Effectiveness of Individual and Family Self–Management Combined mHealth Program for People with Stage 3 Chronic Kidney Disease: A Randomized Controlled Trial

Sangrawee Maneesri, Khemaradee Masingboon, Nujjaree Chaimongkol*

Abstract: The rising prevalence of chronic kidney disease is a global and Thai public health concern and self-management strategies may be an effective way to help prevent its progression. This randomized controlled trial tested the effectiveness of the Individual and Family Self-Management Combined mHealth Program for People with Chronic Kidney Disease. Forty people with stage 3 chronic kidney disease were randomly assigned to either the experimental (n = 20) or control group (n = 20). The research instruments included the research protocol, the Healthy Kidney application, the Self-Management Behaviors Questionnaire, and the Clinical Outcomes Record Form. The outcomes of the program were evaluated three times, at baseline (week 1), immediately post-intervention (week 4), and at follow-up (week 16). An independent t-test and repeated measures analysis of variance were used in the data analysis.

Results indicated that during follow-up, the experimental group had higher self-management behaviors and lower diastolic blood pressure than the control group. The self-management behaviors, and systolic and diastolic blood pressure of the experimental group significantly improved three months after the intervention. However, the glomerular filtration rate was unchanged. The findings demonstrated that the program effectively improved outcomes for the participants.

The results of this study suggest that the Individual and Family Self-Management Combined mHealth Program can help people with stage 3 chronic kidney disease improve their self-management behaviors and alleviate blood pressure. This study supports the health care context to promote home-based self-management and guide the future development of mHealth applications. Further testing of the program is needed before incorporating it into nursing practice.

Pacific Rim Int J Nurs Res 2023; 27(1) 169-184

Keywords: Chronic kidney disease stage 3, Diastolic blood pressure, Family support, mobile health application, Self-management behaviors, Systolic blood pressure

Received 15 August 2022; Revised 21 September 2022; Accepted 19 November 2022

***Sangrawee Maneesri**, RN, PhD Candidate, Faculty of Nursing, Burapha University, Thailand. E-mail: sangrawee.m@rsu.ac.th*
***Correspondence to: Khemaradee Masingboon**,* RN, DSN, Assistant Professor, Faculty of Nursing, Burapha University, Thailand. E-mail: khemaradee@nurse.buu.ac.th*
***Nujjaree Chaimongkol**, RN, PhD, Associate Professor, Faculty of Nursing, Burapha University, Thailand. E-mail: nujjaree@buu.ac.th*

Introduction

To support healthcare practice, health services have evolved rapidly to embrace information and communication technologies (ICTs). Accordingly, the growing communication infrastructure has allowed users to access the Internet immediately. As a result of the increasing demand from healthcare consumers, there is a growing need to improve efficiency and client satisfaction, leading consumers and health leaders to become increasingly reliant on ICTs to support their work. These developments revolve around operational and strategic management, leading to global innovation in health processes throughout many hospitals. Mobile health (mHealth) has recently evolved into mobile healthcare and public health practice. Examples include mobile and smartphone devices, patient monitoring devices, personal digital assistants, and other wireless devices. Healthcare and public health practice is increasingly used in communication, data collection, patient monitoring, education, and promoting positive changes in health behaviors to prevent the onset of acute and chronic diseases.[1] Integrating an mHealth application (app) for chronic disease management has a positive effect. Previous systematic reviews have found health interventions to be effective in improving self-management behaviors, adherence, and clinical outcomes of diseases, such as diabetes mellitus, hypertension, stroke, and asthma.[2-3]

Additionally, mHealth interventions have yielded positive results in the management of patients with CKD and dialysis. The evaluation of mHealth interventions has revealed significantly increased disease knowledge [4] and some positive changes in behavior and diet related to self-management.[5-6] mHealth applications have consistently demonstrated evidence of patient satisfaction, user acceptance, reduced use of health resources, and cost savings for healthcare services.[7] However, an effective response to delay disease progression is lacking, but for patients, the ultimate goal of care is to delay CKD progression and extend the duration of dialysis.

Although digital interventions (apps, wearables, and software algorithms used in the context of health) can help people self-manage, in some cases, hypertension is uncontrolled; thus, a digital intervention involving self-representation of blood pressure (BP) with reminders is necessary.[8-9] Moreover, family support for lifestyle change has resulted in decreased systolic BP and increased cost-effectiveness. While evidence presents family value in promoting positive health outcomes and supportive self-care for chronic disease,[10] there is a lack of family members' participation in self-management programs.[11] According to a systematic review, the number of randomized controlled trials integrated with information technology (IT) devices to support self-management in patients with CKD is limited, primarily in stage 3.[12]

Conceptual Framework and Review of Literature

The organization Kidney Disease: Improving Global Outcomes (KDIGO), whose goal is to create clinical practice guidelines to improve the care and outcomes of people with kidney disease globally, advocates for optimal blood pressure management to reduce persistent proteinuria and adopting lifestyle modifications that can prevent the progression of CKD.[13] Furthermore, self-management is an important strategy for changing health behaviors and improving clinical outcomes in patients with chronic diseases, i.e., the patient's positive effort in supervising and participating in healthcare. This is done not only to improve health and prevent complications but also to manage symptoms and encourage people to live healthy lifestyles.[14] The conceptual framework for this study was developed based on the Individual and Family Self-Management Theory (IFSMT) and relevant literature. According to IFSMT,[15] self-management is a multidimensional, complex phenomenon that affects individuals, dyads, and families at all developmental stages. Self-management includes condition-specific risk and protective factors, physical and social environment components, and individual and family member characteristics. It includes self-management processes such as promotion of knowledge and belief, enhancement of self-regulation skills and ability, and social facilitation. Self-management influences various outcomes, both short and long term. Self-management behaviors are used to manage chronic conditions and help people to engage in health-promoting behaviors. In this study, we included both people with CKD and their families engaged in self-management to improve CKD outcomes. The IFSMT considers the family and the patient are the same units. A change in any one member of the family leads to a change in the family system.[15] The family characteristics of closeness, caregivers' 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.[16] Therefore, the family is the center of care, enabling patients to have proper self-management behaviors and continuous practice. Moreover, family support and collaboration with healthcare 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.

Current circumstances have shown that self-management support should be easily accessible by the patients, entree to information is increased, health monitoring is possible, and a channel for patient-provider communication is provided; this support can be facilitated by smartphones. As a result, mHealth apps are increasingly used to assist CKD self-management, and growing evidence links their use to better clinical outcomes and behavioral changes.[5,17-18] In this way, the researchers applied this theory, modified program activities from relevant studies,[19-20] and integrated them with an mHealth app for individuals with stage 3 CKD.

Study aim

This study aimed to determine the effects of the IFSM-mHP on self-management behaviors, systolic and diastolic blood pressure, and glomerular filtration rate among people with stage 3 CKD.

Methods

Design: This study was a two-parallel group, randomized controlled trial (RCT) with a pretest, post-test, and follow-up research design. This report was completed following the CONSORT 2010 checklist.[21]

Setting: This study was conducted at an outpatient CKD clinic at a tertiary care hospital in Thailand.

Sample and sampling: The participants were people with stage 3 CKD and their family members. The inclusion criteria for the patients were: aged 18 years and over, having CKD stage 3a (eGFR = 45-59 mL/min/1.73 m^2) or 3b (eGFR = 30-44 mL/min/1.73 m^2), and owning an Android smartphone able to process mobile phone applications and internet access. The inclusion criteria for family caregivers were: being at least 18 years, living with the patient and taking the role of the main caregiver, being responsible for overseeing the patient's diet, medicines, and bringing patients for follow-up visits, and being able to use mobile phone apps.

The exclusion criteria of the patients were as follows: having been diagnosed with CKD greater than stage 3 or who received haemodialysis during the program activities or who had adjusted to increasing their antihypertensive dose during the follow-up period. The discontinuation criteria were: having had a serious illness, being in a critical stage, having required hospitalization during the program, or died, or asking to withdraw because participation in the program was inconvenient.

The sample size was determined using the G*Power program 3.1.9.2 software.[22] The power analysis used the F test for the analysis of variance (ANOVA) and repeated measures to determine within-and between-factors effects, with a power of 0.80, a significance level of 0.05, and the effect size calculated from a previous study's standardized mean difference of 0.56,[23] which was converted into an effect size for the F test of 0.28. Thus, the study required a minimum sample of 32 individuals, with a 25% attrition rate. Consequently, the sample needed to be 20 patients with stage 3 CKD per group.

Of the 67 patients with stage 3 CKD assessed for eligibility criteria, 44 were invited to participate in the study. However, four declined participation, eventually leaving only 40 who were willing to participate. These were randomly assigned to the experimental group (n = 20) and the control group (n = 20). By post-intervention and follow-up, no participants had dropped out (**Figure 1**).

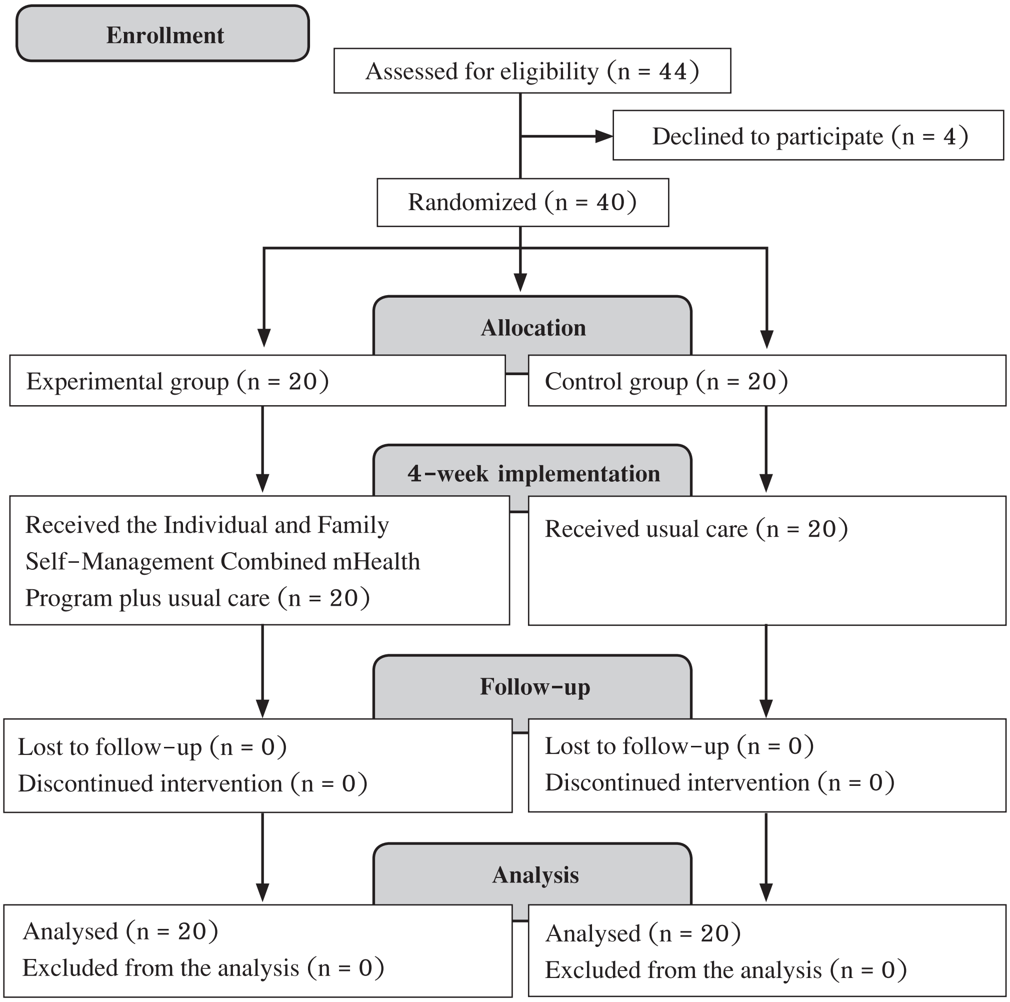

Figure 1. CONSORT flow diagram of the progress through the phases of the parallel randomized trial of two groups

After obtaining informed consent, the primary investigator (PI) used simple randomization to assign participants to either the experimental group or the control group. To avoid contamination, participants were randomly assigned to the experimental or control groups for the week of the CKD clinic service. The PI began by labeling two slips, "E" for the experimental group and "C" for the control group. The head nurse of the CKD clinic then drew a slip from a box, with the first draw at week 2 of the month and the second draw at week 4 of the month. As a result, those who attended the CKD clinic at week 2 were assigned to the experimental group, whereas those who attended the CKD clinic at week 4 were assigned to the control group.

Ethical considerations: This study was registered as a randomized trial by the Thailand Clinical Trial Registry (Project code TCTR20200928004). The study was approved by the Burapha University Research Ethics Board (Project Code G-HS 064/2563) and the hospital in Thailand where the study was conducted (Project Code Oq05463).

The PI provided information about the research study to each prospective participant verbally and through a fact sheet. The information included research objectives, advantages, potential risks, types of questionnaires, the time required, and tasks to be completed. The participant's right to withdraw from the study at any time was also explained. The participants and their family caregivers signed the informed consent form before the questionnaires were sent. Participant confidentiality was ensured using number coding.

Research instruments: A demographic questionnaire, a Clinical Outcomes Record Form, and the Self-Management Behaviors Questionnaire (SMBQ) were used to collect data. The PI developed the demographic questionnaire for both participants and their family caregivers to include age, sex, education level, use of technological devices and mobile apps, and health information. The family caregiver questionnaire asked about the participant's relationship, age, and illness.

The Clinical Outcomes Record Form was developed by the PI to collect information on blood pressure (BP) and estimated glomerular filtration rate (eGFR). Using the standard protocol, a research assistant (RA) carried out the data collection using an Omron Hem-7120 BP monitor with a verified accuracy of 5 mmHg to measure the BP at the CKD clinic. The eGFR value was also obtained from the medical records and calculated using the CKD-EPI creatinine equation.

The Self-Management Behaviors Questionnaire (SMBQ) was developed by Curtin et al,[24] and measures the self-management behaviors of participants. This instrument was translated into Thai by Sritarapipat et al. (2012)[25] using the back-translation technique. This questionnaire has been used in research on the causal model of self-management behaviors of older Thai people with CKD before predialysis.[25] The five dimensions of self-management behaviors are self-care activities, medication adherence, communication, self-advocacy, and partnership in care, in total 37 items. The participants are asked to rate each item on a 1 (never) to 5 (all the time) rating scale. The summed scores of the response values for all elements range from 37 to 185 points, with a higher score reflecting higher self-management behaviors. The cut point of the score indicates the level of self-management behaviors; 37-85.9 points are low; 86-135.9, moderate; and 136-185, high. In the pilot study, the SMBQ was tested for reliability using Cronbach's alpha coefficient of internal consistency, with 15 participants having the same characteristics as the study sample, revealing a value of 0.84, whereas the actual study had a value of 0.87.

Study protocol: The Individual and Family Self-Management Combined mHealth Program (IFSM-mHP) (**Table 1**) was developed by the PI and guided the implementation of the intervention. This protocol was developed using two constructs of IFSMT, context and process.[15] This protocol consisted of four sessions within four weeks, with the PI and second RA delivering interventions. Family caregivers are involved in the patient's CKD management plan and help them use an mHealth app to modify self-management behaviors. The concordance between the program's concepts and activities was reviewed by five experts, including a nephrologist, a nurse specialized in hemodialysis, and three nursing instructors. These programs were revised based on the recommendations before being implemented. To conduct the study protocol, the following worksheets were created by the PI: (1) identifying risk and protective factors, (2) knowledge of CKD self-management, (3) perceived self-efficacy, (4) self-management planning, (5) self-management behavior modification, (6) perceived advantages and disadvantages of program participation, and (7) satisfaction and recommendation with the mHealth app.

Table 1. Summary of the four sessions of the research protocol

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

The evidence-based Healthy Kidney mHealth app was designed by the PI through a collaborative effort between patients and healthcare professionals. It was created by a mobile app developer and was intended for use with the Android operating system and Internet access. The Healthy Kidney platform has six major features: (1) personal information (to record personal and health-related data), (2) eGFR calculator (to calculate the CKD-EPI creatinine 2009 equation), (3) laboratory record and BP monitor (to record laboratory results such as eGFR, urine protein, serum albumin, serum creatinine, and HbA1C and monitor BP at least 1-2 times per week at home; evaluation results represent simple alerts and feedback); (4) trend graph (displaying trend graphs of laboratory results such as eGFR, urine albumin, BP, and HbA1c, which represent the CKD situation); (5) CKD management (including CKD handbooks and VDO media to provide CKD knowledge and management), and (6) communication (this interactive function provides a channel of communication or consultation between patients and healthcare providers).

Usual care: The experimental group received the program intervention and usual care. The control group only received the usual care. Usual care was delivered by a multidisciplinary team through education programs and treatment protocols.

Data collection: Data were collected from November 2020 to November 2021.

The IFSM-mHP was implemented by the PI and two RAs after institutional review board approval. Both RAs were nurse practitioners working at the hospital's kidney unit. The first RA was trained as an outcome evaluator and conducted the data collection. She was shown how to collect data on the patients with stage 3 CKD. Three research instruments were used to collect baseline data (week 1), immediately post-intervention (week 4) and follow-up (week 16). The second RA was trained as a facilitator who helped the PI run the program. She helped the participants set up the Healthy Kidney app on their smartphones and gave them instructions on how to use the app. This study applied a double-blind technique in which the participants and the outcomes assessor were unaware of group assignments.

Data analysis: Frequencies, means, and standard deviations were used to describe the characteristics of the participants, family caregivers, and outcome variables. The characteristics of the experimental and control groups were compared and analyzed using t-tests for continuous variables and chi-square for categorical variables. An independent t-test was used to examine changes in the average eGFR scores two times. Repeated measures ANOVA was used to evaluate the differences in the mean score of self-management behaviors, systolic BP, and diastolic BP between the groups and within the experimental group at three time points. All assumptions were met for between-group and within-subject effects of the mixed ANOVA. The IBM® SPSS® Statistics, version 26, was used to analyze the data, and the statistical significance level was set at $p < .05$.

Results

Participant characteristics

As shown in **Table 2**, most of the individual features of both groups were similar. In the experimental group, more than 50% of the participants were men, 70% were older, with a mean of 63.70 years (SD = 11.63, range 43-87), and 80% had educational attainment lower than a bachelor's degree. Regarding technological devices, 60% mainly used mobile phone apps 5-7 days per week. Sixty percent had CKD stage 3b and 90% underlying hypertension, and participants were mostly overweight (average, 25.00 (SD = 2.89); range, 18.36-30.51) kg/m^2. Fifty-five percent of the family caregivers were a husband or wife (55%), 70% were adults and 70% were healthy.

Table 2. Characteristics of the participants and family caregivers

Characteristics	Experimental group (n = 20)		Control group (n = 20)		Statistical value	*p*-value
	n	%	n	%		
Participants with CKD						
Sex					0.48[a]	.490
Male	15	75	13	65		
Female	5	25	7	35		
Age (years)					0.13[a]	.723
43-59	6	30	5	25		
≥ 60	14	70	15	75		
	M = 63.70 (±11.63) range = 43-87		M = 66.25 (±10.00) range = 47-85		-0.74[b]	.462
Education					2.06[c]	.342
< Bachelor's degree	16	80	19	95		
≥ Bachelor's degree	4	20	1	5		
Use of mobile phone application					3.64[a]	.057
1-4 days/week	8	40	14	70		
5-7 days/week	12	60	6	30		
Current CKD stage					0.10[a]	.749
Stage 3a	8	40	9	45		
Stage 3b	12	60	11	55		

Table 2. Characteristics of the participants and family caregivers (Cont.)

Characteristics	Experimental group (n = 20)		Control group (n = 20)		Statistical value	*p*-value
	n	%	n	%		
Comorbidity					< .001[c]	1.000
Hypertension	18	90	18	90		
No hypertension	2	10	2	10		
Body mass index (kg/m^2)	M = 25.00 (±2.89) range = 18.36–30.51		M = 26.94 (±4.54) range = 21.54–36.79		−1.61[b]	.116
Family Caregiver					0.10[a]	.749
Husband or wife	11	55	12	60		
Child or grandchild	9	45	8	40		
Age of the family caregiver (years)					0.11[a]	.736
20–59	14	70	13	65		
≥ 60	6	30	7	35		
Health of the family caregiver					0.44[a]	.507
Healthy	14	70	12	60		
Having illness	6	30	8	40		

Note. [a] Chi-square, [b] Independent t-test, [c] Fisher's exact test, CKD = Chronic kidney disease

Outcome variable descriptive statistics

The means and standard deviations of the self-management behaviors, systolic BP, and diastolic BP of both groups at three-time points are presented in **Table 3**. In the experimental group, the mean self-management scores were moderate over the three-time points, but gradually increased from baseline (M = 112.20, SD = 20.23). The mean systolic BP value before the intervention was 131.30 mmHg (SD = 22.98), which exceeded the systolic BP processing standard by less than 130 mmHg. However, systolic BP levels gradually decreased after the program. The average diastolic BP score was 79.35 mmHg (SD = 13.07), within the normal range, and continued to decrease following the program.

Table 3. Comparison of the differences in dependent variables of the sample at baseline

Variable	Week	Experimental group (n = 20) M (SD)	Control group (n = 20) M (SD)	t	p-value
Self-management behaviors	1	112.20 (20.23)	113.35 (19.54)	−0.18	.856
	4	121.00 (20.46)	115.30 (15.75)		
	16	125.75 (18.45)	111.00 (18.79)		
Systolic BP	1	131.30 (22.98)	127.50 (14.55)	0.63	.536
	4	126.80 (18.90)	126.30 (12.97)		
	16	120.95 (16.40)	129.70 (11.47)		
Diastolic BP	1	79.35 (13.07)	79.80 (13.76)	−0.11	.916
	4	78.50 (11.30)	79.40 (12.16)		
	16	74.60 (9.82)	82.60 (8.59)		

For the control group, the mean scores for the self-management behaviors were moderate for all three periods, but increased from baseline (M = 113.35, SD = 19.54) in the post-intervention period and decreased during follow-up. At baseline, the mean systolic and diastolic BP were 127.50 mmHg (SD = 14.55) and 79.80 mmHg (SD = 13.76), respectively. Both decreased after the intervention but increased at the follow-up.

The Effectiveness of the IFSM-mHP

For self-management behaviors, the interaction effect (time*group) was significantly different (**Table 4**). The simple effects of groups revealed a significant difference at the follow-up (week 16) (**Table 5**). For the simple effect of time (within-subjects), the mean scores of the self-management behaviors in the experimental group at the follow-up (week 16) were significantly higher than pre-intervention (week 1) (**Table 6**).

For the systolic and diastolic BP, a significant difference was found in the interaction effect (time*group) (**Table 4**). At the follow-up (week 16), the simple effects of groups revealed a significant difference in the mean diastolic BP scores (**Table 5**). For the simple effect of time (within-subjects), the mean systolic BP scores in the experimental group were significantly lower at follow-up (week 16) than before the intervention (week 1) and post-intervention (week 4) (**Table 6**). However, the mean diastolic BP scores in the experimental group were significantly lower at follow-up (week 16) than after the intervention (week 4) (**Table 6**).

Table 4. Repeated measures ANOVA of the scores of self-management behaviors, systolic BP, and diastolic BP.

Source variation	SS	df	MS	F	p-value	η^2_p
Self-management behaviors						
Between subjects						
Group	1241.63	1	1241.63	1.82	.185	.046
Error	25921.17	38	682.14			
Within subjects						
Time	804.02	2	402.01	2.04	.137	.051
Time*Group	1272.12	2	636.06	3.23	.045	.078
Error time	14952.53	76	196.74			
Systolic BP						
Between subjects						
Group	66.01	1	66.01	0.10	.749	.003
Error	24095.32	38	634.09			
Within subjects						
Time	349.72	1.65	211.39	1.76	.185	.044
Time*Group	846.52	1.65	511.68	4.26	.025	.101
Error time	7550.43	62.87	120.10			
Diastolic BP						
Between subjects						
Group	291.41	1	291.41	0.97	.332	.025
Error	11471.38	38	301.88			
Within subjects						
Time	19.52	1.68	11.61	0.19	.787	.005
Time*Group	358.72	1.68	213.32	3.55	.042	.085
Error time	3839.77	63.90	60.09			

Note. η^2_p = Partial eta squared

Table 5. Simple effect of groups on self-management behaviors and diastolic BP between the two groups at three time points

Source	df	SS	MS	*F*	*p*-value	η^2_p
Self-management behaviors						
Pre-intervention (week 1)						
Group	1	13.23	13.23	0.03	.856	.001
Error	38	15029.75	395.52			
Post-intervention (week 4)						
Group	1	324.90	324.90	0.97	.330	.025
Error	38	12670.20	333.43			
Follow-up (week 16)						
Group	1	2175.63	2175.63	6.28	.017	.142
Error	38	13173.75	346.68			
Diastolic BP						
Pre-intervention (week 1)						
Group	1	2.03	2.03	0.01	.916	<.001
Error	38	6841.75	180.05			
Post-intervention (week 4)						
Between subject	1	8.10	8.10	0.06	.810	.002
Error	38	5235.80	137.78			
Follow-up (week 16)						
Between subject	1	640.00	640.00	7.52	.009	.165
Error	38	3233.60	85.10			

Note. η^2_p = Partial eta squared

Table 6. Pairwise comparisons of the mean difference of the self-management behaviors, systolic BP, and diastolic BP between each pair of time points within the experimental and control groups

Time	M_{diff}	SE	*p*-value	95% CI for Difference	
				Lower	Upper
Self-management behaviors					
Experimental group					
Week 16 vs. Week 1	13.55*	3.96	.003	5.26	21.84
Week 16 vs. Week 4	4.75	4.50	.305	−4.67	14.17
Week 4 vs. Week 1	8.80	4.44	.062	−0.50	18.10
Control group					
Week 16 vs. Week 1	−2.35	4.92	.639	−12.66	7.96
Week 16 vs. Week 4	−4.30	4.65	.367	−14.03	5.43
Week 4 vs. Week 1	1.95	4.06	.637	−6.56	10.46
Systolic BP					
Experimental group					
Week 16 vs. Week 1	−10.35*	4.17	.022	−19.07	−1.63
Week 16 vs. Week 4	−5.85*	2.29	.019	−10.63	−1.07
Week 4 vs. Week 1	−4.5	3.71	.240	−12.27	3.27

Table 6. Pairwise comparisons of the mean difference of the self-management behaviors, systolic BP, and diastolic BP between each pair of time points within the experimental and control groups (Cont.)

Time	M_{diff}	SE	*p*-value	95% CI for Difference	
				Lower	Upper
Control group					
Week 16 vs. Week 1	2.20	2.93	.462	−3.93	8.33
Week 16 vs. Week 4	3.40	2.40	.173	−1.63	8.43
Week 4 vs. Week 1	−1.20	2.98	.692	−7.45	5.05
Diastolic BP					
Experimental group					
Week 16 vs. Week 1	−4.75	2.43	.065	−9.84	0.34
Week 16 vs. Week 4	−3.90*	1.51	.018	−7.06	−0.74
Week 4 vs. Week 1	−0.85	2.20	.703	−5.45	3.75
Control group					
Week 16 vs. Week 1	2.80	2.63	.301	−2.71	8.31
Week 16 vs. Week 4	3.20	1.87	.102	−0.70	7.10
Week 4 vs. Week 1	−0.40	2.62	.880	−5.89	5.09

We measured the eGFR only at baseline and week 16. The results indicated that in the experimental group, the mean eGFR at week 16 (M = 44.27, SD = 11.04) was higher than that at baseline (M = 42.47, SD = 9.18). In the control group, the mean eGFR at week 16 (M = 43.48, SD = 10.62) was lower than that at baseline (M = 45.28, SD = 9.86). There was no significant difference between the two groups at both baseline (t = −0.93, p = .357) and at week 16 (t = 0.23, p = .818).

Discussion

The results of this study revealed the effectiveness of IFSM-mHP on the outcomes of participants with stage 3 CKD. The intervention effect was observed at least three months after completing the program, by which the participants had improved self-management behaviors and reduced systolic and diastolic BP significantly. The significant increase in self-management behavior scores was attributed to the component characteristics of the program and intervention integrated with complex methods. The program development was fundamentally based on the IFSMT and a literature review. IFSMT illustrates the complexity of the self-management process and provides a framework for demonstrating how contextual risk, protective factors, and components of the self-management process contribute to patient outcomes.[15] 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.[15] Therefore, patients and family members should participate in activities promoting health behaviors and modifying lifestyles.

Social support is a significant predictor of self-management behaviors in patients with CKD.[26] In this study, family support was the most important for participants. Healthcare providers play different roles in helping patients execute disease management tasks, whereas family caregivers provide more hands-on, day-to-day care than any other individual. After participating in the program, the family caregivers learned how to better support the patients with CKD, including their pathology, diet, exercise, stress relief and medications. They were more confident in providing care for a family member with CKD and were involved in goal setting, planning, implementing, self-monitoring, and evaluating their performance. Furthermore, most of the patients and caregivers express the need to improve kidney function so that dialysis is no longer needed. Accordingly, they were encouraged to adhere to the plan by the time the assessment was completed.

Integrating mHealth apps with standard care provides CKD knowledge and a communication channel with healthcare providers and encourages patients' self-monitoring and management.[17-18,27-29] The significant decrease in systolic and diastolic BP was attributable to the characteristics of the program and response components that were integrated into two approaches. First, the mHealth app can record BP. The recorded data were analyzed, and a BP trend chart was presented on the application. In addition, the researcher's interactive feedback and advice through a health app could help participants identify the factors that contribute to high BP so that problems can be solved effectively and promptly. Therefore, an interactive mHealth intervention can be beneficial in improving BP control in adults, especially those with inadequate BP control.[30]

Second, BP monitoring was critical for managing high BP in patients with CKD. The ideal BP for CKD management should be less than 130/80 mmHg.[31-32] The experimental group received accurate HBPM for the measurement of their BP at least 1-2 times per week in accordance with standard guidelines.[32-33] The effect of self-BP monitoring (SBPM) on BP reduction is significant.[34-35] The increase in SBPM frequency of more than once a week and the improvement in medication compliance resulted in a decrease in BP.[34] The control of systolic and diastolic BP was associated with a lower risk of composite renal outcomes reflective of CKD progression.[36]

The results showed that the mean eGFR scores of experimental group participants increased at week 16 compared to baseline, but declined in the control group. However, the mean eGFR scores were not significantly different between the two groups at week 16. This is consistent with the findings of a systematic review and meta-analysis in which self-management intervention programs had no significant effect on eGFR change.[23,37-38] The integration of mHealth with CKD care could be ineffective in improving eGFR.[39] Since changes in eGFR take time, measurements three months after the program may not reveal a significant change. As a result, one year is the optimal time to measure eGFR.[40]

Limitations

The study was conducted in a single setting, which limits its generalizability in other contexts. Group sampling techniques according to the week of the month may result in selection bias. Thus, strict individual sampling techniques should be employed to achieve more accurate research results. Younger patients and their families were more likely to use mHealth extensively and interactively than older patients. Thus, patient technology literacy should be carefully evaluated by kidney teams before implementation in practice. Finally, with the COVID-19 pandemic, the investigation and adherence to the plan were challenging. The number of participants in the group session decreased because of the location and individual limitations. Accordingly, the PI modified the research activities based on the pandemic situation for the initiation of the study.

Conclusions and Implications for Nursing Practice and Research

The results of this study showed that IFSM-mHP improved the outcomes of patients with stage 3 CKD. Incorporating IT technology improves the CKD management for patients and their family members as well as their home self-management skills, promotes self-monitoring to detect any clinical changes (BP and eGFR), and provides more effective long-distance communication between patients and health providers.

Furthermore, the program was found to be effective for patients with CKD and their family members in promoting knowledge, confidence, and self-regulation skills to manage their illness. As a result, especially during the COVID-19 pandemic, this program should be integrated into current nursing practice in CKD clinics to continue care and promote self-management at home.

This study identified gaps in the introduction of health policies and organizational support for the implementation of mHealth and HBPM in patients with stage 3 CKD. The results may reflect the need for a comprehensive service model that uses mHealth technologies for the home surveillance and self-management of patients with stage 3 CKD. Self-directed mHealth programs with a multidisciplinary approach can be a useful addition to standard care. Since most people with CKD are seniors, the use of technology could be problematic. Thus, it is important to allow family members who are technologically competent to use CKD care programs. Nurses should organize rigorous hands-on training sessions for participants and their caregivers to ensure that they have all the skills required to take advantage of mHealth apps.

Future research should focus on other healthcare settings to confirm the effectiveness of integrating mHealth apps in regular services. Healthcare services should evaluate the long-term viability of self-management behavior change and determine the overall quality of life and cost-effectiveness. The features of the mHealth app should be expanded to cover all aspects of CKD care. Information technology experts should be invited to review the design, user-friendliness, and reliability of the app before deployment. In addition, other platforms and technologies, such as IOS, telehealth, and social media, need to be considered to improve the quality of care for people with CKD.

Acknowledgments

We are grateful to the Burapha University Graduate School and the King Prajadhipok and Queen Rambhai Barni Memorial Foundation for funding and thank all participants in this study.

References

1. World Health Organization. mHealth: use of appropriate digital technologies for public health. 2018 [cited 2022 Oct 29]. Available from: https://apps.who.int/gb/ebwha/pdf_files/ WHA71/A71_20-en.pdf
2. Hamine S, Gerth-Guyette E, Faulx D, Green BB, Ginsburg AS. Impact of mHealth chronic disease management on treatment adherence and patient outcomes: a systematic review. J Med Internet Res. 2015 Feb 24;17(2):e52. doi:10.2196/jmir.3951.
3. Yi JY, Kim Y, Cho Y-M, Kim H. Self-management of chronic conditions using mHealth interventions in Korea: a systematic review. Healthc Inform Res. 2018;24(3): 187-97. doi:10.4258/hir.2018.24.3.187.
4. Tsai Y-C, Hsiao P-N, Kuo M-C, Wang S-L, Chen T-H, Kung L-F, et al. Mobile health, disease knowledge, and self-care behavior in chronic kidney disease: a prospective cohort study. J Pers Med. 2021;11:845. doi:10.3390/jpm11090845.
5. Kosa SD, Monize J, D'Souza M, Joshi A, Philip K, Reza S, et al. Nutritional mobile applications for CKD patients: systematic review. Kidney Int Rep. 2019;4(3):399-407. doi:10.1016/j.ekir.2018.11.016.
6. Welch JL, Astroth KS, Perkins SM, Johnson CS, Connelly K, Siek KA, et al. Using a mobile application to self-monitor diet and fluid intake among adults receiving hemodialysis. Res Nurs Health. 2013 Jun;36(3):284-98. doi:10.1002/nur.21539.
7. Yang Y, Chen H, Qazi H, Morita PP. Intervention and evaluation of mobile health technologies in management of patients undergoing chronic dialysis: scoping review. JMIR Mhealth Uhealth. 2020;8(4):e15549. doi:10.2196/15549.
8. Morton K, Dennison L, May C, Murray E, Little P, McManus RJ, et al. Using digital interventions for self-management of chronic physical health conditions: a meta-ethnography review of published studies. Patient Educ Couns. 2017 Apr;100(4):616-35. doi:10.1016/j.pec.2016.10.019.
9. McManus RJ, Little P, Stuart B, Morton K, Raftery J, Kelly J, et al. Home and online management and evaluation of blood pressure (HOME BP) using a digital intervention in poorly controlled hypertension: randomised controlled trial. BMJ. 2021;372:m4858. doi:10.1136/bmj.m4858.

10. Whitehead L, Jacob E, Towell A, Abu-Qamar M, Cole-Heath A. The role of the family in supporting the self-management of chronic conditions: a qualitative systematic review. J Clin Nurs. 2018 Jan;27(1-2):22-30. doi:10.1111/jocn.13775.
11. Welch JL, Johnson M, Zimmerman L, Russell CL, Perkins SM, Decker BS. Self-management interventions in stages 1 to 4 chronic kidney disease: an integrative review. West J Nurs Res. 2015 May;37(5):652-78. doi:10.1177/0193945914551007.
12. Lee JA, Choi M, Lee SA, Jiang N. Effective behavioral intervention strategies using mobile health applications for chronic disease management: a systematic review. BMC Med Inform Decision Making. 2018 Feb 20;18(1):12. doi:10.1186/s12911-018-0591-0.
13. Kidney Disease Improving Global Outcomes (KDIGO). KDIGO 2012 clinical practice guideline for the evaluation and management of chronic kidney disease. Kidney Int Suppl. 2013;3(1):1-150. doi:10.1038/kisup.2012.73.
14. Curtin RB, Mapes DL. Health care management strategies of long-term dialysis survivors. Nephrol Nurs J. 2001 Aug;28(4):385-92; discussion 393-4.
15. Ryan P, Sawin KJ. The Individual and Family Self-Management Theory: background and perspectives on context, process, and outcomes. Nurs Outlook. 2009 Jul-Aug;57(4):217-25.e6. doi:10.1016/j.outlook.2008.10.004.
16. Grey M, Knafl K, McCorkle R. A framework for the study of self- and family management of chronic conditions. Nurs Outlook. 2006;54(5):278-86. doi:10.1016/j.outlook.2006.06.004.
17. Ong SW, Jassal SV, Miller JA, Porter EC, Cafazzo JA, Seto E, et al. Integrating a smartphone-based self-management system into usual care of advanced CKD. Clin J Am Soc Nephrol. 2016;11(6):1054-62. doi:10.2215/CJN.10681015.
18. Doyle N, Murphy M, Brennan L, Waugh A, McCann M, Mellotte G. The "Mikidney" smartphone app pilot study: empowering patients with chronic kidney disease. JORC. 2019;45(3):133-40.
19. Nguyen NT, Douglas C, Bonner A. Effectiveness of self-management program in people with chronic kidney disease: a pragmatic randomized controlled trial. J Adv Nurs. 2019 Mar;75(3):652-64. doi:10.1111/jan.13924.
20. Lin C-C, Tsai F-M, Lin H-S, Hwang S-J, Chen H-C. Effects of a self-management program on patients with early-stage chronic kidney disease: a pilot study. ANR. 2013;26(3):151-6. doi:10.1016/j.apnr.2013.01.002.
21. Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMC Med. 2010 Mar 24;8:18. doi:10.1186/1741-7015-8-18.
22. Faul F, Erdfelder E, Buchner A, Lang A-G. Statistical power analyses using G*Power 3.1: tests for correlation and regression analyses. Behav Res Methods. 2009;41(4):1149-60. doi:10.3758/BRM.41.4.1149.
23. Zimbudzi E, Lo C, Misso ML, Ranasinha S, Kerr PG, Teede HJ, et al. Effectiveness of self-management support interventions for people with comorbid diabetes and chronic kidney disease: a systematic review and meta-analysis. Systematic Reviews. 2018;7(1):84.doi:10.1186/s13643-018-0748-z.
24. Curtin RB, Walters BA, Schatell D, Pennell P, Wise M, Klicko K. Self-efficacy and self-management behaviors in patients with chronic kidney disease. Adv Chronic Kidney Dis. 2008 Apr;15(2):191-205. doi:10.1053/j.ackd.2008.01.006.
25. Sritarapipat P, Pothiban L, Panuthai S, Lumlertgul D, Nanasilp P. Causal model of elderly Thais' self-management behaviors of pre-dialysis chronic kidney disease. Pacific Rim Int J Nurs Res. 2012;16(4):277-93.
26. Chen YC, Chang LC, Liu CY, Ho YF, Weng SC, Tsai TI. The roles of social support and health literacy in self-management among patients with chronic kidney disease. J Nurs Scholarsh. 2018 May;50(3):265-75. doi:10.1111/jnu.12377.
27. Fakih El Khoury C, Crutzen R, Schols JMGA, Halfens RJG, Karavetian M. A dietary mobile App for patients undergoing hemodialysis: prospective pilot study to improve dietary intakes. J Med Internet Res. 2020;22(7):e17817. doi:10.2196/17817.
28. St-Jules DE, Woolf K, Goldfarb DS, Pompeii ML, Li H, Wang C, et al. Feasibility and acceptability of mHealth interventions for managing hyperphosphatemia in patients undergoing hemodialysis. J Ren Nutr. 2021 Jul;31(4):403-10. doi:10.1053/j.jrn.2020.07.009.
29. Yang FJ, Hou YH, Chang RE. The impact of a social networking service-enhanced smart care model on stage 5 chronic kidney disease: quasi-experimental study. J Med Internet Res. 2020 Apr;22(4):e15565. doi:10.2196/15565.

30. Lu X, Yang H, Xia X, Lu X, Lin J, Liu F, et al. Interactive mobile health intervention and blood pressure management in adults. Hypertension. 2019 Sep;74(3):697-704. doi:10.1161/HYPERTENSIONAHA.119.13273.
31. KDIGO Blood Pressure Work Group. KDIGO 2021 clinical practice guideline for the management of blood pressure in chronic kidney disease. Kidney Int. 2021 Mar;99(3S): S1-87. doi:10.1016/j.kint.2020.11.003.
32. Whelton PK, Carey RM, Aronow WS, Casey DE Jr, Collins KJ, Dennison Himmelfarb C, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on clinical practice guidelines. Hypertension. 2018 Jun;71(6):1269-324. doi:10.1161/HYP.0000000000000066.
33. Unger T, Borghi C, Charchar F, Khan NA, Poulter NR, Prabhakaran D, et al. 2020 International Society of Hypertension Global Hypertension Practice Guidelines. Hypertension. 2020 Jun;75(6):1334-57. doi:10.1161/HYPERTENSIONAHA.120.15026.
34. Jo SH, Kim SA, Park KH, Kim HS, Han SJ, Park WJ. Self-blood pressure monitoring is associated with improved awareness, adherence, and attainment of target blood pressure goals: prospective observational study of 7751 patients. J Clin Hypertens (Greenwich). 2019 Sep;21(9): 1298-304. doi:10.1111/jch.13647.
35. Sheppard JP, Tucker KL, Davison WJ, Stevens R, Aekplakorn W, Bosworth HB, et al. Self-monitoring of blood pressure in patients with hypertension-related multi-morbidity: systematic review and individual patient data meta-analysis. Am J Hypertens. 2020 Mar 13;33(3): 243-51. doi:10.1093/ajh/hpz182.
36. Lee JY, Park JT, Joo YS, Lee C, Yun H-R, Yoo T-H, et al. Association of blood pressure with the progression of CKD: findings from KNOW-CKD study. Am J Kidney Dis. 2021; 78(2):236-45. doi:10.1053/j.ajkd.2020.12.013.
37. Lee MC, Wu SV, Hsieh NC, Tsai JM. Self-management programs on eGFR, depression, and quality of life among patients with chronic kidney disease: a meta-analysis. Asian Nurs Res (Korean Soc Nurs Sci). 2016 Dec;10(4): 255-62. doi:10.1016/j.anr.2016.04.002.
38. Peng S, He J, Huang J, Lun L, Zeng J, Zeng S, et al. Self-management interventions for chronic kidney disease: a systematic review and meta-analysis. BMC Nephrol. 2019 Apr 26;20(1):142. doi:10.1186/s12882-019-1309-y.
39. Chen X, Xie S, Yu X, Chen Z, Zhuo M, Li J. mHealth app for patient self-management of chronic kidney disease improves renal outcome: pilot study. JMIR Publications. iproc 2018;4(2):e11777. doi:10.2196/11777.
40. Nojima J, Meguro S, Ohkawa N, Furukoshi M, Kawai T, Itoh H. One-year eGFR decline rate is a good predictor of prognosis of renal failure in patients with type 2 diabetes. Proc. Jpn. Acad., Ser B. 2017;93(9):746-54. doi:10.2183/pjab.93.046.

โปรแกรมการจัดการตนเองแบบรายบุคคลและครอบครัวร่วมกับแอปพลิเคชันสุขภาพมือถือ สำหรับผู้ป่วยโรคไตเรื้อรังระยะที่ 3: การวิจัยเชิงทดลองแบบสุ่มชนิดมีกลุ่มควบคุม

แสงรวี มณีศรี เขมารดี มาสิงบุญ นุจรี ไชยมงคล*

บทคัดย่อ: ความชุกของโรคไตเรื้อรังที่เพิ่มขึ้นเป็นภาระด้านสาธารณสุขของโลกเช่นเดียวกับประเทศไทย กลยุทธ์การจัดการตนเองเป็นวิธีที่มีประสิทธิภาพในการชะลอความเสื่อมของไตให้ช้าลง การศึกษาครั้งนี้ออกแบบเป็นเชิงทดลองแบบสุ่มชนิดมีกลุ่มควบคุม มีวัตถุประสงค์เพื่อตรวจสอบประสิทธิผลของโปรแกรมการจัดการตนเองและครอบครัวร่วมกับแอปพลิเคชันสุขภาพมือถือ ในผู้ที่เป็นโรคไตเรื้อรังระยะที่ 3 กลุ่มตัวอย่างทั้งหมด 40 ราย สุ่มเข้ากลุ่มทดลอง 20 ราย และกลุ่มควบคุม 20 ราย เครื่องมือวิจัยประกอบด้วยโปรแกรมการวิจัย แอปพลิเคชัน Healthy Kidney แบบสอบถามพฤติกรรมการจัดการตนเองในผู้ป่วยโรคไตเรื้อรังและแบบบันทึกผลลัพธ์ทางคลินิก ประเมินผลลัพธ์ 3 ครั้ง ระยะก่อนการทดลอง (สัปดาห์ที่ 1) ระยะหลังการทดลอง (สัปดาห์ที่ 4) และระยะติดตามผล (สัปดาห์ที่ 16) วิเคราะห์ข้อมูลด้วยการทดสอบค่าเฉลี่ยของกลุ่มตัวอย่าง 2 กลุ่มที่เป็นอิสระต่อกัน (independent t-test) และทดสอบความแปรปรวนแบบวัดซ้ำ (Repeated Measures ANOVA)

ผลการวิจัยพบว่า หลังจากเข้าร่วมโปรแกรมกลุ่มทดลองมีคะแนนพฤติกรรมการจัดการตนเองสูงขึ้นและค่าความดันโลหิตไดแอสโตลิกลดลงมากกว่ากลุ่มควบคุมในระยะติดตามผลอย่างมีนัยสำคัญทางสถิติ พฤติกรรมการจัดการตนเอง ความดันโลหิตซิสโตลิก และความดันโลหิตไดแอสโตลิกของกลุ่มทดลองดีขึ้นอย่างมีนัยสำคัญใน 3 เดือนหลังการทดลอง แต่อย่างไรก็ตามไม่พบความเปลี่ยนแปลงของอัตราการกรองของไต ผลการวิจัยแสดงให้เห็นว่าโปรแกรมนี้สามารถปรับปรุงผลลัพธ์ของกลุ่มตัวอย่างได้อย่างมีประสิทธิภาพ

ผลการศึกษานี้ชี้ให้เห็นว่าโปรแกรมการจัดการตนเองและครอบครัวร่วมกับแอปพลิเคชันสุขภาพมือถือ ช่วยให้ผู้ป่วยโรคไตเรื้อรังระยะที่ 3 ปรับปรุงพฤติกรรมการจัดการตนเองและลดความดันโลหิตได้ การศึกษานี้สนับสนุนบริบทการดูแลสุขภาพเพื่อส่งเสริมการจัดการตนเองที่บ้านและเป็นแนวทางในการพัฒนาแอปพลิเคชันสุขภาพมือถือในอนาคต ก่อนนำโปรแกรมไปใช้ในการปฏิบัติการพยาบาลควรมีการทดสอบเพิ่มเติม

Pacific Rim Int J Nurs Res 2023; 27(1) 169-184

คำสำคัญ: โรคไตเรื้อรังระยะที่ 3 ความดันโลหิตไดแอสโตลิก การสนับสนุนจากครอบครัว แอปพลิเคชันสุขภาพมือถือ พฤติกรรมการจัดการตนเอง ความดันโลหิตซิสโตลิก

แสงรวี มณีศรี *นิสิตหลักสูตรปรัชญาดุษฎีบัณฑิต สาขาการพยาบาล (หลักสูตรนานาชาติ) คณะพยาบาลศาสตร์ มหาวิทยาลัยบูรพา ประเทศไทย*
E-mail: sangrawee.m@rsu.ac.th
ติดต่อที่: เขมารดี มาสิงบุญ* *RN, DSN ผู้ช่วยศาสตราจารย์ คณะพยาบาลศาสตร์ มหาวิทยาลัยบูรพา ประเทศไทย E-mail: khemaradee@nurse.buu.ac.th*
นุจรี ไชยมงคล *RN, PhD รองศาสตราจารย์ คณะพยาบาลศาสตร์ มหาวิทยาลัยบูรพา ประเทศไทย E-mail: nujjaree@buu.ac.th*