Participant Information Sheet

Title	Do enhanced general practice services improve health outcomes and health service use? Flinders QUality Enhanced general practice Services Trial (Flinders - QUEST)
Protocol Number	Q1720
Project Sponsor	Flinders University
Principal Investigator	Professor Richard Reed
Location	Adelaide, South Australia

PART 1 What does my participation involve?

1. Introduction

You are invited to take part in this research project. This is because your General Practitioner (GP) identified that you have health care needs that might possibly benefit from the enhanced general practice services that you may be offered in the research project.

This Participant Information Sheet tells you about the research project. 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, a doctor or a member of the QUEST research team.

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 from your GP 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 your Consent Forms to keep.

2. What is the purpose of this research?

Studies performed overseas have found that enhanced general practice services can improve health outcomes for people with high health care needs. These enhanced services include enrolment to a preferred GP, access to longer appointment times and follow-up after significant health events such as a hospitalisation.

Whether enhanced general practice services would be effective in Australia however is not known. This research will test whether Australian general practices that are supported to provide enhanced services do in fact produce better health outcomes for their patients.

The results from this research study will be used to help guide decisions about the types of services GPs should provide to help their patients achieve the best possible health outcomes.

3. What does participation in this research involve?

You will be participating in a randomised controlled trial. Randomised controlled trials are the gold standard for evaluating models of care and typically compare an intervention group (in this case receiving enhanced services) with a control group (in this case receiving usual care).

In this research project, 20 general practices and 1100 people will participate in the trial. Half the general practices will provide their enrolled study participants with enhanced services (the Intervention arm). The other half of the general practices will provide their enrolled study participants with usual care (the Control arm). General practices will be randomly allocated to the Intervention or Control arms of the trial. The random allocation of practices to the Intervention or Control groups will be performed using a computer program at Flinders University. This will be like tossing a coin; and your General Practitioner will not know (and cannot influence) the result of whether their practice will be in the Control or Intervention arm in advance."

General practices in the Intervention arm will be supported (by Research staff from Flinders University as well as financially) to provide the enhanced services for a period of 12 months to participants enrolled in the trial.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no additional costs associated with participating in this research project, nor will you be paid. If you are in the Intervention arm of the study the enhanced general practice services delivered as part of the research project will be provided to you at no additional charge. You will however be required to pay your normal practice consultation fees.

4. What do I have to do?

If you decide you want to take part, you will be asked to sign two Consent Forms. One Consent Form relates to taking part in the study and the other Consent Form is specifically to allow the researchers to access your health information held by Medicare.

By signing these forms you are telling us that you: (1) understand what you have read; (2) consent to take part in the study; (3) consent to have the tests and treatments that are described; (4) consent to the use of your personal and health information.

You will be asked to answer a short questionnaire about your health conditions, how your health impacts your day-to-day activities, how you find and use health information and how you interact with doctors and other health care providers. Over a 12 month period you will be asked to complete these questionnaires three times (i.e., upon registering for the study, at 6 months and at 12 months). In recognition of your contribution to the study, you will receive a gift card (valued at $10) when we send you each questionnaire.

5. Do I have to take part in this study?

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 Forms to sign and you will be given a copy to keep.

Your decision as to whether to take part or not to take part, or to take part and then withdraw, will not affect your treatment by your GP (or any other health professional) or your relationship with Flinders University.

6. What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research. If however you are in a practice that has been allocated to the Intervention arm of the research, study benefits may include longer appointment times with your GP and better follow-up if you experience a significant health event such as a hospitalisation. You will also be contributing to health research and, if the study is successful, you will be helping other people with health conditions.

7. What are the possible risks and disadvantages of taking part?

There are unlikely to be any risks associated with the study or disadvantages in terms of effects on your health.

8. Can I have other treatments during this research project?

Yes. There are no restrictions whatsoever on the treatments or medications you can receive during this research project.

9. How will we find out details about your health?

An important component of this study is finding out information about your health. We will ask you questions about your health in three surveys we would like you to complete. In addition, we would like to obtain information from various other sources such as your general practice records, public and private hospital records and Medicare and Pharmaceutical Benefits Scheme (PBS) records.

To enable access to your Medicare and PBS records you will be asked to fill out two Consent Forms authorising the study access to your complete Medicare and PBS data as outlined on the back of the Consent Form. Medicare collects information on your doctor visits and the

associated costs, while the PBS collects information on the prescription medications you have filled at pharmacies. The Consent Form is sent securely to the Department of Human Services (DHS) who holds this information confidentially.

10. What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any issues linked to withdrawing.

If you do withdraw your consent during the research project, the research 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 by the researchers 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.

11. Could this research project be stopped unexpectedly?

It is unlikely that this research project could be stopped unexpectedly but it might occur, for example, if funding was withdrawn from the project. In addition it is possible that your general practice may withdraw from the study. If the practice was in the Intervention arm of the study this would mean that their enrolled participants may no longer receive the enhanced services that were being provided as part of the study.

12. What happens when the research project ends?

If you have been a part of the Intervention arm of the study, your general practice will no longer be assisted to provide the enhanced general practice services to you. If you have been a part of the Control arm of the study, there will be no difference in the usual care that is provided to you from your general practice and treating doctor.

When the research project ends, you will be asked whether or not you would like to receive a summary of the results of the study.

PART 2 How is the research project being conducted?

13. What will happen to information about me?

By signing the Consent Forms, you consent to the 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.

Information about you will be obtained from your health records held at your general practice and health services (such as hospitals) for the purpose of this research. By signing the Consent Forms, you agree to the study team accessing health records if they are relevant to your participation in this research project.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities,

or as required by law. By signing the Consent Forms, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities.

The Flinders QUEST trial is bound by Commonwealth privacy legislation and must adhere to the guidelines of the National Health and Medical Research Council of Australia. All information collected will be treated confidentially and will be used for health research only.

Your data will be stored electronically on a central Flinders University Research Storage Protection server. This server is designed to securely store, protect and manage sensitive data and is underpinned by a number of security processes that ensure the confidentiality, integrity and availability of the information. Only QUEST trial staff will have access to your health information for the purposes of the research project.

At the completion of the Flinders QUEST trial (in 2019), we will continue to collect your health information (from general practice, hospitals and Medicare records) until the end of 2020. The purpose of this is to determine whether there have been any longer term benefits from the enhanced general practice services.

At the completion of the study, your information will be securely stored for a period of 15 years. Your Medicare and PBS data however will be destroyed after 7 years. This will include the Medicare/PBS Consent Form and the electronic data that has been sent to us by the DHS.

Your information will only ever be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored.

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, except with your permission.

Information about your participation in this research project may be listed in your health records.

In accordance with relevant Australian and 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.

14. 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.

15. Who is organising and funding the research?

This research project is being conducted by the Discipline of General Practice at Flinders University and is being led by Professor Richard Reed (Head of General Practice). The Royal

Australian College of General Practitioners and the Commonwealth Department of Health are funding this research. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages). General practices taking part in the research study are receiving additional payments to provide the enhanced general practice services.

16. Who has reviewed the study?

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 Southern Adelaide Clinical HREC.

A description of this clinical trial is available on http://www.anzctr.org.au, search ACTRN12617001589370. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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.

17. Further information and who to contact

Trial Manager

Name	Dr Leigh Roeger
Position	Trial Manager
Telephone	08 7221 8532
Email	leigh.roeger@flinders.edu.au

Clinical contact person

Name	Professor Richard Reed
Position	Chief Investigator
Telephone	08 7221 8530
Email	richard.reed@flinders.edu.au

For matters relating to research at the site at which you are participating, the details of the complaints person are:

Complaints contact person

Name	Villis Marshall
Position	Director, Office for Research
Telephone	08 8204 6453 / 0466 393 503
Email	Health.SALHNOfficeforResearch@sa.gov.au

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:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Southern Adelaide Clinical
Position	Executive Officer
Telephone	08 8204 6453
Email	Health.SALHNOfficeforResearch@sa.gov.au