

Participant Information Sheet

Please complete the survey below.

Thank you!

University of Sydney (USYD)

Participant Information Sheet

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

Researcher Name: Nada Mustapha-Khodragha (Master of Public Health, USYD)

Researcher contact information: nmus2652@uni.sydney.edu.au OR 0402919115

Coordinating Principal Investigator: Dr Danielle Marie Muscat (Faculty of Medicine and Health, USYD)

Site of dialysis

- Blue Mountains District ANZAC Memorial Hospital Nepean Hospital Penrith Community Dialysis Centre Westmead Hospital

Participant information sheet

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.

Behavioural change strategy for reducing interdialytic weight gain in haemodialysis treated patients. Participant Information Sheet and consent form, Version 1.0. 14/05/2024

I agree to take part in this project.

- Yes
- No

Consent From

Please complete the survey below.

Thank you!

University of Sydney (USYD)**Consent Form for Participation in a Student Research Project**

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

Researcher Name: Nada Mustapha-Khodragha (Master of Public Health, USYD)

Researcher contact information: nmus2652@uni.sydney.edu.au OR 0402919115

Coordinating Principal Investigator: Dr Danielle Marie Muscat (Faculty of Medicine and Health, USYD)

3) Site of Dialysis

- Blue Mountains District ANZAC Memorial Hospital
 Nepean Hospital
 Penrith Community Dialysis Centre
 Westmead Hospital

4) Declaration by Participant (please select all boxes that apply)

- 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.

5) Name of Participant

6) Participant signature

7) Date of Consent

(All parties signing the consent section must date their own signature.)

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

9) 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.

10) I consent to a follow-up, if required, by the researchers' after the study is complete.

- Yes
- No

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.

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

11) Name of Researcher

12) Signature

13) Date

(All parties signing the consent section must date their own signature.)

Participant demographic form

Please complete the survey below.

Thank you!

Year of birth

Weight

Postcode (please specify)

Gender

- Female
- Male
- Self-described
- Trans or gender diverse
- Prefer not to say

Are you of Aboriginal or Torres Strait Islander Origin?

- Yes- Aboriginal
- Yes- Torres Strait Islander
- Yes-Both
- Neither
- Unknown

Were you born in Australia?

- Yes
- No (please answer question below)

If you were not born in Australia, please specify your country of birth.

Ethnicity

- Australian
- New Zealander
- Asian
- Indian
- Middle Eastern
- European
- North American
- South American
- African
- Decline to answer
- Other

Ethnicity- please specify in the box below

Do you speak any language other than English at home?

- Yes
- No

Languages spoken other than English

- Arabic
- Cantonese
- Greek
- Italian
- Mandarin
- Vietnamese
- Other (please specify below)

Language other than English spoken at home.

Highest Level of Education completed

- Postgraduate Degree
- Graduate Diploma or Graduate Certificate
- Bachelor's degree
- Advanced Diploma and Diploma
- Certificate III/IV
- Year 12
- Year 11 and below

Time on dialysis

- 1-6 months
- 6-12 months
- 1-4 years
- 5-8 years
- 9-12 years
- >12 years

We would like to know about your ability to understand and apply information that is related to your health.

For the following question, please tick the box that best represents your response.

	Not at all	A little bit	Somewhat	Quite a bit	Extremely
How confident are you at filling out medical forms by yourself?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

IDWG

Please complete the survey below.

Thank you!

29) Site of dialysis

- Blue Mountains
- Nepean
- Penrith Community Dialysis Centre
- Westmead

	session 1	session 1	session 2	session 2
week	{Pre-dialysis weight (kg)}	{Post-dialysis weight (kg)}	{Pre-dialysis weight (kg)}	{post-dialysis weight (kg)}
{IDWG}				
1	_____	_____	_____	_____
2	_____	_____	_____	_____
3	_____	_____	_____	_____
4	_____	_____	_____	_____
5	_____	_____	_____	_____
6	_____	_____	_____	_____
7	_____	_____	_____	_____
8	_____	_____	_____	_____
9	_____	_____	_____	_____
10	_____	_____	_____	_____
11	_____	_____	_____	_____
12	_____	_____	_____	_____
average IDWG	_____	_____	_____	_____

Pre-dialysis systolic BP

Please complete the survey below.

Thank you!

30) Site of dialysis

- Blue Mountains Hospital
- Nepean Hospital
- Penrith Community Dialysis Centre
- Westmead Hospital

session 1 session 2

week	Pre-dialysis systolic blood pressure	Pre-dialysis systolic blood pressure
1	_____	_____
2	_____	_____
3	_____	_____
4	_____	_____
5	_____	_____
6	_____	_____
7	_____	_____
8	_____	_____
9	_____	_____
10	_____	_____
11	_____	_____
12	_____	_____
average pre-dialysis sBP	_____	_____

Behaviour Questionnaire

Please complete the survey below.

Thank you!

We would like to know about the strategies that you used to control how much fluid you had. For each of the following statements, please tick the box that best represents your response.

Over the past four weeks....

	Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree
31) I kept track of the amount of fluid I had each day.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
32) I used strategies to have less fluids.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
33) I found it difficult to make changes to control my fluids.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
34) I used strategies to reduce the amount of fluid that I had when I was thirsty.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
35) I used strategies to reduce salt content in my food.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
36) I used strategies to drink less fluid when I was out with people.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
37) I used strategies to drink less fluid when I had a dry mouth.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
38) I used strategies to drink less fluid when I was feeling hot.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Confidence survey

Please complete the survey below.

Thank you!

We would like to know how confident you are in doing certain activities. For each of the following questions, please tick the box that best represents your response.

How confident do you feel that you can....

	Not confident at all	Slightly confident	Somewhat confident	Fairly confident	Totally confident
39) meet your daily fluid needs?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
40) keep track of the amount of fluid you had each day?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
41) use strategies to have less fluids?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
42) use strategies to manage how much fluid you have when you are feeling thirsty?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
43) use strategies to manage how much fluid you have when you are out with other people?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
44) use strategies to manage how much fluid you have when you have a dry mouth?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
45) use strategies to manage how much fluid you have when you are feeling hot?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
46) use strategies to manage how much fluid you have when you have been tempted to have a lot of salt in your diet?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>