Participant Information Sheet
REMIT-2D Study

Lyell McEwin Hospital

Title	Initiation of a novel In-Hospital Treatment for Patients with Type 2 Diabetes (REMIT-2D) project.
Short Title	A type-2 diabetes in-hospital treatment
Protocol Number	HREC/19/CAHLN/156
Project Sponsor	Medical Research Future Fund
Coordinating Principal Investigator/ Principal Investigator	Professor Gary Wittert Head Discipline of Medicine, Medical Specialties University of Adelaide , SAHMRI North Terrace Ph. (08) 8128 4830 Email: gary.wittert@adelaide.edu.au
Associate Investigator(s)	Dr Odette Pearson Senior Research Fellow, University of South Australia, and Wardliparingga Aboriginal Research Unit SAHMRI Prof Robert Adams Professor of Medicine, University of Adelaide A/Prof Billingsley Kaambwa Head of Health Economics, College of Medicine and Public Health, Flinders University Prof Mark Boyd Chair of Medicine, Lyell McEwin Hospital, Elizabeth Vale, University of Adelaide Dr Isuru Ranasinghe National Heart Foundation Future Leader Fellow and Senior Research Fellow in the Discipline of Medicine, Central Adelaide Local Health Network A/Prof Peak Mann Mah Endocrinologist and General Physician, Northern Adelaide Local Health Network Dr Elaine Pretorius Divisional Director (Medical), Division of Medicine, Norther Adelaide Local Health Network

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in a research project because you have been admitted to the Lyell McEwen hospital with a heart problem and you may also have been told that you have a condition called Type 2 Diabetes.

The research project is called: REMIT-2D, short for "Reducing Morbidity by Initiation of a novel In-Hospital Treatment for Patients with Type 2 Diabetes". The project evaluates whether a new in-hospital educational treatment for patients hospitalised with Type 2 Diabetes improves care.

This participant information sheet tells you about the research project. It explains the tests and treatments involved. 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 your 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 have the tests and treatments that are described
• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information Sheet and Consent Form to keep.

2 What is the purpose of this research?

Around 280 Australians develop diabetes every day. That's one person every five minutes. People with diabetes are more likely to be hospitalised and if so, spend more time in hospital.

When patients with Type 2 Diabetes are hospitalised, this provides an important and frequently missed opportunity to improve their care by:

- optimising the coordination of care
- offering extra support when necessary
- training people's self-management skills.

The aim of this research project is to implement and improve an in-hospital educational treatment for people admitted to the Lyell McEwin Hospital with a heart condition and Type 2 Diabetes to improve (self) care and reduce the chance of being hospitalised. The treatment will be aimed towards improvement of the participants' understanding of diabetes related information and the participants' self-management skills. We will also try to identify potential barriers for improvement in the participants' care.

The study results may help to improve the care for participants with Type 2 Diabetes. The final aim is to make an easier journey for people with Type 2 Diabetes throughout their treatment.

This research has been initiated by the study doctor, Professor Gary Wittert and has been funded by the Commonwealth Government's Medical Research Future Fund.

3 What does participation in this research involve?

This is a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. You will be randomly allocated (like flipping a coin) to one of 4 groups. The results are compared to see if one is better to proceed with what is already standard care for patients with diabetes (one study group) or to receive new in-hospital educational treatments (4 study groups).

If you decide to participate in this study, we will first ask you to sign the study consent form. After you have signed this we can put you in one of the four study groups and we will plan a session with you to complete a set of questionnaires. We estimate that it will take you around 1.5 hours to complete this set of questionnaires. The study care coordinator will stay with you when you are completing these questionnaires and will assist you whenever necessary. Some of the questionnaires will be interviewer-based, meaning that the study care coordinator will ask you questions and will write down the answer. The study care coordinator will also collect some extra medical data from your medical documentation. You may choose to have a relative or friend present with you when you complete the questionnaires.

The questionnaires will be delivered via electronic tablets by the Care Coordinator and include questions regarding your:

- general information
- physical activity
- emotional burden arising from living with and managing diabetes
- belief in your ability to self-manage diabetes
- fruit and Vegetable intake
- sugar intake behaviour
- sleep quality
- mental health
- understanding of health information and services

Study group 1:
If you are allocated to study group 1, you will receive 3 standard handouts from the Diabetes Australia Foundation on healthy diet, physical activity and understanding diabetes.

Study group 2, 3, or 4:
If you are allocated to study group 2, 3, or 4, the study care coordinator will plan an extra 30 min session with you to discuss:

- Study group 2:
  - The study self-care, coping, sleep, **AND a Diabetes Australia factsheet on healthy diet**
- Study group 3:
  - The study self-care, coping, sleep, **AND the Study factsheet on muscle resistance training plus the Diabetes Australia factsheet on healthy diet**
- Study group 4:
  - The study self-care, coping, sleep, **AND the study healthy diet, and muscle resistance training**

The study project manager will contact you at 6 weeks and 12 months after hospital discharge to ask you to have a follow-up test for your HbA1C level (average 3-month blood sugar level)

and triglyceride level. In addition, you will get a phone call from the project manager to repeat the Diabetes Distress Scale Questionnaires. The project manager will provide you with the required form for this. The testing can be done at a SA Pathology collection centre and the Care coordinator will give you a list of these at discharge along with the pathology request forms. in your community.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and prevents the wrong conclusions. The principal investigator and the REMIT-2-D Expert project team will be responsible for the monitoring and review of data collection and storage.

There are no additional costs associated with participating in this research project, nor will you be paid. All medication, tests, and medical care required as part of the research project will be provided to you free of charge.

If you decide to participate in this research project, the study doctor will inform your local doctor.

4 What do I have to do?

For this study you will be asked to:

- While in hospital, complete a set of questionnaires with help from a study Care Coordinator, which will take approximately 1.5 hours.
- While in hospital, attend an education session with the study Care Coordinator which will take approximately 30 mins (only for participants assigned to study group 2, 3, or 4)
- At 6 -weeks from hospital discharge - have a blood test to measure your average 3-month blood sugar level (HBA1C) and cholesterol (triglyceride)
- At 6 weeks form discharge – receive a phone call from the study manager who will remind you to have your blood test done and repeat the diabetes distress scale questionnaire.

Participation in this study does not require any lifestyle restrictions, dietary restrictions, or medication changes.

5 Other relevant information about the research project

The current study aims to include 198 participants hospitalised for a heart condition and being diagnosed with Type 2 Diabetes over a period of 8 months. Recruitment will take place in the Lyell McEwin Hospital in South Australia. Included participants will be allocated to three different study groups (one usual care group and three educational study groups) and followed-up for 12 months.

The Principal Investigator of this study, Professor Gary Wittert, is based at the South Australian Health and Medical Research Institute (SAHMRI). Associate investigator Professor Mark Boyd is based at the Lyell McEwin Hospital. The other associate investigators are from a variety of different institutions and are experts in aspects of this study.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information Sheet and Consent Form to sign and you will be given a copy to keep.

Your decision on 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 the Lyell McEwin Hospital.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at the Lyell McEwin Hospital. If you choose not to participate, you will receive the standard treatment, and nothing will change for you. The study care coordinator will discuss these options with you before you decide whether to take part in this research project. You may also wish to discuss your options with the ward nursing or medical staff or a trusted family member or friend.

8 What are the possible benefits of taking part?

If you are allocated to the *new health information* you may receive some added knowledge and understanding about how to manage your diabetes condition. Otherwise by participating in this research you could be benefitting patients with T2DM in the future.

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

There may be some risks associated with having a blood test and may include discomfort at the site of puncture; possible bruising and swelling around the puncture site; rarely an infection; and, uncommonly, faintness from the procedure. Otherwise there are no risks associated with this study.

Each health education component is proven to be of benefit in other programs, but the purpose of this study is to discover which components of the treatment package are of most benefit.

If you find participation in the study too tiring or upsetting, we will adapt to your needs by delivering diabetes education that you prefer but we will not be able to include your information in the study.

10 What will happen to my test samples?

Samples of your blood will be analysed at 6 weeks to test your average 3-month blood sugar level and cholesterol level. This will be done as part of routine care. However, we will need specific consent from you for analysis of these samples for research purposes, so this has been added to the consent form.

Samples of your blood obtained for this research project will not be transferred to other organisations. After analyses of the required blood glucose control variables, the blood sample will be disposed of as usual.

11 What if new information arises during this research project?

Sometimes during a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Given the nature of the treatment package it is highly unlikely that educational resources for diabetes-related health literacy will impact the continuation of the study but if it is we will notify you.

12 Can I have other treatments during this research project?

You can continue with all your regular treatment during this research project.

13 What if I withdraw from this research project?

You can withdraw without providing an explanation at any time. If you decide to withdraw from the project, please notify a member of the research team. The study doctor and relevant study staff 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 them to do this, you must tell them before you join the research project.

14 Could this research project be stopped unexpectedly?

No, this research is highly unlikely to be stopped unexpectedly.

15 What happens when the research project ends?

Nothing else will be required of you however the Principle Investigator will send you a copy of the results. At all times your individual data will be protected and de-identified.

Part 2 How is the research project being conducted?

16 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 for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your information will only be used for this research project and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at this and other health services for this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

The data collected from the study will be entered into a database (called REDCap) provided by the University of Adelaide. Study participants will be allocated a unique study code and identifiers *will not* be entered in the study database. The database is password protected and only accessible by the principal investigator and project managers. After the Project, the original data files will be archived on an encrypted USB drive at Adelaide University and stored in a safe until for five years and subsequently destroyed.

An important component to studying the effects of health education tools is to also to assess the availability and use of health services and medications. This is an area of health that is poorly understood and may involve utilisation of other available health databases.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

17 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

18 Who is organising and funding the research?

This research project is being conducted by Professor Gary Wittert and is being funded by the Commonwealth Government's Medical Research Future Fund

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

19 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 HREC of the Central Adelaide Local Health Network.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

20 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 or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact Professor Gary Wittert, the principal study doctor, Carolyn Astley, the Project manager, or Kate Neadley, the Care-coordinator (during office hours):

Clinical contact person

Name	Professor Gary Wittert
Position	Principal investigator
Telephone	*08 8128 4887*
Email	gary.wittert@adelaide.edu.au

Project manager

Name	Carolyn Astley
Position	Project manager REMIT-2D project
Telephone	08 8128 4887
Email	carolyn.astley@sahmri.com

Study care coordinator

Name	Kate Neadley

Position	Study care coordinator
Telephone	08 8128 4887
Email	katie.neadley@gmail.com

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:

Complaints contact person

Name	Mr Ian Tindall
Position	HREC Chair
Telephone	08 7117 2229
Email	Health.CALHNResearchEthics@sa.gov.au

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Central Adelaide Local Health Network (CALHN) Human Research Ethics Committee
	HREC Executive Officer
Telephone	08 7117 2229
Email	Health.CALHNResearchEthics@sa.gov.au

Reviewing HREC name	Aboriginal Health Research Ethics Committee (AHREC)
	HREC Executive Officer
Telephone	08 7117 2229
Email	ahcsa@ahcsa.org.au

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

Name	**Roy Sneddon**
Position	**NALHN Research Governance Officer**
Telephone	08 8182 9346
Email	*healthnalhnrgo@sa.gov.au*

Consent Form - *Adult providing own consent*

Title	Initiation of a novel In-Hospital Treatment for Patients with Type 2 Diabetes (REMIT-2D)
Short Title	A type-2 diabetes in-hospital treatment
Protocol Number	HREC/19/CAHLN/156
Project Sponsor	Medical Research Future Fund
Coordinating Principal Investigator/ Principal Investigator	Professor Gary Wittert
Associate Investigator(s)	Dr Odette Pearson Prof Robert Adams A/Prof Billingsley Kaambwa Prof Mark Boyd Dr Isuru Ranasinghe A/Prof Peak Mann Mah Dr Elaine Pretorius
Location	Lyell McEwin Hospital SA Department for Health and Ageing

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 give permission for my medical records to be accessed during this study; ☐ Yes ☐ No

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the University of Adelaide concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential; ☐ Yes ☐ No

I agree to have a blood test performed at 6 weeks from discharge from hospital to measure my blood sugar (HbA1C) and cholesterol (triglyceride) levels.

I give permission for the Care Coordinator to call me at 6 -weeks post hospital discharge to answer a repeat Diabetes Distress scale questionnaire; ☐ Yes ☐ No

I give permission for my de-identified data to be used from other health databases up to 2 years from the end of the study; ☐ Yes ☐ No

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 study 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 _____

Name of Witness* to

Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior 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 Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior 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.

I understand that, if I decide to discontinue the study treatment I will not be required to participate in any further study procedures.

I consent to the use of blood samples taken from me for use, as described in the relevant section of the Participant Information Sheet, for:

- This specific research project.

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to
Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

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 the research project.

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

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

Title	Initiation of a novel In-Hospital Treatment for Patients with Type 2 Diabetes (REMIT-2D) project
Short Title	A type-2 diabetes in-hospital treatment
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Coordinating Principal Investigator/ Principal Investigator	Professor Gary Wittert
Associate Investigator(s)	Dr Odette Pearson Prof Robert Adams A/Prof Billingsley Kaambwa Prof Mark Boyd Dr Isuru Ranasinghe A/Prof Peak Mann Mah Dr Elaine Pretorius
Location	Lyell McEwin Hospital SA Department for Health and Ageing

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 the Lyell McEwin Hospital.

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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 Study Doctor/Senior 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.