Queensland University of Technology
Brisbane Australia

PARTICIPANT INFORMATION FOR QUT RESEARCH PROJECT

A pragmatic randomised controlled trial (RCT) of a nurse-led self-management intervention to support people with chronic kidney disease (stages 3-5) in Vietnam.

QUT Ethics Approval Number 1500000678

RESEARCH TEAM

Principal Researcher:	Thi Nguyet Nguyen	PhD student
Associate Researchers:	Professor Ann Bonner	Principal Supervisor
	Dr Clint Douglas	Associate Supervisor

School of Nursing, Faculty of Health, Queensland University of Technology (QUT)

DESCRIPTION

You are invited to participate in this study because you have a kidney problem called chronic kidney disease. This study does not interfere with your usual kidney treatment provided by your medical doctor or nurse.

This study is being conducted as part of PhD study for Ms Nguyen Thi Nguyet at QUT, Australia. The purpose of this study is to evaluate the effectiveness of a chronic kidney disease self-management education program for Vietnamese people with chronic kidney disease (CKD). This education program is designed to help you to better look after your kidneys.

This Participant Information Sheet contains detailed information about the study. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this study before you decide whether or not to take part in it. Please read this very carefully and please feel free to ask any questions you may have about any information in this document. You may also wish to discuss the study with your relatives or friends. Please feel free to do this. You can take as long as necessary to fully understand this study before decide to sign in the consent form to participate.

Once you clearly understand what the study is about and if you agree to take part in it, you will be asked to sign a Consent Form.

PARTICIPATION

Your participation in this study is entirely voluntary.

At the start of the study, you will be invited to complete 5 questionnaires which will take approximately 30 to 40 minutes of your time to complete. These questionnaires are: i) information about you (gender, age, marital status, highest education level, occupation, incomes, health insurance, number of people are living with you, length of your disease, and your understanding about the blood test results), ii) your understanding about kidney disease, iii) your behaviour when you have chronic kidney disease, iv) your confident in doing certain activities when you have chronic disease, and v) your quality of life.

The study also involves collecting information from your hospital record. The information is blood test results, other chronic diseases you may have, list of current medication used, and your blood pressure reading. You will be invited to complete the questionnaires again 8 and 16 weeks later at the clinic (or via a telephone call) taking about 30 – 40 minutes each time. In addition, information will be collected from your hospital record at week 16.

After completing the questionnaires, you will be randomly allocated to one of two groups (control group or intervention group).

If you are allocated to the control group, you will receive normal renal treatment by your renal doctors and nurses.
If you are allocated to the intervention group, you will receive normal renal treatment AND an education program.

Regardless of which group you are allocated to, the healthcare provided at Bach Mai hospital Clinic will not be affected in any way. The table below explains the process of the study.

Time	Control group	Intervention group
Week 0: Start of the study	You will be invited to complete 5 questionnaires as listed above before being assigned randomly to either the control or intervention group. The questionnaires take about 30 to 40 minutes to complete.	
	You will receive normal renal treatment at the clinic.	You will receive normal renal treatment plus an education (teaching) program. This is a booklet, and a one-hour face-to-face teaching session that will teach you about kidney problems and give you information about how to look after yourself (this is called self-management). You will also have the opportunities to ask any questions related to your kidney problems. It will take about 60 minutes to complete this session.
4 weeks later (Week 4)	You will receive normal renal treatment at the clinic.	You will receive normal renal treatment at the clinic and a phone call of 20 to 30 minutes to follow up on the teaching and to discuss any questions you may have about using the booklet and practicing self-management from the Principal researcher.
8 weeks later (Week 8)	When you return to the hospital, you will be invited to complete 3 questionnaires (your understanding about kidney disease, your behaviour when you have chronic kidney disease, and your confident in doing certain activities when you have chronic disease). This should take about 30 to 40 minutes of your time. If you do not return to the hospital at this time, you will be asked to complete 3 questionnaires via a telephone call of 30 to 40 minutes duration.	
12 weeks later (Week 12)	You will receive normal renal treatment at the clinic.	You will receive normal treatment at the clinic and a phone call of 20 to 30 minutes to follow up on the teaching and to discuss any questions you may have about using the booklet and practicing self-management from the Principal researcher.
16 weeks later (Week 16): End of the study	If you return to the hospital at this time, you will be invited to complete 4 questionnaires [(i) your understanding about kidney disease, ii) your behaviour when you have chronic kidney disease, iii) your confident in doing certain activities when you have chronic disease, and iv) your quality of life]. You will also be invited to complete the evaluation questions. It may take approximately 30 to 40 minutes to complete. The researcher will also review your hospital record for the same health information (i.e. the blood test results, other chronic diseases, and blood pressure results) as the start of the study. If you do not return to the hospital at this week, you will be asked to complete 4 questionnaires (listed above) via a telephone call of 30 to 40 minutes duration. At the completion of the research, when you are coming to the clinic, you will be offered the booklet of "Looking after My Kidneys and Health" received by the intervention group.	

If you agree to participate, you do not have to complete any question(s) you are uncomfortable answering. Your decision to participate or not participate in will no way impact upon your current or future relationship with Bach Mai Hospital or QUT. If you do not want to continue to participate, you can withdraw from the study at any time without comment or penalty, and any information already obtained from you will be destroyed.

EXPECTED BENEFITS

You will have access to the booklet of "Looking after My Kidneys and Health". However, you may receive it at the start of the research or at the end of the study time period. Your responses to the questionnaires will be used to analyse to the results of the study, therefore, the results may benefit people with kidney problems by providing improvements to how doctors and nurses can support people to understand and manage their kidney problems which may lead to slowing the progression of the disease.

To recognise your time to participate in this study and to answer the questionnaires, the research team is offering you 180,000 VND (equivalent to AU$10). A cumulative payment by cash will be made at the end of your participation.

RISKS

Your participation in this study is optional. There are minimal risks associated with your participation in this study.

If you are allocated to the control group, you may experience emotional discomfort due to the time to complete the questionnaires at the clinic or via telephone calls. The total time required to complete the questionnaires will be approximately 30 to 40 minutes each time.

If you are allocated to the intervention group, you may experience emotional discomfort due to the time to complete the questionnaires, participate in the teaching session, and follow-up telephone calls. The time taken to complete these tasks will be approximately 20 to 60 minutes at each time.

We will ensure that any risk is minimised. You will be invited to participate in the study at a time convenient to you. If you need to listen to phone call, it will be organised to suit your timeline. If any of the questions cause you to be upset or confused, you can choose not to answer these questions, or not participate in the one-hour face-to-face teaching session, and phone call follow-ups.

If needed, counselling is available through the Bach Mai Hospital. You can access the counselling services via the Department of Nephro-Urology at Bach Mai Hospital. You can also contact your renal doctors via telephone calls or face-to-face at the clinics of the Nephro-Urology Department to ask any questions you may have. You will be given with routine information about your treatment plan including medications and your healthcare will not be affected by this study by your renal doctors.

PRIVACY AND CONFIDENTIALITY

Data including all comments and responses will be treated confidentially. This means that no personal information about you will be disclosed to any other person. All of the data will be stored in a secure area and only utilised for the purpose of the study. Any data collected as part of this study will be stored securely according to QUT's management of research data policy. The results will be reported as group data and no names or other forms of identity will be disclosed.

This study is funded by Australia Award Scholarship and QUT student allocation. However, only the researcher and supervisor team will have the right to access to the data obtained during or following the study.

CONSENT TO PARTICIPATE

A consent form will be given directly to you. You will give your consent to participate in this study by reading and signing the form and returning this to the research assistants.

QUESTIONS / FURTHER INFORMATION ABOUT THE PROJECT

If you have any questions or require further information please contact one of the researchers listed below.

Thi Nguyet Nguyen	+84 9 0407 1289	nguyet.nguyenthi@hdr.qut.edu.au
Ann Bonner	+61 7 3138 0823	ann.bonner@qut.edu.au
Clint Douglas	+61 7 3138 3896	c2.douglas@qut.edu.au

CONCERNS / COMPLAINTS REGARDING THE CONDUCT OF THE PROJECT

QUT is committed to research integrity and the ethical conduct of research projects. However, if you do have any concerns or complaints about the ethical conduct of the study you may contact the QUT Research Ethics Advisory Team on +61 7 3138 5123 or email ethicscontact@qut.edu.au. The QUT Research Ethics Advisory Team is not connected with the research project and can facilitate a resolution to your concern in an impartial manner.

Thank you for helping with this research project. Please keep this sheet for your information.

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CONSENT FORM FOR QUT RESEARCH PROJECT
– Participants –

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RESEARCH TEAM CONTACTS

Thi Nguyet Nguyen	+849 0407 1289	nguyet.nguyenthi@hdr.qut.edu.au
Ann Bonner	+617 3138 0823	ann.bonner@qut.edu.au
Clint Douglas	+617 3138 3896	c2.douglas@qut.edu.au

STATEMENT OF CONSENT

By signing below, you are indicating that you:

- Have read and understood the information document regarding this study.
- Have had any questions answered to your satisfaction.
- Understand that if you have any additional questions you can contact the research team.
- Understand that you are free to withdraw at any time, without comment or penalty.
- Understand that you can contact the Research Ethics Advisory Team on +61 7 3138 5123 or email ethicscontact@qut.edu.au if you have concerns about the ethical conduct of the study.
- Agree to the researchers accessing my medical records at Bach Mai hospital.
- Agree to participate in the study.

Name .....

Signature .....

Address .....

.....

Phone Number .....

Date .....

Please return this sheet to the investigator.