

**Addressing safety, quality, and cost of care through a telehealth, outpatient transitional care model: the TTOMMI trial**

**Participant Information Sheet**

**HREC reference:** 17554

**Project sponsors:** Professor Gerry O’Callaghan, Executive Director of Medical Services, CALHN and Ms Amanda Clark, Executive Director of Nursing Workforce and Patient Experience, CALHN

**Coordinating Principal Investigator (CPI):** Professor Sepehr Shakib, Director, Clinical Pharmacology, Royal Adelaide Hospital.

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# Introduction

You are invited to take part in this project because you have been identified as an inpatient of the Queen Elizabeth Hospital (TQEH) or the Royal Adelaide Hospital (RAH) with multiple chronic health conditions. The research project aims to improve support for people with multiple chronic conditions after they have been discharged from hospital. This information sheet tells you about the project. Knowing what is involved will help you decide if you want to participate. Please read this information carefully. Ask questions about anything that you do not understand or want to know more about. Participation in this research is voluntary. If you do not wish to take part, you do not have to. You will receive the best possible care whether you take part or not.

# Aim of this research

The aim of this research is to trial a transitional care service for people with multiple chronic health conditions after they have been discharged from hospital. The service involves a nurse (Transition Coordinator) contacting people via telephone after their hospital discharge to follow-up and coordinate any additional care or services they require. The project intends to trial this service and see if providing people with additional support after discharge helps them to stay well.

# What does participation involve?

Participating in the transitional care service will involve: (1) an assessment of your risk of hospital readmission and support needs after discharge, and (2) receiving a telephone call from a nurse 2 days, 1 week, and 4 weeks after you leave hospital. In these phone calls, the nurse will ask about how you are managing your health and help coordinate any additional care or services you require. Participating will also involve: (3) sharing your deidentified administrative and clinical information that is gathered as part of the transitional care service, and (4) having the option to complete an anonymous survey about your experience when the project has finished. The survey will ask about your experience, satisfaction, and views on having a nurse provide additional follow-up support via telephone after hospital discharge. All information gathered as part of this study will be deidentified and analysed independently by the research team at the University of South Australia (UniSA).

As part of the research, the research team will be accessing deidentified clinical information about people who participate in the service. This will help us assess the relative benefit of providing the transitional care service **to** patients.

# Who is conducting this study?

This study is being conducted by a team of clinicians and researchers from the Central Adelaide Local Health Network (CALHN) and UniSA. The project is being funded by a CALHN CEO Clinical Rapid Implementation Project Scheme (CRIPS) grant.

# Do I have to take part?

This is a research project and you do not have to be involved, participation in any research project is voluntary. If you do not wish to participate, your medical care will not be affected in any way. Also, you may withdraw from the project at any time after you have commenced. Non- non-participation or withdrawal will not affect ongoing treatment/medical care. Your participation in this study shall not affect any other right to compensation you may have under common law

**Privacy**

In accordance with relevant Australian and/or South Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

# What will happen to information I provide?

By giving consent to participate in the research, you are agreeing to share your deidentified clinical data related to the project with the research staff for the purposes of this research only. All records (either electronic or hard copy medical records) containing personal information will remain confidential and no information which could lead to identification of any individual will be released, unless required by law. This requirement is standard and applies to information collected both in research and non-research situations. Such requests to access information are rare; however, we have an obligation to inform you of this possibility. 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.

Data gathered as part of this project will be stored in a password-protected database on a secure server at the University of South Australia, in a manner consistent with the Data Protection Act. The data will be accessible to the research team and will only be used for the purpose of this research. The findings may be published and/or presented in a variety of forums including reports, academic journals, and conferences. The study’s data confidentiality and security measures include:

* **Location of data storage:** All data gathered as part of this project will be stored in a password-protected database on a secure server at the University of South Australia, in a manner consistent with the Data Protection Act.
* **Who has access:** The Coordinating Principal Investigator and other investigators listed at the end of this information sheet.
* **How is the data secured:** Dr Kate Davis will be the Study Data Manager and responsible for a data management plan. The plan will outline systematic steps for data handling and record keeping of collected data and will be lodged in accordance with University of South Australia policies and procedures.
* **Duration of storage of data:** 15 years, consistent with national guidelines and UniSA policy and procedures guidelines for general research.
* **Method of data destruction:** In line with UniSA ‘Ownership and Retention of Data’ Policy, Point 7. Destruction of Research Data, Research Records and Primary Material. (This includes any information collected prior to a participant’s withdrawal from the study).
* **How we will disseminate results of the study:** It is important to disseminate research results to the healthcare community and research participants. This will be achieved through academic journal publication, conference, and internal institutional publication. A copy of the published articles related to the research will be sent to participants. Articles will be either mailed by post or emailed as requested by participants.

# What are the possible benefits of taking part?

We cannot guarantee that you will receive benefits from this research, however, possible benefits may include additional care coordination after hospital discharge, improved symptom management and self-efficacy, reduced likelihood of being readmitted to hospital, and the opportunity to report your own experience. There will be no payment or reimbursement for participation in the research.

# What are the possible risks and disadvantages of taking part?

Aside from your time, we do not expect there will be any foreseeable risks or costs associated with taking part in the transitional care service or survey. Other than possible inconvenience or discomfort associated with answering the survey, there are no anticipated disadvantages. You are free at any stage to withdraw from receiving the transitional care service or completing the survey.

# What happens when the research project ends?

The aim of the project is to support patients through the transition from hospital to their home. When the research project ends, participants will continue to access their local primary (GP) and specialist healthcare services as usual.

# Who has reviewed the research project?

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 Chairperson, on 7117 2229 or email: [Health.CALHNResearchEthics@sa.gov.au](mailto:Health.CALHNResearchEthics@sa.gov.au)).

# Complaints and contacts

For further information about the study or transitional care service, please contact Professor Sepehr Shakib (Coordinating Principal Investigator) or Dr Kate Davis (Study Investigator) using the contact details below.

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| **Study investigator details** | |
| **Name:** | **Professor Sepehr Shakib** |
| **Position:** | Director, Clinical Pharmacology, Royal Adelaide Hospital |
| **E-mail:** | [Sepehr.shakib@sa.gov.au](mailto:Sepehr.shakib@sa.gov.au) |
| **Telephone:** | 0411100278 |

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| **Name:** | **Dr Kate Davis** |
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| **E-mail:** | [Kate.davis@unisa.edu.au](mailto:Kate.davis@unisa.edu.au) |
| **Telephone:** | + 61 8 8302 2129 or 0417893274 |

If you have ethical concerns about the study, questions about your rights as a participant, or should you wish to make a confidential complaint, please contact CALHN Research Services (telephone: 08 7117 2229, email: [Health.CALHNResearchEthics@sa.gov.au](mailto:Health.CALHNResearchEthics@sa.gov.au)).

Reviewing HREC approving this research, HREC Executive Officer details and Complaints Contact:

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| **Ethics Committee** | |
| **HREC Name** | Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC) |
| **Contact** | HREC Support Officer |
| **Telephone** | (08) 7117 2229 |
| **Email** | [Health.CALHNResearchEthics@sa.gov.au](mailto:Health.CALHNResearchEthics@sa.gov.au) |