจริยธรรมการวิจัยในมนุษย์ โรงพยาบาลสมุทรปราการ	ประธานคณะกรรมการพัฒนางานวิจัย โรงพยาบาลสมุทรปราการ

หมายเลขรับรอง : Oq05463
วันที่รับรอง : 9 พฤศจิกายน 2563
วันที่รับรองหมดอายุ : 8 พฤศจิกายน 2564

HRD2/D/PAN5/งานวิจัย/รับรองจริยธรรม

เอกสารแสดงความยินยอม

ของผู้เข้าร่วมโครงการวิจัย (Consent Form)

รหัสโครงการวิจัย : …………G-HS 064/2563……….

โครงการวิจัยเรื่อง ประสิทธิผลของโปรแกรมสนับสนุนการจัดการตนเองร่วมกับแอพพลิเคชั่นสุขภาพมือถือ ต่อพฤติกรรมการจัดการตนเอง ความดันโลหิต และอัตราการกรองของไต ของผู้ที่มีโรคไตเรื้อรังระยะที่ 3: การทดลองแบบสุ่มและมีกลุ่มควบควบคุม

ให้คำยินยอม วันที่ …….......….. เดือน ………..........…..……… พ.ศ. ………………

ก่อนที่จะลงนามในเอกสารแสดงความยินยอมของผู้เข้าร่วมโครงการวิจัยนี้ ข้าพเจ้าได้รับการอธิบายถึงวัตถุประสงค์ของโครงการวิจัย วิธีการวิจัย และรายละเอียดต่าง ๆ ตามที่ระบุในเอกสารข้อมูลสำหรับผู้เข้าร่วมโครงการวิจัย ซึ่งผู้วิจัยได้ให้ไว้แก่ข้าพเจ้า และข้าพเจ้าเข้าใจคำอธิบายดังกล่าวครบถ้วนเป็นอย่างดีแล้ว และผู้วิจัยรับรองว่าจะตอบคำถามต่าง ๆ ที่ข้าพเจ้าสงสัยเกี่ยวกับการวิจัยนี้ด้วยความเต็มใจ และไม่ปิดบังซ่อนเร้นจนข้าพเจ้าพอใจ

ข้าพเจ้าเข้าร่วมโครงการวิจัยนี้ด้วยความสมัครใจ และมีสิทธิที่จะบอกเลิกการเข้าร่วมโครงการวิจัยนี้เมื่อใดก็ได้ การบอกเลิกการเข้าร่วมการวิจัยนั้นไม่มีผลกระทบต่อการรักษาโรคที่ข้าพเจ้าจะพึงได้รับต่อไป ผู้วิจัยรับรองว่าจะเก็บข้อมูลเกี่ยวกับตัวข้าพเจ้าเป็นความลับ จะเปิดเผยได้เฉพาะในส่วนที่เป็นสรุปผลการวิจัย การเปิดเผยข้อมูลของข้าพเจ้าต่อหน่วยงานต่าง ๆ ที่เกี่ยวข้องต้องได้รับอนุญาตจากข้าพเจ้า

ข้าพเจ้าได้อ่านข้อความข้างต้นแล้วมีความเข้าใจดีทุกประการ และได้ลงนามในเอกสารแสดงความยินยอมนี้ด้วยความเต็มใจ กรณีที่ข้าพเจ้าไม่สามารถอ่านหรือเขียนหนังสือได้ ผู้วิจัยได้อ่านข้อความในเอกสารแสดงความยินยอมให้แก่ข้าพเจ้าฟังจนเข้าใจดีแล้ว ข้าพเจ้าจึงลงนามหรือประทับลายนิ้วหัวแม่มือของข้าพเจ้าในเอกสารแสดงความยินยอมนี้ด้วยความเต็มใจ

ลงนาม ……………………………...………………… ผู้ยินยอม

(…………………………………………………..)

ลงนาม ………………………..……………………..พยาน

(……………………………………………………)

เอกสารชี้แจงผู้เข้าร่วมโครงการวิจัย

(Participant Information Sheet)

(สำหรับกลุ่มทดลอง)

รหัสโครงการวิจัย : …………G-HS 064/2563……….
โครงการวิจัยเรื่อง : ประสิทธิผลของโปรแกรมสนับสนุนการจัดการตนเองร่วมกับแอพพลิเคชั่นสุขภาพมือถือ ต่อพฤติกรรมการจัดการตนเอง ความดันโลหิต และอัตราการกรองของไต ของผู้ที่มีโรคไตเรื้อรังระยะที่ 3: การทดลองแบบสุ่มและมีกลุ่มควบควบคุม
เรียน ผู้เข้าร่วมโครงการวิจัย

ข้าพเจ้า นางสาวแสงรวี มณีศรี นิสิตปริญญาเอก คณะพยาบาลศาสตร์ มหาวิทยาลัยบูรพา ขอเรียนเชิญท่านเข้าร่วมโครงการวิจัยประสิทธิผลของโปรแกรมสนับสนุนการจัดการตนเองร่วมกับแอพพลิเคชั่นสุขภาพมือถือ ของผู้ที่มีโรคไตเรื้อรังระยะที่ 3 ก่อนที่ท่านจะตกลงเข้าร่วมการวิจัย ขอเรียนให้ท่านทราบรายละเอียดของโครงการวิจัยดังนี้

โครงการวิจัยนี้มีวัตถุประสงค์เพื่อประเมินผลของโปรแกรมสนับสนุนการจัดการตนเองร่วมกับแอพพลิเคชั่นสุขภาพมือถือ ต่อพฤติกรรมการจัดการตนเอง ความดันโลหิต และอัตราการกรองของไต ของผู้ที่มีโรคไตเรื้อรังระยะที่ 3 ทั้งนี้เพื่อประโยชน์ในการชะลอความก้าวหน้าของโรคไตเรื้อรัง

หากท่านตกลงที่จะเข้าร่วมการศึกษาวิจัยนี้ ข้าพเจ้าขอความร่วมมือให้ท่านร่วมกิจกรรมของโครงการฯ โดยการตอบแบบสอบถามข้อมูลส่วนบุคคลและแบบสอบถามพฤติกรรมการจัดการตนเอง จำนวน 3 ครั้ง ครั้งที่ 1 คือครั้งแรกที่พบผู้วิจัย (สัปดาห์ 1) ครั้งที่ 2 เมื่อเสร็จสิ้นกิจกรรมกลุ่ม (สัปดาห์ 4) และครั้งที่ 3 (สัปดาห์ 12) แต่ละครั้งใช้เวลาในการตอบประมาณ 45 นาที นอกจากนี้ผู้วิจัยจะขอให้ท่านเข้าร่วมกิจกรรมกลุ่มที่ผู้วิจัยพัฒนาขึ้น จำนวน 4 ครั้ง ณ ห้องประชุมคลินิกชะลอไตเสื่อม โรงพยาบาลสมุทรปราการ ดังนี้ ครั้งที่ 1 (สัปดาห์ 1) กิจกรรมการระบุและประเมินปัจจัยเสี่ยง/ปัจจัยป้องกัน ใช้เวลา 30 นาที ครั้งที่ 2 (สัปดาห์ 2) กิจกรรมการให้ความรู้และความเชื่อในการดูแล ใช้เวลา 1 ชั่วโมง ครั้งที่ 3 (สัปดาห์ 3) กิจกรรมพัฒนาทักษะการควบคุมตนเอง รวมทั้งการสนับสนุนการจัดการตนเองจากสมาชิกในครอบครัวและแอพพลิเคชั่นสุขภาพมือถือ ใช้เวลา 2 ชั่วโมง และครั้งที่ 4 (สัปดาห์ 4) กิจกรรมการพัฒนาความสามารถในการประเมินตนเองและจัดการ

การตอบสนองที่เกิดจากการเปลี่ยนแปลงพฤติกรรมสุขภาพ ใช้เวลา 30 นาที ซึ่งการนัดหมายเพื่อมาทำกิจกรรมในครั้งที่ 1 และตอบแบบสอบถามครั้งที่ 1 และ 3 เป็นการนัดหมายเพื่อตรวจรักษาปกติของโรงพยาบาล ส่วนการนัดหมายเพื่อมาทำกิจกรรมในครั้งที่ 2, 3, 4 และตอบแบบสอบถามในครั้งที่ 2 เป็นการนัดหมายเพื่อมาทำกิจกรรมของโครงการวิจัย ผู้วิจัยจะมีค่าชดเชยการเดินทางหรือชดเชยการเสียเวลาให้แก่ท่านและสมาชิกในครอบครัว จำนวน 200 บาท/คน/ครั้ง และเมื่อเข้าร่วมงานวิจัยจนเสร็จสิ้นโปรแกรมท่านจะได้รับเครื่องวัดความดันโลหิตแบบดิจิตอล 1 เครื่อง

ผลของการวิจัยนี้เป็นประโยชน์ต่อตัวท่านและสมาชิกในครอบครัว ที่จะได้เรียนรู้และพัฒนาทักษะในการจัดการตนเองในเรื่องการควบคุมอาหาร การรับประทานยา การออกกำลังกาย และการควบคุมความดันโลหิต นอกจากนั้นยังได้แอพพลิเคชั่นมือถือในการค้นหาความรู้ ติดต่อสื่อสารกับบุคคลากรสุขภาพ บันทึกและติดตามผลตรวจทางห้องปฏิบัติการและความดันโลหิต มีการแจ้งเตือนเมื่อพบความผิดปกติพร้อมทั้งให้คำแนะนำ ซึ่งส่งผลให้เกิดการปรับเปลี่ยนพฤติกรรมการจัดการตนเอง สามารถควบคุมความดันโลหิต และชะลอการเสื่อมของไต

การเข้าร่วมโครงการวิจัยนี้เป็นไปด้วยความสมัครใจ ท่านมีสิทธิปฏิเสธการเข้าร่วมโครงการวิจัยได้และสามารถถอนตัวออกจากการเป็นผู้เข้าร่วมโครงการวิจัยได้ทุกเมื่อ โดยการปฏิเสธหรือถอนตัวของท่านจะไม่มีผลกระทบต่อสิทธิประการใด ๆ ที่ท่านจะพึงได้รับ ข้อมูลต่าง ๆ ของท่านจะถูกเก็บไว้เป็นความลับและจะไม่มีการเปิดเผยชื่อของท่าน การนำเสนอข้อมูลจะเป็นในภาพรวม ทั้งนี้ข้อมูลจะถูกเก็บไว้ในเครื่องคอมพิวเตอร์ที่มีรหัสผ่านของคณะผู้วิจัยเท่านั้น ส่วนเอกสารจะเก็บไว้ในตู้เอกสารที่ใส่กุญแจไว้เป็นเวลา 1 ปี หลังการเผยแพร่ผลการวิจัยและจะถูกนำไปทำลายหลังจากนั้น

หากท่านมีคำถามหรือข้อสงสัยประการใดสามารถติดต่อข้าพเจ้า นางสาวแสงรวี มณีศรี คณะพยาบาลศาสตร์ มหาวิทยาลัยบูรพา หมายเลขโทรศัพท์ 080-2215229 ข้าพเจ้ายินดีตอบคำถามและข้อสงสัยของท่านทุกเมื่อ หรือติดต่อที่ ผู้ช่วยศาสตราจารย์ ดร. เขมารดี มาสิงบุญ อาจารย์ที่ปรึกษาหลัก หมายเลขโทรศัพท์ 081-9875586 และถ้าผู้วิจัยไม่ปฏิบัติตามที่ได้ชี้แจงไว้ในเอกสารชี้แจงผู้เข้าร่วมโครงการวิจัย สามารถแจ้งมายังคณะกรรมการพิจารณาจริยธรรมการวิจัยในมนุษย์ มหาวิทยาลัยบูรพา กองบริหารการวิจัยและนวัตกรรม หมายเลขโทรศัพท์ 038-102620

เมื่อท่านพิจารณาแล้วเห็นสมควรเข้าร่วมในการวิจัยนี้ ขอความกรุณาลงนามในใบยินยอมร่วมโครงการที่แนบมาด้วย และขอขอบพระคุณในความร่วมมือของท่านมา ณ ที่นี้

เอกสารชี้แจงผู้เข้าร่วมโครงการวิจัย

(Participant Information Sheet)

(สำหรับกลุ่มควบคุม)

รหัสโครงการวิจัย : ....G-HS 064/2563..........

โครงการวิจัยเรื่อง : ประสิทธิผลของโปรแกรมสนับสนุนการจัดการตนเองร่วมกับแอพพลิเคชั่นสุขภาพมือถือ ต่อพฤติกรรมการจัดการตนเอง ความดันโลหิต และอัตราการกรองของไต ของผู้ที่มีโรคไตเรื้อรังระยะที่ 3: การทดลองแบบสุ่มและมีกลุ่มควบควบคุม

เรียน ผู้เข้าร่วมโครงการวิจัย

ข้าพเจ้า นางสาวแสงรวี มณีศรี นิสิตปริญญาเอก คณะพยาบาลศาสตร์ มหาวิทยาลัยบูรพา ขอเรียนเชิญท่านเข้าร่วมโครงการวิจัยประสิทธิผลของโปรแกรมสนับสนุนการจัดการตนเองร่วมกับแอพพลิเคชั่นสุขภาพมือถือ ของผู้ที่มีโรคไตเรื้อรังระยะที่ 3 ก่อนที่ท่านจะตกลงเข้าร่วมการวิจัย ขอเรียนให้ท่านทราบรายละเอียดของโครงการวิจัยดังนี้

โครงการวิจัยนี้มีวัตถุประสงค์เพื่อศึกษาประสิทธิผลของโปรแกรมสนับสนุนการจัดการตนเองร่วมกับแอพพลิเคชั่นสุขภาพมือถือ ต่อพฤติกรรมการจัดการตนเอง ความดันโลหิต และอัตราการกรองของไต ของผู้ที่มีโรคไตเรื้อรังระยะที่ 3 ทั้งนี้เพื่อประโยชน์ในการชะลอความก้าวหน้าของโรคไตเรื้อรัง

หากท่านตกลงที่จะเข้าร่วมการศึกษาวิจัยนี้ ข้าพเจ้าขอความร่วมมือให้ท่านร่วมกิจกรรมของโครงการฯ โดยการตอบแบบสอบถามข้อมูลส่วนบุคคลและแบบสอบถามพฤติกรรมการจัดการตนเอง จำนวน 3 ครั้ง ดังนี้ครั้งที่ 1 คือครั้งแรกที่พบผู้วิจัย (สัปดาห์ 1) ครั้งที่ 2 (สัปดาห์ 4) และครั้งที่ 3 (สัปดาห์ 12) แต่ละครั้งใช้เวลาในการตอบประมาณ 45 นาที ซึ่งการนัดหมายเพื่อตอบแบบสอบถามในครั้งที่ 1 และ 3 เป็นการนัดหมายเพื่อตรวจรักษาปกติของโรงพยาบาล ส่วนการนัดหมายเพื่อตอบแบบสอบถามในครั้งที่ 2 เป็นการนัดหมายเพื่อมาทำกิจกรรมของโครงการวิจัย ผู้วิจัยจะมีค่าชดเชยการเดินทางหรือชดเชยการเสียเวลาให้แก่ท่าน จำนวน 200 บาท และหลังจากเสร็จสิ้นโปรแกรมในสัปดาห์ที่ 12 ท่านจะได้รับเครื่องวัดความดันโลหิตแบบดิจิตอล 1 เครื่อง ผลของโครงการวิจัยนี้จะเป็นประโยชน์ในภาพรวมคือทำให้ผู้ที่มีโรคไตเรื้อรังระยะที่ 3 เกิดการปรับเปลี่ยนพฤติกรรมการจัดการตนเอง ควบคุมความดันโลหิต และชะลอการเสื่อมของไต

การเข้าร่วมโครงการวิจัยนี้เป็นไปด้วยความสมัครใจ ท่านมีสิทธิปฏิเสธการเข้าร่วมโครงการวิจัยได้และสามารถถอนตัวออกจากการเป็นผู้เข้าร่วมโครงการวิจัยได้ทุกเมื่อ โดยการปฏิเสธหรือถอนตัวของท่านจะไม่มีผลกระทบต่อสิทธิประการใด ๆ ที่ท่านจะพึงได้รับ ข้อมูลต่าง ๆ ของท่านจะถูกเก็บไว้เป็นความลับและจะไม่มีการเปิดเผยชื่อของท่าน การนำเสนอข้อมูลจะเป็นในภาพรวม ทั้งนี้ข้อมูลจะถูกเก็บไว้ในเครื่องคอมพิวเตอร์ที่มีรหัสผ่านของคณะผู้วิจัยเท่านั้น ส่วนเอกสารจะเก็บไว้ในตู้เอกสารที่ใส่กุญแจไว้เป็นเวลา 1 ปี หลังการเผยแพร่ผลการวิจัยและจะถูกนำไปทำลายหลังจากนั้น

หากท่านมีคำถามหรือข้อสงสัยประการใดสามารถติดต่อข้าพเจ้า นางสาวแสงรวี มณีศรี คณะพยาบาลศาสตร์ มหาวิทยาลัยบูรพา หมายเลขโทรศัพท์ 080-2215229 ข้าพเจ้ายินดีตอบคำถาม และข้อสงสัยของท่านทุกเมื่อ หรือติดต่อที่ ผู้ช่วยศาสตราจารย์ ดร. เขมารดี มาสิงบุญ อาจารย์ที่ปรึกษาหลัก หมายเลขโทรศัพท์ 081-9875586 และถ้าผู้วิจัยไม่ปฏิบัติตามที่ได้ชี้แจงไว้ในเอกสารชี้แจงผู้เข้าร่วมโครงการวิจัย สามารถแจ้งมายังคณะกรรมการพิจารณาจริยธรรมการวิจัยในมนุษย์ มหาวิทยาลัยบูรพา กองบริหารการวิจัยและนวัตกรรม หมายเลขโทรศัพท์ 038-102620
เมื่อท่านพิจารณาแล้วเห็นสมควรเข้าร่วมในการวิจัยนี้ ขอความกรุณาลงนามในใบยินยอมร่วมโครงการที่แนบมาด้วย และขอขอบพระคุณในความร่วมมือของท่านมา ณ ที่นี้

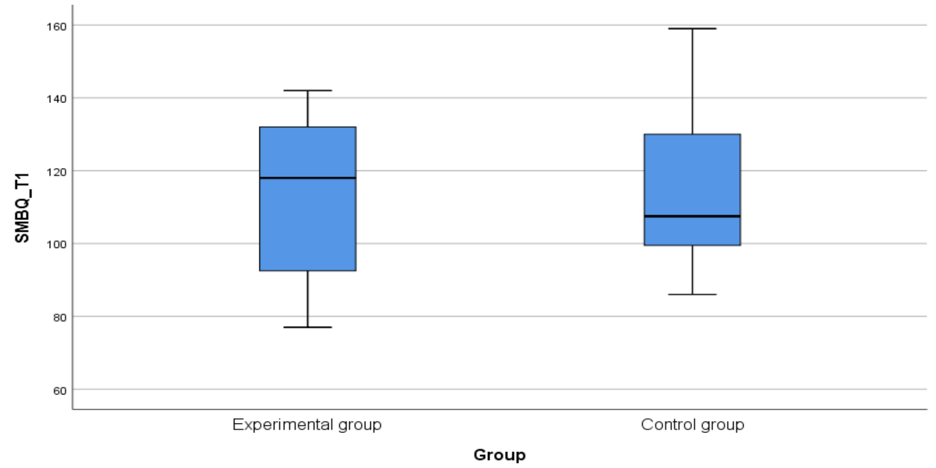
APPENDIX D

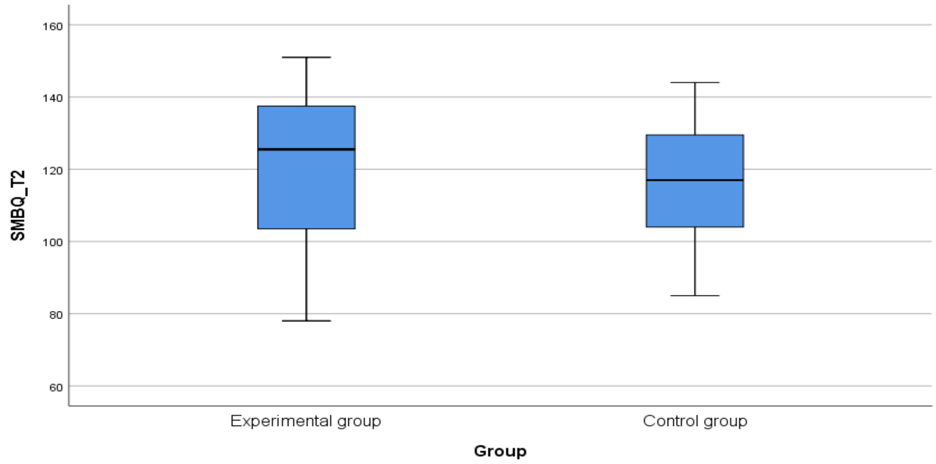
Evaluation of assumptions

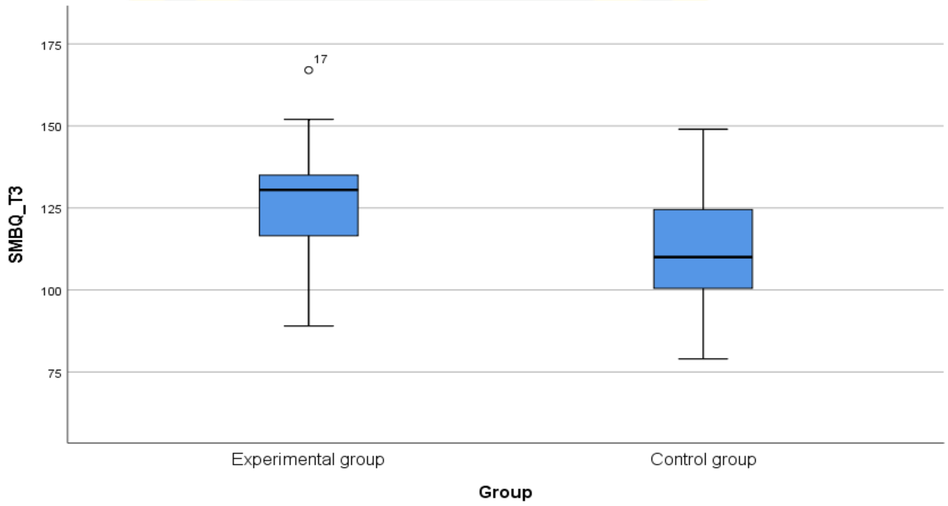
Test assumptions

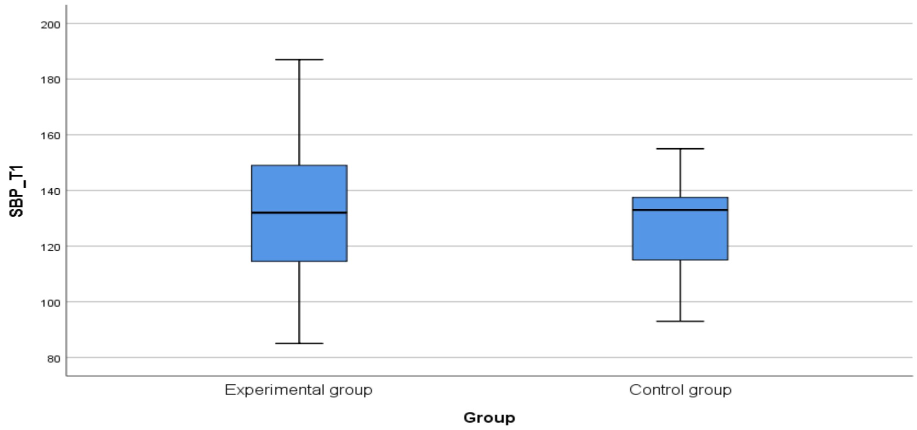
1. Univariate outlier of the variables

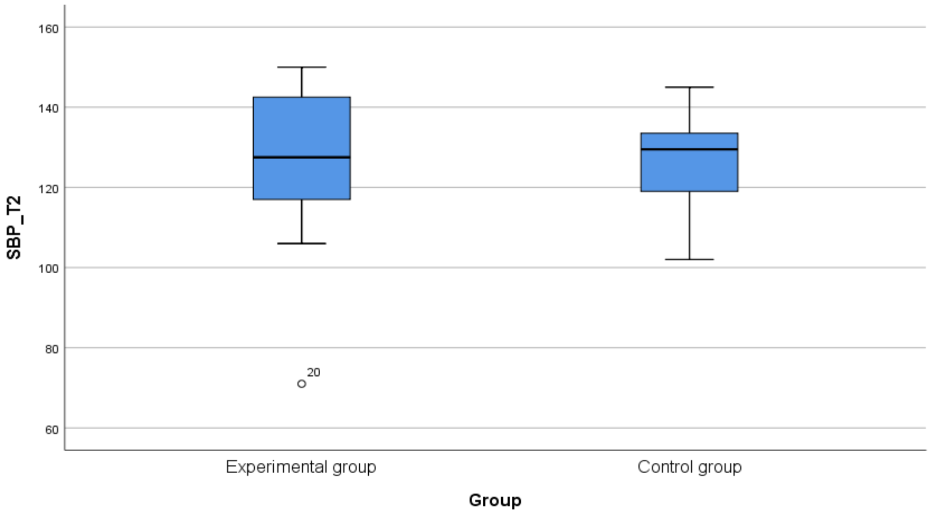
1.1 Univariate outlier was tested by Box-plot

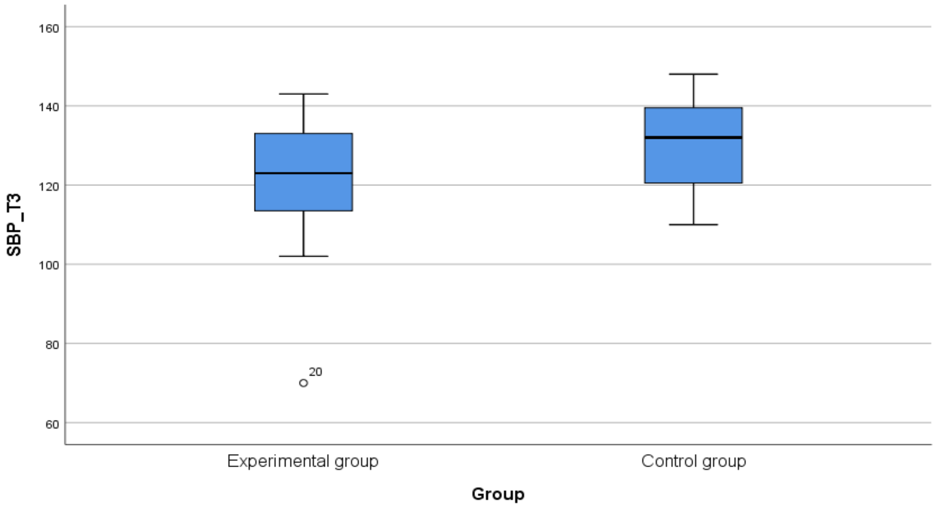


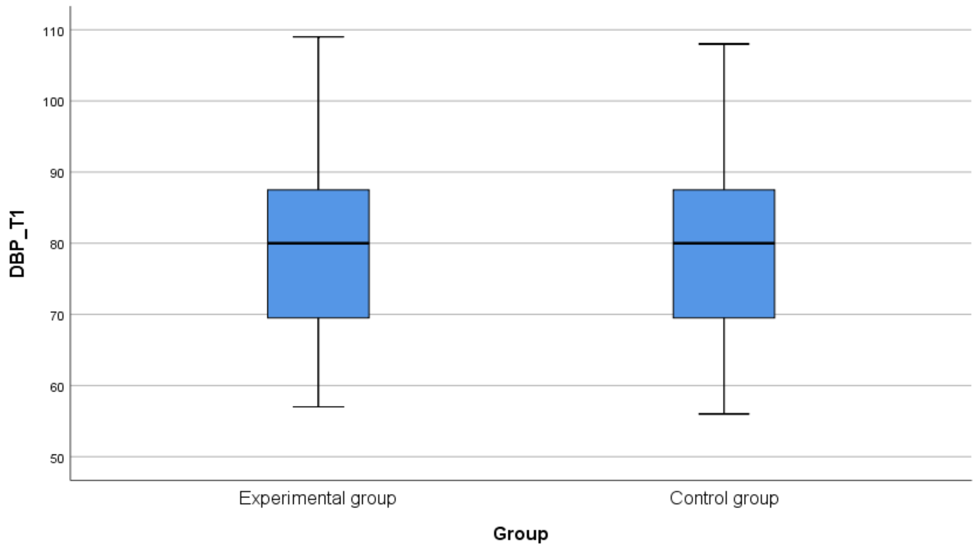


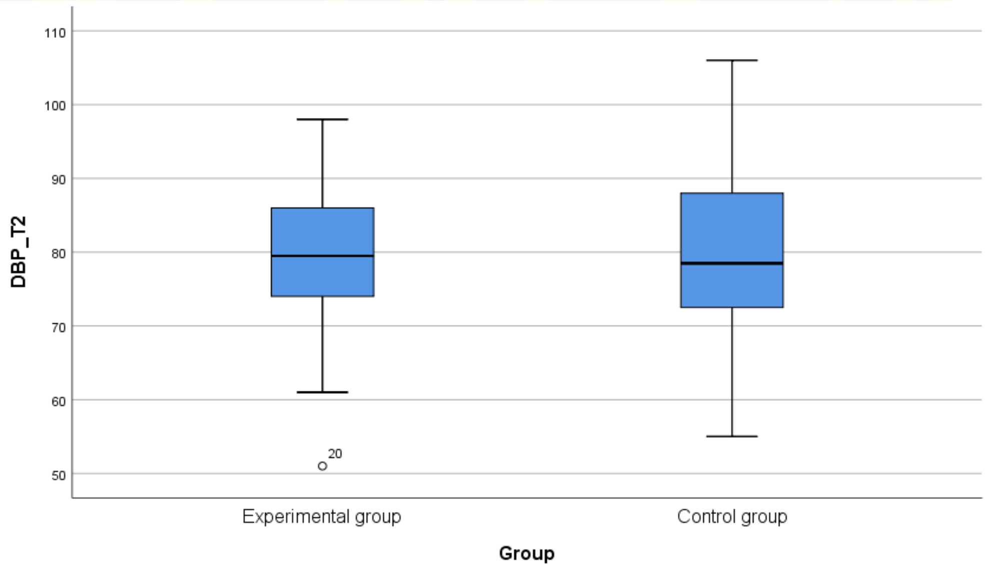


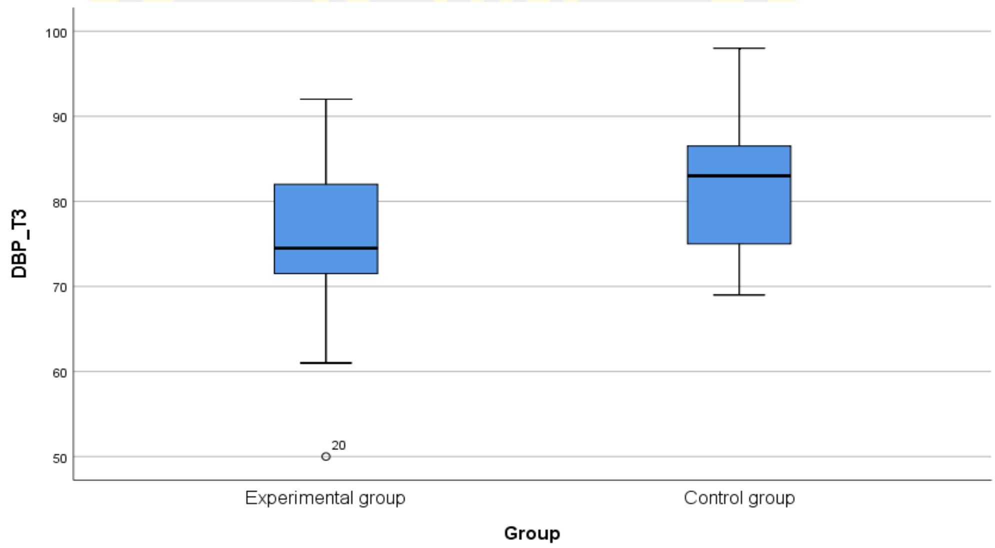

200
180
160
140
120
100
80
SBP_T1
Experimental group
Control group
Group


160
140
120
100
80
60
SBP_T2
20
Experimental group
Control group
Group


160
140
120
100
80
60
SBP_T3
20
Experimental group
Control group
Group


110
100
90
80
70
60
50
DBP_T1
Experimental group
Control group
Group


110
100
90
80
70
60
50
DBP_T2
20
Experimental group
Control group
Group


100
90
80
70
60
50
DBP_T3
20
Experimental group
Control group
Group

1.2 Multivariate outlier was tested by Mahalanobis distance

Group 1	MAH_1	MAH_SMBQ	MAH_2	MAH_SBP	MAH_3	MAH_DBP
1	3.53022	.3169	.91505	.8218	.63132	.8892
2	3.58464	.3099	.25261	.9687	.23483	.9718
3	.58686	.8994	2.84497	.4162	1.73044	.6302
4	2.74432	.4327	3.78417	.2857	2.61193	.4554
5	3.24086	.3560	1.75203	.6254	1.03360	.7931
6	3.03918	.3856	2.69448	.4412	2.83540	.4177
7	1.83423	.6075	4.66707	.1979	4.18307	.2424
8	5.03802	.1690	.82787	.8428	.18532	.9799
9	1.66587	.6445	.72233	.8679	.64442	.8862
10	.76349	.8582	2.85695	.4142	2.65987	.4471
11	.06624	.9956	6.07019	.1082	1.26761	.7368
12	.83649	.8407	3.06984	.3810	3.16398	.3670
13	1.39944	.7057	.63766	.8878	.41377	.9374
14	5.40782	.1443	1.87104	.5996	.35477	.9494
15	2.28883	.5147	2.62779	.4526	1.97102	.5784
16	6.95694	.0733	1.43196	.6981	2.31825	.5090
17	6.42567	.0926	1.48089	.6867	6.64420	.0841
18	2.37500	.4983	12.64336	.0055	5.96757	.1132
19	4.25534	.2352	5.51117	.1380	5.48422	.1396
20	5.84668	.1193	15.65466	.0013	6.93458	.0740

Group 2	MAH_1	MAH_SMBQ	MAH_2	MAH_SBP	MAH_3	MAH_DBP
21	6.28594	.0985	2.06385	.5593	3.53728	.3160
22	1.40275	.7049	5.04843	.1683	3.37224	.3377
23	6.43778	.0921	6.83278	.0774	8.82305	.0317
24	.69437	.8745	2.22573	.5269	.47635	.9241
25	8.81414	.0319	.60369	.8956	4.47376	.2146
26	4.15166	.2455	.69446	.8745	.24201	.9705
27	1.60721	.6578	2.10671	.5506	3.97252	.2644
28	.41434	.9373	2.57413	.4620	4.03422	.2578
29	1.65092	.6479	2.18199	.5355	5.85948	.1187
30	2.74656	.4324	4.43108	.2185	5.14735	.1613
31	2.36890	.4995	4.23383	.2373	4.51667	.2108
32	4.32693	.2283	.60121	.8962	3.66268	.3003
33	1.85271	.6035	.48313	.9226	.65851	.8829
34	2.64045	.4504	3.22764	.3578	.51501	.9156
35	1.69555	.6379	1.55960	.6686	.87720	.8309
36	3.39307	.3349	1.73703	.6287	1.97455	.5777
37	4.77633	.1889	2.17961	.5360	3.17245	.3658
38	.90629	.8239	1.34857	.7176	2.91119	.4055
39	.58359	.9002	.75568	.8600	.85786	.8356
40	.57184	.9028	2.69739	.4407	1.70931	.6349

1 = Experimental group 2 = Control group

2. Normality of distribution

2.1 Test of univariate normality

Variables	Group	Kolmogorov-Smirnov[a]			Interpret
		Statistic	df	Sig.	
SMBQ_T1	1	.163	20	.173	Normality
	2	.148	20	.200*	Normality
SMBQ_T2	1	.152	20	.200*	Normality
	2	.121	20	.200*	Normality
SMBQ_T3	1	.141	20	.200*	Normality
	2	.079	20	.200*	Normality
SBP_T1	1	.134	20	.200*	Normality
	2	.172	20	.121	Normality
SBP_T2	1	.110	20	.200*	Normality
	2	.132	20	.200*	Normality
SBP_T3	1	.143	20	.200*	Normality
	2	.170	20	.130	Normality
DBP_T1	1	.080	20	.200*	Normality
	2	.080	20	.200*	Normality
DBP_T2	1	.147	20	.200*	Normality
	2	.071	20	.200*	Normality
DBP_T3	1	.157	20	.200*	Normality
	3	.108	20	.200*	Normality
eGFR_Pre	1	.177	20	.102	Normality
	2	.148	20	.200*	Normality
eGFR_Post	1	.142	20	.200*	Normality
	2	.168	20	.140	Normality

1 = Experimental group 2 = Control group

* This is a lower bound of the true significance a. Lilliefors Significance Correction

3. Homogeneity

3.1 Levene’s test of equality or error variances[a]

Variables	*F*	*df1*	*df2*	Sig.
SMBQ_T1	.189	1	38	.666
SMBQ_T2	1.640	1	38	.208
SMBQ_T3	.015	1	38	.904
SBP_T1	3.338	1	38	.076
SBP_T2	1.048	1	38	.312
SBP_T3	.451	1	38	.506
DBP_T1	.035	1	38	.852
DBP_T2	.230	1	38	.634
DBP_T3	.062	1	38	.804

Tests the null hypothesis that the error variance of the dependent variable is equal across groups.

a. Design: Intercept + group

Within Subjects Design: Times

4. Assumption of sphericity (within-subject)

4.1 Mauchly's test of sphericity[a]

Dependent variable	Mauchly's W	Approx. Chi-Square	df	Sig.
SMBQ	.993	.259	2	.879
SBP	.791	8.671	2	.013
DBP	.811	7.768	2	.021

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. Design: Intercept + group

Within Subjects Design: Times

BIOGRAPHY

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