PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Study Title: The use of a behavioural change strategy for reducing interdialytic weight gain in patients with kidney failure undergoing haemodialysis: A cluster randomised controlled trial.

Coordinating Principal Investigator: Dr Danielle Marie Muscat, Post-Doctoral Research Fellow USYD.

Sites / Location: [XXX]

Invitation

You are invited to participate in a research project which aims to seek to understand how effective behavioural change strategies are in managing fluid amongst people who are receiving haemodialysis treatment for their kidney disease.

The research project is being conducted by Nada Mustapha-Khodragha, School of Public Health, University of Sydney.

Before you decide whether or not you wish to participate in this research project, it is important for you to understand why the research project is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

What is the purpose of the research project?

The purpose of this project is to determine how effective behavioural change strategies are in managing fluid amongst people who are receiving haemodialysis treatment for their kidney disease. Fluid management is important during dialysis because having too much fluid can cause high blood pressure, swelling, breathing difficulties and high weight gain, which can then lead to increased hospitalisation and mortality.

Behavioural change strategies have been successfully used in previous research for helping participants to manage other health related behaviours, such as reducing unhealthy snacking, however they have never been used to help manage fluids in patients on haemodialysis treatment. This project aims to address this gap in the research.

The results of this research will be used by the researcher *Nada Mustapha-Khodragha* to obtain a *Master of Public Health* degree.

Who will be invited to participate in the research project?

You are invited to participate in this research project because you are currently receiving haemodialysis treatment for your chronic kidney disease and your participation can help to contribute to our understanding of how behavioural change strategies can be used to help people undergoing dialysis to manage their fluids.

Do you have a choice?

Participation in this research project is voluntary. It is completely your choice to participate or not. If you decide not to participate, it will not affect the care you receive now or in the future. You can change your mind and withdraw your participation in the research project at any time.

If you decide to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

What will happen on the research project?

- This research project will be conducted over 12 weeks (about 3 months)
- If you consent to participate in this research project, you will then be asked to complete an online demographic questionnaire at the beginning of the study. This survey will be conducted with the researchers and the information collected in this survey will include age, gender, Aboriginal and Torres Strait Islander status, country of birth, ethnicity, highest level of education, health literacy, postcode, language spoken other than English and the time on dialysis (months). This will take about 30 minutes and will be completed during your normal dialysis session.
- Participants will be randomly allocated to either an intervention or a control group for the duration of the research study period (twelve weeks).
- Interdialytic weight gain will be the main measure of this study. Your weight will be measured by a nurse at the beginning and end of each dialysis session for twelve weeks. This data will be collected by the research staff at four-week intervals.
- Pre-dialysis blood pressure (BP) will also be measured by a nurse at the beginning of each dialysis session for twelve weeks. This data will be collected by the research staff at four-week intervals.
- At the end of the study period (after four weeks), you will be given two short online surveys to complete related to your behaviours and confidence managing fluids. These will take approximately 10 minutes each to complete and will be completed during your normal dialysis session.

Are there any benefits?

This research project aims to further knowledge of strategies to manage fluids for patients undergoing haemodialysis treatment and may *improve* future clinical practice. However, it may not directly benefit you.

Are there any risks?

Minimal Risk – there is no foreseeable risk of harm or discomfort, and any foreseeable risk is no more than an inconvenience.

Confidentiality / Privacy

Any identifiable information that is collected about you in connection with this research project will be in coded form and will remain confidential. Only the research project team members named above will have access to your details.

All data will be held securely at the University of Sydney and all data will be password protected. Your data will be held for 5 years after the completion of the research project. You will not be identifiable in any publication or presentation. The findings will be presented in an aggregated form.

Will taking part in this research project cost me anything, and will I be paid?

Participation will not cost you anything, and you will not be paid.

What happens with the results?

We plan to present the results to the Faculty of Public Health at the University of Sydney. In any publication or presentation, information will be presented in an aggregated form, and you will not be identifiable. Results of the research project will be provided to you if you wish.

Who has approved this research?

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 HREC of Nepean Blue Mountains Local Health District. The HREC reference number for this study is [Insert HREC reference number].

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2024)*. This statement has been developed to protect the interests of people who agree to participate in human research studies. The NBMLHD HREC contact details are via the NBMLHD HREC. Phone: (02) 4734 1988 and Email: NBMLHD-Ethics@health.nsw.gov.au

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, then you may contact the researcher.

Research contact person.

Name	Nada Mustapha-Khodragha
Position	Researcher
Telephone	0402919115
Email	nmus2652@uni.usyd.edu.au

If you have any concerns about the conduct of the research project, or your rights as a research project participant, you may contact one of the following:

Complaints for Nepean Hospital:

The Nepean Hospital Feedback & Complaints Team
Email: NBMLHD-NepeanFeedback@health.nsw.gov.au , Ph. 4734 3174
You should quote [HREC reference number].

Complaints for Blue Mountains Hospital:

Contact on the Participant Information and Consent Form: Quality Safety Manager & Client Liaison Officer, Ph. 4784 6514
Email: NBMLHD-BlueMountainsFeedback@health.nsw.gov.au

Thank you for taking the time to consider this research project. If you wish to participate, please *sign the attached consent form.*

This information sheet is for you to keep.

Consent Form

Study Title: The use of a behavioural change strategy for fluid management in end-stage chronic kidney disease patients undergoing haemodialysis: A cluster randomised controlled trial.

Coordinating Principal Investigator: Danielle Muscat, USYD

Sites / Location: [XXX]

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 research 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 research project without affecting my future care.	☐
I acknowledge that any regulatory authorities may have access to my medical records **specifically related** to this research project to monitor the research in which I am agreeing to participate. However, I understand my identity will not be disclosed to anyone else or in publications or presentations.	☐
I understand that I will be given a signed copy of this document to keep.	☐

Name of Participant (please print): _____

Signature: _____ Date: _____

If you wish to receive a copy of the results of this study, please include your email in the box below.

Participant email (please print) _____

If you consent to the researchers contacting you throughout the study period to check on your progress, please include your phone number in the space below.

Participant phone number (please print) _____

Declaration by Researcher

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher† (please print): _____

Signature: _____ Date: _____

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

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