

SUPPORTING VULNERABLE DIALYSIS PATIENTS' SELF-MANAGEMENT DURING COVID-19: STUDY PROTOCOL OF A HEALTH EDUCATION PROGRAM

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ABSTRACT

*In Vietnam, chronic kidney disease (CKD) is the most important health problem across the country with an estimated six million people having CKD and about 80.000 people having end-stage kidney disease (ESKD). Providing health education programs to people with dialysis during COVID-19 is extremely important to support people to have better dialysis care and improve their quality of life. **Methods/ design:** One-group pretest-posttest intervention design is used to conduct this study. **Conclusion:** The expected outcomes of this research are to improve dialysis patients' knowledge of kidney disease, COVID-19 prevention skills, and dialysis self-management to assist dialysis patients in Vietnam to have better self-care for their disease in order to have a better quality of life.*

Keywords: Health education program, dialysis, chronic kidney disease, self-management

1. INTRODUCTION

Chronic kidney disease (CKD) is a growing health problem globally with around 80% of people with CKD living in low-to-middle-income countries [1] and Vietnam is not exceptional. In Vietnam, the number of people with CKD is increasing rapidly. According to Tuyen (2011), it is estimated that there are 100 to 150 new patients with CKD per million of the population per annum, and about 10,000 patients with ESKD are on hemodialysis [2]. Hyodo et al. (2017) estimated that six

million people have CKD, which is about 6% of the total Vietnamese population and each year a further 8,000 people are newly diagnosed with ESKD [3]. The problem of CKD is on the rise, which is reflected in the number of people progressing to ESKD and requiring kidney replacement therapy such as dialysis. Hence, the growing number of people with dialysis has led to an increased need for healthcare services. In addition, the recent COVID-19 pandemic, especially during 2020-2021, has affected and caused the global deaths of many people, particularly those suffering from chronic

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Received: Nov 30, 2022

Accepted: Jan 09, 2023

Published: Jan 10, 2023

diseases including people with CKD. The Vietnam Ministry of Health, in response to the COVID-19 pandemic, has stopped the referral of people with chronic diseases to tertiary hospitals, suspension of outpatient visits, home care and non-urgent hospital admissions to mitigate the viral spread in this highly vulnerable group, however, this also led to negative consequences for dialysis patients' health. Dialysis patients need dialysis treatments routinely at least three times a week at outpatient dialysis units, and so this service cannot be suspended. The previous intervention study on people with pre-dialysis in Vietnam indicated the effectiveness of health education program provided by nurses to improve patients' CKD knowledge and self-management behavior to self-manage their disease condition [5]. This finding further highlight that nurses can provide patient education in clinical setting to help patients to better manage their kidney disease in order to have a better life. However, less intervention study has been undertaken for those with hemodialysis in Vietnam. This research aims to provide an individual health education program to Vietnamese dialysis patients to support patients understanding their health and improve dialysis patients' self-management during COVID-19.

2. METHODS

- Study population

People with CKD who require regular hemodialysis are invited to participate in the study. Eligible participants are people attending regular hemodialysis at the study site, aged ≥ 18 years, able to speak, read, and understand the Vietnamese language and have a mobile phone number for follow-

up. Participants are excluded if they are participating in another educational program offered at the study site or elsewhere, who decline to participate or have cognitive impairment or are seriously unwell.

- Study settings

The study is conducted at the Hanoi Kidney hospital. The Hanoi Kidney hospital comprises 100 beds and outpatient clinics for those receiving dialysis treatment. Typically, approximately 100 people are admitted to the hospital each day.

- Study design

One-group pretest-posttest intervention design is used to conduct this study. The duration of this study is 12 weeks with follow-up education via Zalo group messages or phone calls from week 1 to week 11 and pre-post survey questionnaires at week 0 and week 12. Figure 1 depicts the study flow diagram.

- Sample size

Due to the time limitations to conducting this research and the length of the follow-up included participants within 12 weeks. This research aims to include 100 Vietnamese dialysis participants aged equal or greater than 18 years old.

- Sampling methods

The data will be collected at Hanoi Kidney Hospital in Hanoi, Vietnam. All eligible dialysis participants attending in Dialysis Department will be invited to participate in the study.

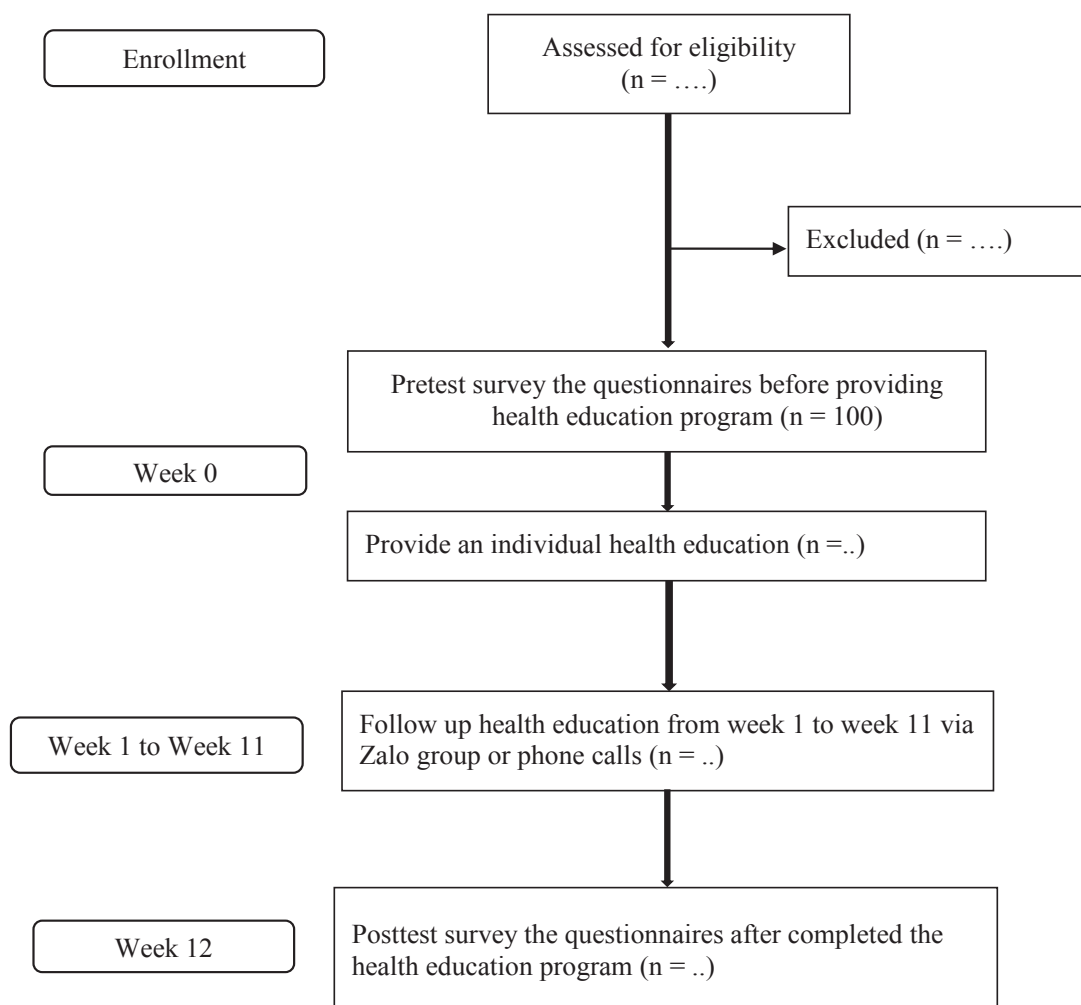


Figure 1. Study flow diagram

- Intervention

Participants will receive both the standard dialysis care from their healthcare providers, plus a 12-week health education program delivered by four trained registered dialysis nurses. The intervention includes participants receiving a booklet and a handout regarding COVID-19 prevention and self-care instructions; then they are invited to an individual face-to-face educational session. In this session, three dialysis nurses will be trained to provide individual face-to-face health education sessions to each included participant. The trained dialysis nurses will use the teach-back method to help participants understand the content of the booklet and leaflet. This method adopts the principle that the educator uses plain language to explain the instructions, then asks the participant to repeat back using their own words. If there are gaps in patients' understanding, the educator will explain again until the participant demonstrates an adequate understanding. Then participants will be followed up via Zalo group messages or phone calls (Figure 2).

In this study, the Dialysis booklet [4] has been developed and published based on the content of the CKD booklet used in previous clinical research [5], dialysis guideline from the Vietnam Ministry of Health [6], and guideline for caring dialysis patients from Hanoi Kidney Hospital [7-8]. The main content of the Dialysis booklet is to assist people with knowledge of kidney disease particularly on dialysis knowledge, dialysis nutrition, self-care activities, self-care of arteriovenous fistula (shunt). The information on the prevention of COVID-19 is also added in the Dialysis booklet. The health education program is divided into four time points.

+ Week 0: eligible dialysis patients are invited to complete questionnaires (requiring approximately 20-30 minutes) before participating in the face-to-face educational session with trained dialysis nurses during dialysis treatment in clinical setting at Hanoi Kidney Hospital. The trained dialysis nurses use the teach-back method to teach them knowledge regarding chronic kidney disease and dialysis, self-care activities, and COVID-19 prevention. This educational session takes approximately 60 minutes to allow the participant to demonstrate their understanding of what they have learned and can be longer to accommodate each participant.

+ Week 1: Participants are followed up at the study site, or remotely via Zalo messages or a mobile phone call by trained dialysis nurses to ask them to recall all the content delivered in Week 0.

+ Week 2 to Week 11: follow-up information within the group via Zalo messages to encourage participants to seek family and social support for long-term behavioral change to live well with CKD and dialysis during COVID-19 pandemic. Trained dialysis nurses are available to answer every question related to the education support program to patients from Week 2 to Week 11. Each patient will be follow-up at least one time from Week 2 to Week 11.

+ Week 12: all participants will be invited to complete the questionnaires again at dialysis unit or phone calls by research assistants. This assessment will help to evaluate the effectiveness of the health education program for dialysis participants.

The purposes of the follow-up are to identify improvements and to encourage participants to continue behavioral changes through positive reinforcement. Trained dialysis nurses will discuss with participants about the Dialysis booklet, support participants to build on small changes and use problem-solving skills to overcome daily challenges. For instance, participants will be asked to read and self-monitor their renal clinical tests if known. Participants will be encouraged to continue using the Dialysis booklet at home and to seek family support for long-term behavioral change. At the follow-up, participants can ask any questions they may have regarding the booklet and self-care instructions. The flow chart of the health education program in this study is presented in Figure 2.

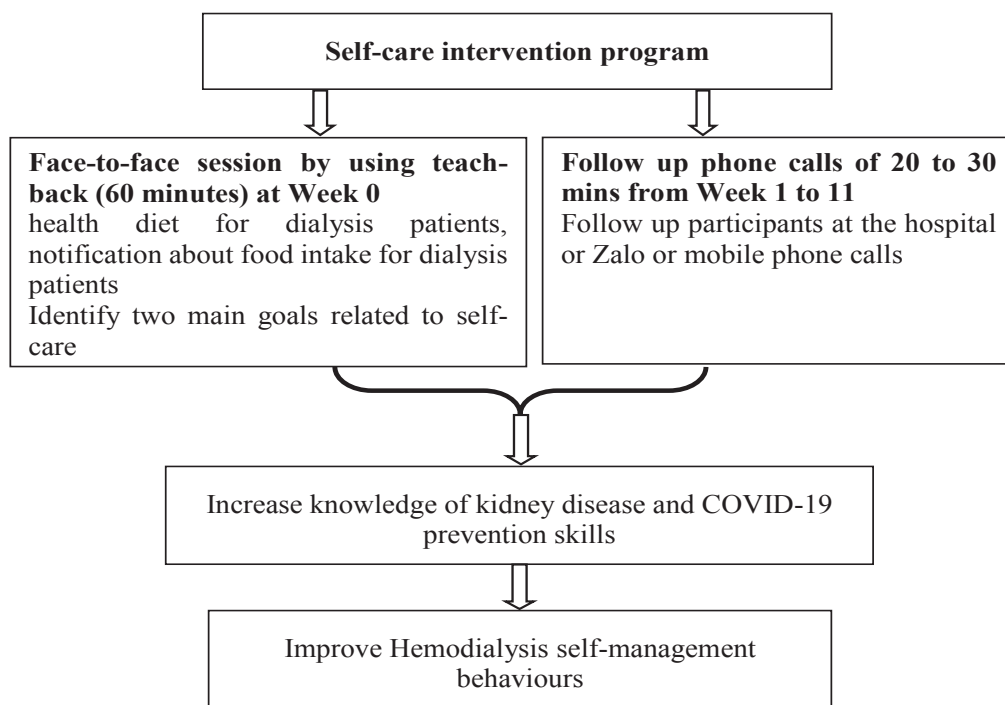


Figure 2. Flow chart of the educational support program to dialysis patients

- Data collection

Four research assistants (dialysis nurses) will be recruited and trained on how to approach participants and assist them in answering questions (at Week 0 and Week 12). Participants will be asked to complete the self-reported questionnaires at week 0 and week 12 (Figure 1). The self-reported questionnaires are included: 1) Demographic data such as age, gender, marital status, individual and household income, level of education, and occupation...; 2) Kidney disease knowledge; 3) Knowledge of COVID-19; 4) Hemodialysis self-management; 5) Self-care practice of the shunt. Renal clinical data will be extracted from patients' medical records.

- Outcome measures

Demographic questionnaire

This questionnaire comprises questions regarding age, gender, marital status, individual and household incomes, level of education, and occupation using a self-structured questionnaire.

Renal and clinical data

This data was obtained from patients' medical records and comprised blood pressure, weight and height (or BMI), blood results (sodium, potassium, phosphate, calcium, bicarbonate, creatinine, urea, eGFR, albumin, hemoglobin).

Kidney Disease Questionnaire

In this study, we will use the Kidney Disease Questionnaire (KDQ) with 26 items

which was developed by Devins et al. [9]. This questionnaire is translated following the international translation process of Sousa and Rojjanasrirat [10]. However, healthcare professionals who are registered nurses and renal doctors in renal clinics suggested adding some questions particularly for hemodialysis. Therefore, the V.KDQ with 15 items was used as a self-reported instrument that measures the participant's knowledge related to kidney hemodialysis management [9]. The V.KDQ takes approximately 10 minutes to complete. The items are scored as 1 = correct, or 0 = incorrect/don't know, and total scores range from 0 to 15. The higher score the participants receive, the better their knowledge of kidney disease and dialysis. The V.KDQ will be assessed before providing a self-care intervention program (week 0) and after completing the self-care intervention program (week 12). This instrument has a good reliability with Cronbach's alpha greater than .75. This instrument also has been translated from English to Greek to test for the reliability and validity of the KDQ [11].

Knowledge of COVID-19 prevention (KCP)

The survey instrument used in this study was designed according to the guidelines recommended for the awareness and prevention of COVID-19 by the Centre for Disease Control (CDC) - WHO [12]. This questionnaire is translated following the international translation process of Sousa and Rojjanasrirat [10]. The KCP with 14 items was developed by Reuben et al. [12], however, to adjust it for suitability with Vietnamese people, the V.KCP with 10 items will be used to measure the sample. The four items were removed from the V.KCP as health care providers suggested for example items asked about 'have you heard of COVID-19'; 'what causes COVID-19'. The V.KCP takes approximately 5 minutes to complete. The items are scored as 1 = correct, or 0 = incorrect/don't know, and total scores range from 0 to 10. The higher score the participants receive, the better their knowledge of COVID-19 prevention. The V.KCP will be assessed before providing a self-care intervention program (week 0) and after completing the self-care intervention program (week 12).

Hemodialysis Self-management behavior

Self-management by patients undergoing hemodialysis will be measured by using the hemodialysis Self-management Instrument (HDSMI) [13]. The HDSMI was developed to measure the level of self-management in a study in Taiwan [13]. Cronbach's alpha coefficients for the HDSMI were found to be 0.87 for the total scale and to be in range of 0.70 – 0.78 for the subscales. The V.HDSMI is a self-reported instrument that measures the participant's self-management regarding partnership, emotional management, problem solving, and self-care while undergoing hemodialysis. However, due to the cultural differences between Vietnam and Taiwan, some of the language was slightly modified and two items are deleted according to healthcare professional suggestion. Finally, the V.HDSMI has 18 items and respondents answer each item on a Likert scale from 1–4; 1 = never, 2 = sometimes, 3 = usually, 4 = always. Total scores of the V.HDSMI range from 18 to 72 with a higher score indicating a higher level of self-management behavior in managing hemodialysis. The instrument takes about 15 minutes to complete.

Self-care practice

The self-care practice of the shunt with 4 items which was developed by Mahmoud et al. [14]. This questionnaire is a self-reported instrument that measures the participant's self-care practice of the shunt. Respondents answer each item on a 5-point Likert scale.

- Statistical analysis

The Statistical Package for Social Sciences version 21 is used to analyse data for this phase of the study. Descriptive analysis is used to calculate means and standard deviations or medians and ranges, depending on the nature of data distribution. The Chi-square test, One-sample t-test, and Independent t-tests, are used to examine the difference of demographic characteristics, renal clinical characteristics, and the effectiveness of the intervention on the outcome variables between two groups at week 0 and week 12.

- Ethics and consent to participate

Ethical approval was obtained from Human Research Ethics Committee, Hanoi University of Public Health and the hospital in which the study was conducted (approval no. 022-230/DD-YTCC). Potential participants are given a verbal explanation of the study and provided with an information sheet prior to consenting. The results are reported as group data and no names or other forms of identity are disclosed.

3. DISCUSSION

To the authors' knowledge, the health education program to support dialysis patients is the first health intervention for dialysis people in Vietnam. This study will provide a useful health education program as well as the Dialysis booklet for dialysis patients to assist them to have better self-care for the disease and improve their quality of life. This intervention is feasible to deliver during hospital visits for dialysis patients as each patient needs 3 to 4 hours inward to have kidney dialysis. Trained registered dialysis nurses can come to provide the teach-back health education for dialysis patients while they are lying next to the kidney dialysis machine. In addition, our health education program can apply in different healthcare settings, particularly in dialysis units at all hospital levels. The health education program of this study might help to inform the health education program of future support education

programs for other chronic diseases which have been shown in previous research [5, 15]. More broadly, the health education program should be available to all dialysis patients in healthcare clinics and hospitals across Vietnam. Providing health education program may encourage dialysis patients to identify their kidney problems and undertake realistic personal goal-setting, which will help to achieve better self-management of their disease at home.

The study has some limitations that need to be taken into consideration for future studies. The first limitation is the follow-up period may be too short as for clinical outcomes may need more time to capture the intervention effects. Second, lack of blinding and outcomes are measured by using self-reported instruments. The final limitation of this study is lack of randomized eligible included participants. Due to the nature of the dialysis department setting, patients could share their program participation

with other dialysis patients easily, thus it is impossible to apply blinding and random sampling in this study. Hence, the outcomes of the study may not generalize well to the population.

4. CONCLUSION

The expected outcomes of this research are to improve dialysis patients' knowledge of kidney disease, COVID-19 prevention skills, and dialysis self-management to assist dialysis patients in Vietnam to have better self-care for their disease in order to have a better quality of life. It is expected that this health education program will be useful for dialysis patients. In addition, the published Dialysis booklet is a useful document not only for patients, but also for families and healthcare providers to assist dialysis patients to have better self-manage their disease.

ACKNOWLEDGEMENT

This project has received funding from Australian Alumni Grants Fund 2022.

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