Effectiveness of Self-Management Enhancement Program for Thais with CKD at Pre-dialysis Stages: A Randomized Controlled Trial

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Abstract: This randomized controlled trial aimed to examine the effects of a nurse-led, self-management, enhancement program used as an intervention for self-management behaviors, disease control, and quality of life among Thais with chronic kidney disease, pre-dialysis. Purposive sampling was used to recruit 120 participants, of whom 60 were equally diagnosed with chronic kidney disease at stages 3 and 4. Participants were randomly assigned to either the experimental (n=60) or control group (n=60). The experimental group received the 6-week intervention in addition to usual care, while the control group received only usual care. Outcome variables included self-management behaviors, systolic blood pressure, diastolic blood pressure, HbA_{1c}, serum creatinine, and quality of life. Data were collected through self-reported questionnaires, blood pressure measurements, and laboratory procedures, at baseline, 4 weeks, 12 weeks, and 24 weeks after participation in the program. Data were analyzed using descriptive statistics, paired t-test, and independent t-test. Results revealed that after program completion and compared to the control group, at 4 weeks the experimental group had significantly better self-management behaviors; at 12 weeks, lower systolic blood pressure, diastolic blood pressure, and HbA_{1c}; and, at 24 weeks, better quality of life. However, there was no significant difference in serum creatinine between groups at 24 weeks. Findings indicate the program improved health outcomes. Hence, self-management enhancement should be incorporated into nursing practice for individuals with chronic kidney disease at pre-dialysis stage.

Pacific Rim Int J Nurs Res 2016; 20(4) 320-336

Keywords: Chronic Kidney Disease, Disease Control, Intervention Program, Pre-dialysis Stage, Quality of Life, Self-Management Behaviors, Self-Management Enhancement Program.

Introduction

In Thailand, chronic kidney disease (CKD) is becoming a major public health concern since its incidence is increasing alarmingly.[1] Hypertension (HT) and Diabetes (DM) have been well-established as the underlying risk factors of CKD.[2] Thus, living with CKD usually involves management of CKD itself and both HT and DM. Moreover, it has been consistently reported that individuals with CKD stage

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3 and stage 4 often confront the profound impacts of disease on physical, psychological, and social dimensions as well as economic burden.[3-5] In other words, all dimensions of quality of life (QOL) of those with CKD at pre-dialysis stage are subject to impairment and deterioration due to the presence of CKD-related symptoms, complications, and CKD progression.[6] QOL, an important marker of disease burden, refers to the subjective perception of the effects of disease or its treatment on one's health.[7] Having progressive CKD with co-existing conditions implies impaired QOL, and therefore both CKD and its co-existing conditions, particularly HT and DM, should be controlled.

With a particular focus on disease control, it should be emphasized that individuals with CKD pre-dialysis should be enabled to maintain their clinical stability of disease as indicated by the normal or near-normal range of certain clinical markers. There are three practical strategies for achieving disease control. First, controlling high BP to the particular target BP of less than 140/80 mmHg is recommended.[8] Second, controlling high blood glucose to near normal level or HbA_{1c} of less than 7.0 % is considered optimal glycemic control.[9] Third, controlling proteinuria to the normal range of 30-300 mg/24 hours is shown to be associated with slowed CKD progression.[10] To achieve these, daily performance of key self-management behaviors including adherence to medications, diet modifications, BP and blood glucose monitoring, regular exercise, avoidance of nephro-toxins and smoking cessation are necessarily.[11-12] However, in previous studies, self-management behaviors in terms of medical management in this population were reported to be low and insufficient in association with the presence of co-morbid diseases.[13-14]

Enhancing self-management helps individuals with CKD pre-dialysis to perform day-to-day activities needed to manage their chronic conditions by altering behaviors to optimize health outcomes.[15] Skills that are necessary to self-manage CKD in daily living include: goal selection; information collection; information procession and evaluation; problem solving; decision making; resource utilization; patient-provider relationship; action taking; and self-reaction.[15-16] To successfully train individuals with these skills, self-efficacy is found to be the most influential predictor by having the direct positive effect on self-management behaviors.[13-14] Hence, self-efficacy enhancement should be included in skills training.[17] Additionally, informational support has been shown to be associated with increased self-management behaviors.[14] Thus, knowledge is an essential prerequisite for self-management adoption. Individuals with CKD pre-dialysis who are provided with these elements are expected to address their health problems via medical, emotional, and role management in achieving desirable health outcomes.

However, few studies pertaining to self-management intervention conducted in Thais with CKD pre-dialysis were found.[18-20] Moreover, these studies were heterogeneous with respect to theory-based, intervention components, and outcome measures. Also, it is noted that all studies lacked rigorous design with large sample sizes and inclusion of QOL as an outcome. Besides, little is known about the effectiveness of theory-based self-management enhancement program in Thais with CKD pre-dialysis. This indicates the necessity of developing and conducting programs and testing its efficacy in this population.

Review of Literature and Conceptual Framework

CKD education may increase both objective and perceived kidney disease knowledge and improve a range of outcomes across the CKD spectrum among individuals with CKD.[11]However, education alone is not sufficient to promote and sustain healthy behavior change, particularly where there is such a complex regimen.[8] Provision of education appears to be regarded as necessary but not a sufficient contributor

to behavior change. However, when education is supplemented with ongoing self-management skills training, regardless of type of chronic diseases, significantly greater improvements in a variety of health outcomes are observed.[21-23] With the acquisition and adoption of effective self-management, it is required that individuals with chronic disease are trained with specific skills of self-management needed to handle medical, emotional, and role consequences.[24]

Given the necessary processes and skills of self-management that are imperative for individuals with CKD at stages 3 and 4 to deal with their existing conditions,[25-26] there are six self-management processes to be achieved: goal selection, information collection, information evaluation and processing, decision-making, action, and self-reaction.[16]These considered suitable for those with CKD pre-dialysis to engage in behavioral change that controls and reduces the impact of CKD. These six self-management processes seem to be more practical and applicable when are integrated with five skills of self-management which include problem-solving, decision-making, resource utilization, patient-provider relationship and, action taking.[15] Within the training of integrated processes and skills of self-management, the primary tasks that are vital to success of self-management are threefold 1) medical management, examples of which include taking medication, adhering to special diet, or using medical devices, 2) emotional management, such as adjusting to situation-induced emotions including anger, fear, sadness, depression, or grief, and 3) role management which refers to maintaining, changing, and creating new meaningful behaviors and life roles.[15,24] However, self-management skills training alone combined with knowledge provision might not be adequate to influence ones' self-management behaviors unless cognitive processes to change behaviors, for example increase in self-efficacy, are involved.[27] To be successful, enhancing perceived self-efficacy should also be incorporated into the process of training for self-management skills. Perceived self-efficacy can be developed and influenced through four main sources including 1) mastery experiences by performing an activity, 2) vicarious experience by observing others who are successful in performing an activity, 3) verbal persuasion by using reinforcing and encouraging words, and 4) emotional arousal by promoting positive feedback.[17]

There is a variety of studies that have proved the positive association between perceived self-efficacy and self-management behaviors in individuals with CKD.[13-14,28-29] Moreover, self-management programs based on self-efficacy theory have been shown to be effective and efficient in the care of persons with chronic illness.[17] Interventions that are delivered using face-to-face education within a group format have also yielded promising results.[26,30] There is strong evidence across studies in individuals with CKD at pre-dialysis stage of the beneficial effect on physiological outcomes including BP control,[19-20,31-32] glycemic control,[18-19,31-32] CKD progression control,[34] adherence to therapeutic regimens,[33] self-management behaviors,[18-20,32,35-36] psychological outcomes including knowledge,[18,34-35] self-efficacy,[33,37] and QOL.[32-33] Therefore, self-management intervention that is tailored to such individuals should primarily include initiating informational support in the form of group-based knowledge provision, training processes and skills of self-management, and enhancing perceived self-efficacy.

QOL is regarded as one of evaluation indicator for successful self-management intervention in CKD.[21] However, it has been reported that QOL decreases in the early stages of CKD in association with an impaired glomerular filtration rate (GFR).[6] Some reports suggest that the presence of co-morbidities is a major determinant of a decline in QOL.[7-8] Therefore, self-management interventions that focus on controlling co-morbidities of CKD would improve QOL in individuals with CKD at pre-dialysis stages.

One of the most important parts of CKD treatment is about controlling the disease to prevent

CKD progression.[8] Keeping BP less than 140/90 mmHg, HbA_{1c} lower than 7%, and proteinuria 30-300mg/24 hours is considered the optimal disease control that not only slows CKD progression but also increases QOL.[8-10] However, to optimize disease control, self-management skills are required to deal with medical, emotional, and role aspect.

It is clear that Thais with CKD at pre-dialysis stage lack sufficient self-management behaviors particularly regarding medical management.[14] Prior studies have indicated that inadequate self-management behaviors were associated with suboptimal disease control which in turn led to impaired QOL.[6,21,36] It is therefore important to initiate a theory-based approach to involve individuals with CKD taking a central role in alterations to their lifestyle to promote disease control and improve QOL. Nonetheless, it is noteworthy that no integrated theory-based studies have been conducted in Thailand with this population to evaluate their self-management behaviors, disease control, and QOL. Hence, this study aimed to test the effects of the strategy to enhance self-management through providing knowledge, training self-management skills and increasing perceived self-efficacy on self-management behaviors, disease control, and QOL. It was conceptually hypothesized that compared to individuals with receiving usual care, those with CKD pre-dialysis receiving a 6-week self-management enhancement program would at 4 weeks have better self-management behaviors, at 12 weeks better disease control in terms of risk factors control, and at 24 weeks better CKD progression control and QOL than baseline.

Methods

Design: This study used a randomized control trial.

Sample and Sampling: The samples were Thais who were diagnosed with stage 3 or 4 CKD. Purposive sampling was used to recruit the 120 eligible participants. Inclusion criteria were: 1) aged 50-70 years; 2) having underlying both DM and HT; 3) able to read and write in Thai; and 4) willing to participate in the study. Exclusion criteria were: 1) having severe complications associated with underlying diseases and CKD; and 2) expected to undergo renal replacement therapy (RRT) in the period of next six months. Discontinuation criterion was that participants did not complete at least one session of the intervention that participants.

The sample size was determined based on three components of power analysis including: 1) α of .05 (one-tailed probability test); 2) statistical power of 0.8; and 3) effect size of 0.5 which is usually the minimum effect size considered acceptable in RCT.[41] The sample size was estimated using a calculating formula for comparisons of two groups at single time point. As a result, the required numbers of participants were 100. Twenty percent of estimated sample size was further added to overcome the attrition rate. Therefore, the actual total numbers of participants were 120 persons, 60 per group.

In this study, initially, 148 potential participants with CKD at pre-dialysis stages were approached, of whom, 28 refused to participate in the program due to: being far away from the setting (12 persons); lack of caregivers to accompany them to the setting (10 persons); and lack of interest in the program (6 persons). One hundred and twenty (120) eligible participants were stratified into CKD stage 3 and stage 4 with 60 participants for each stage. The participants with both stages were randomized into the experimental and control group with 30 participants per group of each stage. All participants completed 4 weeks, 12 weeks, and 24 weeks follow-up

Randomization: After obtaining informed consent, the PI proceeded to allocate the participants to the experimental or control group using simple randomization. With randomization method, initially, stratified randomization was made using CKD stage as a stratum. As a result, the participants were divided in to CKD stage 3 and stage 4. Subsequently, the PI made two slips of paper with "E" is the experimental group and "C" is the control group and drew out a slip from a box. The participants of each stage were assigned to either "E" or "C" as stated in chosen slip (Figure 1).

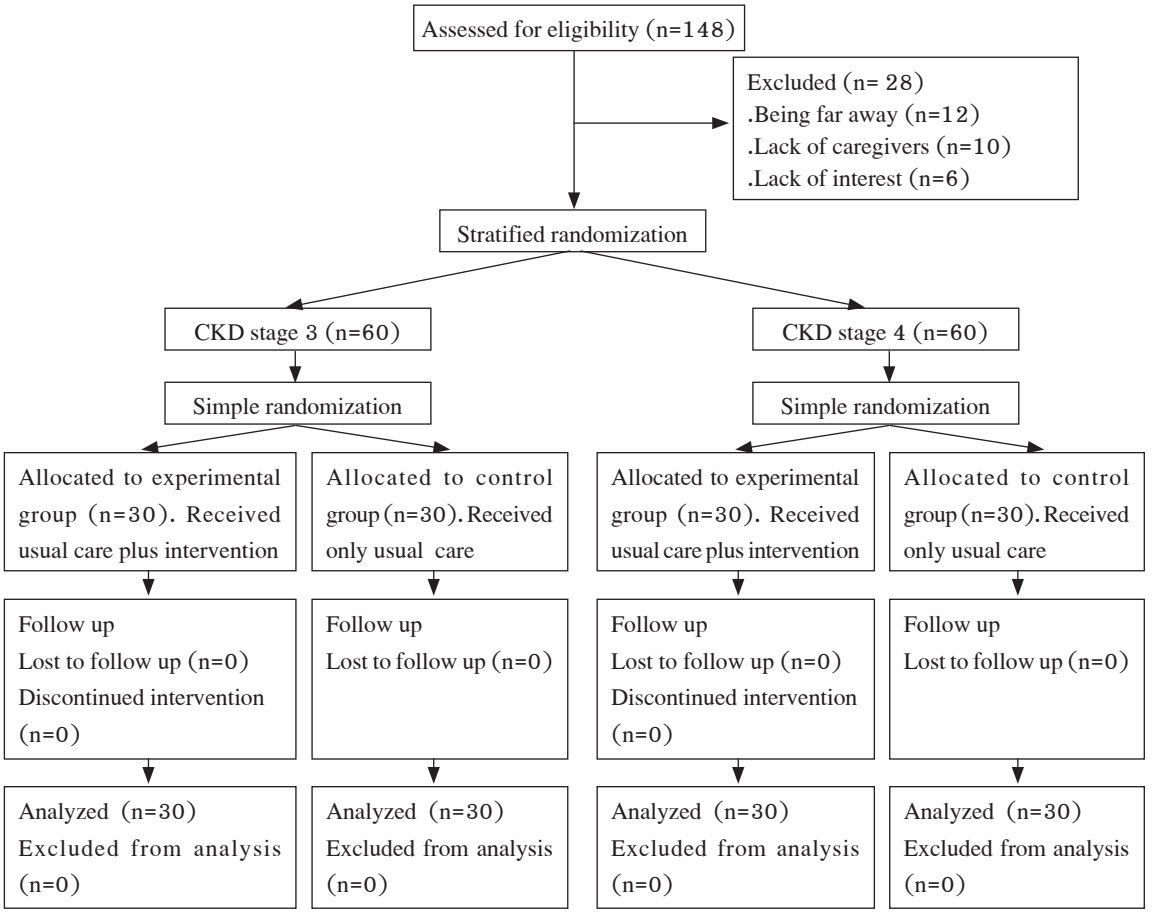

Figure 1. Flow chart of the participants throughout the trial

Setting: The study was conducted from August 2014-March 2015 at one tertiary care hospital in Songkhla Province, southern Thailand. The PI implemented intervention sessions at one nursing college adjacent to the setting, and all follow-ups were implemented at that setting.

Ethical Consideration: Study approval was given by the Research Ethics Review Committee of the Faculty of Nursing, Chiang Mai University and the study setting. All potential participants were informed about: study's objectives; procedures; potential risks and benefits; voluntary participation; and protection of confidentiality and rights to withdraw at any point in the study without consequence on current treatment or hospital service. Prior to signing the informed consent form, participants were assured of confidentiality and anonymity and had enough time to ask questions about the study.

Training and Preparing Research Assistants: There were two research assistants (RAs) in this study who assisted in collecting data by administering the questionnaires. They were introduced to a full description of the study, procedures, data collection method, questionnaire administration, protection of human rights, and informed consent, and given time to ask questions about these processes. They were trained in how to complete questionnaires and spent time collecting data at baseline and follow-ups with

ten individuals with CKD at pre-dialysis stages under the close supervision of the PI. Problems that emerged from training were discussed and solved to reach mutual understanding. With preparing and training, the RAs were fully qualified to assist the PI with their practical experience.

Procedures: After obtaining study approval, the eligible participants were randomly assigned into the experimental group and the control group. The RAs helped to collect data using questionnaires, and BP was measured by the PI according to the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure(JNC7) guideline, indicating the accurate measurement of BP that included sitting quietly at least 5 minutes, and avoiding caffeine, exercise, and smoking for at least 30 minutes prior to measurement. In addition, an appropriately sized cuff and at least two readings 5 minutes apart with average record were recommended.[42] HbA_{1c} and serum creatinine were tested by the laboratory staff of the study setting at baseline. The experimental group received a 6-week intervention in addition to usual care, while the control group received only usual care. For follow-up, an appointment was made with the participants after program completion for assessment of outcomes: 4 weeks for self-management behaviors; 12 weeks for BP and HbA_{1c}; and 24 weeks for serum creatinine and QOL. These different times of outcome measures were supported by the previous evidences that self-management intervention had positive effects on theses outcomes in respective time points of measurement.[19,34,37]

Instruments

The Demographic Data Recording Form was developed to obtain participants' personal data of age, gender, marital status, education level, occupation, income, payment scheme, living arrangements, duration of having CKD, co-morbid diseases, smoking status, alcohol drinking status, exercise, and participation in other CKD education courses.

The Self-Management Behavior Questionnaire (SMBQ) was used to measure self-management behaviors. This self-reported questionnaire, translated into Thai and modified by Sritarapipat,[14] was originally developed by Curtin.[13] The SMBQ is a 37-item instrument consisting of five dimensions of self-management behaviors, including: communication with health care providers (8 items); partnership in care (7 items); self-care activities (11 items); self-advocacy behaviors (10 items); and, medication adherence behavior (1 item). Examples of an item from two different dimensions are: "During the past six months, how often have you kept track of blood glucose (sugar) levels?" (self-care activities); and, "In the past six months, how often have you used additional treatments other than what your doctor prescribed?" (medication adherence behavior). Possible responses to each item range from 1 = "never" to 5 = "all of the time." A total score, which could range from 37 to 185, is obtained by summing the response values across all items. The total score indicates the level of self-management behaviors, whereby a score of 37 to 85.9 = low; 86 to 135.9 = moderate; and, 136-185 = high.[14]The SMBQ in the pilot study was tested for reliability using Cronbach' alpha coefficient of internal consistency with 15 participants who had the same characteristics as study sample, revealing the value of 0.88, while the value of actual study was 0.92.

The Kidney Disease Quality of Life -36 Questionnaire (KDQOL-36) was used to assess CKD-related QOL and translated into Thai by Thaweethamcharoen.[38]The instrument was originally developed by RAND Health Organization, University of Arizona for individuals with CKD and on dialysis and has been translated into several languages. The KDQOL-36, a self-reported measure, consists of 1) SF-12 (12 items) which measure physical functioning (physical component summary [PCS])

and mental functioning (mental component summary [MCS]), burden of kidney disease subscale (4 items), symptoms and problems subscale (12 items), and effects of kidney disease on daily subscale (8 items). However, in this study, one dialysis specific question in the symptoms and problems subscale concerning dialysis was excluded because the participants did not have enough severe kidney disease to require dialysis. Thus the total number of items was 35. Examples of items are: "During the past four weeks, were you limited in the kind of work or other activities?" (PCS); and, " To what extent were you bothered by shortness of breath?"(burden of kidney disease).The possible response to each item varies with its response scale. Response to items include: 1= "not at all" to 5= "extremely". The scores of the KDQOL-36 are transformed into 0 to 100, with higher scores indicating better QOL.[38]This instrument was tested for reliability using Cronbach' alpha coefficient of internal consistency, indicating the value of 0.92 in the pilot study and 0.95 in the main study.

Biological measures: A mercury sphygmomanometer, the Hemoglobin A1C Measurement-DCA 2000 Analyzer, and the Beckman Coulter AU Analyzer were instruments measuring BP, HbA_{1c}, and serum creatinine, respectively. The accuracy and precision of these instruments were verified using the calibration done by quality control section of the study setting.

Intervention Program

The Instruction Manual for Enhancing Self-Management of Pre-dialysis CKD Patients (IMESM) was developed by the PI and was used as guideline for implementing the intervention. This manual primarily includes six sessions for enhancing self-efficacy and training self-management skills.

The *VDO media* regarding CKD knowledge was downloaded from the Nephrology Society of Thailand website.[43] The VDO was delivered in the form of the animated cartoons with sound, lasting about 30 minutes. The content featured in the VDO included cause of CKD, risk factors, signs and symptoms, complications, medical treatment, nutritional management, and medication use.

The Participants' Personal Booklet, *Living a Healthy Life with Chronic Kidney Disease*, was developed based on a literature review and used as guiding manual for participants with CKD at pre-dialysis to initiate self-learning at home. This booklet includes information and knowledge necessary to self-management in dealing with medical, emotional, and role management.

In order to ensure the participants' readiness to perform their self-management behaviors, the following specific monitoring tool was used. The *Personal Written Action Plan* (PWAP) was developed for the participants recording their health data and specifying activities they wanted to perform in managing day to day CKD-related problems. With the participants' intention of undertaking selected activities, the *Motivation and Self-efficacy Rating Scale,* a part of the PWAP, was employed rating the strength of their efficacy belief on a 10-point scale, ranging in 1 unit intervals from 0 ("Cannot do"); through intermediate degrees of assurance, 5 ("Moderately certain, can do"); to complete assurance, 10 ("Highly certain, can do").

The *Perceived Self-Management Self-Efficacy Questionnaire* (PSMSEQ) was first developed by Curtin[13] and translated into Thai by Sritarapipat.[14] This instrument consists of 12 self-reported items regarding confidence to perform three subcategories of self-management including medical management, emotional management, role management, and overall CKD self-management. The response of items is on a five-point Likert scale ranging from 1 = Not at all confident to 5 = Very confident. Possible total scores of the PSMSEQ range from 12 to 60. For the purpose of description, the total score was classified into three equal levels including low self-efficacy (12 – 27.9), moderate self-efficacy (28 – 43.9), and high self-efficacy (44 - 60). Higher scores indicate higher levels of perceived self-efficacy of self-management. This scaling was specific for pre-dialysis CKD-related self-efficacy and used to monitor level of participants'

self-efficacy after completion of intervention to ensure that they had enough self-efficacy levels in performing self-management behaviors. They needed to gain a score of at least 44.

The IMESM, PWAP, and Participants' Personal Booklet were reviewed for content validity by a panel of five experts in nephrology, and nephrological nursing. In addition, the booklet was confirmed from five individuals with CKD to evaluate the readability and understandability. Some words lacking clarity or were ambiguous were corrected and modified before distribution. The VDO media and the PSMSEQ were not validated because these two instruments were unmodified and standardized.

Intervention implementation

The intervention was a nurse-led, self-management, enhancement program that aimed to train the participants with nine skills of self-management, to enhance the participants' perceived self-efficacy and, to provide the participants with information regarding CKD and self-management concept. The participants with CKD stage 3 and stage 4 were further divided into four groups, with 15 participants per group. See **Table 1.**

Table 1. Summary of six sessions of self-management skills training

Sessions	Self-management skills training	Self-efficacy enhancement strategy	Method
Week 1	Program introduction, health education, health problems identification, and formulation of personal action plan	- Verbal persuasion	- Group-based discussion - Education - Demonstration
Week 2	Skills of 1) goal selection, 2) information collection and 3) information procession and evaluation	- Verbal persuasion	- Group-based discussion
Week 3	Skills of 4) problem solving, 5) decision making, 6) action taking, and 7) self-reaction	- Verbal persuasion	- Group-based discussion - Group support
Week 4	Skills of 8) resource utilization, and 9) patient-provider relationship	- Vicarious experience - Verbal persuasion	- Group-based discussion - Group support
Week 5	Review of all nine self-management skills, emotional, stress, and role management, and exercise training	- Skill mastery - Vicarious experience - Verbal persuasion - Emotional arousal	- Group-based discussion - Group support - Demonstration
Week 6	Repeated review of all nine self-management skills, program summary, and follow up plan	- Skill mastery - Vicarious experience - Verbal persuasion - Emotional arousal	- Group-based discussion - Group support - Return-demonstration

Each session lasted about 2.5-3.0 hours with 2 intermittent breaks during session in progress, held once a week for 6 consecutive weeks. In session 4 and 5, the participants were assessed for perceived self-efficacy level using motivation and self-efficacy rating scale as specified in personal action plan. It was found that the participants' self-efficacy score was higher than 7 scores. This indicated that they had high perceived self-efficacy levels in completing tasks they chose. Moreover, in session 6, participants' perceived self-efficacy level was assessed using the PSMSEQ. It revealed that all participants had high level of perceived self-efficacy with scores more than 44. In addition, all six sessions of self-management skills training

were designed to be highly interactive, flexible and motivated with an emphasis on self-efficacy enhancement. Peer support occurred automatically and naturally through group-based discussion. The participants were allowed to share their successful experience in self-management to the others during group based session.

Usual care: Refers to a broad range of typical medical services provided to the individuals with CKD stages 3 and 4 who regularly attend the CKD clinic at medical outpatient department of the study setting.

Data Analysis: Descriptive statistics, the Chi-square, Fisher's Exact, and t-test were used for analyzing the demographic data. The assumptions of normal distribution and homogeneity of variances were tested prior to data analysis, indicating normal distribution and homogeneity of variances of dependent variables. Thus, the use of t-test was allowed. The paired t-test was used to test the difference in all dependent variables between baseline and post-test of both the experimental and control groups. The independent t-test was employed to test the difference in all dependent variables between the experimental and control groups at post-test.

Results

All participants were those diagnosed with CKD stages 3 and 4 with an equal number of 60 in the control and experimental groups. Both groups were similar in all demographic characteristics at baseline in terms of age, gender, marital status, educational level, occupation, income, payment scheme, living arrangement, duration of having CKD, co-morbidities, smoking and alcohol consumption status, and exercise. Also, participation in other CKD education courses was similar (Table 2). Likewise, all dependent variables of both groups were similar at baseline (Table 3).

Table 2. Demographic characteristics of the participants in the control and experimental groups

Characteristics	Control (n=60)		Experiment (n=60)		Statistic test value	p-value
	n	%	n	%		
Age						
$\overline{X} \pm SD$	59.75 ± 6.38		59.48 ± 6.41		-.228[t]	.820
(Range)	50-70		50-70			
50-59	33	55.0	33	55.0	1.000[b]	.573
60-70	27	45.0	27	45.0		
Gender						
Male	21	35.0	23	38.3	.850[b]	.425
Female	39	65.0	37	61.6		
Marital status						
Single	5	8.3	6	10.0	.862[a]	.835
Married	35	58.3	38	63.3		
Widowed	11	18.3	10	16.6		
Divorced/separated	9	15.0	6	10.0		
Educational level						
Elementary school	39	65.0	33	55.0	2.710[a]	.607
Secondary school	9	15.0	9	15.0		
High school/vocational certificate	6	10.0	7	11.6		
Diploma/high vocational certificate	5	8.3	7	11.6		

Table 2. Demographic characteristics of the participants in the control and experimental groups (cont.)

Characteristics	Control (n=60)		Experiment (n=60)		Statistic test value	p-value
	n	%	n	%		
Occupation						
Unemployed	26	43.3	20	33.3	8.953[a]	.176
Grocer/business owner	14	23.3	13	21.6		
Agriculturist	12	20.0	8	13.3		
Private employee	7	11.6	11	18.3		
Retired government officer	1	1.6	8	13.3		
Demographic characteristics	**Control (n=30)**		**Experiment (n=30)**		**Statistic test value**	**p-value**
	n	**%**	**n**	**%**		
Household income (Baht/month)						
$\overline{X} \pm SD$	9,566 ± 4,336		10,866 ± 5,703		.994[t]	.324
(Range)	5,000-20,000		5,000-30,000			
< 10,000	24	40.0	25	41.6	1.135[a]	.567
10,000-15,000	23	38.3	20	33.3		
> 15,000	13	21.6	15	25.0		
Payment scheme						
Universal healthcare coverage	36	60.0	31	51.6	1.336[a]	.513
Social insurance	13	21.6	14	23.3		
Medical expense reimbursement	11	18.3	15	25.0		
Living arrangement						
With spouse	19	31.6	18	30.0	.695[a]	.952
With family members	33	55.0	33	55.0		
Duration of CKD						
1-2 years	9	15.0	6	10.0	2.303[a]	.941
3-4 years	44	73.3	46	76.6		
> 4 years	7	11.6	8	13.3		
Co-morbid diseases (both HT and DM)	60	100	60	100		
Smoking status						
Never	43	71.6	46	76.6	1.336[a]	.513
Have quit smoking	17	28.3	14	23.3		
Demographic characteristics	**Control (n=60)**		**Experiment (n=60)**		**Statistic test value**	**p-value**
	n	**%**	**n**	**%**		
Alcohol consumption status						
Never	48	80.0	52	86.6	.436[b]	.232
Seldom	12	20.0	8	13.3		
Exercise						
Never	49	81.6	51	85.0	1.210[a]	.546
Sometimes	11	18.3	9	15.0		
Participation in other CKD education courses						
Never	22	36.6	18	30.0	2.400[a]	.301

Table 2. Demographic characteristics of the participants in the control and experimental groups (cont.)

Demographic characteristics	Control (n=60)		Experiment (n=60)		Statistic test value	p-value
	n	%	n	%		
Having participated at						
Hospital	36	60.0	36	60.0		
Sub-district health promoting hospital	2	3.3	6	10.0		

Note. [a] = Chi-square test; [b] = Fisher's Exact test; [t] = t-test

Table 3. Comparison of Differences in Dependent Variables of the Sample at Baseline (n=120)

Dependent variables	Experimental group (n = 60)		Control group (n = 60)		t-test	p-value
	$\overline{X}$	SD	$\overline{X}$	SD		
Self-management behaviors	87.45	5.16	88.95	4.47	-1.70	.092
Systolic BP	154.43	10.27	154.60	9.50	-0.92	.927
Diastolic BP	87.07	6.86	86.30	6.67	.620	.536
HbA_{1c}	8.33	.713	8.33	.744	.006	.995
Serum creatinine	2.40	.613	2.41	.587	-.064	.949
Quality of life	50.24	7.33	48.34	10.12	1.17	.241

Regarding the hypotheses, as shown in Table 4, at post-test, the experimental group was found to have significantly higher mean score of self-management behaviors (4 weeks after receiving the program), lower mean systolic BP, diastolic BP, HbA_{1c} (12 weeks after receiving the program), lower mean serum creatinine and higher mean score of QOL (24 weeks after receiving the program) than baseline. Thus, these hypotheses were totally supported.

As shown in Table 5, at post-test, the experimental group was found to have significantly higher mean score of self-management behaviors (4 weeks after receiving the program), lower mean systolic BP, diastolic BP, HbA_{1c} (12 weeks after receiving the program), and higher mean score of QOL (24 weeks after receiving the program) than the control group. However, there was no significant difference in serum creatinine between groups. It is important to note that although all dependent variables were significantly different between groups, except that of serum creatinine, some clinical outcomes including systolic BP and HbA_{1c} did not meet normal limit and standard level (< 140 mmHg and < 7.0 %, respectively). Hence, these hypotheses were partially supported.

Table 4. Comparison of Dependent variables between Baseline and Post-test (n=120) in Each Group

Dependent variables	Experimental Group (n = 60)			Control group (n = 60)		
	Baseline $\overline{X} \pm SD$	Post-test $\overline{X} \pm SD$	t-test	Baseline $\overline{X} \pm SD$	Post-test $\overline{X} \pm SD$	t-test
Self-management behaviors	87.45 ± 5.16	138.95 ± 4.19	69.33**	88.95 ± 4.47	90.05 ± 4.84	-1.66[ns]
Systolic BP	154.43 ± 10.27	150.00 ± 9.39	-7.56**	154.60 ± 9.50	157.67 ± 8.55	-6.46**
Diastolic BP	87.07 ± 6.86	82.50 ± 6.18	-7.13**	86.30 ± 6.67	86.03 ± 4.76	.419[ns]
HbA_{1c}	8.33 ± .713	7.97 ± .732	13.99**	8.33 ± .744	8.53 ± .738	-9.19**
Serum creatinine	2.40 ± .613	2.38 ± .618	-4.68**	2.41 ± .587	2.42 ± .588	-5.15**
Quality of life	50.24 ± 7.33	67.70 ± 5.32	16.77**	48.34 ± 10.12	52.27 ± 9.81	-2.65*

Note. * = p < .05, ** = p < .001, [ns] = not significant

Table 5. Comparison of Dependent variables between the Experimental and Control Groups at Post-test (n=120)

Dependent variables	Experimental group (n = 60)	Control group (n = 60)	t-test	p-value
	$\bar{X}$ ± SD	$\bar{X}$ ± SD		
Self-management behaviors	138.95 ± 4.19	90.05 ± 4.84	59.12	.000
Systolic BP	150.00 ± 9.39	157.67 ± 8.55	-4.67	.000
Diastolic BP	82.50 ± 6.18	86.03 ± 4.76	-3.50	.001
HbA_{1c}	7.97 ± .732	8.53 ± .738	-4.13	.000
Serum creatinine	2.38 ± .618	2.42 ± .588	-.374	.709
Quality of life	67.70 ± 5.32	52.27 ± 9.81	10.70	.000

Discussion

Overall, the findings from this study indicated that self-management enhancement program was effective in improving self-management behaviors, reducing systolic BP, diastolic BP, HbA_{1c}, and improving QOL among Thais with CKD at pre-dialysis stages, focusing on stage 3 and stage 4. Furthermore, these improved outcomes were clinically significant. The main findings basically supported the majority of proposed hypotheses and conceptual framework that self-management enhancement program leads to increased self-management behaviors which promote disease control, thereby increasing QOL.

The significant increase in self-management behaviors which were at high level may be due to the program component characteristics that incorporated several combined methods into the intervention. Firstly, the development of this program was fundamentally based on the assumption that self-management behaviors are directly influenced by increased perceived self-efficacy. Thus, enhancing the participants' perceived self-efficacy was thought to induce behavioral change following the participation in self-management enhancement program. In this study, four main sources of self-efficacy including skill mastery, vicarious experience, verbal persuasion, and emotional arousal were enhanced in conjunction with training self-management skills. These findings were consistent with previous studies that showed that increased self-management behaviors were associated with increased self-efficacy levels.[13-14]

Secondly, the participants' increased self-management behaviors are also explained by training self-management skills with the formulation of action plan. The necessary nine skills as generated by the integration between Creer's six self-management processes[16] and Lorig's five self-management skills,[15] taught with face-to-face, group-based training. After training, the participants had the ability to set realistic goals that were achieved by a range of activities as they chose and identified in their personal action plan. The aim of self-management skills training was to enable the participants to self-manage the daily tasks encompassing medical, emotional, and role management.[16] Furthermore, a personal action plan served as an essential tool for enhancing not only perceived self-efficacy, but also self-management behaviors.[23]

Thirdly, another explanation was that increased self-management behaviors might be because of informational support. Knowledge provision in the form of the VDO presentation regarding CKD was delivered together with self-management booklet entitled "Living a Healthy Life with CKD" in the first session of intervention. Informational support was shown to be a key determinant in increasing self-management behaviors and was inextricably linked to the improved health outcomes in CKD.[18-20]

Disease control in terms of risk factors control as indicated by systolic BP, diastolic BP, and HbA_{1c} was significantly improved as a direct result of increased self-management behaviors. By controlling disease, the participants' self-management behaviors were used to adopt lifestyle modifications as specified in their personal action plan. CKD-related lifestyle modifications involved the participants altering long-term habits, typically of eating or physical activity, and maintaining the new behaviors for months, which were consistently reported in personal action plan. Having been exposed to skills training, the participants also gained skills in performing self-monitoring blood pressure (SMBP) and self-monitoring blood glucose (SMBG) at home. Both SMBP and SMBG helped them lower their earlier BP and blood glucose levels by reminding them to continue self-management practice. This in turn resulted in BP control and glycemic control. These findings were congruent with previous studies of Thais with CKD pre-dialysis that showed significant improvements in BP control and glycemic control following participation in self-management intervention.[18-19] However, CKD progression control as represented by serum creatinine was not significantly different between groups. Possible reasons to support insignificant findings were that the presence of co-morbidities and advanced age are the major factors impairing kidney function.[39] Obviously, in this study, the most participants were older adults having both HT and DM as co-morbid disease which are the modifiable factors accelerating CKD progression.[2] Also, too early a time of data collection for serum creatinine at post-test might be difficult to prove a change in serum creatinine within 24 weeks after completing the program. This finding was found in contrast to a previous similar study that demonstrated the significant reduction in serum creatinine levels during 12 month follow up after a self-management intervention.[37] The supported explanation is that the participants of the previous study had a longer time to perform ongoing self-management behaviors in retarding the deterioration of kidney function than those of present study. Moreover, all participants were those with CKD stages 3 and 4 which has a certain degree of renal reserve. Hence, serum creatinine level may not be changed within 24 weeks until more than half of kidney function has been improved.[8]

QOL was significantly improved due to the presence of disease control, particularly risk factors control. It was possible that the participants may have felt better with improved disease control which eventually resulted in the perception of better QOL. Also, the participants' ability to keep both BP and blood glucose under control helped them reduce CKD-related complications which might affect physical function and limit functional status. This indicated that the participants felt more capable of dealing with disease-related symptoms and experienced better QOL than those who did not. However, it is important to consider that the participants in the control group had significantly greater QOL ($p < .05$) than at baseline (Table 4). This may be due in part to the acquisition of usual care that was routinely provided to individuals with CKD at pre-dialysis in the study setting. From receiving usual care, the participants in the control group might have better subjective perception of QOL as a result of emotional and peer support during participation in class of usual care. These findings were consistent with that of the previous studies that demonstrated the significant increase in QOL in individuals with CKD at pre-dialysis stages after participation in self-management enhancement program.[40]

Limitations

First, the posttest measure of self-management behaviors overlapped with that of the pretest measure. The participants' self-management behaviors as assessed by the SMBQ might not correspond consistently with program effects since the SMBQ asked the participants to rate self-management behaviors over the past 24 weeks. Second, BP was measured by only the PI at both baseline and post-test, which might induce the

expectation bias. Third, the intervention was conducted at only one setting that might limit the generalizability of results

Conclusion, Contributions to Nursing Science and Practice, and Recommendations

As the study had limitations, the findings of this study should be used with caution. The intervention program was shown to be effective in improving self-management behaviors, reducing systolic BP, diastolic BP, and HbA_{1c}, and improving QOL. Thus, the findings of this study make concept of self-management clearer, better understood and complement the existing body of knowledge regarding self-management. Additionally, this effective program can be used as nursing intervention to optimize health outcomes in individuals with CKD at pre-dialysis stages. Further studies should be undertaken, using RCT with a double-blinded design to eliminate the potential sources of bias. Also, as this study met with little success in determining CKD progression control as indicated by serum creatinine at 24 weeks after completing the program, an assessment of serum creatinine over a longer period of time is recommended.

Acknowledgements

We would like to gratefully acknowledge the active participation in the study of all participants and the support provided by Faculty of Nursing, Chiang Mai University.

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ประสิทธิผลของโปรแกรมการส่งเสริมการจัดการตนเองสำหรับผู้เป็นโรคไตเรื้อรังระยะก่อนการบำบัดทดแทนไต: การวิจัยเชิงทดลองแบบสุ่ม

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บทคัดย่อ: การศึกษาครั้งนี้มีวัตถุประสงค์เพื่อทดสอบผลของโปรแกรมการส่งเสริมการจัดการตนเองต่อพฤติกรรมการจัดการตนเอง การควบคุมโรคและคุณภาพชีวิตในผู้ที่เป็นโรคไตเรื้อรังระยะก่อนการบำบัดทดแทนไต กลุ่มตัวอย่างได้มาจากการคัดเลือกแบบเฉพาะเจาะจง จำนวน 120 คน โดยได้รับการวินิจฉัยเป็นโรคไตเรื้อรังระยะที่ 3 จำนวน 60 คน และระยะที่ 4 จำนวน 60 คน กลุ่มตัวอย่างได้รับการสุ่มเข้ากลุ่มทดลองและกลุ่มควบคุม กลุ่มละ 60 คน กลุ่มทดลองได้รับโปรแกรมในเวลา 6 สัปดาห์เพิ่มเติมจากการดูแลตามปกติ ขณะที่กลุ่มควบคุมได้รับการดูแลตามปกติเพียงอย่างเดียว ตัวแปรผลลัพธ์ประกอบด้วย พฤติกรรมการจัดการตนเอง ความดันซิสโตลิก ความดันไดแอสโตลิก ค่าน้ำตาลเฉลี่ยสะสม ซีรั่มครีเอตินิน และคุณภาพชีวิต รวบรวมข้อมูลก่อนและที่ระยะเวลา 4, 12, 24 สัปดาห์หลังการเข้าร่วมโปรแกรม โดยใช้แบบรายงานด้วยตนเอง การวัดความดันโลหิตและวิธีการทางห้องปฏิบัติการ วิเคราะห์ข้อมูลโดยใช้สถิติบรรยาย สถิติทีคู่และสถิติทีอิสระ ผลการวิจัยพบว่ากลุ่มทดลองมีพฤติกรรมการจัดการตนเองหลังสิ้นสุดโปรแกรม 4 สัปดาห์ ดีกว่ากลุ่มควบคุม มีความดันซิสโตลิค ความดันไดแอสโตลิคและน้ำตาลเฉลี่ยสะสม หลังสิ้นสุดโปรแกรม 12 สัปดาห์ ต่ำกว่ากลุ่มควบคุม และมีคุณภาพชีวิตหลังสิ้นสุดโปรแกรม 24 สัปดาห์ดีกว่ากลุ่มควบคุม อย่างไรก็ตามพบว่าไม่มีความแตกต่างอย่างมีนัยสำคัญของซีรั่มครีเอตินินระหว่างกลุ่ม ผลการวิจัยแสดงให้เห็นว่าโปรแกรมมีความสัมพันธ์กับผลลัพธ์ที่ดีขึ้น ดังนั้นจึงควรนำการส่งเสริมการจัดการตนเองไปใช้ในการปฏิบัติการพยาบาลสำหรับผู้ที่เป็นโรคไตเรื้อรังระยะก่อนการบำบัดทดแทนไต

Pacific Rim Int J Nurs Res 2016; 20(4) 320-336

คำสำคัญ: โรคไตเรื้อรังระยะก่อนการบำบัดทดแทนไตการควบคุมโรค คุณภาพชีวิต พฤติกรรมการจัดการตนเอง โปรแกรมการส่งเสริมการจัดการตนเอง

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