

## ORIGINAL ARTICLE

# Effectiveness of an innovative self-management intervention on the physiology, psychology, and management of patients with pre-end-stage renal disease in Taiwan: A randomized, controlled trial

Shu F. V. WU,<sup>1</sup> Mei C. LEE,<sup>2</sup> Nan C. HSIEH,<sup>3</sup> Kuo C. LU,<sup>4</sup> Hung L. TSENG<sup>2</sup>  
and Li J. LIN<sup>5</sup>

Departments of <sup>1</sup>Gerontological Health Care, <sup>3</sup>Information Management, <sup>5</sup>Department of Research and Development and <sup>2</sup>School of Nursing, National Taipei University of Nursing and Health Sciences, Taipei and <sup>4</sup>Department of Medicine, Cardinal Tien Hospital, School of Medicine, Fu-Jen Catholic University, New Taipei City, Taiwan

## Abstract

**Aim:** End-stage renal disease (ESRD) not only threatens a patient's life expectancy but also burdens the family and society with medical expenses. The mortality and prevalence rates are extremely high in Taiwan. Thus, this article investigated the effectiveness of an innovative self-management program on the physiology, psychology, and management of patients with pre-ESRD.

**Methods:** This study was designed as a randomized, controlled trial and was set in the department of nephrology in a regional teaching hospital in Taiwan. In total, 112 patients with pre-ESRD were assigned randomly to either an experimental ( $n = 67$ ) or a control ( $n = 45$ ) group. The baseline data collection included physiological indicators, psychological factors (depression, anxiety), and measures of self-efficacy and self-management. Routine hospital care was provided for the control group after the pretest and an innovative self-management intervention was used in the experimental group for 4 weeks after the pretest. The effectiveness of the intervention was evaluated 3 months later.

**Results:** Improvements in the physiological indicators, such as blood urea nitrogen and creatinine, and the psychological indicators, such as depression, self-efficacy, and self-management, reached statistical significance.

**Conclusion:** The innovative self-management program effectively decreased patients' functional indicators (blood urea nitrogen, creatinine) and level of depression and enhanced their self-efficacy and self-management.

**Key words:** depression, pre-end stage renal disease, self-efficacy, self-management.

## INTRODUCTION

The 2013 United States Renal Data System Annual Data Report showed that the incidence of chronic kidney disease (CKD) in the general population in the USA

was 14%. Most persons did not realize that they had the disease and the mortality rate of patients with CKD was 118 deaths per 1000 patient years. The number of newly reported cases of end-stage renal disease (ESRD) in 2013 was 117,162 and the incidence rate was 363 per million per year (USRDS, 2015). The incidence and prevalence of ESRD have been high in Taiwan for many years and the country has been dubbed “the kingdom of dialysis.” The incidence of patients receiving dialysis in Taiwan in 2010 was 361 per million per

*Correspondence:* Shu-Fang Vivienne Wu, Department of Gerontological Health Care, National Taipei University of Nursing and Health Sciences, 365, Ming Te Road Peitou 112 Taipei, Taiwan. Email: shufang@ntunhs.edu.tw

Received 5 October 2016; accepted 25 September 2017.

year. Although patients with ESRD accounted for only 0.15% of the total number of the insured population, they consumed up to 7.2% of healthcare resources (Health Promotion Administration, Ministry of Health and Welfare, Taiwan, 2008). The high prevalence and incidence of CKD and ESRD are a serious global problem.

Chronic kidney disease usually is divided into five stages: (i) Stage 1: normal renal function with mild proteinuria. Kidney damage with a normal or relatively high estimated glomerular filtration rate (eGFR) ( $\geq 90$  mL/min/1.73 m<sup>2</sup>); (ii) Stage 2: a mild reduction in the eGFR (60–89 mL/min/1.73 m<sup>2</sup>) with kidney damage; (iii) Stage 3: a moderate reduction in the eGFR (30–59 mL/min/1.73 m<sup>2</sup>); (iv) Stage 4: a severe reduction in the eGFR (15–29 mL/min/1.73 m<sup>2</sup>); and (v) Stage 5: ESRD, with an eGFR of  $<15$  mL/min/1.73 m<sup>2</sup> (USRDS, 2015). A report from the National Health Research Institutes of Taiwan indicated that ~6.9% of Taiwanese who are aged  $\geq 20$  years suffer from stages 3–5 CKD (Hsu *et al.*, 2006), but the percentage of patients who knew about their disease was low. Only 8% of patients with stage 3 CKD and 25% of patients with stage 4 CKD were aware of their kidney problems. Moreover, only 71.4% of patients with ESRD knew that they had renal disease and the mortality rate and the risk of developing cardiovascular disease were 83% and 100%, respectively (Wen *et al.*, 2008). Therefore, if there was an effective intervention that could be started early by health professionals, then the progression to ESRD that requires dialysis could be delayed.

Patients with CKD have to coexist with the disease and adapt to it. The disease can have long-term devastating effects on a patient's physical health, emotions, family, lifestyle, and relationships (Tong *et al.*, 2009). Lorig and Holman (2003) defined "self-management" as the ability of patients with a chronic disease to undertake health-promoting behaviors and to be responsible for the management of their daily life. Barlow, Wright, Sheasby, Turner, and Hainsworth (2002) believed that patients should manage their symptoms, treatments, physical and psychosocial status and adjust their lifestyle in order to coexist with their chronic disease. Patients with CKD must learn to self-manage their disease and maintain a balanced and comfortable life (Lin, 2011).

Self-management has been conceptualized as a subset of self-care behavior. Focused on managing the actual or potential impact of disease, the concept of self-management of a disease includes the self-care

behaviors of self-monitoring, symptom management, and other related concepts. Self-efficacy is the moderator or mediator of the concept of self-management (Richard and Shea, 2011). A study that investigated the factors that are associated with self-management behaviors in patients with diabetic nephropathy found that there was a highly positive correlation between self-efficacy and self-management and that self-efficacy predicted better self-management (Ho, 2012). Another study showed that patients with CKD and high self-efficacy had the potential to improve health outcomes (Wells and Anderson, 2011). The case management model (Ni, 2011), the case management model of empowerment through conceptual development (Chen, 2010), and the self-regulation theory-centered self-management program (Lin, Tsai, Lin, Hwang & Chen, 2013) all were applied to patients with CKD and the results showed differences in self-efficacy in these patients. Curtin *et al.* (2008) studied the correlation among self-efficacy, physical and mental function, and self-management in 174 patients with CKD and found that self-efficacy was significantly related to self-management behaviors, such as communication with caregivers, partnership in care, self-care, and medication adherence.

In 2006, Taiwan implemented pre-ESRD preventive plans and patient education programs for patients with kidney disease, but these plans did not highlight a self-directed role for patients with chronic disease, so that patients' health behaviors could not really be changed; therefore, an innovative intervention has become necessary. Many systemic literature reviews regarding chronic disease have indicated that self-management is more effective than traditional health education for changing patients' behaviors (Lorig and Holman, 2003). Patients with pre-ESRD was one group of patients with CKD whose disease progressed rapidly. Few interventional studies have been conducted with this population in clinical settings, but intervention is necessary in order to delay the progression to dialysis (Lin, Yang, Hwang, & Sung, 2013b).

Anxiety and depression are common psychological problems in patients with CKD. Fatigue, complex treatment regimens, related side-effects, and the liquid diet restrictions that are followed by patients with CKD all have a psychological impact and result in a feeling of uncertainty. Self-management programs have been widely applied to chronic disease education programs, which are designed to delay deteriorating kidney function, preclude depression, and improve one's quality of life. In addition to physical discomfort and

psychological problems, patients must adapt to the social impact of, and implications resulting from, chronic disease (Tong *et al.*, 2009). The symptoms of depression in patients with CKD are very similar to uremic symptoms, such as a loss of appetite, sleep disturbances, fatigue, and gastrointestinal dysfunction, and thus are not easy to diagnose (Amira, 2011; Hedayati and Finkelstein, 2009). Bautovich, Katz, Smith, Loo, and Harvey (2014) indicated that 20% of patients with CKD could suffer from depression, with a reduced quality of life and treatment compliance and increased risk of hospitalization and mortality. The prevalence of depression in patients with CKD was ~20–30% and the severity of depression was aggravated by the progression of the disease (Bossola *et al.*, 2010).

For renal healthcare personnel, helping patients with CKD to control their existing chronic disease might effectively delay the progression of that disease and enable them to respond to the psychological impact of it. Studies of CKD using self-management programs based on self-efficacy are few in number and group health education, including the sharing of experiences among patients, is also lacking in traditional health education programs. Health instructions are unilaterally and randomly provided to individuals by nurses or case managers in writing or verbally.

## METHODS

### Aim

The aim of the current study was to use an innovative self-management intervention that was based on self-efficacy in order to explore its effectiveness on the physiological indicators (renal function), psychological parameters (e.g. self-efficacy, anxiety, and depression), and management.

### Design

This study was designed as a randomized, controlled trial.

### Study population

The study's participants were patients with pre-ESRD in the Department of Nephrology in a regional teaching hospital in Taiwan, single-blind, and randomly assigned into an experimental or control group by using a random number table (with 45 participants in the intervention group and 67 participants in the control group). They were researcher-enrolled participants and assigned

participants to interventions. An innovative self-management intervention was used to explore the differences in clinical management indicators, self-efficacy, self-management, and improvement in anxiety and depression between groups. The inclusion criteria were: (i) patients with a diagnosis by a physician of stage 3b–5 CKD for >3 months; (ii) clear consciousness and without mental illness; (iii) the ability to speak Mandarin and Taiwanese and willing to participate in the current study; (iv) aged  $\geq 20$  years; and (v) attended at least three out of the four group activities. The exclusion criteria were: (i) renal replacement therapy; (ii) cognitive dysfunction or the inability to understand the questionnaire; and (iii) mental illness, such as severe depression or schizophrenia, based on the medical history.

### Sample size

G-Power 3.1.2 was used to calculate the sample size (Faul, Erdfelder, Buchner, and Lang, 2009) on the basis of an effect size of 0.35 in the past literature (Lii, Tsay, and Wang, 2007). The required number in the sample was at least 68 (34 people in each group) according to power = 0.80,  $\alpha = 0.05$ , and an effect size = 0.35, according to the two-tailed test. Moreover, the rough estimate of the attrition rate was 20%; therefore, the total sample required was at least 82 people (41 people in each group).

### Usual care

Routine care in the current study was defined as routine blood tests every 3 months for patients with pre-ESRD, as well as traditional health education that was provided by nurses or case managers who offered health guidance for 5–10 min during each visit, according to their patient's individual blood test results. At present, the clinical case management of CKD is based on the national health insurance payment system, which focuses on health education and which is unable to highlight the patient's self-directed role in disease control.

### Innovative self-management intervention

Self-efficacy as a theoretical framework and problem-centered approaches was used to encourage patients to set personal goals. The experiences that were shared by peers, an information manual, a consultative framework, and the application of self-confidence and empowerment skills were used to develop patients' self-confidence in order to help them to actually execute self-care practices. The course included a video, a group

trainee manual about self-efficacy, and the management of CKD (Lee *et al.*, 2014), participation in the self-efficacy-enhancing program, and telephone interviews. Small-group interventions (10–15 patients per group) were held once per week for 1 month. Each intervention lasted for 100 min, including a 90 min group discussion and a 10 min video.

### Instruments

The post-test (program effectiveness) was conducted when the patients saw a physician after 3 months and the performance indicators included renal function, anxiety, depression, self-efficacy, and self-management.

### Demographic and disease characteristics

The demographic characteristics included the patients' age, time since the diagnosis of kidney disease, CKD stage, sex, educational level, religion, marital status, occupation, living conditions, and medication history. The laboratory tests included blood urea nitrogen (BUN), creatinine, eGFR, and electrolytes, including calcium, phosphorus, sodium, and potassium.

### Hospital Anxiety and Depression Scale

The Hospital Anxiety and Depression Scale was developed by Zigmond and Snaith (1983) for people with physical illness. The scale has 14 questions, including seven questions on anxiety and seven questions on depression, and the questions are arranged in a staggered pattern: odd questions to measure the level of anxiety and even questions to measure the level of depression. A Likert scale of scores from 0–3 is used to score each item and the total score ranges from 0 to 21 for each subscale; the higher the score, the greater the degree of anxiety or depression. A score of  $\leq 7$  indicates no anxiety or depression. Scores of 8–10 and  $\geq 11$  indicate that patients have suspected cases of anxiety or depression or have been determined to have anxiety or depression, respectively. This scale has been used widely in various studies. Martin, Tweed, and Metcalfe (2004) conducted a reliability and validity analysis of the scale in 160 patients with ESRD and the result showed that the Cronbach's  $\alpha$  for the overall scale, the anxiety subscale, and the depression subscale was 0.87, 0.83, and 0.73, respectively. A Chinese version of the hospital anxiety and depression scale was used with persons with dialysis in Taiwan and its Cronbach's  $\alpha$  for the anxiety and depression subscales was 0.96 and 0.95, respectively, with good internal consistency (Chen, Kuo, Chang, Liu, and Hsu, 2007). Therefore, this scale

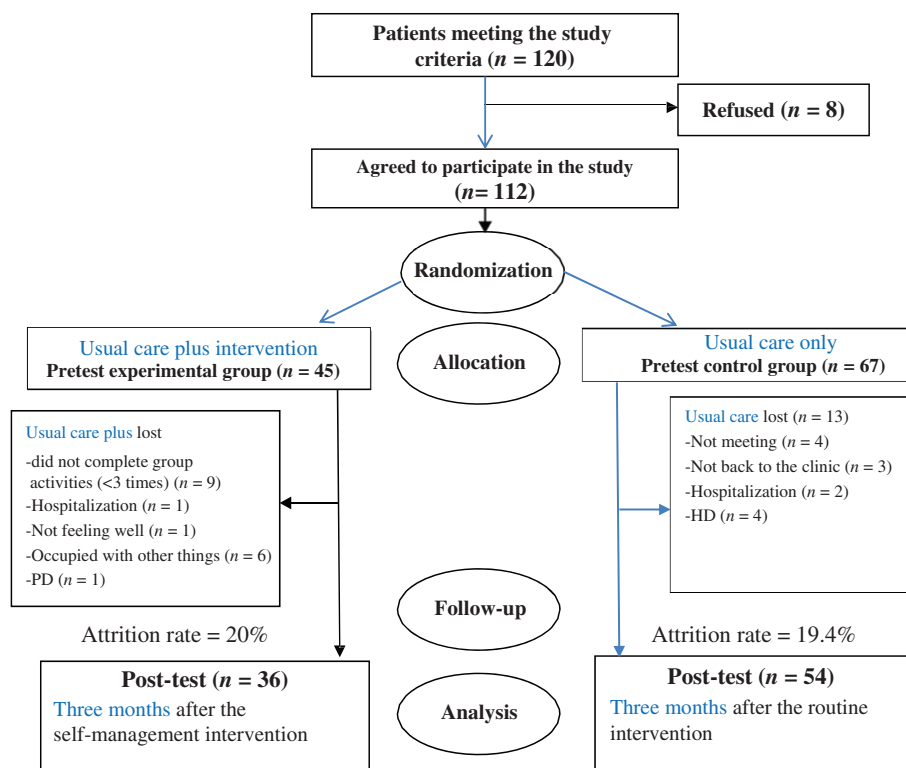
was suitable to measure mental health status as a result of disease management in patients with CKD.

### Chronic Kidney Disease Self-efficacy Instrument

This psychometric instrument was developed to assess the self-management of disease in 594 patients with early CKD by Lin *et al.* (2012) and has been used to measure self-confidence in the ability to manage disease in patients with CKD. The scale has 25 questions and scores range from 0 to 10 and reflect the level of confidence: 0: "Completely without confidence;" 10: "Completely confident." The total score ranges between 0 and 250 and the higher the score, the greater the patient's confidence in controlling a certain behavior in the disease management program. An exploratory factor analysis (EFA) was conducted on this scale and four subscales were extracted: autonomy, self-integration, problem-solving, and seeking social support. Its factor loading and explanation of total variance were 0.56–0.97 and 64.35%, respectively, and the Cronbach's  $\alpha$  for the four subscales was 0.84–0.90. After 2 weeks, the test–retest reliability coefficient was 0.72 ( $P < 0.001$ ) and the average value of the content validity index (CVI) was 0.89 (Lin *et al.*). This scale was used for patients with CKD in Taiwan and the average value of the CVI was 0.96. The Cronbach's  $\alpha$  for this scale was 0.76, indicating that this scale had good reliability and validity (Wu, Lu, and Lin, 2012). This scale was used to measure the level of self-confidence about self-efficacy in patients with pre-ESRD in the current study.

### Chronic Kidney Disease Self-management Instrument

This scale is used for patients with early CKD and includes four subscales: self-integration, problem-solving, seeking social support, and compliance with the recommended program (Lin, Wu, Wu, Chen, & Chang, 2013c). The Likert scale of scores is from 1 to 4 and the meaning of the different scores is 1: "Never;" 2: "Sometimes;" 3: "Usually;" and 4: "Always." There are 29 questions and the total score ranges from 1 to 116; the higher the score, the better the self-management. Lin *et al.* (2013a) used this scale to assess 252 patients with stage 1–3 CKD in Taiwan and an EFA and principal component analysis were conducted. The results showed that the KMO = 0.92, the loading of the four subscales ranged from 0.57 to 0.87, explained the variance of 60.51%, and the Cronbach's  $\alpha$  for the overall scale was 0.77–0.92. After 2 weeks, the test–retest



**Figure 1** Process of participant recruitment.

reliability coefficient was 0.72 (Lin *et al.*, 2013c). This scale has been used widely in many CKD studies; the values of CVI were 0.97 (Ni, 2011) and 0.96 (Chen, 2010) and the Cronbach's  $\alpha$  was 0.95 (Chen; Ho, 2012) and 0.96 (Ni). The Cronbach's  $\alpha$  of the four scales was 0.81–0.95 (Chen) and 0.81–0.96 (Ni). The value of the CVI in the current study was 0.98, and after the post-test, the Cronbach's  $\alpha$  was 0.96. Therefore, this scale was suitable to measure the ability for self-management in patients with CKD in the current study.

### Ethical considerations

The current study was approved by the institutional review board of the enrolled medical institution (serial no.: CTH-102-3-1-007) in order to protect the study participants' human rights. After the researchers explained the study and the participants signed the informed consent form, they were invited to join the study. All the study's participants were voluntary. Their data were anonymously coded for questionnaire compilation and data analysis. The investigators' phone numbers were provided to the participants and they were

informed that they could withdraw from the study at any time without any consequence.

### Data analysis

IBM SPSS Statistics for Windows v. 20.0 (IBM Corporation, Armonk, NY, USA) was used for archiving and statistical analysis. The statistical methods included descriptive statistics (frequency distributions, percentages, means, and standard deviations); inferential statistics (independent samples *t*-tests and chi-squared tests and ANCOVA). A generalized linear model was used to analyze the effectiveness after the intervention. Figure 1 shows the recruitment process for this randomized control trial.

## RESULTS

### Baseline participant characteristics

A total of 112 participants completed the pretest, 45 participants in the experimental group and 67 participants in the control group. Nine patients in the experimental group withdrew from the study, as did

13 patients in the control group. Three months after the intervention, a total of 90 patients completed the post-test, 36 participants in the experimental group (39.5%) and 54 in the control group (55.5%). The total drop-out rate in the post-test was 19.6% and the drop-out rates of the experimental and the control groups were 20% and 19.4%, respectively.

The mean age of the participants was 70.16 years (standard deviation, SD = 11.6) and the average time since diagnosis of CKD was 4.29 years (SD = 5.61). The patients with Stage 3b CKD ( $n = 45$ , 40.2%) outnumbered those in stages 4–5 and most of the patients were male ( $n = 69$ , 61.6%). Most of the patients had a primary school education ( $n = 59$ , 52.7%).

The independent samples *t*-test and chi-squared test were used to detect differences in the baseline characteristics between the two groups and the results showed that there was a significant difference in the medication use in terms of the use of Chinese medicine ( $X^2 = 7.64$ ,  $P = 0.006$ ). Twelve patients in the experimental group used Chinese medicine. The other demographic and disease characteristics showed no significant difference between group (Table 1).

### Description and comparison of the outcome indicators for the two groups in the pretest before the intervention

The outcome indicators of the two groups on the pretest were self-efficacy, anxiety and depression, social support, and self-management. Before the intervention, only self-efficacy showed a significant difference between the two groups and there was no significant difference in the other indicators (Table 2). The average total score for self-efficacy for all on the pretest was 115.29 (SD = 60.33). The average total score for self-efficacy in the experimental group was 131.33 (SD = 54.04), higher than that in the control group (score = 104.51, SD = 62.33). This statistically significant difference ( $t = -2.35$ ,  $P = 0.02$ ) indicated that the experimental group had greater self-confidence in the control of CKD than the control group before the intervention. The other comparisons of the outcome indicators between groups on the pretest showed no significant difference (Table 2).

### Physiological indicators after the intervention

An ANCOVA was used to analyze the difference in BUN between the experimental and the control groups after the self-management intervention. The results showed that the mean score for the experimental group

was 37.7 (SD = 18.23), lower than that of the control group (score = 42.26, SD = 24.64). This difference was significant ( $F = 23.58$ ,  $P < 0.001$ , partial  $\eta^2 = 0.234$ ). The difference in creatinine between the groups was also significant after the self-management intervention. The results showed that the mean score of the experimental group was 2.96 (SD = 2.14), lower than that of the control group (score = 3.04, SD = 2.17), and that the difference between the two groups was statistically significant ( $F = 5.40$ ,  $P = 0.023$ , partial  $\eta^2 = 0.066$ ). There was no significant difference in the other indicators (Table 3).

### Depression, anxiety, self-efficacy, and self-management after the intervention

An ANCOVA was used to determine the difference in the average scores of depression between the experimental and the control groups after the self-management intervention. The results showed that the average score of the experimental group was 2.39 (SD = 2.71), lower than that of the control group (score = 4.25, SD = 2.88), and that the difference between the two groups was statistically significant ( $F = 5.44$ ,  $P = 0.022$ , partial  $\eta^2 = 0.065$ ). The average score for self-efficacy in the experimental group was 220.5 (SD = 20.44), higher than that in the control group (score = 127.46, SD = 61.9), and that the difference was statistically significant ( $F = 44.42$ ,  $P < 0.001$ , partial  $\eta^2 = 0.36$ ). The average score for self-management in the experimental group was 89.14 (SD = 9.45), higher than that in the control group (score = 63.87, SD = 13.66), and that the difference was also statistically significant ( $F = 18.35$ ,  $P < 0.001$ , partial  $\eta^2 = 0.190$ ). The other variables between groups were not statistically significant (Table 4).

## DISCUSSION

This study explored the effect on the renal function of patients with pre-ESRD after an innovative, self-efficacy-centered, self-management intervention. The results showed that the average values of BUN and creatinine were 37.7 mg/dL and 2.96 mg/dL, respectively, in the experimental group 3 months after the intervention; these were lower than those in the control group. This implied that the 3 month innovative self-management intervention was significantly more effective than traditional education in decreasing BUN and creatinine. Studies regarding self-management intervention in patients with pre-ESRD that showed a significant

**Table 1** Comparison and analysis of the demographic data of the participants between groups in the pretest

Variable	Experimental group ( <i>n</i> = 45) Mean (SD) or N (%)	Control group ( <i>n</i> = 67) Mean (SD)	<i>2/t</i>	$\chi^2/P$
Age	67.82 (9.43)	71.73 (12.68)	1.77	0.080
Years since diagnosis of renal disease	3.70 (3.64)	4.68 (6.61)	0.91	0.367
CKD stage			2.09	0.148
3b	22 (48.9)	23 (34.3)		
4	12 (26.7)	25 (37.3)		
5	9 (20.0)	18 (26.9)		
Sex			1.67	0.196
Male	31 (68.9)	38 (56.7)		
Female	14 (31.1)	29 (43.3)		
Level of education			-2.45	0.160
Primary education	17 (37.8)	23 (34.3)		
Junior high school	9 (20.0)	12 (17.9)		
High school and higher degree	14 (31.1)	10 (14.9)		
Religion			0.26	0.798
Buddhism	9 (20.0)	11 (16.4)		
Taoism	32 (71.1)	54 (80.6)		
Other religion	4 (8.9)	2 (3.0)		
Marital status			-0.26	0.789
Unmarried	1 (2.2)	5 (7.5)		
Married	38 (84.4)	46 (68.7)		
Widowed	6 (13.3)	11 (16.4)		
Current occupation			0.70	0.403
No	34 (75.6)	55 (82.1)		
Yes	11 (24.4)	12 (17.9)		
Living status			0.84	0.360
Alone	3 (6.7)	8 (11.9)		
With family	42 (93.3)	59 (88.1)		
Medical history				
Hypertension			0.35	0.852
No	8 (17.8)	11 (16.4)		
Yes	37 (82.2)	56 (83.6)		
High blood sugar			0.19	0.664
No	20 (44.4)	27 (40.3)		
Yes	25 (55.6)	40 (59.7)		
High LDL-C			0.49	0.485
No	36 (80.0)	57 (85.1)		
Yes	9 (20.0)	10 (14.9)		
High cholesterol			0.97	0.325
No	31 (68.9)	40 (59.7)		
Yes	14 (31.1)	27 (40.3)		
Proteinuria			0.66	0.416
No	16 (35.6)	29 (43.3)		
Yes	29 (64.4)	38 (56.7)		
High triglycerides			0.69	0.407
No	31 (68.9)	41 (61.2)		
Yes	14 (31.1)	26 (38.8)		
High uric acid			0.83	0.362
No	25 (55.6)	43 (64.2)		
Yes	20 (44.4)	24 (35.8)		
Cancer			1.13	0.287
No	38 (84.4)	61 (91.0)		

Table 1 Continued

Variable	Experimental group ( <i>n</i> = 45) Mean (SD) or <i>N</i> (%)	Control group ( <i>n</i> = 67) Mean (SD)	<i>2/t</i>	$\chi^2/P$
Yes	7 (15.6)	6 (9.0)		
Medication use				
Chinese medicine			7.64	0.006*
No	33 (73.3)	62 (92.5)		
Yes	12 (26.7)	5 (7.5)		
Radio advertising medicine			2.10	0.152
No	45 (100.0)	64 (95.5)		
Yes	0 (0.0)	3 (4.5)		
Others			0.39	0.530
No	44 (97.8)	64 (95.5)		
Yes	1 (2.2)	3 (4.5)		

\**P* ≤ 0.05.

CKD, chronic kidney disease; LDL-C, low-density lipoprotein-cholesterol; SD, standard deviation.

Table 2 Comparison of the outcome indicators between groups on the pretest

Variable	Experimental group ( <i>n</i> = 45) Mean (SD)	Control group ( <i>n</i> = 67) Mean (SD)	<i>t</i> -value	<i>P</i> -value
Self-efficacy	131.33 (54.04)	104.51 (62.30)	−2.35	0.020*
Anxiety	3.33 (4.28)	2.72 (4.26)	−0.75	0.455
Depression	4.87 (3.67)	5.63 (4.04)	1.01	0.314
Self-management	66.27 (14.37)	60.66 (15.81)	−1.91	0.059

\**P* ≤ 0.05.

effectiveness in the control indicators of renal function followed the participants for only 6–12 months (Chen *et al.*, 2011; Flesher *et al.*, 2011; Kazawa and Moriyama, 2013; Lin, Yang, *et al.*, 2013b). Therefore, longer term follow-up is necessary in order to determine the effect on renal function. Moreover, the clinical assessment of change in renal function is currently based on the eGFR, followed by BUN, creatinine, urinary protein, and the creatinine ratio. The calculation parameters for the eGFR include creatinine, age, and race; the value of the eGFR varies with age, even if the creatinine level is the same. Although the intervention in the current study was effective in improving BUN and creatinine, it was not effective in increasing the eGFR. Therefore, if this intervention were really able to further delay the deterioration of renal function, the result should be considered conservatively because long-term follow-up is necessary to prove its effectiveness.

The intervention was not effective in controlling indicators, such as blood pressure, blood sugar, and blood lipids; a possible reason for this was that the study's participants were recruited in winter. Most of the participants said that there would be an opportunity to eat a big meal because of Chinese New Year and Mother's Day when they completed the questionnaire. The

measurement of renal function might have been influenced if a blood test was performed immediately after a big meal. If patients have good self-management behaviors, then this would not be a problem when dealing with special occasions. In addition, the effectiveness of the intervention was measured only 3 months afterwards and specific physiological indicators might not improve in such a short time.

This innovative self-management intervention effectively reduced the symptoms of depression. The literature has indicated that patients with stage 3–5 CKD have a high risk of developing depression (Chiang, Livneh, Yen, Li, and Tsai, 2013). Taiwan's National Health Insurance Research Database indicated that the occurrence rate of severe depression in patients with CKD was 1.61-fold higher than that of the general population. This was an important risk factor for the increase in physiological symptoms and the concurrence of complications and, as a result, the quality of life was affected (Chen, 2014; Lee, Kim, Cho, and Kim, 2013; Peng *et al.*, 2013). As the psychological problems of anxiety and depression are seen commonly in patients with CKD and are related to their quality of life, clinical healthcare personnel should identify psychological distress in patients with CKD as soon as possible in order

Table 3 Physiological indicators after the intervention, according to the ANCOVA

Variable	Experimental group ( <i>n</i> = 45)			Control group ( <i>n</i> = 67)			ANCOVA		Partial $\eta^2$	$R^2$ -value (adjusted $R^2$ -value)	Power
	Pretest Mean (SD)	Post-test Mean (SD)		Pretest Mean (SD)	Post-test Mean (SD)		<i>F</i> -value	<i>P</i> -value			
Renal function											
BUN	42.49 (29.12)	37.7 (18.23)		42.45 (22.00)	42.26 (24.64)		23.580	0.001**	0.234	0.761 (0.733)	0.998
Cr.	3.12 (2.31)	2.96 (2.14)		3.11 (1.93)	3.04 (2.17)		5.400	0.023*	0.066	0.956 (0.950)	0.631
eGFR	27.64 (12.38)	27.81 (13.81)		24.94 (11.74)	26.83 (13.30)		0.010	0.935	<0.001	0.822 (0.802)	0.051
Blood pressure											
SBP	142.81 (22.08)	137.84 (18.83)		142.63 (20.55)	144.00 (22.74)		0.001	0.983	<0.001	0.305 (0.217)	0.050
DBP	74.00 (12.67)	75.97 (13.63)		75.02 (12.80)	74.20 (13.38)		0.040	0.850	0.001	0.260 (0.166)	0.054
Blood sugar											
Ac sugar	116.74 (29.14)	119.00 (45.65)		121.49 (43.90)	122.46 (50.52)		0.190	0.279	0.020	0.214 (0.092)	0.189
HbA1C	6.82 (1.19)	7.13 (1.28)		6.95 (1.22)	7.00 (1.42)		1.870	0.180	0.039	0.391 (0.272)	0.268
Blood											
TCH	177.19 (63.90)	163.26 (47.51)		173.02 (37.68)	161.81 (53.00)		3.270	0.077	0.077	0.370 (0.244)	0.425
TG	142.06 (65.02)	139.22 (81.66)		163.43 (125.00)	159.30 (165.67)		0.490	0.489	0.011	0.888 (0.865)	0.105
LDL	102.59 (29.73)	106.23 (33.92)		102.11 (30.91)	102.38 (31.98)		1.840	0.183	0.047	0.476 (0.349)	0.262

\**P* < 0.05 and\*\*\**P* < 0.001.

Control variables were the pretest scores, age, sex, level of education, chronic kidney disease stage, use of Chinese medicine, and self-efficacy.

Ac sugar, ante cibum (before meals) sugar; BUN, blood urea nitrogen; Cr., creatinine; DBP, diastolic blood pressure; eGFR, estimated glomerular filtration rate; HbA1C, hemoglobin A1c; LDL, low-density lipoprotein; SBP, systolic blood pressure; SD, standard deviation; TCH, total cholesterol hormone; TG, triglyceride.

**Table 4** Effect on depression, anxiety, self-efficacy, and self-management after the intervention, according to the ANCOVA ( $n = 112$ )

Variable	Experimental group ( $n = 45$ ) Mean (SD)	Control group ( $n = 67$ ) Mean (SD)	ANCOVA		Partial $\eta^2$	$R^2$ -value (adjusted $R^2$ -value)	Power
			F-value	P-value			
Depression	2.39 (2.71)	4.25 (2.88)	5.45	0.022*	0.065	0.377 (0.305)	0.634
Anxiety	1.11 (1.79)	2.20 (3.64)	0.75	0.389	0.010	0.237 (0.138)	0.137
Self-efficacy	220.50 (20.44)	127.46 (61.9)	44.42	<0.001**	0.360	0.755 (0.730)	1.000
Self-management	89.14 (9.45)	63.87 (13.66)	18.35	<0.001**	0.190	0.730 (0.699)	0.988

\*  $P < 0.05$  and\*\*  $P < 0.001$ .

Control variables were the pretest, age, sex, level of education, chronic kidney disease stage, and use of Chinese medicine.

to provide psychological support and the necessary assistance in time to help patients establish and manage their new life in order to increase their quality of life and to coexist peacefully with CKD. This intervention was not effective in reducing anxiety. Any effect on psychological distress in patients with chronic disease needs long-term follow-up to see the specific benefits.

In terms of the self-efficacy of patients with pre-ESRD, this innovative self-management intervention increased patients' self-confidence in the control of CKD, successfully increasing the implementation of self-management behaviors. As this intervention was a self-management program based on self-efficacy theory and the literature has indicated that self-efficacy can stimulate the development of new personal self-management skills, then high self-efficacy, the adoption of healthy behaviors, and the maintenance of health are positively correlated (Curtin, Mapes, Schatell, and Burrows-Hudson, 2005; Wu, Li, Chang, Courtney, and Chang, 2007). The current study provides evidence for a self-management intervention based on self-efficacy theory.

The results showed that an innovative self-management intervention can effectively improve the self-management ability of patients with pre-ESRD. Corbin and Strauss (1988) divided self-management tasks into three facets: (i) medical practice management (e.g. drug compliance and dietary changes); (ii) life role management (e.g. lifestyle changes to respond to the impact that is caused by the disease); and (iii) emotional management (e.g. learning to deal with the emotional responses due to the impact of the illness, such as anger, fear, frustration, and depression). Medical professionals need to help patients to understand that they play a key role in self-management by gradually integrating those skills into daily life and achieving a balance between life and CKD. Current studies regarding self-management interventions for patients with CKD without dialysis are few. Lin, Tsai *et al.* (2013a) used a self-regulation

theory-centered, self-management education program and followed its effectiveness for 3, 6, and 12 months. Those study results showed that although the level of self-efficacy was enhanced, the ability for self-management in patients with early CKD was not increased. A self-regulation theory-centered program can increase confidence, but there is no evidence to prove that it can improve self-management behaviors. As the study was only a pretest–post-test trial with a single group, the authors explained that a randomized trial was needed to verify the effectiveness of self-management. In comparison, the self-management program in the current study was based on a different theory and the self-management intervention, based on self-efficacy theory, was shown to be effective 3 months after the intervention.

### Study limitations

Ninety participants in the current study were from a regional hospital in north-eastern Taiwan, so that the results cannot be generalized to different regions and medical units (medical centers and district hospitals). A large-scale, randomized trial that is conducted in different medical units throughout Taiwan is therefore recommended. Most patients with CKD returned to the clinic at different times for follow-up every 3 months. This resulted in increased difficulty in recruitment and a high rate of attrition. Moreover, the effectiveness of an intervention on renal function cannot be seen in a short time. Similarly, although the self-efficacy and self-management ability of the patients improved and the tendency for depression decreased, the long-term effectiveness of this intervention cannot be seen, specifically because of the short period of follow-up (only 3 months). Therefore, it is recommended that the period of follow-up be extended to at least 1 year in order to determine the long-term effectiveness of this

intervention. The effects of the self-management intervention in this study might have been influenced by a Hawthorne effect related to the increased amount of attention that was paid to the participants in the intervention group by the group facilitator. However, a standard research procedure for the intervention was provided in order to minimize this limitation.

## CONCLUSION

This experimental study explored the effectiveness of an innovative self-efficacy-centered, self-management intervention on the renal function, depression, anxiety, self-efficacy, and self-management of patients with pre-ESRD. The study's results found that the tendency toward worsening indicators of renal function, such as BUN ( $P < 0.001$ ) and creatinine ( $P < 0.05$ ), can be relieved but there was no effect on the other indicators of renal function. This intervention effectively decreased the tendency toward depression ( $P < 0.05$ ) and increased self-efficacy ( $P < 0.001$ ) and the ability for self-management ( $P < 0.001$ ). These results provide an evidence-based self-management intervention in addition to case management for clinical healthcare providers. The authors recommend promoting this intervention to the kidney disease alliance or replacing traditional group health education with this intervention in order to increase the effectiveness of the control of CKD to help more patients with CKD to successfully adapt to the impact of the disease. The result also provides a reference for the delivery of relevant health care. As such, it is advised that future research enthusiastically propose the use of a self-management program for patients with CKD. The final goal is to reduce the incidence of ESRD and to coexist peacefully with CKD. A long-term, large-scale, randomized experimental trial that is conducted throughout Taiwan is recommended. When the Taiwan Society of Nephrology conducts "CKD educator training courses," training in increasing self-efficacy can be added to assist renal disease case managers to lead and enhance self-efficacy consultative groups in order to improve the quality of care for renal disease. Incentive payments for conducting patients' consultative groups could be added when the Taiwanese Government enacts payment reform in the future.

## ACKNOWLEDGMENT

A qualitative research study is required to clarify individual needs. We are grateful for the grant support that

was provided by the Ministry of Science and Technology, R.O.C. (NSC101-2314-B-227-006-MY3).

## CONFLICT OF INTEREST

The authors declare no conflict of interest.

## AUTHOR CONTRIBUTIONS

S. F. V. W. and M. C. L. contributed to the conception and design of this study; M. C. L. and H. L. T. carried out the statistical analysis; S. F. V. W., N. C. H., and K. C. L. drafted the manuscript; and K. C. L., N. C. H., and L. J. L. critically reviewed the manuscript and supervised the whole study process. All the authors read and approved the final manuscript.

## REFERENCES

- Amira, O. (2011). Prevalence of symptoms of depression among patients with chronic kidney disease. *Nigerian Journal of Clinical Practice*, 14, 460–463.
- Barlow, J. H., Wright, C. C., Sheasby, J. E., Turner, A. P. & Hainsworth, J. E. (2002). Self-management approaches for people with chronic conditions: A review. *Patient Education and Counseling*, 48, 177–187.
- Bautovich, A., Katz, I., Smith, M., Loo, C. K. & Harvey, S. B. (2014). Depression and chronic kidney disease: A review for clinicians. *Australian and New Zealand Journal of Psychiatry*, 48, 530–541.
- Bossola, M., Ciciarelli, C., DiStasio, E., Conte, G. L., Vulpio, C., Luciani, G. *et al.* (2010). Correlates of symptoms of depression and anxiety in chronic hemodialysis patients. *General Hospital Psychiatry*, 32, 125–131.
- Chen, P. Y., Kuo, S. C., Chang, H. C., Liu, Y. J. & Hsu, T. Y. (2007). Preliminary study of the relationship between health locus of control, psychological distress and health promotion behavior in a group of hemodialysis patients. *Journal of Taiwan Nephrology Nurses Association*, 6, 27–41 (in Mandarin).
- Chen, S. H. (2014). A comparison of major depression incidence among patients with chronic kidney disease and end-stage renal disease on different renal replacement therapies. Unpublished Master's dissertation, National Yang-Ming University, Taipei, Taiwan (in Mandarin).
- Chen, S. H., Tsai, Y. F., Sun, C. Y., Wu, I. W., Lee, C. C. & Wu, M. S. (2011). The impact of self-management support on the progression of chronic kidney disease: a prospective randomized controlled trial. *Nephrology Dialysis Transplant*, 26, 3560–3566.

- Chen, Y. C. (2010). Effectiveness of incorporating empowerment concept in chronic kidney disease case management model of care. Unpublished Master's dissertation, National Yang-Ming University, Taipei, Taiwan (in Mandarin).
- Chiang, H. H., Livneh, H., Yen, M. L., Li, T. C. & Tsai, T. Y. (2013). Prevalence and correlates of depression among chronic kidney disease patients in Taiwan. *BioMed Central Nephrology*, 14, 78.
- Corbin, J. & Strauss, A. (1988). *Unending work and care: Managing chronic illness at home*. San Francisco, CA: Jossey-Bass.
- Curtin, R. B., Mapes, D., Schatell, D. & Burrows-Hudson, S. (2005). Self-management in patients with end stage renal disease: Exploring domains and dimensions. *Nephrology Nursing Journal*, 32, 389–395.
- Curtin, R. B., Walters, B. A., Schatell, D., Pennell, P., Wises, M. & Klicko, K. (2008). Self-efficacy and self-management behaviors in patients with chronic kidney disease. *Advances in Chronic Kidney Disease*, 15, 191–205. doi: 10.1053/j.ackd.2008.01.006
- Faul, F., Erdfelder, E., Buchner, A. & Lang, A. G. (2009). Statistical power analysis using G\*Power 3.1: Tests for correlation and regression analysis. *Behavior Research Methods*, 41, 1149–1160.
- Flesher, M., Woo, P., Chiu, A., Charlebois, A., Warburton, D. E. & Leslie, B. (2011). Self-management and biomedical outcomes of a cooking, and exercise program for patients with chronic kidney disease. *Journal of Renal Nutrition*, 21, 188–195.
- Health Promotion Administration, Ministry of Health and Welfare, Taiwan. (2008). *Epidemiological studies and risk factor surveillance program outcomes*. [Cited 2 Mar 2015.] Available from URL: <http://s2.misa.com.tw/ckd/client/ResultList01.php?ParentID=0kzs1ptxnxokrhsh&REFD OCTYPID=0kzs1qj22igkh7iw&REFDOCID=0kzu0ld2jgzxzy78> (in Mandarin).
- Hedayati, S. S. & Finkelstein, F. O. (2009). Epidemiology, diagnosis, and management of depression in patients with CKD. *American Journal of Kidney Diseases*, 54, 741–752.
- Ho, S. S. (2012). Exploring the determinations of self-management in patients with diabetic nephropathy. Unpublished Master's dissertation, National Yang-Ming University, Taipei, Taiwan (in Mandarin).
- Hsu, C. C., Hwang, S. J., Wen, C. P., Chang, H. Y., Chen, T., Shiu, R. S. *et al.* (2006). High prevalence and low awareness of CKD in Taiwan: a study on the relationship between serum creatinine and awareness from a nationally representative survey. *American Journal of Kidney Diseases*, 48, 727–738.
- Kazawa, K. & Moriyama, M. (2013). Effects of a self-management skills-acquisition program on pre-dialysis patients with diabetic nephropathy. *Nephrology Nursing Journal*, 40, 141–148.
- Lee, Y. C., Wu, S. F. V., Lee, M. C., Chen, F. A., Yao, Y. H. & Wang, C. L. (2014). The use of a systematic review to develop a self-management program for CKD. *Journal of Nursing*, 61, 66–77 (in Mandarin).
- Lee, Y. J., Kim, M. S., Cho, S. & Kim, S. R. (2013). Association of depression and anxiety with reduced quality of life in patients with pre dialysis chronic kidney disease. *International Journal of Clinical Practice*, 67, 363–368.
- Lii, Y. C., Tsay, S. L. & Wang, T. J. (2007). Group intervention to improve quality of life in haemodialysis patients. *Journal of Clinical Nursing*, 16, 268–275.
- Lin, C. C. (2011). Self-management of patients with chronic illness. *Journal of Taiwan Nephrology Nurses Association*, 10, 1–18 (in Mandarin).
- Lin, C. C., Tsai, F. M., Lin, H. S., Hwang, S. J. & Chen, H. C. (2013a). Effects of a self-management program on patients with early-stage chronic kidney disease: A pilot study. *Applied Nursing Research*, 26, 151–156.
- Lin, C. C., Wu, C. C., Anderson, R. M., Chang, C. S., Chang, S. C., Hwang, S. J. *et al.* (2012). The chronic kidney disease self-efficacy (CKD-SE) instrument: development and psychometric evaluation. *Nephrology Dialysis Transplant*, 27, 3828–3834.
- Lin, C. C., Wu, C. C., Wu, L. M., Chen, H. M. & Chang, S. C. (2013c). Psychometric evaluation of a new instrument to measure disease self-management of the early stage chronic kidney disease patients. *Journal of Clinical Nursing*, 22, 1073–1079.
- Lin, C. M., Yang, M. C., Hwang, S. J. & Sung, J. M. (2013b). Progression of stages 3b-5 chronic kidney disease: preliminary results of Taiwan national pre-ESRD disease management program in Southern Taiwan. *Journal of the Formosan Medical Association*, 112, 773–782.
- Lorig, K. R. & Holman, H. R. (2003). Self-management education: History, definition, outcomes, and mechanisms. *The Society of Behavioral Medicine*, 26, 1–7.
- Martin, C. R., Tweed, A. E. & Metcalfe, M. S. (2004). A psychometric evaluation of the hospital anxiety and depression scale in patients diagnosed with end-stage renal disease. *The British Journal of Clinical Psychology*, 43, 51–64.
- Ni, H. J. (2011). Effectiveness of chronic kidney disease case management program. Unpublished Master's dissertation, National Yang-Ming University, Taipei, Taiwan (in Mandarin).
- Peng, T., Hu, Z., Guo, L., Xia, Q., Li, D. & Yang, X. (2013). Relationship between psychiatric disorders and quality of life in nondialysis patients with chronic kidney disease. *The American Journal of the Medical Sciences*, 345, 218–221.
- Richard, A. A. & Shea, K. (2011). Delineation of self-care and associated concepts. *Journal of Nursing Scholarship*, 43, 255–264.
- Tong, A., Sainsbury, P., Chadban, S., Walker, R. G., Harris, D. C., Carter, S. M. *et al.* (2009). Patients'

- experiences and perspectives of living with CKD. *American Journal of Kidney Diseases*, 53, 689–700.
- United States Renal Data System. (2015). *Chronic kidney disease in the general population*. [Cited 26 Feb 2015.] Available from URL: <http://www.usrds.org/2015/view/Default.aspx>
- Wells, J. R. & Anderson, S. T. (2011). Self-efficacy and social support in African Americans diagnosed with end stage renal disease. *The Association of Black Nursing Faculty Journal*, 22, 9–12.
- Wen, C. P., Cheng, T. Y., Tsai, M. K., Chang, Y. C., Chan, H. T., Tsai, S. P. *et al.* (2008). All-cause mortality attributable to chronic kidney disease: A prospective cohort study based on 462,293 adults in Taiwan. *The Lancet*, 371, 2173–2182.
- Wu, S. F. V., Li, Y. C., Chang, J. R., Courtney, M. & Chang, Y. L. (2007). The application of self-efficacy counseling skills to health education in patients with diabetes. *The Journal of Nursing*, 54, 70–77.
- Wu, S. F. V., Lu, K. C. & Lin, K. C. (2012). *Self-management tailored program for chronic kidney disease* (Research project no.: NSC101-2314-B-227-006-MY3). Taipei: Ministry of Science and Technology (in Mandarin).
- Zigmond, A. S. & Snaith, R. P. (1983). The hospital anxiety and depression scale. *Acta Psychiatrica Scandinavica*, 67, 361–370.