Participant Information Sheet/Consent Form

Non-Interventional Study - *Adult providing own consent*

Title	Assessing the effectiveness of lifestyle modifications including self-management strategies in managing chronic kidney disease (CKD) stages 1-3 in a rural setting
Short Title	Assessing the effectiveness of lifestyle modifications at managing CKD in a rural setting.
Principal Investigator	Dr. Zeest Naveed, Swan Hill Primary Health Medical Centre
Associate Investigator(s)	Dr. Indra Choudhury, Charles Sturt University Aryan Sharma, Charles Sturt University.
Location	Swan Hill Primary Health Medical Centre.

Part 1 What does my participation involve?

Introduction

You are invited to take part in this research project, Assessing the effectiveness of lifestyle modifications including self-management strategies in managing chronic kidney disease (CKD) stages 1-3 in a rural setting. This participant information sheet is for a research project about the strategies that patients such as yourself use at home to look after themselves and manage chronic kidney disease (CKD). We believe that your knowledge and experiences would provide an invaluable contribution to our research and we would appreciate your participation. We anticipate recruiting about 50 participants.

The research project is aiming to assess how CKD patients in Swan Hill approach their kidney health and understand how well they can manage their chronic condition through lifestyle modifications. This research will help us better understand the needs of rural patients and allow CKD patients to take better control and care of their condition.

This Participant Information Sheet/Consent Form tells you about the research project. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to the research activities that are described
• Consent to the use of your personal and health information as described.

What is the purpose of this research?

The results of this research will be used by the study doctor Aryan Sharma to obtain a Doctor of Medicine degree.

Participation in this research is voluntary. Your choice to participate or not participate in this study will in no way affect your medical care. Your medical care providers will not know whether you have chosen to participate. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. There are no costs associated with participating in this research project, nor will you be paid.

This study will involve a questionnaire for you to complete which is expected to take approximately 10 minutes. These questions are on a 4-point scale and are based on how you feel about and manage your kidney disease. You can either complete the physical form or scan the QR code on the posters for an electronic version. Simply select one of the four responses which best reflect your real situation. Additionally, the questionnaire will ask your name and date of birth. This information is collected solely to gather your demographic data and last kidney function results (called eGFR) from the electronic records. The demographic data collected will be your gender, age, location, marital status, employment and ethnicity which is stored on your medical file. This information will help us understand your kidney disease progression.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Swan Hill Primary Health Medical Centre.
If you decide to participate in the study please complete the consent form and survey attached and submit them by placing in the box located at the Swan Hill Primary Health Medical Centre reception.

What are the possible benefits of taking part?

You may not receive a direct benefit from participating in this study. You may derive satisfaction by contributing to research that has the potential to benefit the community of CKD patients in the future. Your responses will help us understand which management strategies are most effective in rural patients. This can form the basis of encouraging future research to develop guidelines for rural patients, ultimately benefitting rural communities.
There are no risks associated with this questionnaire, however if you feel uncomfortable by any question, you are welcome to withdraw from the research.

What if I withdraw from this research project?

This study is completely voluntary, and you can withdraw from it at any point until either 50 participants have been recruited, or until participant results have been de-identified. If you wish to withdraw from the study during the questionnaire, then you are not required to submit your

responses. If you wish to withdraw from this study after submitting the questionnaire, please complete the withdrawal form available at the Swan Hill Primary Health Medical Centre reception, or contact Aryan Sharma on Aryan.Sharma2002@outlook.com or +61481349419, or Dr. Indra Choudhury on ichoudhury@csu.edu.au.

What happens when the research project ends?

Part 2 How is the research project being conducted?

What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you (as listed above) for the research project. Any information obtained in connection with this research project that can identify you will remain confidential.

After the survey data, kidney test data and demographic data is collected, it will be consolidated in a single password-protected file, on a password-protected USB drive. Each participant will be given a unique identified, e.g. Participant 1, in the dataset used for analysis, and all data will be stripped of patient name and date of birth. The original survey results, consent and withdrawal of consent forms will be scanned and stored electronically on a separate password-protected USB drive, allowing the hard-copies to be safely shredded to maintain participant confidentiality. These scanned results will be retained until data analysis is complete to enable any required checking of data field and then securely deleted, ensuring it is irrecoverable. The de-identified data will be retained for 7 years after the completion of the project and then securely destroyed as required by law.

If you fill out the electronic survey by scanning the QR code, your data will be securely stored on the Qualtrics database, allowing the student researcher to download the data in an encrypted excel sheet for data analysis, and deletion of all electronically stored data on the Qualtrics database to maintain anonymity.

You will not be identified in any reports, presentations, or publications about the study. No individual data will be reported, only summary statistics for combined group data. A summary of results will be available to participants on request at the completion of the project.

Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the Bendigo Health HREC
This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2023)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

Further information and who to contact

The person you may need to contact will depend on the nature of your query.
If you want any further information concerning this project, you can contact the student researcher Aryan Sharma on +61481349419.

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	*Bendigo Health HREC*
HREC Executive Officer	*Dr Sarah Lindsay*
Telephone	*54546412*
Email	*researchoffice@bendigohealth.org.au*

Local HREC Office contact (Single Site -Research Governance Officer)

Name	Research Governance Office
Position	Research Governance Manager
Telephone	5454 6412
Email	researchoffice@bendigohealth.org.au

Consent Form - *Adult providing own consent*

Title	Assessing the effectiveness of lifestyle modifications including self-management strategies in managing chronic kidney disease (CKD) stages 1-3 in a rural setting
Short Title	Assessing the effectiveness of lifestyle modifications at managing CKD in a rural setting.
Protocol Number	117396
Project Sponsor	Charles Sturt University
Principal Investigator	Dr. Zeest Naveed, Swan Hill Primary Health Medical Centre
Associate Investigators	Dr. Indra Choudhury, Charles Sturt University Aryan Sharma, Charles Sturt University.
Location	Swan Hill Primary Health Medical Centre.

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation - *Adult providing own consent*

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Location	Swan Hill Primary Health Medical Centre.

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Swan Hill Primary Health Medical Centre.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.