**Using Mobile Phone Technology to   
Understand Fatigue, Mood and Activity   
Levels in People Receiving Peritoneal Dialysis**

**PARTICIPANT INFORMATION SHEET**

1. **Introduction**

You are invited to participate in a research study that is exploring the link between tiredness (fatigue), mood and physical activity levels for people receiving peritoneal dialysis

1. **What is the purpose of the study?**

Tiredness is commonly experienced by people receiving peritoneal dialysis that can impact your quality of life. It is complex and is related to many factors including mood and physical activity levels. Tiredness, along with mood and physical activity, have been recently identified as the outcomes that matter the most to people receiving peritoneal dialysis, however, little is known about the links between tiredness, mood and physical activity in people receiving peritoneal dialysis. To design treatments targeting tiredness, mood and physical activity levels, understanding the links between these factors is essential. This will be assessed using mobile phone technology (i.e. mobile application or APPs) which allows for capturing of information in real-time (i.e. as it happens).

1. **What does the study involve?**

If you agree to participate in the study, you will be assisted by an investigator in the download and use of the mobile application. The mobile application is pre-loaded with questions relating to tiredness and mood which you will be prompted to answer five times throughout the day over a seven-day period. The times are after you wake up, before you go to bed and then semi randomly on three occasions between these periods: Wakeup, 10am-1pm, 1pm-4pm, 4pm-7pm and at bedtime. You will also be asked to wear a watch for the same seven-day period which will capture your physical activity undertaken during this time.

1. **Who is undertaking this research?**

This research is being carried by researchers attached to the University of South Australia School of Health Sciences (UniSA) and Central Northern Adelaide Renal and Transplantation Service (CNARTS). If you have any questions relating to this study, please contact Mr Brett Tarca.

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1. **What changes will be made to my treatment if I decide to enter the study?**

Your medical care will continue as normal. The study will be assessing your tiredness,   
mood and physical activity levels using mobile technology and a watch over a single   
seven-day period but will not influence your usual care.

1. **What if I choose not to enter the study?**

This is a research project and you do not have to be involved. If you do not wish to   
participate, your medical care will not be affected in any way.

1. **What if I choose to enter the study and then change my mind?**

You may withdraw from the project at any time after you have commenced. Again, this will not affect your medical care in any way.

1. **What benefits will the study have to me?**

The study will not change your medical care but may inform future research trials involving interventions targeted at reducing the effects of tiredness, improving mood and physical activity levels. You will be compensated with a $100 Coles Myer gift card upon full individual completion of all study requirements.

1. **Will I be inconvenienced in any way by being in the study?**

All assessments are completed via mobile application and a physical activity measuring watch. If you do not own a mobile phone, one can be provided to you for the duration of the study and returned upon completion. You will be instructed on the use of all devices. You will also require an active e-mail for registering yourself on the mobile application. Should you be inconvenienced in any way, you are welcome to withdraw from the study at any point.

1. **Are there any foreseeable risks associated with being in the study?**

The questions asked may require you to think about things such as your, tiredness, mood and stress levels, that may be confronting for you. The research team can offer support or refer you to receive further support beyond the program. There are no other foreseeable risks associated with being in the study.

1. **Confidentiality and Data Security**

All data collected will be de-identified (your name will be replaced by a number) to ensure confidentiality is maintained. You will not be identified in any publication or presentation. Only information relevant to the study will be collected. Only researchers/investigators involved in the study data collection, analysis and reporting of results will have access to the data. All data collected in paper form will be stored securely at UniSA, School of Health Sciences in a locked filling cabinet in a locked office. All data collected in electronic form will be stored on the UniSA database or a password protected USB which will be locked in a filing cabinet in a locked room when not in use. All data will be stored for 15 years then destroyed.

In addition to the processes described above, data may otherwise be discoverable through processes of law or for assessing compliance with research procedures. You have a right to access the information collected and stored by researchers about you. You also have a right to request that any information with which you disagree be corrected. You have a right to ask that any stored specimens be destroyed but should be aware that data which has already been derived from those specimens may not be able to be destroyed

**12. Who can I contact if I have concerns?**

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007) incorporating all updates. This statement has been developed to protect the interests of people who agree to participate in human research studies. The study has been approved by the Central Adelaide Local Health Network Human Research Ethics Committee. If you wish to speak to someone not directly involved in the study about your rights as a volunteer, or about the conduct of the study, you may also contact the CALHN HREC Chairperson, on 7117 2229

**MEASURING TIREDNESS, MOOD AND ACTIVITY   
IN PATIENTS ON PERITONEAL DIALYSIS**

**WHO**

Patients over 18 year’s old  
receiving peritoneal dialysis

**WHAT**

**HOW**

**WHY**

Understanding the changes that   
you experience throughout the day   
can assist in the specific design of interventions to enhance your   
quality of life



**REWARD**

You will receive a $100 Coles Myer   
Gift Card for your participation



A mobile application notifies you when it is time to answer 20 questions about your tiredness and mood



A wristwatch records your movement throughout   
the day and night

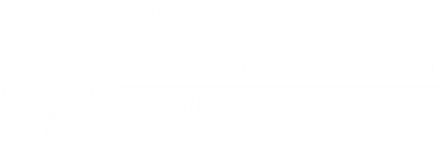


Both assessments are   
completed over 1 week

Exploring tiredness, mood and physical activity levels throughout the day and night over 1 week

**INTERESTED**

Inform the Home Training Unit staff or contact   
Brett Tarca - 8302 2906  
 brett.tarca@mymail.unisa.edu.au



**PARTICIPANT CONSENT FORM**

**PROTOCOL NAME:** Using Mobile Phone Technology to Understand Fatigue, Mood   
and Activity Levels in People Receiving Peritoneal Dialysis

HREC REFERENCE #:

**INVESTIGATORS**: Mr Brett Tarca, A/Prof Shilpa Jesudason, Mrs Michelle Ovenden, Ms Monique Borlace,   
Dr Katia Ferrar, Dr Tom Wycherley, Dr Terry Boyle, Dr Richard Le Leu, Mr Anthony Meade and Prof Paul Bennett.

LOCATION: Home visits or at a routine medical visit in clinic.

***If you consent to being involved in the study please sign and date below***

* I give permission for treating dialysis team to release my contact details (phone number / address / e-mail) to the research team for the purpose of discussing the project and / or arranging time and location for assessments to be completed.
* I give permission for my treating dialysis team to provide the research team with my medical history, dialysis history and dialysis related clinical data.
* The nature, purpose and risks of the research project have been explained to me. I have read the Participant Information Sheet or that someone has read it to me in a language that I understand. I understand it and agree to take part.
* I understand that I may be offered further support or clinical options if the study identifies factors that are impacting on my wellbeing.
* I understand that, while information gained during the study may be published, I will not be identified, and my personal results will remain confidential.
* I understand that any research data is potentially subject to disclosure through processes of law
* I understand that I can withdraw from the study at any stage and that this will not affect my medical care, now or in the future.
* I have had the opportunity to discuss taking part in this investigation with a family member or friend.
* I understand the data from this study will be stored in electronic and audio files for a period of 15 years in a password protected computer at the University of South Australia, Adelaide.
* I understand I should retain a copy of this Consent Form and Participant Information Sheet for future reference.
* I am happy to be informed of any future research projects that I may be involved in

Participant Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Dated: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Investigator to complete***

I certify that I have explained the study to the participant/volunteer and consider that he/she understands what is involved.

Signed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Dated: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_