**Title**
Effectiveness of self-management program in people with chronic kidney disease: A pragmatic randomized controlled trial

**Authors**
Nguyet Thi NGUYEN, RN, PhD[1,2,3]
Clint DOUGLAS, PhD, RN, Associate Professor[1]
Ann BONNER, PhD, RN, Professor[1,3,4]

[1]School of Nursing, Queensland University of Technology, Brisbane, Australia
[2]Hanoi Medical College, Hanoi, Vietnam
[3]NHMRC Chronic Kidney Disease Centre of Research Excellence, University of Queensland
[4]Kidney Health Service, Metro North Hospital and Health Service, Brisbane, Australia

Corresponding author: Nguyet Thi NGUYEN
Email: nguyet.nguyenthi@hdr.qut.edu.au
Twitter username: anhnguyet2402

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ABSTRACT

**Aims**: To examine the effectiveness of a self-management intervention compared with usual care in adults with chronic kidney disease on self-management, knowledge, self-efficacy, health-related quality of life and blood pressure.

**Design**: A parallel group randomized controlled trial.

**Methods**: Patients aged ≥ 18 years with chronic kidney disease stages 3−5 were recruited between November 2015 and June 2016. Participants were randomly allocated into either the intervention ($n$ = 68) or control group ($n$ = 67). The control group received usual care, while the intervention group received usual care plus a self-management program from a nurse. The intervention was guided by social cognitive theory and included a face-to-face educational session followed by telephone support. Both groups were followed for 16 weeks.

**Results**: There were no significant differences in self-management, knowledge, self-efficacy, health-related quality of life, and blood pressure between the two groups at baseline. At week 16, compared with the control group, large effect sizes for improved self-management, knowledge, and self-efficacy were detected. For health-related quality of life, the physical and mental health components significantly improved. However, no significant differences in either systolic or diastolic blood pressures were found.

**Conclusion**: In earlier stages of chronic kidney disease, a simple self-management education benefits patients.

**Impact:** Effective self-management in the earlier stages of chronic kidney disease contributes to slowing its progression, improving health outcomes, and lowering the burden on healthcare systems. This study demonstrated that social cognitive theory increases chronic kidney disease self-management by strengthening knowledge and self-efficacy. Nurses can provide this education.

**Trial registration:** Australian New Zealand Clinical Trials Registry ACTRN12616000038493.

**Keywords**: blood pressure, chronic kidney disease, health-related quality of life, knowledge, nurse, randomized controlled trial, self-efficacy, self-management, social cognitive theory

SUMMARY STATEMENT

**Why is this research needed?**

- There is limited evidence to support practice in delivering self-management education to people with earlier stages of chronic kidney disease as most of the previous studies have occurred in those receiving haemodialysis.
- Strategies used to improve chronic kidney disease self-management have varied in content, format and delivery.

**What are the key findings?**

- A simple chronic kidney disease self-management program demonstrated large effects on improving self-management behaviour, knowledge and self-efficacy.
- Health-related quality of life for those with chronic kidney disease was improved following a self-management intervention.

**How should the findings be used to influence policy/practice/research/education?**

- Social cognitive theory can be embedded into an education program and delivered in renal outpatient clinics.
- Nurses are able to provide chronic kidney disease self-management education to assist patients to achieve better disease management and improve their overall health and well-being.

## INTRODUCTION

Chronic kidney disease (CKD) is a growing health problem worldwide, with approximately 80% of people with CKD living in low to middle income countries (Mills et al., 2016). The global prevalence of CKD in adults is estimated at between 10% to 16% largely due to the rising prevalence of diabetes and hypertension (Dienemann et al., 2016). The disease is classified into stages according to the estimated glomerular filtration rate (eGFR) with stage five also termed end-stage kidney disease (ESKD) when kidney replacement therapy (KRT) is required to sustain life (Webster, Nagler, Morton, & Masson, 2017). The majority of people with this disease are in stages 3–5 (Hill et al., 2016). CKD creates a significant impact on the physical health, psychological well-being, and social domains of life, and it contributes to lower health-related quality of life (HRQoL) (Almutary, Douglas, & Bonner, 2017). Empowering people through providing simple information to improve their knowledge and confidence to better self-manage chronic disease is likely to affect overall health and wellbeing (Jordan & Osborne, 2007), and in CKD is known to slow the disease progression (Lee, Wu, Hsieh, & Tsai, 2016; Lin, Liu, Hsu, & Tsai, 2017; Lopez-Vargas, Tong, Howell, & Craig, 2016).

Vietnam is an example of a low income country and it is estimated that six million people have CKD (Hyodo et al., 2017). The healthcare system in this country has an almost non-existent primary healthcare service and, as a consequence, the acute hospital system is severely over-stretched with the growing burden of chronic disease. It is usual in acute hospitals to find 2−3 patients occupying the same bed, and outpatient clinics, where people have to return to have medications prescribed, are extremely overcrowded. Hence, slowing the progression of CKD to avoid needing KRT and to reduce the disease burden on society and healthcare systems requires urgent attention in this country.

**Background**

CKD is usually asymptomatic and often unrecognized until at an advanced stage of kidney failure. The lack of debilitating symptoms may mean that people are less inclined to believe that they have CKD (Braun, Sood, Hogue, Lieberman, & Copley-Merriman, 2012; Picariello, Moss-Morris, Macdougall, & Chilcot, 2017), and could reduce their engagement in self-management behaviour. Providing self-management education is essential to assist people in knowing what CKD is, how to identify early symptoms, and how to take steps to manage their disease.

There have been five systematic reviews of CKD self-management (Bonner et al., 2014; Lee et al., 2016; Lin et al., 2017; Lopez-Vargas et al., 2016; Welch et al., 2014), although most of the included studies involved participants with ESKD and, specifically, being treated with haemodialysis. In these systematic reviews, there have been eight randomized controlled trials (RCTs) involving 1,011 people with CKD who were not on dialysis (Blakeman et al., 2014; Byrne, Khunti, Stone, Farooqi, & Carr, 2011; Campbell, Ash, & Bauer, 2008; Chen et al., 2011; Flesher et al., 2011; Paes-Barreto et al., 2013; Teng, Yen, Fetzer, Sung, & Hung, 2013; Williams, Manias, Walker, & Gorelik, 2012). Since the systematic reviews have been published there has been one further RCT (Joboshi & Oka, 2016).

Across the nine studies there was inconsistent use of a framework or theory to inform the interventions; only social cognitive theory (SCT) was used in more than one study (Byrne et al., 2011; Joboshi & Oka, 2016). Briefly, the goal of SCT is to effectively explain and change behaviour. This theory is about how human behaviour is modified by improving a person's self-efficacy—a belief in their ability to successfully perform that behaviour (Bandura, 1997). While self-efficacy is a central tenet of SCT, it is the outcome of self-efficacy which is

important. By having greater confidence in your ability to self-manage a chronic disease, a person is more likely to engage in that behaviour, and overtime, health outcomes are likely to improve. In the two previous studies which reported using SCT, (Byrne et al., 2011; Joboshi & Oka, 2016), it was unclear how the components of SCT were used to improve self-efficacy or self-management behaviours. Nevertheless, both of these studies did show that an educational intervention could affect these outcomes in people with CKD.

The previous studies also differed with regard to the intervention. For example, four studies focused on improving overall CKD knowledge (Blakeman et al., 2014; Byrne et al., 2011; Chen et al., 2011) whereas others specifically focused on diet (Campbell et al., 2008; Chen et al., 2011; Flesher et al., 2011; Joboshi & Oka, 2016). The format of the self-management interventions also varied with the most frequently used format being face-to-face education delivered by nurses (Byrne et al., 2011; Chen et al., 2011; Flesher et al., 2011; Joboshi & Oka, 2016; Williams et al., 2012). The duration of the interventions ranged from 12 weeks (Campbell et al., 2008; Joboshi & Oka, 2016) to twelve months (Chen et al., 2011; Flesher et al., 2011; Teng et al., 2013; Williams et al., 2012). Due to the heterogeneity of the studies, it is not possible to identify the ideal format and duration of a CKD self-management program.

Notably the studies also measured different patient-reported and clinical outcomes. Regarding patient-reported outcomes, and although improvement in self-management was the aim in all nine studies, only six studies measured this outcome using six different instruments (Blakeman et al., 2014; Flesher et al., 2011; Joboshi & Oka, 2016; Paes-Barreto et al., 2013; Teng et al., 2013; Williams et al., 2012). Knowledge about CKD was assessed as an outcome in three studies (Blakeman et al., 2014; Chen et al., 2011; Teng et al., 2013). Self-efficacy was measured in only one study (Joboshi & Oka, 2016). Improvement in HRQoL, an indicator of

the beneficial effects of improved self-management (Pagels et al., 2012), was assessed in only two studies (Blakeman et al., 2014; Campbell et al., 2008). Nevertheless, across all studies, self-management programs seemed to show benefits in improved patient-reported self-management, knowledge, self-efficacy, and HRQoL. In regards to clinical outcomes, change in eGFR (Chen et al., 2011; Flesher et al., 2011; Joboshi & Oka, 2016; Paes-Barreto et al., 2013; Williams et al., 2012) and BP (Blakeman et al., 2014; Flesher et al., 2011; Joboshi & Oka, 2016; Williams et al., 2012) were the two most frequently assessed. Overall inconsistent findings were demonstrated for these clinical outcomes.

In summary, the existing evidence for practice is weak because the previous studies have methodological limitations and, due to heterogeneity of methods and outcomes, a meta-analysis is not possible. This study seeks to avoid these limitations and to contribute to the evidence-base by robustly using a behavioural change theory, SCT, to inform a CKD self-management intervention which is simple and inexpensive to deliver. Its effectiveness will be determined by using person-centred outcome measures (PROMs) which align with SCT (i.e. knowledge, self-efficacy, self-management behaviour and HRQoL). Figure 1 presents the theoretical framework of the study.

## THE STUDY

### Aims

The aim of the study was to examine the effectiveness of a self-management intervention compared with usual care in improving self-management behaviour, knowledge, self-efficacy, HRQoL, and BP in adults with CKD stages 3−5.

## Hypotheses

The study hypothesized that participants in the intervention group will have: (1) greater self-management behaviour, knowledge, self-efficacy, HRQoL than those in the control group; and (2) lower systolic and diastolic blood pressure compared to those in the control group.

## Design

The study design was a single-blind pragmatic randomized controlled trial (pRCT) with one-to-one allocation into two parallel groups with repeated measures. A pRCT enables a broader range of patients to be included in an intervention, thus enhancing external validity and the translation of results into clinical care (de Boer et al., 2016; Saturni et al., 2014).

## Participants and setting

Participants were recruited from renal outpatient clinics at a large general hospital in Hanoi, Vietnam from November 2015 to June 2016. The inclusion criteria were aged ≥ 18 years, with a medical diagnosis of CKD stages 3−5 and not receiving dialysis, able to communicate in Vietnamese, contactable by phone, and willing to consent to participate. Participants were excluded if they had cognitive impairment or were seriously unwell (both determined by a medical practitioner) or were enrolled in another trial.

## Intervention

*Control group*

Participants randomized to the control group received usual CKD care provided by renal medical practitioners and nurses at the outpatient clinic. Usual care consisted of brief verbal information (2-5 minutes) about taking medications, reducing salt, smoking cessation, and reducing alcohol consumption. There was no structured program or the provision of written material to patients.

*Intervention group*

Participants assigned to the intervention group received both usual CKD care and a 12-week self-management intervention delivered by the first author who is an experienced nurse teacher. The intervention involved a CKD booklet and a handout, one face-to-face session and two brief follow-up sessions. The face-to-face session was provided in a private room at the renal clinic on an individual basis, while the follow-up sessions were undertaken by phone. The CKD self-management program is presented in Table 1.

The CKD booklet was translated and adapted by the first author with permission from *Living with Reduced Kidney Function* handbook (Kidney Health Australia, 2008) and *Living Well with Chronic Kidney Disease* handbook (American Kidney Fund, 2010); both of these booklets are suitable for people with low literacy skills. The Vietnamese CKD booklet explained the function of the kidneys, the early signs and symptoms of CKD, and strategies for managing or delaying the progression of CKD, such as the benefits of maintaining a healthy lifestyle and adherence to medications. It also contained a diary for participants to record and monitor their clinical data, treatment plan, and questions for medical appointments. Prior to the study, a nephrologist checked the content for accuracy. The handout summarized the main points in the CKD booklet and important self-management skills such as taking medications, nutrition and exercise, smoking cessation, understanding renal clinical results, and using available resources to self-manage CKD.

The intervention started with a 1-hour face-to-face session, focused on improving CKD knowledge and self-management by utilizing the four self-efficacy information sources. In SCT, self-efficacy can be improved through performance accomplishment, vicarious experience, verbal persuasion, and self-appraisal as strategies to support self-management

behaviour (Bandura, 1997). *Performance accomplishment* is the confidence that comes from within a person when they feel a sense of success, particularly if they believe that they have mastered that behaviour (Bandura, 1997). Performance accomplishment is the most important strategy to assist participants to actually engage in performing self-management behaviour (Bandura, 1997). Participants were asked to identify CKD-related problems and set two realistic achievable goals based on their priorities. These goals were recorded in their CKD booklet and monitored at each follow-up. *Vicarious experience* can increase self-efficacy through observation of people similar to oneself successfully performing a task (Bandura, 1997). In Vietnam peer learning through vicarious experience in renal clinics is not common. We developed written scenarios of people who successfully overcome challenges to self-manage their kidney problems, using local images and pictures throughout the CKD booklet. *Verbal persuasion* was used to enhance self-efficacy and support participants to start taking action. *Self-appraisal* was used to encourage participants to identify where they were succeeding with self-management such as adhering to medications, and also to express their concerns or difficulties in managing CKD, for instance struggling with reducing salt in their diet. Participants were then supported to identify possible solutions to achieve their goals.

Participants received two follow-up phone calls of 20−30 minutes at weeks 4 and 12 by the nurse to reinforce the self-management action plan and to review progress towards goals. The focus was to identify improvements and to encourage participants to continue behaviour change through positive reinforcement. Structured around the CKD booklet topics, the discussion supported participants to build on small changes and to use problem-solving skills to overcome daily challenges. Participants were encouraged to use the booklet at home. At the completion of the study, participants in the control group were provided with the CKD booklet.

**Outcome measures**

*Primary outcomes*

The primary outcome was CKD self-management. The original Chronic Kidney Disease Self-Management (CKD-SM) instrument comprises 29 items (Lin, Wu, Wu, Chen, & Chang, 2012), and it was modified with permission from the instrument developer. Three items were added, including one item about medication [I take my medications even when I am not at home] and two items about problem-solving [I take action when my early warning signs and symptoms get worse; When I have questions about my kidney disease, I discuss what to do with my doctors or nurses]. These three items were added because the original CKD-SM instrument did not include these aspects of self-management. Therefore, a 32-item CKD-SM instrument was used to measure self-management behaviour factors, including self-integration, problem-solving, seeking social support, and adherence to recommended regimen (Lin et al., 2012). Each item is scored on a Likert scale from 1−4 with 1 being 'never' and 4 'always'. Total scores of the CKD-SM range from 32 to 128 and higher scores indicate a greater level of self-management behaviour in managing CKD.

Another primary outcome was kidney disease knowledge. The Kidney Disease Knowledge Survey (KiKS) consists of 28 items that measures the participants' knowledge related to kidney disease management, such as kidney function, treatment options for kidney failure, signs and symptoms of disease progression, potential medications that harm or benefit the kidney, BP targets, and other information related to preserving kidney function (Wright, Wallston, Elasy, Ikizler, & Cavanaugh, 2011). Each item is scored as 1 for a correct response, or 0 for an incorrect response. Total scores of the KiKS range from 0 to 28 and higher scores indicate better understanding of kidney disease.

Both the CKD-SM instrument and KiKS have been shown to be valid and reliable in previous studies in people with CKD (Anaya et al., 2016; Lin et al., 2012; Wembenyui, 2017; Wright et al., 2011). Permission was sought from both instrument developers prior to translating into Vietnamese. We followed the translation process developed by Sousa and Rojjanasrirat (2011) whereby two bilingual healthcare professionals independently translated both instruments from English to Vietnamese (forward-translation). Then two new bilingual healthcare professionals independently translated the instruments from Vietnamese to English (backward-translation). Both versions were then compared by the authors. No changes were required at this point. Then both the Vietnamese versions of the CKD-SM and KiKS were validated by an expert panel of ten members and tested for reliability in a CKD sample in Vietnam in a previous study (de-identified for review). In this study, the reliability of the CKD-SM was $\alpha = .87$ and the KiKS Kuder-Richardson-20 was .57.

*Secondary outcomes*

The Self-efficacy for Managing Chronic Disease (SECD) measures the level of confidence with undertaking a range of chronic disease-related activities and is widely used in chronic disease studies (Lorig, Sobel, Ritter, Laurent, & Hobbs, 2001). The SECD contains six items and each item scores from 1 to 10 with higher scores indicate greater levels of self-efficacy. The SECD was translated by two bilingual Masters qualified nurses using an independent forward and backwards process similar to above. The reliability of the SECD in this study was $\alpha = .92$.

The SF-36v2 measures participants' perceptions of HRQoL (McHorney, Ware, & Raczek, 1993) and has been extensively used in CKD populations. The SF-36v2 is available in Vietnamese language (Bullinger et al., 1998; Ware et al., 2008), and the Cronbach's alpha in

this sample for the physical component (PCS) and mental component (MCS) summary subscales were .85 and .87, respectively.

A manual BP cuff was used to measure BP at each clinic appointment and recorded in the medical record. Both systolic pressure (SBP) and diastolic pressure (DBP) in mmHg were obtained.

Additionally, participants' demographic and renal clinical characteristics were obtained at baseline. Demographic characteristics were age, gender, marital status, level of education, and occupation. Renal clinical characteristics were eGFR, comorbidities, medications, time diagnosed with CKD, and body mass index (BMI) with all extracted from patients' medical records. The CKD-EPI formula (National Kidney Foundation, 2015) was used to calculate eGFR for each participant using age, gender, and serum creatinine level, which was then used to classify participant's stage of CKD. A list of chronic diseases was collected to enable the Charlson comorbidity index (CCI) to be calculated (Quan et al., 2011). The CCI is classified into three levels: mild (score of 1–2), moderate (score of 3–4), and severe comorbidity (scores $\geq 5$).

**Sample size calculation**

This study aimed to improve participants' self-management behaviour. The sample size was calculated assuming 80% power (1-beta = .8), a type 1 error rate (alpha) of .05 (two-tailed), and a medium effect size (Cohen's $d = 0.5$) on improved self-management reported by Bonner et al. (2014) in other CKD studies where participants were not receiving dialysis. A minimum of 134 participants (67 per group) were required.

**Randomization**

A random-number table was generated in Microsoft Excel to produce an allocation sequence for the control and intervention groups. A number was placed inside an opaque sealed envelope according to the random-number table. All sealed envelopes were then mixed and placed into a box. After baseline data was collected, each participant selected an envelope. Allocation concealment was achieved with a trained recruitment research assistant assessing for eligibility, conducting recruitment, collecting baseline data, and supervising participants selecting an envelope. The recruitment research assistant then used the coding sheet to randomly allocate participants into either the control or intervention group.

**Blinding**

To minimize bias, participants and the recruitment research assistant were blinded until allocation. The outcome research assistant did not have access to the coding sheet or the interpretation of the code, was therefore blinded to group allocation.

**Procedure**

Recruitment flyers were given to potential eligible participants by renal nurses on arrival to the outpatient clinic. Due to the very long waiting time, often 3−4 hours in clinics, the recruitment research assistant could provide a written information sheet, verbally explain the study and answer questions, and obtain consent. Then baseline data and random group allocation occurred. The recruitment research assistant then referred participants in the intervention group to the nurse who delivered the 1-hour teaching session. At weeks 4 and 12, a 20−30 minutes telephone self-management follow-up occurred. The outcome research assistant collected repeated measures in the outpatient clinic or via telephone. The CKD-SM, KiKS, and SECD

were measured at baseline, weeks 8 and 16. HRQoL and BP were measured at baseline and week 16.

**Validity and reliability**

To enhance validity and reliability of the data, measurements with good psychometric properties were used to assess the study outcomes. The psychometric properties of the CKD-SM, KiKS, SECD, and HRQoL have been shown to be acceptable in previous studies (Anaya et al., 2016; Freund et al., 2013; Hu, Gruber, & Hsueh, 2010; Lin et al., 2012). All eligible participants were randomly allocated to the control or intervention group and included in the data analysis using intention-to-treat (Hoffmann, Bennett, & Del Mar, 2017). The study was conducted and reported in accordance with the CONSORT 2010 Statement (Moher et al., 2010).

**Ethical considerations**

The study was approved by the (de-identified university) Human Research Ethics Committee and the hospital in which the study was conducted (Approval No. 1500000678). Potential participants were given a verbal explanation of the study and provided with an information sheet prior to consenting. Participants were assured that they had the right to refuse to participate or to withdraw from the study at any time, and if they refused or withdrew from the study there would be no effect on the healthcare they received. Confidentiality was assured, and no personal information was disclosed to any other person. All data were stored in a secure area and only utilized for the purpose of the study. The results were reported as group data, and no names or other forms of identity were disclosed.

## Data analysis

Data were entered into IBM SPSS Statistics version 22 (IBM Corporation, NY, USA) and an intention-to-treat analysis was performed. Missing data was not replaced and outcomes were normally distributed. Baseline characteristics for control and intervention groups were compared. Linear mixed models were used to evaluate the effects of the intervention on primary and secondary outcomes. Group, time, and group × time were included in each of the models as fixed effects. In order to account for correlation between patients' repeated measures over time, patient-level random effects were also included in each model. The group × time interaction was examined to determine the overall treatment effects between groups over time. Outcome variables were assessed prior to testing. Residuals were normally distributed, had a mean of zero, and had a constant variance (Tabachnick & Fidell, 2013). Cohen's *d* effect size was used to calculate the magnitude of the treatment effect of the intervention group compared to the control group at each time point using the pooled standard deviation ($SD_{pooled}$). Values of Cohen's *d* are small, medium, and large effect (0.2, 0.5, and 0.8, respectively; Cohen, 1988).

# RESULTS

## Participant flow

A total of 148 people were assessed for eligibility and of these 135 agreed to participate in the study with 67 allocated into the control group and 68 in the intervention group. At week 8, the intervention and control groups had lost two participants each and by week 16, the control group had lost six participants and the intervention group had lost five participants. Figure 2 depicts the study flow of participants.

## Demographic and renal clinical characteristics

Participants' demographic and renal clinical characteristics are reported in Table 2. Ages of ranged from 22 to 80 years old with a mean age of 48.9 (*SD* 13.8). Half of the participants were female (67/135). The majority of participants were in either CKD stages 3B (48/135) or 4 (43/135). There were no differences in demographic and renal clinical characteristics between the two groups at baseline.

**Effects of self-management program on study outcomes**

Table 3 presents the primary and secondary outcomes at each time point.

*Primary outcomes*

Linear mixed models were used to examine the change in self-management and knowledge at each time point (see Table 3). Overall the effect of the intervention on self-management behaviour between groups over time was significant ($F = 178.84$, $p < .001$). Figure 3A shows that although there was no difference in mean scores for self-management at baseline, there was a large improvement in the intervention group by week 8 (mean difference = 12.44, 95% Confidence Intervals [CI] = 7.48−17.40, $d = 0.84$), and a further improvement by week 16 (mean difference = 18.13, 95% CI = 13.14−23.11, $d = 1.25$). Compared to the control group, participants in the intervention group also had improvements in kidney disease knowledge over time ($F = 226.89$, $p < .001$). Figure 3B shows that while knowledge scores were similar at baseline and remained stable in the control group, there was a large improvement in the intervention group by week 8 (mean difference = 5.71, 95% CI = 4.80−6.62, $d = 2.15$), and sustained improvement by week 16 (mean difference = 7.43, 95% CI = 6.50−8.36, $d = 2.86$).

*Secondary outcomes*

Similar mixed models were used to examine the change in participants' self-efficacy, HRQoL, SBP and DBP (see Table 3). The overall intervention effect on self-efficacy between groups over time was significant ($F = 40.81$, $p < .001$). Figure 3C shows that there was no difference in self-efficacy scores at baseline, which remained unchanged in the control group over weeks 8 and 16. By contrast, the intervention group had increased in self-efficacy scores at week 8 (mean difference = 1.02, 95% CI = 0.49−1.55, $d = 0.64$), and a larger increase after 16 weeks (mean difference = 1.43, 95% CI = 0.90−1.96, $d = 0.96$). Figures 3D and 3E display that there were no differences in mean scores for HRQoL at baseline. However, at 16 weeks compared to the control group, the intervention group reported improved HRQoL with medium effect sizes for both PCS (mean difference = 6.91, 95% CI = 1.22−12.60, $d = 0.72$) and MCS (mean difference = 7.83, 95% CI = 1.88−13.78, $d = 0.59$). Figures 3F and 3G show that there were no change found between groups over time for SBP ($F = 1.15$, $p = .28$) and DBP ($F = 0.19$, $p = .66$).

**Adverse events**

No intervention-related adverse events were observed during the study period.

## DISCUSSION

This study demonstrated that a self-management intervention guided by SCT improved self-management behaviour, knowledge, self-efficacy, and HRQoL in patients with CKD stages 3−5. Compared to the control group, the intervention group showed large improvements in self-management behaviour, knowledge, and self-efficacy. Physical and mental health improvements were also detected after 16 weeks. The effect on BP, however, was not demonstrated during the study period.

The effectiveness of the self-management intervention on the study outcomes is consistent with SCT. The intervention group pattern of findings showed increases in participants' knowledge and self-efficacy which translated into improved self-management behaviour and HRQoL. Behaviour modification theories such as SCT to inform clinical care are crucial. We found a large improvement in self-efficacy in the intervention group indicating that these participants believed in their ability to take action. As few CKD interventions have been informed by theories, and that important PROMs have not always been reported (Bonner et al., 2014; Welch et al., 2014), this study provides evidence for theory-guided clinical practice in CKD.

Knowledge is a precondition for behaviour change, and in our study the intervention group showed a large improvement in kidney disease knowledge. Improvement in kidney disease-related knowledge is integral to self-management behaviour because people need to have sufficient understanding of the disease to take action to self-manage (Havas, Douglas, & Bonner, 2017; Narva, Norton, & Boulware, 2015). We also found a large improvement in self-management behaviour compared to the control group after 16 weeks indicating that improvement in behaviour is achievable when knowledge and confidence (i.e. self-efficacy) are also part of the self-management program. Setting realistic and achievable goals together with follow-up support on the phone may have also contributed to building self-confidence to do the everyday tasks to self-manage CKD.

Changes in HRQoL reflect how patients are able to self-manage CKD to achieve overall well-being and it can serve as an important indicator to evaluate the effectiveness of self-management interventions (Wyld, Chadban, & Morton, 2016). After 16 weeks, the improvement in both the physical and mental health component scores in this study indicated that the intervention group had better HRQoL compared to the control group. This is an

important finding as CKD is often asymptomatic due to the long, slow decline in renal function, and people do adapt to this slow change and the effects on their life. Response shift (Howard, Mattacola, Howell, & Lattermann, 2011) may mask the treatment impact of self-management on HRQoL although, given that our study was only 16 weeks, the improvement seen in HRQoL was probably real.

We did not find any change in BP in the intervention group, and this finding is similar to other studies (Flesher et al., 2011; Joboshi & Oka, 2016; Williams et al., 2012). In the context of CKD, people may need longer than 16 weeks to develop self-management habits to control BP. Nevertheless, good BP control is an important outcome of improved self-efficacy and changed behaviour.

Self-management of CKD requires food management, BP management, blood result management, and medication management (Ong, Jassal, Porter, Logan, & Miller, 2013). Each of these tasks is shaped by the culture and context in which they occur. The Vietnamese culture is strongly influenced by familial relationships and people often live in extended, multigenerational families (Van, Duangpaeng, Deenan, & Bonner, 2012). Self-management is not only an individual issue, but should be considered in the broader family context, where the family is often involved in supporting and creating a good environment that helps in maintaining everyday activities to manage CKD (Chen et al., 2018). For example, families often provide support to their family member who has CKD to eat the correct food and to take their medication. The support from family members is an important aspect in each individual's disease management (Hoang, Green & Bonner, 2018); therefore, healthcare providers should recognize this and include family members in self-management education sessions (Thirsk &

Clark, 2014). Further research is needed about the role of family members in supporting CKD self-management.

### Limitations

There are some limitations to this study. First, this study attempted to blind outcome evaluators to group allocation although it was not always possible because some participants receiving the intervention disclosed their allocation to the outcome research assistant. Second, the Vietnamese version of the KiKS demonstrated low reliability although this may have been due to the variability of CKD knowledge in this sample. This instrument requires further testing in this target population. Finally, the duration of the study may have been too short and the sample size too small to capture the intervention effects on clinical outcomes such as BP and eGFR.

## CONCLUSION

The self-management program was found to be an effective and simple approach to engage people with CKD in developing knowledge, confidence, and skills to manage their illness. This approach has also shown that nurses can provide self-management education in busy outpatient clinics. The study has significant implications which can inform the development and application of self-management programs in clinical practice, in healthcare for chronic disease, and for the role of the nurse. It was also the first self-management trial for CKD in Vietnam and it contributes to extending nursing knowledge in this area internationally so that patient care can be improved.

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**TABLE 1** Chronic kidney disease self-management intervention

| Time | Social cognitive theory – Information sources | Goals for Participants | Teaching Strategies |
|---|---|---|---|
| Week 0 (1-hour face-to-face) | Performance accomplishment | • Identify one problem of concern for CKD knowledge and self-management<br>• Identify two priority goals related to self-management behaviour | • Progressive goal setting<br>• Documentation of the goals to follow up during Weeks 4 and 12. |
| | Vicarious experience | • Share two scenarios from the CKD booklet<br>• Share experience of choosing healthy food and reading food labels using local images and pictures | • Provide successful examples in the CKD booklet.<br>• Provide clear images and pictures. |
| | Verbal persuasion | • Summary of the CKD booklet<br>• Assist participants to improve understanding of their kidney problems and able to self-manage their disease<br>• One-on-one teaching about food labels and salt intake<br>• Assist participants to develop achievable goals and identify strategies to manage their kidney disease | • Handout<br>• Face-to-face education<br>• Questions and answers |
| | Self-appraisal | • Positive reinforcement in responding to participants' concerns<br>• Able to self-assess healthy or unhealthy food and the clinical results | • Promote discussion<br>• Encourage participants to read food labels before buying and eating.<br>• Use participants' clinical results to assess with normal range from the CKD booklet. |
| Weeks 4 and 12 (20−30 minutes; telephone call) | Performance accomplishment | • Review self-management goals from Week 0 | • Monitor participants' goals<br>• Feedback on participant's success in following healthy eating and physical activity<br>• Encourage participants to achieve and maintain their goals<br>• Exhibit empathy and caring<br>• Incorporate problem-solving activities<br>• Questions and answers |
| | Verbal persuasion | • Discuss positive physiological and psychological responses to healthy eating and physical activity | |
| | Vicarious experience | • Provide exercise safety tips for home use in the CKD booklet | |
| | Self-appraisal | • Enhance participants to talk and get helps from family members, friends, and significant others | |

**TABLE 2** Baseline participants demographic and renal clinical characteristics ($N = 135$)

| | Control Group ($n = 67$) | | Intervention Group ($n = 68$) | | |
|---|---|---|---|---|---|
| Variable | Mean (*SD*) | Number (%) | Mean (*SD*) | Number (%) | *p*-value |
| Age (years) | 48.9 (13.9) | | 48.8 (13.7) | | .97 |
| Gender | | | | | .07 |
| Female | | 28 (41.8) | | 39 (57.4) | |
| Male | | 39 (58.2) | | 29 (42.6) | |
| Marital status | | | | | .17 |
| Married | | 59 (88.1) | | 54 (79.4) | |
| Single/Divorced/Widowed | | 8 (11.9) | | 14 (20.6) | |
| Education | | | | | .55 |
| Primary school | | 11 (16.4) | | 8 (11.7) | |
| Secondary school | | 17 (25.4) | | 18 (26.5) | |
| High school | | 17 (25.4) | | 24 (35.3) | |
| College/ University | | 22 (32.8) | | 18 (26.5) | |
| Occupation | | | | | .89 |
| High skilled jobs | | 15 (22.4) | | 17 (25.0) | |
| Low skilled jobs | | 33 (49.2) | | 34 (50.0) | |
| Unemployed | | 19 (28.4) | | 17 (25.0) | |
| Stages of CKD | | | | | .82 |
| Stage 3A | | 13 (19.4) | | 13 (19.1) | |
| Stage 3B | | 26 (38.8) | | 22 (32.4) | |
| Stage 4 | | 19 (28.4) | | 24 (35.3) | |
| Stage 5 | | 9 (13.4) | | 9 (13.2) | |
| Medications used | | | | | .92 |
| 0−3 medications | | 12 (17.9) | | 14 (20.6) | |
| 4−5 medications | | 36 (53.7) | | 36 (52.9) | |
| ≥ 6 medications | | 19 (28.4) | | 18 (26.5) | |
| Comorbidities | | | | | .30 |
| 3 comorbidities | | 30 (44.8) | | 24 (35.3) | |
| 4 comorbidities | | 32 (47.8) | | 34 (50.0) | |
| ≥ 5 comorbidities | | 5 (7.4) | | 10 (14.7) | |
| Time diagnosed with CKD (years) | | | | | .47 |
| ≤ 1 | | 17 (25.4) | | 20 (29.4) | |
| > 1−5 | | 29 (43.3) | | 33 (48.5) | |
| > 5 | | 21 (31.3) | | 15 (22.1) | |
| BMI | 21.50 (2.65) | | 22.02 (3.38) | | .33 |
| eGFR (mL/min/1.73m²) | 31.30 (14.27) | | 30.62 (14.44) | | .79 |

CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; BMI, body mass index; *SD*, standard deviation.

**TABLE 3** Comparison of primary and secondary outcomes at each time point ($N = 135$)

| | Mean (*SD*) | | | | | | Mean difference [95% CI] | |
|---|---|---|---|---|---|---|---|---|
| | Control Group ($n = 67$) | | | Intervention Group ($n = 68$) | | | | |
| | T0 | T1 | T2 | T0 | T1 | T2 | ΔT0-T1 | ΔT0-T2 |
| Self-management | 84.93 (15.92) | 84.71 (15.68) | 84.62 (15.36) | 84.29 (14.51) | 97.15 (13.93) | 102.74 (11.41) | 12.44 [7.48, 17.40]** | 18.13 [13.14, 23.11]** |
| Knowledge | 18.16 (3.00) | 18.23 (2.81) | 18.26 (2.68) | 17.85 (3.12) | 23.94 (2.14) | 25.69 (1.69) | 5.71 [4.80, 6.62]** | 7.43 [6.50, 8.36]** |
| Self-efficacy | 6.14 (1.47) | 6.12 (1.49) | 6.17 (1.47) | 6.53 (1.86) | 7.14 (1.57) | 7.60 (1.40) | 1.02 [0.49, 1.55]** | 1.43 [0.90, 1.96]** |
| PCS | 62.52 (17.33) | — | 66.99 (15.39) | 64.28 (16.65) | — | 73.90 (13.47) | — | 6.91 [1.22, 12.60]* |
| MCS | 68.17 (18.71) | — | 70.19 (14.66) | 67.12 (19.12) | — | 78.01 (12.08) | — | 7.83 [1.88, 13.78]* |
| SBP | 129.46 (17.36) | — | 132.05 (14.15) | 128.28 (19.77) | — | 127.57 (15.33) | — | 4.48 [-1.54, 10.49] |
| DBP | 82.16 (11.52) | — | 81.85 (10.14) | 80.88 (10.50) | — | 79.69 (9.87) | — | 2.16 [-1.59, 5.92] |

PCS, physical health component summary; MCS, mental health component summary; SBP, systolic blood pressure; DBP, diastolic blood pressure; T0, baseline; T1, 8 weeks follow up; T2, 16 weeks follow up; mean difference [95% CI] differs significantly from control group; ΔT0-T1, mean difference at 8 weeks follow up in the intervention group; ΔT0-T2, mean difference at 16 weeks follow up in the intervention group.
*$p < .05$, **$p < .01$; significant $p < .05$

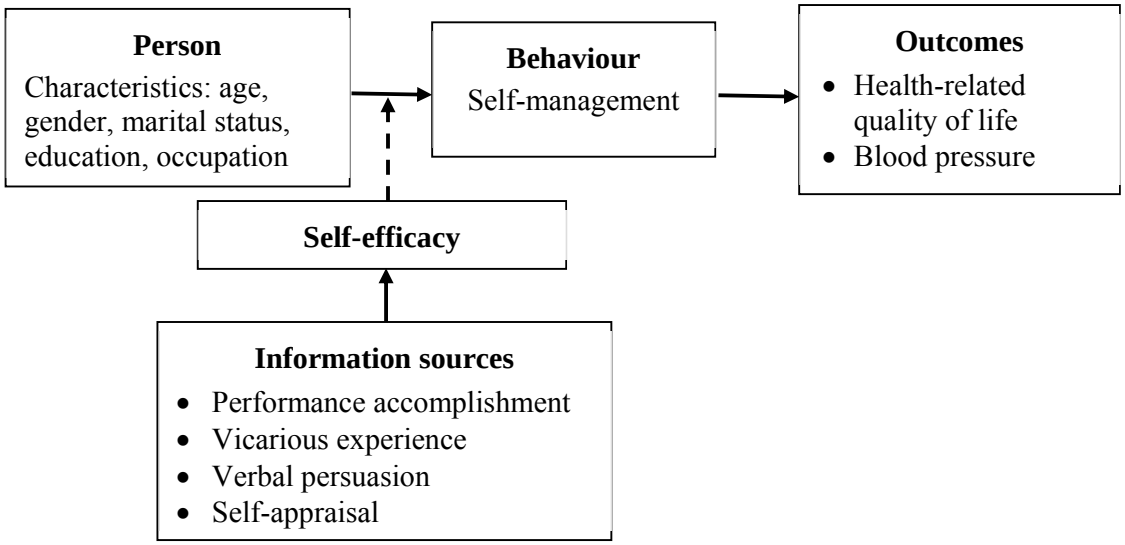


**FIGURE 1** Theoretical framework of the study guided by social cognitive theory (Bandura, 1997)

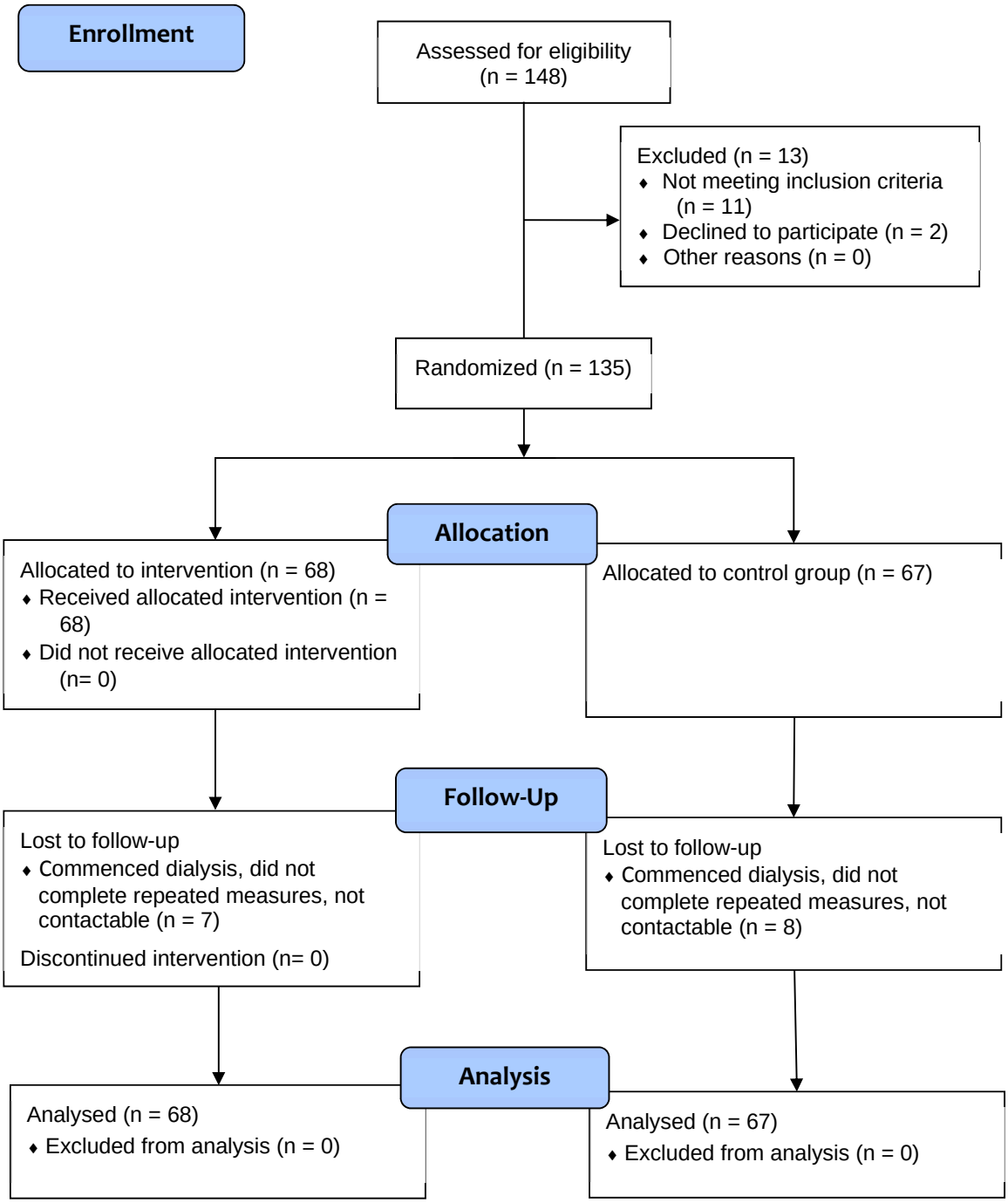


**FIGURE 2** CONSORT 2010 participant flow diagram

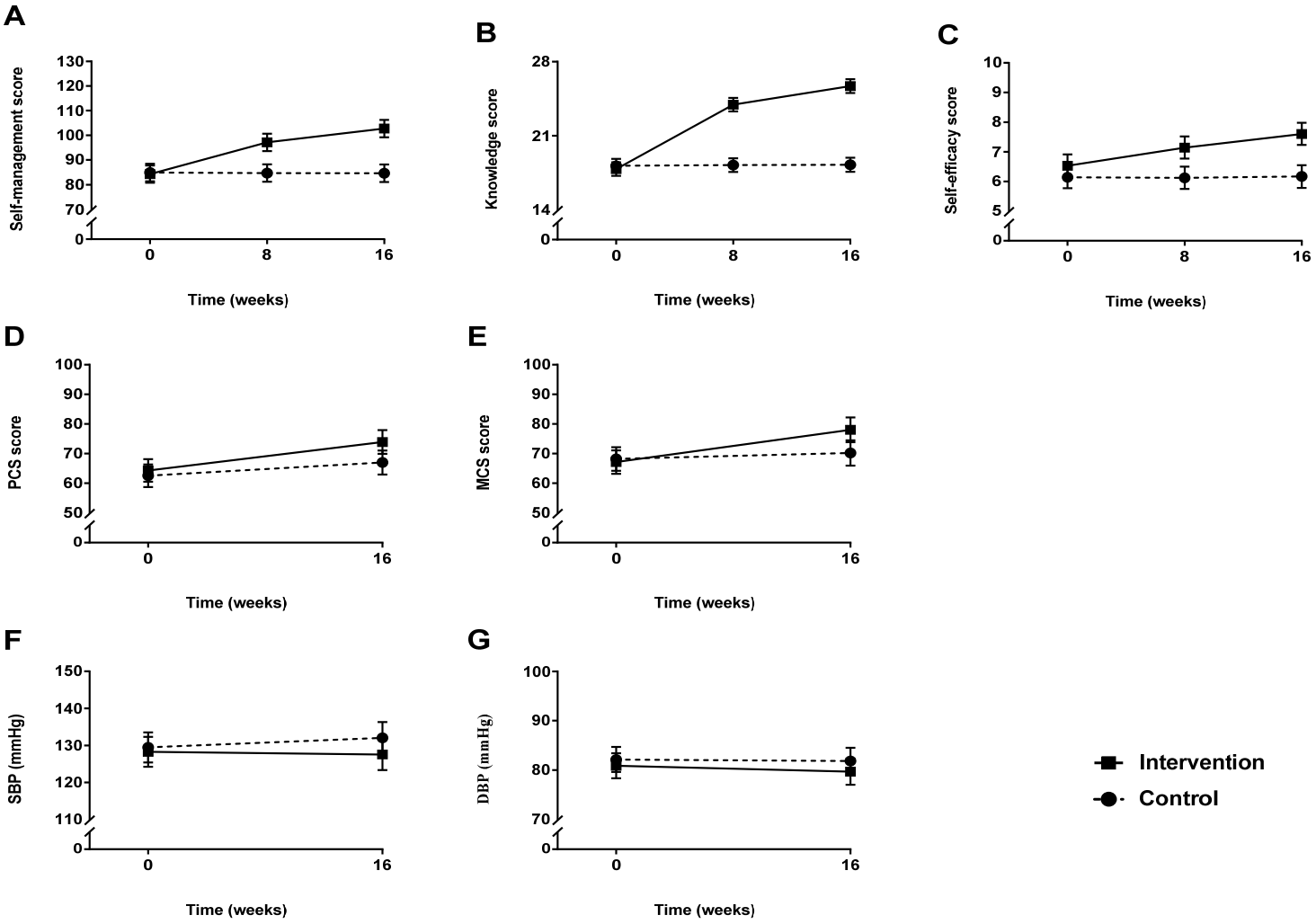


**FIGURE 3** Change mean score [95% CI] of primary and secondary outcomes over time