Title: Remote symptom assessment and management via mobile app for adults with chronic kidney disease living in Vietnam

Date: 16/08/2025

This version of the study protocol has been reviewed by the Human Research Ethics Committee, ethics approval number 135/2025/CN/HDDD VMEC, dated 16/08/2025.

PARTICIPANT INFORMATION SHEET

Remote symptom assessment and management via mobile app for adults with chronic kidney disease living in Vietnam

We would like to invite you to participate in a research project to evaluate a new symptom assessment and management program.

This document tells you about the research and describes what will happen if you decide to participate. Please read this information sheet carefully, and if you have any questions about the research or need further information, do not hesitate to contact Ms XXX.

Why is the research being conducted?

Adults with chronic kidney disease have many symptoms that lower quality of life and put a huge burden on the healthcare system. Recently, mobile health apps have been introduced in chronic kidney disease care, helping with symptom management and improving patient outcomes. While symptom management via mobile health apps is emerging in other countries, it has not commenced in Vietnam.

This study aims to develop and evaluate a remote symptom assessment and management program delivered through a mobile application for adults with chronic kidney disease to help them manage their symptoms. This is the first program focusing on symptom assessment and management in Vietnam. Patients can use this mobile application to assess their symptoms and know how to self-manage them better.

Below is a brief description of our research and what will happen if you decide to participate.

Am I eligible?

To participate in this study, you must be:

- 18 years old or older, AND
- diagnosed with chronic kidney disease grade 4 or 5, AND
- able to speak and read Vietnamese, AND
- own a smartphone running Android, AND
- no cognitive impairment or acute illness, AND
- not participating in other trials, AND
- attending in E Hospital.

What you will be asked to do?

If you decide to participate in this study, you will be randomly allocated to one of two groups (intervention group or control group). You will have an equal chance of being assigned to either the intervention or control group.

If you are assigned to the intervention group, you will be asked to download the mobile application (at no cost) to your phone and use it for 6 weeks. We will ask you to complete questionnaires with the assistance of research assistants, which will take about 30 minutes on three separate occasions. These questionnaires include (i) personal information (age, gender, marital status, education level, occupation, income, previous education about symptom management, digital health literacy), (ii) symptoms, (iii) health-related quality of life, (iv) your

evaluation about app usability. The study also involves collecting information from your medical records, including your diagnosis, your treatment plan, and other diseases you may have.

If you are allocated to the control group, we will invite you to complete the same questionnaires as the intervention group, except for the questionnaire related to app usability. You will receive the usual care from your doctors and nurses. At the end of the study, you will be offered to use the mobile application.

The expected benefits of the research

It is possible that you may benefit from the symptom assessment and management program that is provided if you are allocated to the intervention group or the control group after completing this study. Upon completing each time point assessment, you will receive $15 AUD for completing all study activities.

Risks to you

There are no foreseeable risks or harm associated with your participation in this study. If any of the questions cause distress, you can choose not to answer those questions. You can withdraw from the study at any time without any disadvantage. The information provided in this study will be de-identified. If you have any concerns regarding your health, distress, or discomfort from participating in this study, please raise your concerns with your doctors or nurses at E Hospital.

What are the costs of participating in this study?

If you decide to participate in this research, no cost is involved. The research will take place during your haemodialysis treatment times or outpatient appointments in E Hospital.

Your participation is voluntary

Your participation in this study is voluntary. There is no obligation for you to take part; if you do not consent, it will have no effect on your medical care or affect you in any other way. Feel free to discuss this with your doctors, nurses, and family before deciding.

Can I withdraw from the study?

You can withdraw from the study at any point. Your decision to participate in this study will not affect your relationship with your healthcare providers; you will still receive your usual care. You can withdraw your consent by advising the researcher either verbally or in writing. If you do withdraw your consent during the research, the research team will stop collecting information from you. You will also be given the option to withdraw your data or allow us to use the data collected until the point by which you withdraw in the research analysis.

How do I give my consent to participate?

If you decide to participate in this study, you will be asked to sign a consent form (see below) to confirm your willingness to participate.

What will happen to information about me?

Information collected from this study that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission or as required by law. Any incidental findings that arise from the data analysis, for example, symptoms that are life-threatening, will be reported to the attending doctors. All identifiable information obtained from you will be replaced with a unique code. A unique code that links your identifiable information will be stored separately in an electronic database accessible only to the research team. Your identifiable information will not be disclosed in any research publication.

How will the collected information be stored?

All paperwork will be stored in a secured cabinet at the Department of Nephrology and Dialysis, E Hospital, during the trial. Paperwork will be brought to Australia using a secured courier service and kept in a locked filing cabinet at the School of Nursing and Midwifery, Griffith University. Electronic files will be stored in a password-protected computer server in Griffith University Research Space Drive. The stored data will be accessible only by the research team. All materials related to this research will be kept confidential for at least 15 years from the publication of the results, as per national requirements, and then disposed of by secure destruction methods.

Will the results of the research be published?

It is anticipated that the results of this research will be published as a thesis and journal articles and presented at conferences. No information will be published that could identify you as a participant in this study.

Feedback to you

At the end of the research, you will be asked if you would like to receive the results. Please contact your attending nephrologist or a research team member mentioned above to obtain a lay summary of the result. This report will contain aggregated data that will not identify you as a participant.

Privacy Statement

"The conduct of this research involves the collection, access, storage and/or use of your identified personal information. The information collected is confidential and will not be disclosed to third parties without your consent, except to meet government, legal or other regulatory authority requirements. A de-identified copy of this data may be used for other research purposes, including publishing openly (e.g. in an open access repository). However, your anonymity will at all times be safeguarded. For further information, consult the University's Privacy Plan at http://www.griffith.edu.au/about griffith/planspublications/griffith-university-privacy-plan or telephone (07) 3735 4375."

The ethical conduct of this research

Ethical approval for this study has been granted by the Institutional Ethical Review Board for Biomedical Research Vinmec International General Hospital JSC- VinUniversity (135/2025/CN/HDDD VMEC, date 16/08/2025).

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for adults with chronic kidney disease living in Vietnam

CONSENT FORM

By signing below, I confirm that I have read and understood the information sheet and in particular:

- I understand that my involvement in this research will include the completion of questionnaires before the start, in the middle and end of the research and participation in using the intervention program via a mobile app if assigned to the intervention group.
- I give permission to the researchers to access my medical records.
- I have had any questions answered to my satisfaction.
- I understand the benefits to me of my participation in this research.
- I understand the purposes and procedures of the research described in the study.
- I understand that my participation in this research is voluntary.
- I understand that I am free to withdraw at any time without explanation or disadvantages.
- I understand that my name and other personal information that could identify me will be removed or de-identified in publications or dissemination of this research.

I give my consent to take part in this research: ☐ **Yes** ☐ **No**

Full Name	
Signature	
Date	