

ORIGINAL ARTICLES

## A mobile application to support self-management among people with chronic kidney disease in Vietnam: Study protocol for a codesign-based intervention

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### ABSTRACT

**Background:** In Vietnam, chronic kidney disease (CKD) is becoming a major problem with an estimated six million people having the disease due to the rise in diabetes and hypertension. Due to the COVID-19 pandemic, the Ministry of Health took swift action to limit the referral of people with chronic diseases to city-based healthcare services to protect this highly vulnerable group. Thus, providing a mobile support program for kidney health is extremely important to provide alternative healthcare and support access.

**Methods/ design:** The Smart Kidney Health Support program is a telehealth program aiming to provide information/ updated guidelines and support for CKD, treatments, dietary, exercises, and mental wellness for people with CKD. This Smart Kidney program will be designed and developed as a mobile application. The program development consists of two phases: Phase 1 is the development of a mobile app tool using codesign methods; Phase 2 is to pilot this mobile-based program in which the feasibility and acceptability of the program will be evaluated.

**Conclusion:** The expected outcome of this project is to have a comprehensive, hands-on, and innovative mobile health support program to support and assist people with CKD in Vietnam to better self-manage their disease, treatments, and lifestyle.

**Keywords:** Codesign, telehealth program, codesign-based intervention, kidney health, social support, chronic kidney disease.

### INTRODUCTION

Chronic kidney disease (CKD) is a major health problem in Vietnam (1). It is a disease that progresses to a point where very costly treatments are required to sustain life, thus increasing the burden on individuals, families, and communities. There is increasing evidence indicating that patients who undertake support from kidney care programs are more actively involved in looking after their disease, controlling the disease's sign

and symptoms and manage their lifestyle behaviours (2, 3, 4). However, the existing kidney support programs are varied in terms of aims, target outcomes (changes in dietary, exercises, and health behaviours) and program forms (e.g. booklets, training sessions and so on). A study in Taiwan (3) aimed to examine the effectiveness of using a mobile health app to improve CKD patients' disease self-management. However, the codesign based intervention focused merely on assisting the patients' dietary and physical



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exercises. To our knowledge, there is only a health educational program developed and tested among the CKD population in Vietnam (4). Results of the previous study have shown the effectiveness of health education support for patients with CKD, although it has been designed to educate people with pre-dialysis and has not developed a Smart app to support CKD patients. Hence, the proposed Smart Kidney Health Support program will be developed using a clear codesign framework. The use of codesign methods is to ensure that the Smart Kidney program meets patients' needs and expectations.

In addition, the COVID-19 pandemic has affected negatively the healthcare system in Vietnam which leads to depleting the healthcare system's resources for disease treatment and prevention. Consequently, there is a lack of resources and a decrease in health services provided for other disease populations, especially people with chronic diseases, who demand a lifelong care and support. Therefore, the Smart Kidney program will be a possible solution to tackle the current problem in health care in Vietnam. This is the first health support program using mobile technology for patients with CKD in Vietnam. This study aims to develop a Smart Kidney Health Support (i.e., Smart Kidney) program which provides a holistic kidney support program (disease, treatments, dietary, physical exercises, and mental support) for people with CKD including two main objectives:

- To develop a smart kidney health support program to assist people with CKD in Vietnam using codesign methods.
- To evaluate the feasibility and acceptability of the smart kidney health support program

## DESIGN

### Intervention design

A mixed-methods codesign approach is used to conduct this study. Co-design is a form of participatory action research, in which stakeholders or service/end users (eg. employers, customers, patients and so on) are actively involved in the design process to help ensure that the outcome meets their needs and expectations (5). In health care, codesign has been used much in mobile health interventions that aim to make better experiences for patients, caregivers, and staff. In this project, the mobile-based Kidney Health Support application is developed based on a co-design model and mobile technologies. Then the Kidney Health Support program using the mobile application is applied to a group of people with chronic kidney disease to assess the program's feasibility and acceptability. A pre- and post- intervention design is used to pilot the Smart Kidney Health Support program. The study flow chart below presents the study phases and detail steps.

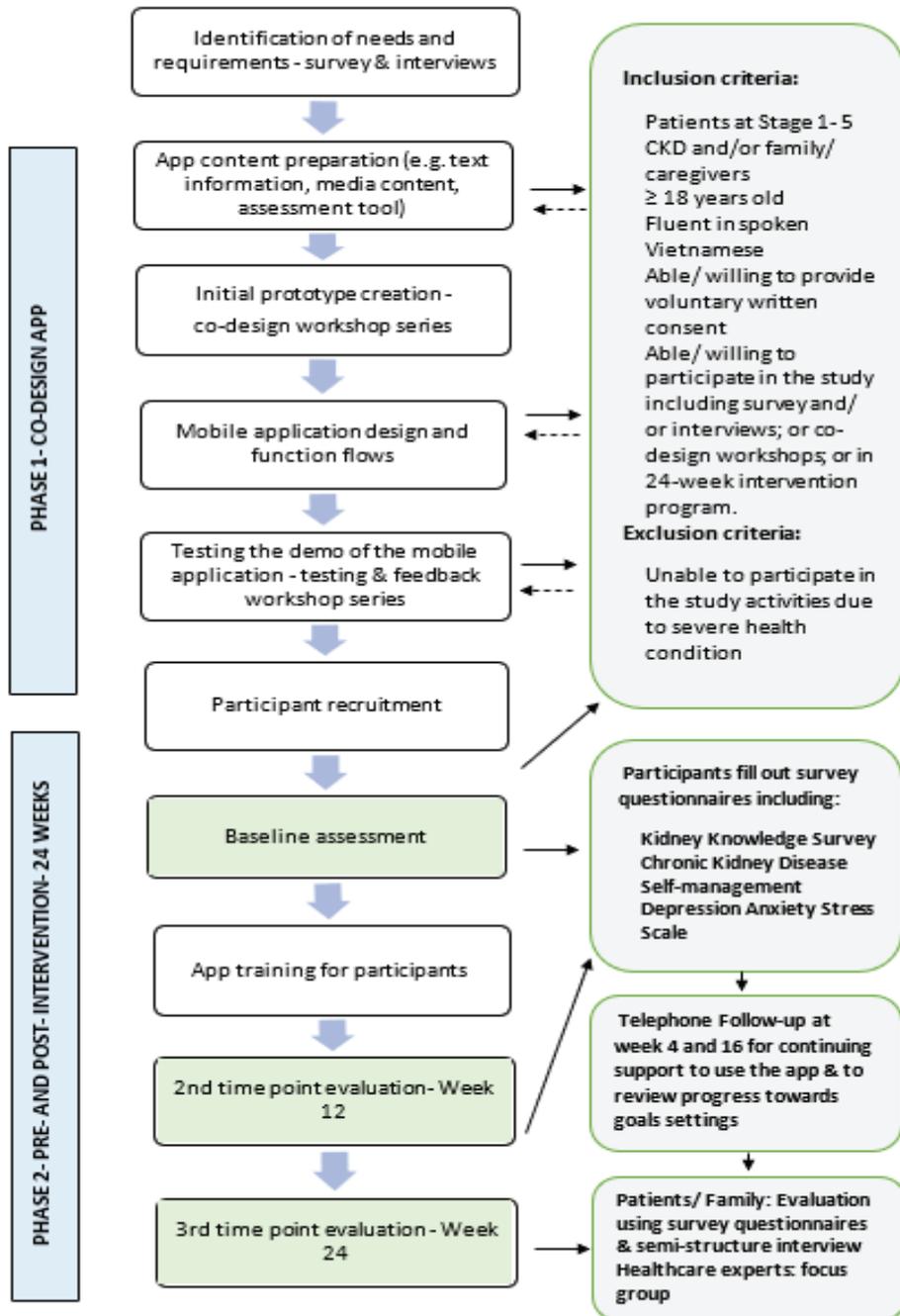


Figure 1. Study flow diagram

## METHODS

The study is undertaken in two main phases:

### *Phase 1 - Developing a mobile-based kidney health support program*

#### Study settings

The application development is conducted at the VinUniversity campus, Hanoi, Vietnam. In addition, patients with CKD are approached and recruited from the two regional hospitals in Hanoi.

#### Participants

Multiple participants involve and provide their inputs in the development of the Smart Kidney Health Support application.

i) Research team: The research team includes the principal investigator and three coprincipal investigators who are experts in kidney health and support, chronic kidney management as well as public health and social work.

ii) Healthcare experts: Numbers of healthcare specialists in kidney health and chronic kidney diseases as well as in clinical nutrition and psychology, who have at least a doctoral degree and five-year of experience in their field, are participating in this phase. Their main responsibilities are to create and consult about content for the main functions of the mobile application.

iii) IT team: The IT team will involve application developers, graphic designers, and other IT persons who are required for the development of a mobile application.

iv) Patients: This phase involves people with CKD examining their needs in using a mobile application to support their disease management. More importantly, patients participate in the co-design process to contribute their input in creating the mobile application. A convenience sample of patients is recruited from the two study settings. The target sample size is presented in the following section. Inclusion criteria are adult patients ( $\geq 18$  years old) who are having CKD at any stage; able to communicate verbally in Vietnamese and are willing to participate in the study. Exclusion criteria are patients who are too ill to participate in the study.

Chronic kidney disease refers to impaired kidney function or kidney structure damage ascertained through changes in specific markers for more than three months. These markers include a decrease in the glomerular filtration rate ( $<60\text{mL}/\text{min}/1.73\text{m}^2$ ) and/

or markers of kidney damage, including an increase in albuminuria (6). Chronic kidney disease is categorized into five stages in accordance with the level of kidney function measured by the estimated glomerular filtration rate (eGFR). At CKD stages 1 to 3, there is normal to moderately decreased kidney function, stages 4 and 5 represent severely impaired kidney function, stage 5 is also known as ESKD and is determined when the  $\text{eGFR} < 15 \text{ mL}/\text{min}/1.73\text{m}^2$  and refers to end organ failure in which survival requires kidney replacement therapy including either kidney transplantation or dialysis. In this project, we target patients at all stages of CKD (7).

### Codesign app development process

Participants are asked to participate in the app development process as follows:

#### *Step 1: Identification of needs and requirements for the Smart Kidney app*

This step includes: i) patients/ family members' identification facilities and barriers in approach information and support for kidney health; ii) healthcare experts' revision of the six intended modules/ functions for the app (presented in Table 1).

- 200 patients with CKD, who are fit the inclusion criteria, participate in completing the need survey
- 20 patients are invited into an individual interview to get more insights in their needs, challenges and advantages in using a mobile health app
- 02 healthcare experts who are specialized in kidney disease participate in the revision of the modules

#### *Step 2: Database prepared for each module*

For each finalized app module, database is prepared by the research team with the

consultations of 03 healthcare experts including a medical doctor specialized in kidney health, a nutritionist specialized in chronic kidney disease and a psychologist. At this step, database including text and media files (e.g. relevant information, guidelines, images, videos and so on) are ready to use by the mobile app.

### *Step 3: Initial prototype creation*

Prototype creation is a process in which the initial skeleton framework of the mobile application is created and then, modified throughout the iterative feedback process involving the co-design team and patients (8, 9). This prototype creation step comprises a series of workshop including one initial workshop and several following workshops. The initial workshop recruit 30 participants (patients and caregivers if needed for supporting the patients) to input their ideas for the app design and flows. The participants work on the look and feel of the app (e.g. language expression, colors, images and so on), and the app flows (i.e. a set of data stages and interactive steps that are then displayed in the app).

The following workshops comprise 3 to 5 sessions (face-to-face and/or video-conference) that aim to provide feedback on

the app development process. Adopting an iterative feedback process, several feedback cycles are conducted to achieve the final consensus regarding the app prototype. 06 participants (patients and caregivers if needed for supporting the patients) join the workshops to provide their feedback on the app prototype. All workshops are led by the research team with the participation of the IT team. The outcome of this step is the final app prototype.

### *Step 4: Mobile app designs and function flows*

Based on the inputs of patients, caregivers and the research team, the IT team works to create the mobile app designs and function flows resulting on the app demo version.

### *Step 5: Testing the demo of the mobile app*

A series of workshops (from 3 to 5 workshops, face-to-face and/or video-conference) are held to test the app demo version. 06 patients, 03 healthcare experts and the research team are required to participate in this step. In each feedback cycle, the app users (patients, caregivers, the research team and other healthcare experts) experience the app and provide feedbacks on the demo version to improve the app's design and function flows. The result of this step is the final version of the Smart Kidney app.

**Table 1. Intended modules/ functions and description of the mobile Kidney Health Support app**

<b>App modules</b>	<b>Description of the mobile health app requirements</b>	<b>App features</b>
<b>Kidney basics</b>	<ul style="list-style-type: none"> <li>• Provide information and guidelines on kidney health, kidney disease (signs and symptoms, stages) and causes and risk factors (the major risk factors of kidney disease including diabetes, heart disease, high blood pressure and eGFR)</li> <li>• Offer a function to assist patients in interpreting patients' test results</li> </ul>	<ul style="list-style-type: none"> <li>• Online training session on knowledge: pre- and post-test</li> <li>• Collect kidney diagnoses, kidney health test results</li> </ul>
<b>Treatments for kidney failure</b>	<ul style="list-style-type: none"> <li>• Offer knowledge for patients on different treatments for kidney failure</li> <li>• Follow-up treatment plans for patients</li> </ul>	<ul style="list-style-type: none"> <li>• Online training session on knowledge: pre- and post-test</li> <li>• Collect data of treatment plans, appointments, medicines</li> </ul>
<b>Diet support</b>	<ul style="list-style-type: none"> <li>• Offer training sessions for patients on healthy kidney diet</li> <li>• Allow them to record their diets every day.</li> <li>• Patients have experts in nutrition and CKD to evaluate and follow up on their diet plans.</li> </ul>	<ul style="list-style-type: none"> <li>• Online training session on knowledge: pre- and post-test</li> <li>• Diet diaries</li> <li>• Support an evaluation system/ scale to evaluate diet plans</li> </ul>
<b>Physical exercises and goal settings</b>	<ul style="list-style-type: none"> <li>• Offer training sessions for patients on healthy kidney physical exercises</li> <li>• Allow them to plan physical exercises every day/ week.</li> <li>• Patients have experts in physical exercises and CKD to evaluate and follow up on their physical exercise plans.</li> </ul>	<ul style="list-style-type: none"> <li>• Online training session on knowledge: pre- and post-test</li> <li>• Videos about specific physical exercises</li> <li>• Physical exercise diaries</li> <li>• Support an evaluation system/ scale to evaluate physical exercise plans</li> </ul>
<b>Mental wellness program and Covid19 supports</b>	<ul style="list-style-type: none"> <li>• Provide information and instructions/ guidelines for patients to practice mental wellness activities and coping strategies against COVID-19</li> <li>• Provide a list of psychologists/ counsellors and mental health settings to help patients in needs navigate their access to health care</li> </ul>	<ul style="list-style-type: none"> <li>• Videos to guide wellness activities</li> <li>• Support an assessment system for depression, anxiety and stress screening</li> </ul>
<b>Peer support group</b>	<ul style="list-style-type: none"> <li>• Allow patients exchange experiences, knowledge and support each other via a discussion forum and online communities</li> <li>• The forum also allows healthcare experts to join in and follow up the discussion threads</li> </ul>	<ul style="list-style-type: none"> <li>• Discussion forum</li> <li>• Online communities</li> </ul>

## **Phase 2 – Implementation of the Smart Kidney Health Support Program**

### **Study settings**

The study is set to conduct in the Department of Nephro-Uronoly, Duc Giang General Hospital and Hanoi Kidney Hospital. Duc Giang General Hospital is located in urban area of Hanoi. This hospital provides treatment for people who lives in that area, as well as surrounding provinces. Typically, 30 people attend the Nephro-Urology outpatient clinics or are admitted to the hospital each day. While Hanoi Kidney Hospital is located in the center of Hanoi.

### **Participants**

Patients with CKD attend outpatient hospital clinics for regular appointment with renal medical practitioners and people who are currently going on with haemodialysis treatment at the dialysis units.

#### **Inclusion criteria:**

Participants were diagnosed with CKD (in all stages of CKD), aged  $\geq 18$  years, able to speak, read, and understand Vietnamese language. They also are able to use smartphone, be contactable via telephone for follow-up and willing to participate in the study

#### **Exclusion criteria:**

Participants are excluded if they are enrolled in other clinical trials, had cognitive impairment, or seriously unwell.

#### **Sample size:**

The National Institute for Health Research (10) recommends sample size between 24 and 50 participants for test the feasibility and acceptability of a health support program. However, people may drop-out from the study so it is recommended that the study should include at least 20% of the sample (11). Thus,

this study aims to recruit 60 participants who had been diagnosed with CKD (any stage) to participate in the program.

### **Pilot the Smart Kidney Health Support program:**

Participants participating in this study phase receives standard CKD care from their healthcare providers, which is focused on taking medications and receiving basic healthcare advice, and a 24-week support program. Participants receive the Smart Kidney program on the day that they agree to participate in the research. Participants also receive two follow-up phone calls support at 4 weeks and 16 weeks.

The Smart Kidney Health Support program will start with supporting participants to use the Smart Kidney app to learn about knowledge of disease, treatments, medication, healthy dietary, physical exercises and mental wellness support. Then they use the app available functions to interact with healthcare experts and peers as well as to practice their own treatment plans, dietary, physical exercises and mental wellness activities recommended. Patients' information including kidney diagnoses, kidney test results, current treatment plans, medicines, dietary diaries, physical exercise goals etc. are recorded from the first day of providing the Smart Kidney program and are monitored at each follow-up. By doing that, the investigators assist participants to review problems and issues related to their kidney disease management and improving their self-management skills to overcome it.

Participants receive two follow-up phone calls of 20 – 30 minutes at week 4 and 16 by the research team for continuing support to use the Smart Kidney app to reinforce their participation in the support program and to review progress towards goals settings. The focus is to identify improvement and

to encourage participants be more actively involved in looking after their disease. The investigators support participants to continue using the Smart Kidney app to better self-manage their disease and encourage them to seek family and friends support for long-term using the app. The phone call follow-up also allow time for participants to ask any questions about the Smart Kidney app and related issues that may have.

### **Methods and Measures**

Participants participating the Smart Kidney program are evaluated at three-time points (baseline, week 12 and week 24). The evaluation is based on quantitative and qualitative methods.

#### **Quantitative methods:**

Participants are assessed using a survey. The survey comprises three main measurement tools as follows:

#### **Measures**

**Knowledge:** Knowledge of kidney disease is measured by using the Kidney Knowledge Survey (KiKS). The KiKS is a self-reported instrument comprising 28 items that measure the participant's knowledge related to kidney disease management, such as kidney function, treatment options for kidney failure, signs and symptoms of disease progression, potential medication that harm or benefit the kidney, blood pressure targets, and other information related to preserving kidney function (12). The KiKS takes approximately 10 minutes to complete. The items are scored as 1 = correct, or 0 = incorrect, and total scores range from 0 to 28. This instrument has been translated into Vietnamese and assessed for validity and reliability in people with CKD in Vietnam (4).

**Self-management behavior:** Self-management behavior is measured by using the Chronic Kidney Disease Self-management (CKD-

SM) instrument. The CKD-SM self-report instrument comprises 30 items and measures whether participants perform a range of self-management behavior factors, including understanding my kidney disease (11 items); taking action to manage my kidney disease (11 items); seeking social support (5 items); and adhering to a healthy diet (3 items). The subscales are constructed by summing the scores on the separate items belonging to the subscale. Respondents answer each item on a Likert scale from 1–4; 1 = never, 2 = sometimes, 3 = usually, 4 = always. Total scores of the CKD-SM are also constructed by summing the scores on the four subscales and range from 32 to 128. High scores indicate a high level of self-management behavior in managing CKD. The instrument takes about 15 minutes to complete. This instrument has been translated into Vietnamese and assessed for validity and reliability in people with CKD in Vietnam (13).

**Mental health screening:**The Depression Anxiety Stress Scale (DASS21) comprises three sub-scales: depression (DASS-D), which measures hopelessness, low self-esteem and positive affect; anxiety (DASS-A), which assesses anxious arousal and other related symptoms; and stress (DASS-S), which measures tension and negative affect. A 4-point Likert scale is used as the item response options (from 0 – “Did not apply to me at all” to 3 – “Applied to me very much, or most of the time”). The total score of the instrument is then doubled to be able to compare with the original DASS categories (i.e., from no to severe depression, anxiety and stress) and ranges from 0 to 42.

The DASS has been used widely in both clinical and community settings and translated and validated into various languages other than English (14, 15). The Vietnamese version of the 21 item DASS is available to use and has sufficient internal consistency

reliability, with a Cronbach's alpha ranging from 0.70 (DASS-S) to 0.88 (overall scale; 16). The instrument has previously been used in a study in Vietnam of people with ESKD receiving haemodialysis (17).

### **Qualitative methods:**

Two qualitative methods are adopted in this study including the focus group and semi-structured interviewing methods. Qualitative approach is essential when we know little about the issues we wish to examine (5).

a. Focus group is held to explore feasibility and acceptability of the program from the viewpoint of healthcare experts who participate in the program. The focus group takes about 30-60 minutes and are audio/video-recorded.

b. Semi-structure interview is employed to allow the participants to articulate on their experiences and opinions regarding the app usage. Each interview takes about 20-60 minutes, and all be audio recorded.

### **Data collection**

Step 1: The investigators meet with a renal medical partitioner who are able to identify eligible potential participants who were diagnosed with CKD. In addition, research assistants are provided an essential training session in data collection (e.g., conducting survey, focus group and interview) to ensure that all data collected with the same quality.

Step 2: The investigators meet eligible participants to introduce themselves, the purpose and methods of the study and invite them to participate. Participants can ask the nurse investigators questions about the study and also read the Participant Information Sheet before providing written consent. They also can take the Participant Information Sheet home to discuss with their family or friends and bring it back when they next come to the clinics.

Step 3: Participants are invited to complete the self-report instruments before participating in the Smart Kidney program session.

Step 4: Each participant is provided with a 30 to 60-minute face-to-face support of using the Smart Kidney app delivered by the investigators.

Step 5: At weeks 12 and 24 the investigators and research assistants collect data from all participants.

### **Data analysis**

Quantitative data is entered into IBM SPSS version 26 and an intention-to-treat analysis will be performed. Baseline data will be reported. Repeated measure ANOVA will be used to evaluate the effects of the intervention on the outcomes at 3 different time points (baseline, at weeks 12 and 24). For qualitative data, the thematic analysis method (5) is used to analyze the interview data. All recorded audio and video tapes are transcribed into text before conducting the analysis.

### **Ethics and consent to participate**

Before conducting the project, ethic approval was obtained from the institutional ethical review board for biomedical research Vinmec international general hospital JSC – VinUniversity, Hanoi, Vietnam with the ethical clearance number 16/2022/QĐ-VMEC. Ethical considerations specific to this study include consent, confidentiality, security of data and dissemination of results. Participants are informed in writing of the processes and time involved before data collection is conducted. All participants are assured that information is collected anonymously and treated with strict confidentiality. Participants have rights to withdraw at any time. All information of the participants (including information of participants using apps) is used for the research purpose only.

## DISCUSSION

To the authors' knowledge the mobile-based Smart Kidney Health Support program is the first tele-health program for people with CKD in Vietnam. The program is the first one to add holistic and multiple aspects in chronic disease management including disease progress, treatment, diets, physical exercise and mental wellness in a mobile application. This study will provide a hand-on and useful information as well as a tool for people with CKD to manage their health status. Importantly, the Smart Kidney Health Support program will allow online interaction and direct consultation between healthcare experts and people with CKD. This function offers a more flexible way for both patients and healthcare staff to monitor and manage the disease and treatment as well as to enhance self-management among the CKD population. Our mobile-based program may have potentials to be used by different healthcare settings, particularly in primary healthcare clinics, where promoting self-management in people having chronic disease is crucial. More broadly, this health support program might help to inform the design and conduct of future support programs for other chronic disease populations. The codesign based intervention also assure the accurate data/information in app which is the main strength of this study.

Some obstacles might occur that might influence how this study is designed and conducted. Firstly, it is difficult to approach patients at earlier stages of CKD who are in conservative treatment. As such, we are unable to recruit expected numbers of patients we designated for the first step of Phase 1. Thus, the inclusion of other healthcare settings having renal out-patient clinics as the study settings has been done to maximise our possibility to approach people at stage 1 to

4 of CKD. Secondly, the use of smartphones in the older patients with CKD might be limited. Numbers of older patients might not be familiar with or unable to use smartphones. Main reasons are due to the patients' impaired vision, their weak physical health, especially among those receiving haemodialysis and their believes that they were unable to learn new technology-related applications. This is a limitation of the mobile-based intervention. However, excluding the participants who do not use smartphone in their daily basics could help us to focus on the CKD patients who can have direct benefits from the Smart Kidney Health Support Program.

To overcome the above limitation, the program will open for family caregivers/ members of people with CKD to participate so that they can assist the patients in their disease self-management activities. In Vietnam, people with CKD often rely much on their family including daily caregiving and financial support etc (18). The inclusion of family caregivers allows our program to include the wide range of patients with different CKD conditions.

In the long term, the intervention might face the problem of participants who withdraw from the study. Internet accessibility, the high cost of smartphones, lack of regulatory approval, and high cost for in-purchase applications are some of the other key factors hampering penetration of the mobile health apps in the CKD community, faltering their demand.

## CONCLUSION

The expected outcome of this project is to have a comprehensive, hands-on, and innovative mobile health support program to support and assist people with CKD in Vietnam to better self-manage their disease, treatments,

and lifestyle. With codesign approach, it is expected that this mobile-based health intervention will be applicable and useful for patients, families and healthcare providers.

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### Authors' contributions

VLH, LMT and NTN contributed to study design and wrote the study protocol and this manuscript. VLH is the principal investigator who oversee study conduct and management. PL contributes to study conduct, finding analysis and made significant contributions to this manuscript. BTH is in charge in administrative of the project and contributes in writing the manuscript.

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