Original Article

The Effects of Individualized Nutritional Management to Slow the Progression of Stage 3 to 4 Chronic Kidney Disease in Primary Care Units of Northeast Thailand

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Objective: The aim of the present study was to investigate the effect individualized nutritional management can improve nutritional behaviors and slow the progression of stage 3 to 4 chronic kidney disease.

Materials and Methods: This 12-months experimental research was conducted at the primary care units in the Northeast, Thailand from June 2017 to May 2018 study period. The sample consisted of 200 stages 3 to 4 CKD patients. They were recruited and randomly assigned to either the intervention group or the control group. The intervention group received individualized nutritional management and the control group received standard care. The data were analysed using descriptive statistics and independent t-test.

Results: A total of 172 stage 3 to 4 CKD patients were included in the study. Their average age was 69.70 years. The nutritional behavior and absolute eGFR at the end of the study was significantly higher in the intervention group than in the control group (46.93 versus 43.25 ml/min/1.73 m^2; $p<0.05$). The average blood pressure and HbA_1C in the intervention group less than the control group with statistical significance at $p<0.05$. However, body mass index and waist circumference were not significantly different between the two group.

***Conclusion*:** Individualized nutritional management can delay CKD progression.

Keywords: Nutritional management, Chronic kidney disease, Primary care

J Med Assoc Thai 2019;102(Suppl.7): 38-44
Website: http://www.jmatonline.com

Chronic kidney disease (CKD) is a worldwide health crisis with a high economic cost to health systems. In the 2015 Global Burden of Disease Study, kidney disease was the 12th most common cause of death, accounting for 1.1 million deaths worldwide[1]. The hard outcomes of CKD and the progression to end-stage kidney disease were premature cardiovascular death and decreased quality of life[2]. CKD has a high global prevalence of between 11% and 13% with the majority of stage 3[3]. In Thailand, adult population was 17.5%. It is estimated that the total number of stage 3 to 4 CKD patients is 4.1 millions. The prevalence of CKD was highest in the Northeast region compared to other regions, except Bangkok[4]. patients with CKD stages 3 and 4 have about an equal risk of progressing to end-stage renal disease (ESRD) or death due to cardiovascular events[5] although the kidneys still function sufficiently to remove fluid, potassium and a moderate amount of waste.

In order to help slow the progression of CKD, managing blood pressure, glucose and weight, among other things, is important and can be done through adhering to a kidney diet. The malnutrition in CKD patients is associated with increased morbidity and mortality[6]. Poor diet is now the leading risk factor for deaths and disability worldwide, a fact recognised by the United Nations Decade of Action on Nutrition 2016 to 2025[7,8]. Nutrition is a critical aspect in the treatment of CKD stages 3 to 4, before starting kidney replacement therapy. An earlier study showed that dietary interventions may increase health related quality of life, eGFR, and serum albumin, and lower blood pressure and serum cholesterol levels[9-11]. Despite the fact that the influence of certain types of nutrients has been widely studied in relation to kidney function and overall health condition of CKD patients, relatively few studies have reported the results of individualized nutritional management programs that focus on CKD in primary care. The present study aims to investigate whether providing individualized nutritional management can improve nutritional behaviors and slow the

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How to cite this article: Kankarn W, Wichitthongchai C, Sancharon P, Anutrakulchai S. The Effects of Individualized Nutritional Management to Slow the Progression of Stage 3 to 4 Chronic Kidney Disease in Primary Care Units of Northeast Thailand. J Med Assoc Thai 2019;102(Suppl.7): 38-44.

progression of stage 3 to 4 chronic kidney disease. The results provide foundational data and opportunities for improvement, including nutritional management of CKD, and improvement of collaborative care with multidisciplinary team.

Conceptual framework

The theoretical framework of the intervention is based on chronic care model[12]. Primary care practices play an important role in frontline management of chronic disease. As a result, many managed care and integrated delivery systems have taken a great interest in correcting the many deficiencies in current management of CKD. Ensuring access to high quality, team-based care is one of the most effective interventions for improving the health of patients.

Materials and Methods

Study design and participants

The study had been conducted for 12 consecutive months (June 2017 to May 2018). The study adopted a multi-stage, stratified random cluster-sampling scheme. In the first stage, five provinces (Nakhon Ratchasima, Buriram, Surin, Maha Sarakham and Khon Kaen province) were selected from the Northeast of Thailand. In the second stage, one district was randomly selected from each province. In the third stage, one rural village was randomly selected. The participants aged 40 to 75 years old with documented CKD with an estimated glomerular filtration rate (eGFR) between 15 and 59 ml/min per 1.73 m^2 (CKD stage 3 to 4) from each village were invited to join the study. The sample size was calculated by using power = 0.80, medium effect size, alpha = 0.05[13]. It was estimated that 80% of stage 3 to 4 CKD patients were needed to be enrolled to each group. Taking into account that 20% of patients might be lost to follow-up because of non-end point death or other reasons. Approximately, 100 patients for each group were required. For the inclusion criteria to participate in the study, patients must have met all of the following criteria: be able to provide consent, be able to comply with study procedures, visits, and assessments. Patients were excluded if they had any of the following: not consent to participate; likely to die within 12 months; malnutrition; recently having unstable/advanced cardiovascular disease; receiving current for malignancy; receiving immunotherapy for kidney disease; on dialysis or with an organ transplant.

Outcome measures

The outcomes of this study were the differences of mean eGFR between the two groups over the study period, measured by creatinine-based CKD-EPI equation[14], HbA1c, body mass index (BMI), waist circumference, blood pressure (systolic and diastolic) and nutritional behaviors between the two groups.

Laboratory analysis

All patients were scheduled to follow-up clinical and laboratory parameters at their respective medical centers. Serum was sent to a central laboratory in district hospital for measurement of creatinine and measured by creatinine-based CKD-EPI equation. All biochemistry analyses were validated according to the standard protocol of Department of Medical Sciences, Ministry of Public Health, Thailand. Laboratory data were also collected at the beginning and the end of the study.

Control and intervention prompts

To reduce the risk of contamination between physicians co-managing patients with CKD, randomization occurred at the level of the group practice using a computer-generated randomization sequence and concealment. Participants were stage 3 to 4 CKD patients, 40 to 75 years of age. They lived in the six randomized districts in primary care units. The participants of each group were further subdivided into 15 to 20 patient subgroups according to the area of their sub districts.

Study intervention

Baseline information including past medical history, physical examination, and medications as well as blood samples were collected from all patients. While patients in both intervention and control groups received standard clinical care and medications as well as group-based educational programs during their visit to the district hospital, the intervention group also received the individualized nutritional management program. The patients participated in the program that individualized nutritional management, which consisted of an in-depth individualized nutrition assessment, explaining about menu planning and how to adjust to new ways of eating, personalized care plan, periodic monitoring and reassessment, and home visits to encourage individual empowerment. The duration of the first visit and the follow-up visits was on the average of 60 minutes. The intervention was described below:

1) An assessment of medical history included hypertension and diabetes, the kidney disease stage and current plan of care, self-care behaviors to identify the individual.

2) There was an assessment of risk factors and gaps in the plan of care, nutritional deficits, treatment plan, and care plan goals.

3) Assessment of body mass index (BMI), waist circumference, and blood pressure: A diet history, including usual food intake, food habits, individualizing nutrient requirements in CKD should be a coordinated health care team effort.

4) Considerations were needed to be made for food intake preferences (cultural, religious, and personal) and lifestyle factors (financial, food availability, food preparation facilities, physical ability and cooking skills, and transportation to obtain food).

5) Information included size of plate, method of food preparation, setting where meal was consumed, and who prepared the meal: All of this information might have been lost using the format of a traditional dietary intake

assessment.

6) The indirect measurement was done using data such as laboratory values, body weight, and/or self-reported dietary intake records by using Nutritional Subjective Global Assessment (N-SGA).

7) Individualization and one-on-one face-to-face communication was administered[15].

8) Nutritional advice in CKD based on nutrient requirements linked to published evidence and clinical guidelines[16-18] was described below:

8.1) For patients with estimated glomerular filtration rate (eGFR) 30 to 59 mL/min/1.73 m^2 (CKD stage 3), the focus of the dietary counseling was on controlling sodium and protein intake, particularly in regards to protein from animal sources. Therefore, approximately 0.6 to 0.8 g/kg/day with at least 50% of protein with high biological value (HBV) was calculated. For the HBV foods, lists of protein equivalent items were provided to each patient.

8.2) For patients with eGFR 15 to 29 mL/min/1.73 m^2 (CKD stages 4), the nutritional assessment included the same parameters of 8.1 with the addition of midarm circumference, triceps skinfold thickness and midarm muscle circumference. This subgroup of patients got a more detailed nutritional assessment due to its higher risk for malnutrition than those with higher GFR. In addition, the appointments with the detailed nutritional assessment were longer and the current number of dietitians was not enough to provide a complete assessment to all patients with GFR >30 mL/min/1.73 m^2.

Dietary history included a 3-day food record used to evaluate diet quality, to identify food habits and to calculate particularly protein and energy intake. The prescription of protein and energy were in general of 0.6 to 0.8 g/kg/ day and 30 to 35 kcal/kg/day, respectively.

9) Home visits were scheduled to provide the patient an individualized and detailed dietary plan with exchange of food choices and specific recommendations as needed.

10) Besides the individualized counseling, patients were encouraged to participate in a group meeting activity scheduled once a month where the dietitian gave a 60-min talk with the information about the disease and the importance of the dietary aspects as part of the treatment.

For the control group, all of the participants received whatever usual care that their health care providers felt indicated. Usual care meant care delivered by a family doctor providing assessments and treatments for their patients as they saw fit. The family doctors could consult specialists or involve allied health personnel if necessary. Stage 2 to 3 CKD patients were followed-up every 6 months and stage 4 CKD patients were followed-up every 3 months. NCDs nurse provided education about CKD and home visits when patients had problem. The visits were only assessed for clinical outcomes.

Data collection and measurements

Data were collected during a primary care visit by trained nurses using a standard questionnaire by face-to-face interview. Before the survey was performed, all eligible investigators were invited to attend the training. The training content included the purpose of the present study, how to administer the questionnaire, the standard methods of measurement, the study procedures and the importance of standardization. After the training, a strict test was carried out, and only those who scored perfectly on the test could become investigators. During data collection, our inspectors received further instructions and support. There was a central steering committee with a subcommittee for quality control. Measurements consisted of the following.

1) The data of the demographic characteristics, including age, sex, education, socioeconomic status, marital status, medical history and caregiver were collected.

2) The nutrition management behaviors questionnaire consisted of 30 items. The questionnaire was a measure of how the practice was measured in the past week. There were three levels of estimation: routine practice, regular practice, or more than 3 times a week. The score was equal to 3. “Practice sometimes” referred to practice 1 to 3 times a week. The score was 2. “Not practicing” referred to abstain or no practice. The score was 1. The interpretation of scores was as follows: poor nutritional behaviors:

1 to 30 point; moderate nutritional behaviors: 31 to 60 points and good nutritional behaviors: 61 to 90 points, respectively. Its reliability was examined using Cronbach’s alpha coefficient and the alpha coefficient was 0.85 with content validity index of 0.86.

3) The instruments for collecting the clinical outcomes included those for measuring glomerular filtration rate, HbA1c, blood pressure (According to the American Heart Association protocol. The investigators performed blood pressure (BP) measurement three times for each participant at 2-min intervals after at least 5 min of rest, using a standardized automatic electronic sphygmomano meter), BMI and waist circumference: the tool had been validated according to hospital standards.

Statistical analysis

In this analysis, the data of the date of last visit of patients who lost the follow-up or withdrew from the study were censored. Descriptive statistics, namely unpaired student t-test and Chi-square test were used to compare mean values and categorical data, respectively. The distribution of clinical outcome and nutritional behavior data using the Kolmogorov-Smirnov test was statistically normal. Independent t-test was used to compare within the intervention and the control group. All statistical tests were two-tailed, using a *p*-value of less than 0.05 as being statistically significant.

Ethical considerations

The present study was approved by the Khon Kaen University ethics committee for Human Research based on the Declaration of Helsinki and the ICH Good Clinical Practice Guidelines (HE601166). Informed consent was

obtained from all participants. The twelve months wait for the intervention for the control group had a negligible effect given the chronic nature of the conditions for which the intervention is proposed. Specific consent was sought from each participating patient for accessing to their administrative health data and its use by the parties involved in the study. Confidentiality was respected and data security was ensured according to the rules enforced by Khon Kaen University ethics committee for Human Research.

Any publication resulting from this research would respect patient confidentiality.

Results

Baseline characteristics of the participants

One hundred and seventy-two participants met the enrollment criteria, and were included into the intervention (87 cases) and control (85 cases) groups. Table 1 shows the demographic characteristics of the patients in the intervention group and the control group on study initiation. The average age of CKD patients was 69.70 years. There were no significant differences between the intervention group and the control group for age, gender, marital status, educational level, occupation, caregiver, co-morbidities and income. The data suggested similar personal history and lifestyle for the intervention group and the control group as shown in Table 1.

Baseline of clinical outcome and nutrition behaviors

Most patients (90.11%) were at CKD Stages 3 according to eGFR evaluated by the simplified Modification of Diet in Renal Disease equation. The mean eGFR was 45.22±10.90 mL/min/1.73 m^2 and the mean HbA1C was 8.52±2.03 mg/dL. The mean body mass index levels >25 kg/m^2 and waist circumference > 90 cm. The patients had higher mean systolic and diastolic blood pressures (136.87/83.16 mmHg). According to the baseline parameters, the difference between the intervention and control groups, there were no significant differences in the clinical outcomes of body mass index, waist circumference, renal function (eGFR) with stage, HbA1c, blood pressure, and nutrition behaviors as shown in Table 2, 3. After intervention, The nutritional behavior, blood pressure (systolic and diastolic), and HbA1c were different with statistical significance from before intervention at $p<0.05$. However, there were no significant differences in the clinical outcomes of absolute eGFR, body mass index and waist circumference as shown in Table 3.

The absolute eGFR at the end of the study was significantly higher than in the control group (46.93±10.56 versus 43.25±10.45 ml/min/1.73 m^2; $p<0.05$). The mean HbA1c, and blood pressure (systolic and diastolic) in the intervention group were different with statistical significance from those of the control group at $p<0.05$. The nutrition behaviors in the intervention group were different with statistical significance from those of the control group at $p<0.05$. However, there were no significant differences in the clinical outcomes of body mass index and waist circumference as shown in Table 4.

Table 1. Baseline characteristics of the participants

Variables	Intervention group (n = 87)	Control group (n = 85)	*p*-value
	Number (%)	Number (%)	
Gender			0.864
Male	39 (44.80)	32 (37.65)	
Female	48 (55.20)	53 (62.35)	
Marital status			0.255
Single	7 (8.05)	4 (4.71)	
Married	52 (59.77)	62 (72.94)	
Divorced	28 (32.18)	19 (22.35)	
Educational			0.433
Elementary school or lower	56 (64.38)	58 (68.24)	
High school	12 (13.80)	9 (10.59)	
Diploma	11 (12.65)	11 (12.93)	
Bachelor	8 (9.17)	7 (8.24)	
Occupation			0.450
Agriculture	7 (8.05)	13 (15.29)	
Industry	9 (10.35)	8 (9.41)	
Services	13 (14.94)	9 (10.59)	
Not working	58 (66.66)	55 (64.71)	
Current caregiver			0.297
Self-care	33 (37.93)	38 (44.71)	
Family	48 (55.17)	45 (52.94)	
Caregiver	6 (6.90)	2 (2.35)	
Co-orbidities			0.627
DM	7 (8.05)	11 (12.94)	
HT	24 (27.59)	19 (22.35)	
DM with HT	39 (44.82)	42 (49.41)	
Other	10 (11.49)	9 (10.59)	
Non co-orbidities	7 (8.05)	4 (4.71)	
Age (years)*	70.16 (8.79)	69.24 (7.70)	0.471
Average monthly income*	4,443.68 (3,710.41)	4,661.18 (3,001.59)	0.673

* Independent t-test

Discussion

The stage 3 to 4 CKD patients were enrolled in the primary care and most of them were women. CKD was more prevalent in women than in men. Two-thirds of studies -that reported gender-specific CKD prevalence- determined higher prevalence in women. Women, in general, have less muscle mass than men and muscle mass is a major determinant of serum creatinine concentration[3]. The average age of CKD patients was 69.70 years. The CKD-EPI formula reduced the prevalence of CKD stages 3 to 5 in those aged <70 but it increased in those aged >70[20]. Most patients (66.31%) had graduated from elementary school or lower and they had low income. Low-income to middle-income countries are ill-equipped to deal with the devastating consequences of CKD, particularly the late stages of the disease[20]. Diabetes mellitus with hypertension (n = 81, 47.12%) was the most common comorbid condition in these patients. The major CKD risk factors included type 2 diabetes mellitus

Table 2. Baseline of clinical outcome and nutrition behaviors

Variables	Intervention group (n = 87)		Control group (n = 85)		t	*p*-value
	Mean	SD	Mean	SD		
eGFR (CKD-EPI ml/min/1.73 m^2)	45.58	10.95	44.86	10.84	-0.434	0.665
Stage of CKD	Number	%	Number	%	-0.304	0.760
III	79	90.80	76	89.41		
IV	8	9.20	9	10.59		
Body mass index (kg/m^2)	25.31	3.77	25.34	4.14	-0.044	0.965
Waist circumference (cm)	89.80	11.24	90.53	10.83	-0.434	0.665
Blood pressure						
Systolic BP (mmHg)	136.54	16.11	137.20	15.81	-0.271	0.787
Diastolic BP (mmHg)	83.56	9.49	82.76	10.54	0.156	0.602
HbA1c in diabetics (%)	8.58	2.45	8.45	1.61	0.336	0.738
Nutrition behaviors	57.11	10.49	58.92	8.19	-1.807	0.073

Table 3. Clinical outcome and nutrition behaviors compared between before and after intervention

Variables	Before intervention (n = 87)		After intervention (n = 87)		t	*p*-value
	Mean	SD	Mean	SD		
eGFR (CKD-EPI ml/min/1.73 m^2)	45.58	10.95	46.93	10.56	-1.547	0.125
Stage of CKD	Number	%	Number	%	2.036	0.045*
II	-	-	4	4.60		
III	79	90.80	79	90.80		
IV	8	9.20	4	4.60		
Body mass index (kg/m^2)	25.31	3.77	25.19	3.71	0.895	0.373
Waist circumference (cm)	89.80	11.24	90.15	13.49	-0.279	0.781
Blood pressure						
Systolic BP (mmHg)	136.54	16.11	129.28	11.16	5.592	0.000**
Diastolic BP (mmHg)	83.56	9.49	78.99	7.76	4.585	0.000**
HbA1c	8.58	2.45	7.83	1.55	5.543	0.000**
Nutrition behaviors	57.11	10.49	77.97	7.33	22.214	0.000**

Table 4. Clinical outcome and nutrition behaviors compared between intervention and control groups

Variables	Intervention group (n = 87)		Control group (n = 85)		t	*p*-value
	Mean	SD	Mean	SD		
eGFR (CKD-EPI ml/min/1.73 m^2)	46.93	10.56	43.25	10.45	2.294	0.023*
Stage of CKD	Number	%	Number	%	-2.204	0.029*
II	4	4.60	2	2.40		
III	79	90.80	71	83.5		
IV	4	4.60	12	14.10		
Body mass index (kg/m^2)	25.19	3.71	25.33	4.21	-0.240	0.811
Waist circumference (cm)	90.15	13.49	90.65	10.77	-0.267	0.790
Blood pressure						
Systolic BP (mmHg)	129.28	11.16	134.39	16.14	-2.421	0.017*
Diastolic BP (mmHg)	78.99	7.76	83.14	11.51	-2.780	0.006*
HbA1c	7.83	1.55	8.51	1.52	-2.209	0.030*
Nutrition behaviors	77.97	7.33	59.96	7.64	22.214	0.000*

(T2D), hypertension, obesity and ageing[21]. Primary outcomes of the study the nutrition behaviors in the intervention group were different with statistical significance from those of the control group due to individualized

nutritional management program which consisted of an in-depth individualized nutrition assessment, explaining about menu planning and how to adjust to new ways of eating, personalized care plan, periodic monitoring and reassessment, and home visits to encourage individual empowerment.

Secondary outcome, the decline of renal function (eGFR) at stage 3 to 4 of CKD was slower in the individualized nutritional management group than the conventional group because the patients got a more detailed nutritional assessment due to its higher risk for malnutrition and individualization and one-on-one face-to-face communication. They were the cornerstone of achieving higher adherence. The message must be relevant and timely. The format must be interesting and have practical application in the patient's life[22]. Dietary intake for patients with CKD is based on the stage of kidney disease and calculated from standard food[23]. The significance of proper diet in CKD is confirmed in a large retrospective cohort study of Slinin et al[25] which demonstrated that the mortality rate of predialysis adult patients cared for by a dietitian was 19% lower in comparison to those who did not receive this care. The study found that no significant differences in the clinical outcomes of absolute eGFR before and after intervention because of the patients were elderly[19] and eGFR progressively declines at an average rate of 8 mL/min/1.73 m^2/decade and suggests that in many cases their care could be safely and appropriately managed in the primary care setting. The mean HbA1c, and blood pressure in the individualized nutritional management group or the control group was at $p<0.05$. Ricardo et al[25] revealed that adherence to a healthy lifestyle was associated with lower risk of all-cause mortality in people with stage 3 or more advanced CKD to this end, it is highly important to explain to the patient the reasons for the dietary changes proposed, to use approaches that enable/facilitate the communication and to respect and understand the patient's limitations, expectations and desires. Therefore, coordinated multidisciplinary care offered optimal management and improved renal and patient survival in CKD patients[26].

In conclusion, CKD constitutes a major cost burden to healthcare systems worldwide. The results of this randomized control study suggest that individualized nutritional management may slow the progression of late stage CKD and reduce morbidity during the course of the disease. The application of standardized individualized nutritional management intervention for the daily care of CKD patients should be a part of integrated CKD care. There is no nutrition advice strategy that has been shown to work in the majority of patients. Each patient has their own challenge. It is up to the health care team to keep the communication consistent but creative and evolving. Adherence is a true measure of patient engagement.

What is already know on this topic?

Individualized nutritional management may slow the progression of late stage CKD.

What this study adds?

The individualized nutritional management can improve nutritional behaviors, eGFR and decrease blood pressure and HbA1c.

Acknowledgements

The present study was supported by the research fund of Chronic Kidney Disease Prevention in the Northeast of Thailand (CKDNET). The authors wish to thank all the participants who took part in the study. The authors are grateful to the multidisciplinary team.

Potential conflicts of interest

The authors declared no conflict of interest.

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