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RESEARCH ARTICLE

Quality of Life among Patients Suffering from Chronic Kidney Disease in Chronic Kidney Disease Clinic of Thailand

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Abstract:

Background:

Chronic kidney disease (CKD) has directly affected the quality of life (QOL) of patients.

Objective:

The objective of this study was to explore the QOL and its associated factors among CKD patients in Thailand.

Methodology:

A cross-sectional study was conducted with 258 CKD patients from the CKD clinics between January to December 2017. A validated and reliable tool, KDQOL-SF™ 1.3, consisting of 19 domains categorized into three components: physical component summary (PCS), mental component summary (MCS), and kidney disease component summary (KDCS), was adopted to assess QOL through trained data collectors. Ordinal Logistic regression was used to detect the associations between variables at the significance level of 0.05.

Results:

Among two hundred and fifty-eight patients, 53.9% were females, 67.4% were more than 60 years old, and 73.6% were employed. Employed CKD patients had a better PCS compared to unemployed ones (odds ratio (OR)= 2.87, 95% confidence interval (CI) = 1.52-5.42) and patients who had education lower than primary school (OR = 2.41; 95% CI = 1.02-5.69) tended to have a better PCS compared to those who had secondary and higher school education. CKD patients who had no income tended to have a poorer PCS (OR = 0.40; 95% CI = 0.18-0.91) and MCS (OR = 0.39; 95% CI = 0.18-0.83) than those patients who had an income of more than 10,000 baht. 3a CKD stage patients (OR = 2.62; 95% CI = 1.19-5.77) were more likely to have a good MCS compared to 5 CKD stage patients. ESRD patients who had primary school level education (OR = 0.25; 95% CI = 0.07-0.89) tended to have a poorer KDCS than those patients who had secondary and higher school level education.

Conclusion:

The study concludes that QOL among CKD patients in CKD clinics needs to improve. Public health should reform and implement the appropriate policy of CKD clinic and intervention to improve QOL among CKD patients by focusing on CKD patients' occupation, income, education, and the stage of CKD.

Keywords: Chronic kidney disease, CKD patients, Quality of life, Chronic kidney disease clinic, Renal disease.

Article History

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1. INTRODUCTION

Chronic kidney disease (CKD) has been considered a major issue in the health care system worldwide [1]. The incidence and prevalence of CKD patients have been increasing continuously. In 2017, 9.1% (697.5 million cases) of

the world population was affected by CKD [2]. In Thailand, according to the Ministry of Public Health, it was found that 17.60% patients (about 8 million cases) suffered from CKD with an increase of approximately 7,800 people per year. Patients with end-stage renal disease (ESRD) were found in roughly 200,000 cases. One of the third CKD patient dies before the age of 60 years [3]. CKD also has an impact on the general activities and the patient's mental and social role in the society. Such patients suffer from both physical and

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psychological problems, which affect their quality of life (QOL) [4 - 6].

QOL is satisfaction or happiness in life according to the context and experience of the person, which consists of physical, mental, social, and general health [7]. The Kidney Disease Quality of Life Working Group, USA stated that QOL covers holistic well-being, including physical, mental, emotional, social, and mental health [8]. QOL has become the main goal for improving the quality of healthcare services as a measurement of the patient treatment outcome [9 - 11].

The Thai ministry of public health has implemented a policy providing efficient health care service among CKD patients by establishing separate chronic kidney diseases clinics (CKD clinics) in Thai public hospitals all over the country. The purposes of CKD clinics are to delay the progression of chronic kidney disease, provide holistic health services, and improve QOL for CKD patients from a 3rd-5th stage in public hospitals by multidisciplinary health professional team: physician, nurse, pharmacist, nutritionist, and physiotherapist who provide holistic treatment, preparation, and planning for renal replacement therapy (RRT) and financial, social, and psychological support. The objectives of this cross-sectional study were to explore the QOL and determine the factors associated with their QOL among stages 3-5 CKD patients in chronic kidney disease clinic (CKD clinic) under the policy of the ministry of public health, Thailand. Since many studies focused on only end state renal disease and had limited information on the QOL among other stages, this is the first time that the QOL of patients with 3 and 4 CKD stages is being explored in Thai public hospitals all over the country [12 - 14]. This study has adopted the standard kidney disease quality of life Assessment Questionnaire (KDQOL-SFTM) version 1.3, which combines SF-36 and end-stage renal targeted area (ESRD-targeted areas) to assess the QOL among CKD patients [8].

2. MATERIALS AND METHODS

This was a cross-sectional study by interviewing CKD patients in CKD clinics under the policy of the ministry of public health in public hospitals in Thailand between January 2017 and December 2017. According to the Thai ministry of public health, Thailand was divided into 12 health care regions and three levels of hospitals: 82 High-Level Referral Hospitals, 134 Middle-Level Hospitals, and 675 First-Level Hospitals. In this study, a two-stage sampling process based on simple random sampling was used. Firstly, 144 hospitals were randomly selected from each of the three levels of the hospitals; two high level referral hospitals, four middle level hospitals, and six first level hospitals from each region. Secondly, two patients were selected from these hospitals by accidental sampling within their visit to the CKD clinic. The inclusion criteria were 3rd-5th stage CKD patients in CKD clinic who were 18-80 years, both male and female, and consented to be part of the study. Finally, a total of 288 CKD patients were invited for the study and the final sample of the survey included 258 CKD patients from 134 hospitals (134 CKD clinics). The response rate in the survey was 89.58%.

2.1. Research Instruments

A validated and reliable tool (KDQOL-SFTM version 1.3) created by the Kidney Disease Quality of Life Working Group, USA developed uniquely for CKD patients, was used to be the tool of this study. This tool combines a 36-item Short-Form Health Survey (SF-36) and end-stage renal targeted area (ESRD-targeted areas), which can be both general and specific measurements in CKD patients [8, 15 - 17]. The questionnaire consists of 19 domains with a total of 80 questions, and a 100-point scale categorized into 3 components: Physical Component Summary (PCS), Mental Component Summary (MCS), and Kidney Disease Component Summary (KDSCS). PCS and MCS are the generic SF-36 instrument, and the KDSCS is a kidney disease-specific instrument that focuses on the end-stage renal targeted area. In PCS, there are 21 items categorized into 4 domains: physical function (3 items), role limitations caused by physical health problems (4 items), pain (2 items), and general health perception (5 items). In the MCS, there are 14 questions categorized into 4 domains: emotional well-being (5 items), role limitations caused by emotional health problems (3 items), social function (2 items), and energy/fatigue-related (4 items). In KDSCS, there are 43 questions categorized into 11 domains: symptom problem (12 items), effects of kidney disease on daily life (8 items), burden of kidney disease (4 items), work status (2 items), cognitive function (3 items), quality of social interactions (3 items), sexual function (2 items), sleep (4 items), social support (2 questions), dialysis staff encouragement (2 items), and patient satisfaction (1 item). The score of each question is ranged with the lowest score of 0 and the highest of 100. The mean and SD of each domain and component was calculated and used to categorize the level of QOL into three groups: more than one SD above the mean is "good", The mean +/- one SD is "fair", and more than one SD below the mean is "poor" [18].

The study variables included socio-demographic factors, numbers of caregiver (person), CKD stage, duration of CKD (year), associated diseases (Diabetes Mellitus, Hypertension, Chronic Heart Diseases, Gout, Hyperlipidemia, and others (Systemic Lupus Erythematosus (SLE) and Kidney Stones)), setting of the hospital (urban/rural area) and level of the hospital. The outcome variable was quality of life in 3-5 CKD stage patients classified into the PCS, MCS, and KDSCS that focused on ESRD patients.

2.2. Data Collection

Data collection was conducted at the CKD clinic. The researchers introduced the research objectives, benefits, risks, and the rights of the patients and explained that information obtained was kept confidential and used in this research only. Then, CKD patients were asked to sign the consent form and permission to collect data. The questionnaires were distributed by a team of trained data collectors for 30-40 minutes.

2.3. Statistical Analysis

Descriptive statistics were used to characterize demographic data, numbers of caregivers, CKD stage, duration of CKD, associated diseases, setting of the hospital, level of the hospital, and the quality of life score. Univariate and

multivariate ordinal logistic regression analysis with the significance level of 0.05 was performed to assess the associations between the outcomes: QOL and its components and the dependent variables because the outcomes were ordinal with three levels of QOL. The proportional odds assumptions were satisfied for all variables.

3. RESULTS

The face-to-face interviews were conducted by trained data collectors between January 2017 and December 2017. The total of two hundred and fifty-eight participants: more than half of them (67.4%) were aged more than 60 years old with an average of 64.69 years (SD = 13.14, min = 21, and max = 88), 53.9% were female, 67.1% was married, 60.9% had the highest education at primary school, 37.2% had the income less than or equal 5,000 Thai baht (165 US\$), and 73.6% were unemployed. Half of the patients (53.5%) suffered from CKD for 1-3 years, and most of them (95.0%) had associated diseases. 61.6% were from the rural hospital area, and a half (50.8%) were from the First-Level hospital. The characteristics of CKD patients and end-stage renal disease patients (stage V) are shown in Table 1.

In PCS and MCS, the highest mean scores in SF-36 were pain (mean=71.21, SD= 24.76) and emotional well-being

(mean=74.91, SD= 18.99) domain. However, general health (mean=54.49, SD= 24.75) and emotional role (mean=62.79, SD= 44.72) had the lowest mean score. In KDCS, the highest mean score in the ESRD targeted areas was found in the dialysis staff encouragement domain (mean=90.63, SD= 11.59). However, the lowest mean score was found in the cognitive functioning (mean=37.64, SD= 14.65) when compared with other domains in the ESRD targeted areas. For the level of QOL, in the PCS, more than half (58.5%) was at the fair level, in MCS 59.7% was at the good level, and in KDCS 67.7% was at the fair level (Table 2).

The result showed that patients who were employed (OR = 2.87; 95% CI = 1.52-5.42) and had education lower than primary school (OR = 2.41; 95% CI = 1.02-5.69) were more likely to have good QOL in term of PCS. CKD patients who had no income (OR = 0.40; 95% CI = 0.13-0.91) tended to have a poorer PCS than those patients who had income more than 10001 baht. 3a CKD stage patients (OR = 2.62; 95% CI = 1.19-5.77) were more likely to have a good QOL in terms of MCS. CKD patients who had no income (OR = 0.39; 95% CI = 0.18-0.83) tended to have a poorer MCS than those who had income more than 10001 baht. ESRD patients who had primary school education level (OR = 0.25; 95% CI = 0.07-0.89) tended to have a poorer KDCS than those patients who had secondary school and higher level (Table 3).

Table 1. Characteristics of CKD patients and end-stage renal disease patients.

Variables	CKD Patients (n = 258)		End-Stage Renal Disease Patients (n = 65)	
	n	%	n	%
Age (years)				
20-45	25	9.7	15	23.1
46-60	59	22.9	21	32.3
>60	174	67.4	29	44.6
Mean=64.69, SD=13.14 Min=21, Max=88				
Gender				
Male	119	46.1	33	50.8
Female	139	53.9	32	49.2
Marital status				
single	21	8.1	9	13.8
widow/separate	64	24.8	14	21.5
Married	173	67.1	42	64.6
Education				
Lower than primary school	51	19.8	9	13.8
Primary school	157	60.9	37	56.9
Secondary school and higher	50	19.4	19	29.2
Income (baht)				
No income	58	22.5	22	33.8
<=5000	96	37.2	15	23.1
5001-10000	48	18.6	10	15.4
>=10001	56	21.7	18	27.7
Occupation				
Employed	190	73.6	47	72.3
Unemployed	68	26.4	18	27.7
Numbers of caregiver (person)				
None	19	7.4	4	6.2
1-3	201	77.9	56	86.2
>=4	38	14.7	5	7.7

(Table 1) contd....

Variables	CKD Patients (n = 258)		End-Stage Renal Disease Patients (n = 65)	
	n	%	n	%
CKD stage				
3a	51	19.8		
3b	68	26.4		
4	74	28.7		
5	65	25.2		
Duration of disease (years)				
<=3	152	58.9	35	53.8
4-6	68	26.4	20	30.8
7-9	12	4.7	6	9.2
>=10	26	10.1	4	6.2
Associated disease*				
Yes	245	95.0	59	90.8
No	13	5.0	6	9.2
Hospital Setting				
Urban	99	38.4	33	50.8
Rural	159	61.6	32	49.2
Hospital Level				
First-Level	131	50.8	24	36.9
Middle-Level	87	33.7	26	40.0
High-Level Referral	40	15.5	15	23.1

* Associated diseases: Diabetes Mellitus, Hypertension, Chronic Heart Diseases, Gout, Hyperlipidemia, and others (Systemic Lupus Erythematosus (SLE) and Kidney Stones)

Table 2. Summary of mean score of QOL of participants in short form-36 sub-scales and end-stage renal disease target areas.

Parameters	Mean Scores \pm S.D.	Level of QOL (n (%))		
		Poor ($<$ Mean-1SD)	Fair (Mean \pm -1SD)	Good ($>$ Mean + 1SD)
PCS*				
36-Item Health Survey (n = 258)				
Physical functioning	61.91 \pm 28.93	51(19.8)	151(58.5)	56(21.7)
Physical role	56.10 \pm 43.32			
Pain	71.21 \pm 24.76			
General health	54.49 \pm 24.75			
Total	60.89 \pm 24.35			
MCS**				
Emotional well-being	74.91 \pm 18.99	59(22.9)	45(17.4)	154(59.7)
Emotional role	62.79 \pm 44.72			
Social functioning	70.54 \pm 25.33			
Energy/fatigue	64.64 \pm 19.99			
Total	68.22 \pm 21.57			
KDCS***				
ESRD-targeted areas (n = 65)				
Symptoms/List of problems	79.10 \pm 15.61	10(15.4)	44(67.7)	11(16.9)
Effects of kidney disease on daily Life	75.77 \pm 18.09			
Burden of kidney disease	61.72 \pm 29.97			
Work status	47.69 \pm 34.72			
Cognitive functioning	37.64 \pm 14.65			
Quality of social interaction	42.56 \pm 18.84			
Sexual functioning	88.54 \pm 24.15			
Sleep	46.15 \pm 13.30			
Social support	85.64 \pm 17.65			
Dialysis staff encouragement	90.63 \pm 11.59			
Patient satisfaction	69.28 \pm 22.29			
Total	61.64 \pm 7.64			

*PCS: physical components summary **MCS: mental health components summary ***KDCS: kidney disease components summary

Table 3. Factors associated with QOL in the domain of PCS, MCS and KDCS in univariate and multivariate analyses.

Factors	PCS		MCS		KDCS	
	OR (95%CI)	OR _{Adj} (95%CI)	OR (95%CI)	OR _{Adj} (95%CI)	OR (95%CI)	OR _{Adj} (95%CI)
Age (years)						
20-45	0.73		1.03		2.52	
46-60	(0.33-1.62)		(0.45-2.34)		(0.66-9.68)	
>60	1.02		0.87		0.94	
	(0.57-1.84)		(0.49-1.57)		(0.29-3.09)	
	1.00		1.00		1.00	
Gender						
Male	1.38		1.13		1.78	
Female	(0.85-2.23)		(0.69-1.84)		(0.63-5.04)	
	1.00		1.00		1.00	
Marital status						
Single	0.69		0.98		1.51	
Widow/separate	(0.28-1.73)		(0.41-2.34)		(0.33-6.79)	
Married	0.61		0.77		1.00	
	(0.35-1.07)		(0.44-1.33)		(0.28-3.54)	
	1.00		1.00		1.00	
Education						
Lower than primary school	1.20	2.41	1.37		1.11	1.11
Primary school	(0.55-2.59)	(1.02-5.69)*	(0.63-3.02)		(0.21-5.89)	(0.21-5.89)
Secondary school and higher	0.62	0.89	0.72		0.25	0.25
	(0.33-1.18)	(0.44-0.79)	(0.39-1.33)		(0.07-0.89)*	(0.07-0.89)*
	1.00	1.00	1.00		1.00	1.00
Income (baht)						
No income	0.27	0.40	0.36	0.39	0.36	
<=5000	(0.13-0.55)*	(0.18-0.91)*	(0.17-0.77)*	(0.18-0.83)*	(0.10-1.39)	
5001-10000	0.47	0.56	0.56	0.51	0.34	
>=10001	(0.25-0.90)*	(0.27-1.16)	(0.28-1.12)	(0.25-1.04)	(0.08-1.46)	
	0.76	0.80	0.66	0.62	0.28	
	(0.36-1.63)	(0.36-1.80)	(0.29-1.48)	(0.27-1.41)	(0.05-1.59)	
	1.00	1.00	1.00	1.00	1.00	
Occupation						
Unemployed	1.00	1.00			1.00	
Employ	3.17	2.87			1.93	
	(1.80-5.58)*	(1.52-5.42)*			(0.60-6.16)	
Numbers of caregiver (person)						
None	1.00		1.00		1.00	
1-3	0.45		0.49		0.34	
>=4	(0.17-1.15)		(0.17-1.39)		(0.04-3.27)	
	0.29		0.46		0.13	
	(0.09-0.91)*		(0.14-1.49)		(0.01-2.59)	
CKD stage						
3a	1.30		1.36	2.62		
3b	(0.63-2.68)		(1.24-5.72)*	(1.19-5.77)*		
4	1.74		0.41	1.43		
5	(0.88-3.41)		(0.70-2.62)	(0.72-2.85)		
	1.02		1.31	1.35		
	(0.53-1.97)		(0.69-2.49)	(0.70-2.62)		
	1.00		1.00	1.00		
Duration of disease (years)						
<=3	0.81		0.82		0.12	
4-6	(0.36-1.82)		(0.37-1.81)		(0.01-0.97)*	
7-9	0.91		1.01		0.20	
>=10	(0.38-2.19)		(0.42-2.41)		(0.02-1.76)	
	0.63		0.38		0.30	
	(0.17-2.29)		(0.11-1.39)		(0.03-3.64)	
	1.00		1.00		1.00	
Associated disease ^a						
Yes	3.33		0.95		1.98	
No	(0.98-11.38)		(0.31-2.89)		(0.37-10.56)	
	1.00		1.00		1.00	

(Table 3) *contd.....*

Factors	PCS		MCS		KDCS	
	OR (95%CI)	OR _{Adj} (95%CI)	OR (95%CI)	OR _{Adj} (95%CI)	OR (95%CI)	OR _{Adj} (95%CI)
Hospital Setting						
Urban	0.95		1.24		1.41	
Rural	(0.58-1.56) 1.00		(0.75-2.04) 1.00		(0.51-3.94) 1.00	
Hospital Level						
First-Level	1.00		1.00		1.00	
Middle-Level	1.42		1.06		0.76	
High-Level	(0.83-2.42) 1.07 (0.54-2.13)		(0.62-1.81) 1.14 (0.56-2.32)		(0.23-2.44) 2.23 (0.55-9.00)	

Notes: The multivariate analysis was done and shown as OR_{Adj}. Only listed meaningful variables were shown in the table.

*Statistically significant (p-value of <0.05); †Associated diseases: Diabetes Mellitus, Hypertension, Chronic Heart Diseases, Gout, Hyperlipidemia, and others (Systemic Lupus Erythematosus (SLE) and Kidney Stones).

4. DISCUSSION

The QOL of CKD patients in CKD clinics in Thailand was measured by the Standard Kidney Disease Quality of Life Short Form (KDQOL-SF™) [8]. More than half of the 258 CKD patients in CKD clinics had fair QOL in PCS and good QOL in MCS. More than half of 65 end-stage renal disease patients had a fair level of KDCS. The factors associated with QOL in PCS were education, income, and occupation. For the MCS, two factors were associated with QOL among CKD patients: income and CKD stage. The factor associated with KDCS was only the duration of the disease.

In the PCS, the pain domain had the highest mean score. However, the general health domain had the lowest mean score. It might be according to the nature of the disease that affects general health [19, 20]. The study from the United States indicated similarly that the quality of life in the domain of general health reported a low score among patients with CKD [21]. In MCS, the emotional well-being domain had the highest mean score. However, the emotional role domain had the lowest mean score. The previous study in Ghana has supported the results and showed similarity [22]. Emotional role includes problems encountered during working or other regular daily activities as a result of any emotional problems, such as feeling depressed or anxious. It was found that patients with CKD generally have many kinds of emotional responses: sadness, fear, feeling down, tense, and alone and becoming anxious or depressed [23 - 25]. Moreover, associated diseases, such as diabetes also affect mental health as depression [24]. In KDCS, the ESRD targeted-areas, the dialysis staff encouragement domain had the highest mean score. The previous studies from Thailand, Indonesia, and India indicated a similar result on the domain of dialysis staff encouragement that had the highest score among other domains in KDCS [13, 26, 27]. This might also be according to the multidisciplinary care team in the CKD clinic providing effective care for ESRD patients [28 - 30]. This influences the satisfaction score of the staff among these patients. Meanwhile, the cognitive functioning domain had the lowest mean score. This result was consistent with a similar study that showed a low score on this domain [26]. The cognitive functioning domain generally focuses on difficulties faced in performing activities involving concentration and thinking, becoming confused and starting several activities at a time, and reacting slowly to things that

were said or done. The previous studies had also found that ESRD patients involved in those indications might be at a high risk of developing cognitive impairment [31 - 34].

More than half of 258 CKD patients in Thailand had fair QOL in PCS and good in MCS. On the other hand, the study from Nepal had found that more than half of CKD patients had good QOL in the PCS domain and moderate QOL in the MCS domain [34]. More than half of 65 end-stage renal disease patients had a fair level of KDCS. A study from Nepal and Iran reported finding similar to our study [34, 35].

In this study, employed CKD patients were more likely to have a good QOL in terms of PCS. This finding is consistent with the previous study from India, which reported that being employed had a positive impact on QOL in CKD patients [36]. This finding is also consistent with a study in Vietnam, which confirmed that unemployed patients had significantly lower PCS than those who were employed [37]. CKD patients who had education lower than primary school were more likely to have good QOL in terms of PCS. On the other hand, the studies in India and the United States reported that low education was associated with low QOL [36 - 38]. Several studies also reported that a higher education level was related to better QOL in the PCS [34, 37, 39, 40]. The possible reason for the finding might be that those who have a low level of education were healthier than those who had a higher education.

CKD patients who had no income tended to have a poorer PCS and MCS. The previous study found that low income is considered to have poorer quality of life in both physical and mental components [4]. This might be because the financial concerns affect patient's ability regarding their illness and also the mental aspect. Not surprisingly, CKD patients with the 3a stage were more likely to have good QOL in terms of MCS. The previous studies revealed that early stage CKD patients had a higher QOL level than patients in the late stage in the term of MCS domain and confirmed that the stage of CKD affected the QOL score [4, 34, 41]. However, a study in Vietnam [37] reported that patients with Stage 5 CKD had better scores than those with the early stage in the MCS.

ESRD patients who had primary school education were more likely to have a poor QOL in terms of KDCS. This finding is consistent with the previous study from Saudi Arabia, which confirmed that patients who had below secondary school level education had a lower score of KDCS

[42].

This study was conducted in all levels of the public hospitals in Thailand: High-Level Referral Hospital, Middle-Level Hospital, and First-Level Hospital from 12 health regions all over the country. However, the generalizability of findings may be limited because only two patients were selected from each of the selected High-Level Referral Hospitals, Middle-Level Hospitals, and First-Level Hospitals in Thailand. In addition, according to the number of questions in the KDQOL-SF™ (80 questions), some participants dropped their attention and motivation in the latter sections of the questionnaire. This might have impacted their answers (*i.e.* answering “don't know”). These were the limitations found in this study.

The findings of this study contribute to the knowledge related to the QOL and its effect among CKD patients in CKD clinics. The results suggested that financial support should be more emphasized for improving QOL among CKD patients in the CKD clinic. In addition, advanced CKD stage patients should be more focused. The results from this study are also profitable in planning and reforming an ongoing policy of CKD clinics and healthcare services appropriately and efficiently.

CONCLUSION

The study has concluded that the QOL among CKD patients in CKD clinics is at the fair level in PCS and KDCS and related to education, occupation, income, and CKD stage. QOL in terms of general health, emotional role, and cognitive functioning among these patients need to be considered. The future of improvement for the quality of life among patients in CKD clinics need to focus on and financial issue since QOL for both physical and mental aspect tend to be poorer in patients who have no income. Unemployed, primary school and lower education level and the advanced stage of CKD patients should be emphasized. In addition, PCS and KDCS need to be concentrate to improve QOL. This study expects to contribute the future intervention and improve policy implementation regarding CKD clinics for improving the quality of life among this population.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study was approved by the Ethics Review Committee for Research Involving Human Research Subjects, Health Science group of Thammasat University, Thailand (COA. No. 254/2560).

HUMAN AND ANIMAL RIGHTS

No animals were used in this research. All human research procedures were followed in accordance with the ethical standards of the committee responsible for human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2013.

CONSENT FOR PUBLICATION

After research objectives, benefits, risks, and the rights of

the patients were introduced, participants were asked to sign the consent form and permission to collect data. The data obtained was kept confidential and used in this research only.

AVAILABILITY OF DATA AND MATERIALS

Data supporting the findings of this study are available from the corresponding author [SW] on request.

FUNDING

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CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

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