

PARTICIPANT INFORMATION SUMMARY FOR CARERS

You are invited to take part in a research project evaluating the Further Enabling Care at Home (FECH) program. *This summary provides a brief explanation. Detailed information is in the following pages.*

What is this project about?

Family members or friends who provide regular, unpaid, ongoing physical and/or emotional care for an older person living at home are sometimes called 'carers'. This project tests a program designed to support such carers after the older person receiving care goes home from hospital.

Do I have to take part in the research project?

You don't have to take part if you don't want to. If you do decide to take part, you can change your mind and withdraw from the study.

Who is involved in this project?

The study is being conducted by a team of researchers led by Curtin University in Western Australia (WA) and Griffith University in Queensland (Qld). Hospitals involved are Sir Charles Gairdner Hospital in WA, Gold Coast University Hospital and Robina Hospital in Qld.

Why am I being invited to participate?

You are invited to take part as a carer of a patient aged 70 years or older who is being discharged home from one of the included hospitals. The patient will not be included in the study unless you agree to take part as well. If you both take part, information for the study will be collected from you about yourself and about the health, care, and support needs of the person for whom you provide care.

What will I have to do?

- Answer initial questions over the phone about yourself and the patient (for about 30 minutes).
- Complete questionnaires (by phone or online) soon after you join the study then 3, 6, and 12 months later, taking 20-30 minutes each time.
- Allow us to access routinely collected information about your use of health services, such as your visits to a GP or a hospital, and your use of prescription medicines.
- You will have a 1 in 2 chance (like tossing a coin) of being included in the FECH program. If you do receive this program, which is additional to usual post-discharge support, you will be telephoned by a nurse 6 times over 6 months. The first call will last about 15 minutes, the second about 45, and the remainder about 30 minutes each. The nurse's role is to guide you to identify and address any support needs. You may also be invited to describe your experiences of the program in a 10 minute phone interview.

Are there any benefits to being in the project?

We can't promise any benefits for you from participation in the study. However, you may like to contribute to a study that might help some carers.

Are there any potential risks?

There are no expected risks. You might sometimes feel tired or upset talking about the problems you face. Involvement in the study will also take some of your time.

What will happen to my information?

All the information we collect from you is confidential. Information you provide for the study will be identified by a code. All the information we collect from you will be securely stored at the University or hospital.

Will you tell me the results of the research?

You can ask for your own results (your summarised responses to the questionnaires) at any point during this study and at the end. Reports of the study may be published but you will not be identifiable.

Who can I contact about the research?

If you would like a researcher to contact you about becoming involved, you can contact our research team: Tammy Weselman, mob) 0410 426 005 or complete your details, tear off the section below and make sure it is put into the box provided at the nurses' station.

✂.....

Full Name: _____

Daytime phone number: _____ Mobile phone number: _____

Participant Information Sheet/Consent Form (Western Australia)**Interventional Study – Family Carer providing own consent**

Title	Multicentre randomised controlled trial: caregiver, patient, and system outcomes from a program supporting informal caregivers of older people discharged home from hospital
Short Title	Evaluating the Further Enabling Care at Home (FECH) post-discharge program as a way to support carers of older hospital patients.
Protocol Number	APP1157834 Version 6 May 14 2020
Project Sponsor	Curtin University
Coordinating Principal Investigator/ Principal Investigator	Professor Anne-Marie Hill
Chief Investigator(s)	Prof Wendy Moyle, Assoc Prof Rachael Moorin, Prof Keith Hill, Assoc Prof Susan Slatyer, Assoc Prof Christina Bryant, Dr Nicholas Waldron, Prof Samar Aoun, Dr Richard Parsons
Location	Sir Charles Gairdner Hospital

Part 1 What does my participation involve?**1 Introduction**

You are invited to take part in this study as a carer of an older patient discharged home from Sir Charles Gairdner Hospital. For this study, a carer is defined as a family member or friend who provides regular, unpaid, ongoing home based physical and/or emotional care to an older person. The study is evaluating a program designed to support carers of older hospital patients who are returning home.

This Participant Information Sheet tells you about the research project. It explains what is 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.

Your participation is voluntary

Your participation in this study is completely voluntary and there will be no cost to you. If you do not want to take part in this study you do not have to. You should feel under no obligation to participate in this study. Choosing not to take part in this study will not affect your current and future medical care in any way. Care within the hospital for the person for whom you provide care, and for you (if required), will not be affected 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 form. By signing it you are telling us that you:

- Understand what you have read.
- Consent to take part in the research project.
- Consent to take part in the assessments and program 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 and Consent Form to keep.

Your withdrawal from the study

You are under no obligation to continue with the research study. You may change your mind at any time about participating in the research. People withdraw from studies for various reasons and you do not need to provide a reason.

You can withdraw from the study at any time by completing and signing the '**Participant Withdrawal of Consent Form**'. This form is provided at the end of this document, and is to be completed by you and supplied to the research team if you choose to withdraw at a later date. If you withdraw from the study, you will be able to choose whether the study will destroy or retain the information it has collected about you. You should only choose **one** of these options. Where both boxes are ticked in error or neither box is ticked, the study will destroy all information it has collected about you.

2 What is the purpose of this research?

This study is being conducted to evaluate how providing extra support for family carers - after the older person for whom they provide care is discharged from hospital - affects these carers, the older patients themselves, and the Australian health system.

This study will trial the *Further Enabling Care at Home (FECH)* telephone outreach program, which was first evaluated in 2016 at Sir Charles Gairdner Hospital in Western Australia. In that smaller project, the FECH program was found to improve how prepared carers felt to provide care and to reduce their stress. We now want to see if the FECH program benefits family carers and the older persons receiving their care over the longer term as well as being affordable for the Australian health system.

This research was initiated by Associate Professor Christine Toyne of Curtin University. This research has been funded by an Australian National Health and Medical Research Council (NHMRC) Project grant and by Curtin University.

3 What does participation in this research involve?

If you agree to take part, you will continue to receive the usual support provided to carers of patients discharged from this hospital. After you sign and return the consent form, a research assistant will telephone you to arrange a convenient time for an initial telephone survey. This call, conducted just after the discharge, will collect details about you, the older person for whom you provide care, and the care services accessed to support the older person. Responses you provide over the telephone will be entered into an electronic database by the person who calls you.

The study is seeking to determine how a particular type of additional support for family carers may provide benefits for them and the patients for whom they provide care – and any costs or cost savings that the health system may incur as a result. To achieve this, some family carers will receive existing support and some will receive existing support plus additional support. You will be randomly allocated, like tossing a coin, to either receive usual post-discharge support, or to receive usual post-discharge support plus the FECH program. If you take part in the FECH program, the details you have provided about yourself, the care you provide, and the older person's health plus their care and support needs will also be provided to the nurse who delivers that program. This is so that the program can take account of the caregiving situation and you don't need to be asked these questions again.

The FECH program consists of **6 telephone contacts from a nurse in the first 6 months after discharge**. If you are included in the program, each telephone call will be organised to take place at a time that suits you. The first contact will be approximately one week after discharge and take about 15 minutes. We will check some details about you and the care you provide to the older person following discharge. The second telephone call will be about a week later (2-weeks post-discharge) and take approximately 45 minutes. This is when you will be asked about any support needs you have and the nurse will work with you to find ways of addressing these needs. You will then be called again at approximately 1, 2, 4, and 6 months after the discharge, with each telephone call taking approximately 30 minutes. These calls will review your support needs and how they are being met or if they are still to be addressed. To check that the program is being conducted as planned, one of these sessions may be digitally audio recorded.

Some carers who receive the FECH program will also be invited to participate in an individual interview to explore their thoughts about the program, both during and after the FECH program has finished. These interviews will be conducted over the telephone with an experienced interviewer and will take around 10 minutes. Any identifying information will be removed when the interview is typed up and the digital audio recording erased from the recorder. The audio recording will then only be in a secure password protected file until analysis is complete, after which it will be deleted. Some quotes may be used when writing the results up, but individuals will not be identifiable.

All carers who take part, whether receiving usual support only or usual support plus the FECH program, will be asked to complete questionnaires just after the discharge and 3 months, 6 months, and 12 months later. We will call you just after the discharge to ask for some details about you, the person for whom you provide care, and the care you provide, which will take about 30 minutes. You can then complete the questionnaires over the telephone or electronically (your choice on each occasion). Each time you answer the questionnaires it will take about 20-30 minutes. Questions are mainly about your health and well-being but we also seek information about the care needs of the person for whom you provide care and any care services accessed. We will call to remind you when questionnaires are due to be answered. If you are answering these over the phone, we will arrange a suitable time with you. If the patient (the person for whom you provide care) is unable to rate their symptoms over the phone we will ask you to do this instead.

How long does the study last?

Your participation in the study would be for 12 months. If a time arranged for us to call becomes inconvenient, you can call the following number (mob) 0413 097 981 to postpone the calls to ensure that we do not trouble you.

What other information is collected?

So that we can understand how this project benefits the Australian health system, we will collect health care information. We will need information about your use of emergency departments; details of hospital stays; mortality; any Medicare funded services, such as visits to your GP; and medications prescribed – for the 12 months prior and at least 12 months following your agreement to take part in this study, that is, up until December 31 2022. **These data are already routinely collected** and will be provided to our study team by the Data Linkage Branch of the Department of Health of Western Australia and Services Australia. This information will allow us to check the extent of any increased or decreased use of health services or medicines – and related costs to the system - when a carer is included in the FECH program. For example, carers may visit a doctor and be prescribed medicine if they become stressed or are injured when providing care, which would incur costs covered by Medicare or the Pharmaceutical Benefits Scheme. If carer inclusion in the FECH program means that this happens less often, costs to the system would be reduced, which might then justify costs to run the program.

Medicare Benefits Schedule (MBS) and/or Pharmaceutical Benefits Scheme (PBS)

You will be asked to sign a consent form authorising the study to access your complete Medicare Benefits Schedule (MBS) and/or Pharmaceutical Benefits Scheme (PBS) data as outlined in 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 Services Australia, which holds MBS and PBS data confidentially.

What if the person for whom I provide care does not understand about this study?

If the person for whom you provide care is unable to read and understand the study information at the time of the hospital discharge, we are still able to include information already routinely collected for that person by the Department of Health of Western Australian in the study if you agree. This is the same kind of information described in the previous paragraph, but for the patient rather than for you. If this is the case, you will also be asked to provide the enclosed Patient Participant Information Sheet to the older person for whom you provide care (the patient), if and when they are well enough to read and understand this document. This information sheet is accompanied by an 'opt out' form, which provides an opportunity for the older person to refuse consent for information about him or her to be used for this study at that later date.

The opt out form would need to be returned by December 31st 2022 for the patient's data not to be used in the study, if this is their choice

Unless this form is returned, information that you provide as a carer will be linked with the patient's information during our study. This is to determine any impact upon the patient's use of health services from the way in which support is provided for the carer.

Is there any cost involved if I take part in the study?

There are no additional costs associated with taking part in this research project, nor will you be paid.

4 What do I have to do?

If you would like to take part in the study, you should sign and return the consent form to the research team member who is there to answer your questions, by email Tammy.Weselman@curtin.edu.au, or in the reply paid envelope provided. If you have questions and the research team member is not there, if it is too difficult to return the consent form in this way, or if you would prefer not to take part, please call us on mob) 0413 097 981.

5 Other relevant information about the research project

This research project is taking place in Western Australia and Queensland and includes older patients discharged from hospital wards in Sir Charles Gairdner Hospital in Western Australia and Robina and Gold Coast University hospitals in Queensland and their family carers. We are seeking 648 family carers and 648 patients (1,296 people in total) to complete the study. A carer cannot be included if the person for whom they provide care declines the opportunity to take part in the study.

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

As stated before, your decision to take part in this study is **voluntary**, that is, you may decide to be in this study or not take part in it at all. If you do decide to take part, you are able to change your mind at any time during the study. However, before you make any decision, it is important that you understand why this study is being done and what it will involve, including your rights and responsibilities. You will

be given a copy of this Participant Information Sheet and Consent Form to keep for your personal record. Any decision you make will not affect any benefit to which you would otherwise be entitled.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. If you do not wish to participate, you will receive usual support provided to patients and their families after discharge.

8 What are the possible benefits of taking part?

You may not receive any benefit from taking part in this study. You may enjoy sharing your caregiving experience, and having an opportunity to contribute to a study that is intended to benefit family carers, patients, and the health care system in the longer term. Some participants will receive advice and guidance from a nurse that has helped carers to feel better prepared to provide care and/or less stressed in a previous study. However, we cannot guarantee that such advice will be helpful for you or that you will receive it.

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

There are no risks anticipated, although you may feel tired or upset when talking about any problems. You can choose to take a break during any telephone calls or when answering questionnaires online, and continue when you are ready, or another day, or end your participation altogether. Usual post-discharge support provided by the hospital will not be affected.

10 Can I use other support services and health information during this research project?

You may access services and information outside of this project to help you in your caring role. We will ask you about these services and information so we can document this.

11 What if I withdraw from this research project?

If you do withdraw your consent during the research project, please use the attached withdrawal form to do so. The member of the research team can provide a replacement if you cannot find this form. You are also most welcome to call a member of the research team with any queries on mob) 0413 097 981

12 What happens when the research project ends?

At the end of the research project you will not be required to do anything else. A summary of the findings of this study will be made available to you upon request at the end of the study.

Part 2 How is the research project being conducted?

13 What will happen to information about me?

By signing the consent form, you give permission for the study research staff to collect and use your personal information for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. The information you contribute for this study will be identified by a code although, as we conduct the study, we will use your name, for example, when we call you. We will also use your email address if you choose to complete the questionnaires electronically. Only authorised persons, who understand that this information must be kept confidential, will have access to individual contributions, participant names, or email addresses. Access to study information is authorised and logged via the Research Governance System of the Department of Health of Western Australia.

Information about you may be obtained from your health records held at this and other health services for the purpose of 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. Your health records and any information obtained during the research project may be checked (to verify the procedures and the data) by the relevant authorities and authorised representatives. Authorised authorities include the Human Research Ethics Committees of the Department of Health of Western Australia, the Sir Charles Gairdner Osborne Park Health Care Group, Gold Coast Health, Curtin University, and Griffith University, plus the relevant Hospital's Research Governance Department. If this should occur, these personnel are required to comply with the privacy laws that protect you when dealing with your information. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

Storage, retention and destruction of your information

In Western Australia, participant records in hard copy, including consent forms, will be kept during the study in the Centre for Nursing Research at Sir Charles Gairdner Hospital. At the end of the study, any such documents will be provided to Curtin University using a secure method. All electronic study data – which include the questionnaire data, interview transcripts, and the data provided by the Department of Health of Western Australian and/or Services Australia (MBS and PBS data) - will be stored on a secure drive at Curtin University.

Data will be archived and finally securely destroyed according to the archiving rules of the relevant University and Health Department Guidelines, and the guidelines provided by Services Australia, as agreed by the Human Research Ethics Committees that have approved this study. Paper documents will be disposed of in a secure waste bin and electronic data will be deleted in such a way that they cannot be recovered. In accordance with the requirements of Curtin University, the study's questionnaire data will be retained for 25 years following the date of publication of study findings but the data obtained from your health records, including that provided by the Department of Health of Western Australian and/or Services Australia (MBS and PBS data), will be destroyed 7 years after publication of study findings.

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. All health results will be presented as group data, meaning individuals cannot be identified. Any quotes from interviews that are presented will be identified only with the study number used to describe the carer (eg, Carer 1, Carer 2). The processes that have been approved for this study ensure that the data we access from State and Federal Departments are de-identified prior to inclusion in the study analyses and cannot thereafter be re-identified. Furthermore, these data will be provided to us via the secure methods determined by these Departments.

After the study is completed, non-identifiable questionnaire data may be used again by our research team (for example when additional testing of the Further Enabling Care at Home program is undertaken) but the data obtained from your health records, including that provided by the Department of Health of Western Australians and/or Services Australia will not be used in any future or unspecified research outside of the approved study and 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 will be disclosed only with your permission, or as required by law.

Accessing your information

In accordance with relevant Australian and/or Western 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. However, the

data from the Department of Health of Western Australian and/or Services Australia will have been de-identified so the only information we can provide will have been provided to us via questionnaires or interviews. Please contact Anne-Marie Hill via email: anne-marie.hill@curtin.edu.au, if you would like to access a summary of your questionnaire data or a transcript of your interview.

14 Who is organising and funding the research?

This research is led by Professor Anne-Marie Hill of Curtin University. The study is being conducted by Curtin University in Western Australia and Griffith University in Queensland and is funded by the National Health and Medical Research Council (NHMRC) of Australia and Curtin University. Researchers from other universities, from WA Health, and from Queensland Health are also in the study team. You will not benefit financially from your involvement in this research project even if, for example, study findings prove to be of commercial value to the Australian health system. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

15 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 Human Research Ethics Committees of the Department of Health of Western Australia, the Sir Charles Gairdner Osborne Park Health Care Group, Curtin University, and Griffith University have reviewed this study and given approval for the conduct of this research. In doing so, this research conforms to the principles set out by the National Statement on Ethical Conduct in Human Research (2007) and abides by the Good Clinical Practice Guidelines.

16 Further information and who to contact

If you have any questions about the study you can contact: WA State Manager, Trish Starling mob) 0413 097 981, email: trish.starling@curtin.edu.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	Sir Charles Gairdner Osborne Park Health Care Group
HREC Executive Officer	
Telephone	08 6457 2999
Email	SCGH.HREC@health.wa.gov.au

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17 If you are happy to be contacted

Thank you for reading this Participant Information Sheet. If you would like a researcher to contact you about becoming involved, you can contact our research officer, Tammy Weselman, mob) 0410 426 005 or complete your details on this page and make sure it is put into the box provided at the nurses' station.

Full Name: _____

Daytime phone number: _____ Mobile phone number: _____

Consent Form – Family carer providing own consent – Western Australia

Title	Multicentre randomised controlled trial: caregiver, patient, and system outcomes from a program supporting informal caregivers of older people discharged home from hospital
Short Title	Evaluating the Further Enabling Care at Home (FECH) post-discharge program as a way to support carers of older hospital patients.
Protocol Number	APP1157834 Version 6 May 14 2020
Project Sponsor	Curtin University
Coordinating Principal Investigator/ Principal Investigator	Professor Anne-Marie Hill
Chief Investigator(s)	Prof Wendy Moyle, Assoc Prof Rachael Moorin, Prof Keith Hill, Assoc Prof Susan Slatyer, Assoc Prof Christina Bryant, Dr Nicholas Waldron, Prof Samar Aoun, Dr Richard Parsons
Location	Sir Charles Gairdner Hospital

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.

If requested, I am happy to take part in a digitally audio-recorded interview. Yes No

I understand that the answers I have provided to questionnaires may be used again - in a non-identifiable format – by this research team, for example, when this team continues testing the Further Enabling Care at Home program.

I give permission for the research team to access information about me for the purposes of this project from the Data Linkage Branch of the Department of Health of Western Australia. This information will include data routinely collected for the 12 months before the date of the pending or most recent hospital discharge of the older person for whom I provide care (from the hospitalisation when I was identified as suitable for this study) and for the 12 months that follow or December 31 2022 (whichever date is later) about:

- use of ambulance services and hospital emergency departments
- length of hospital stays and related diagnoses or other details relating to hospital admissions and/or mortality.

I understand that such information will remain confidential and will not be reported in any way that could identify me.

I also understand that, to access this information, the research team will need to provide information about me that may include my full name, date of birth, sex, and address to the Data Linkage Branch of the Department of Health of Western Australia.

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.

I understand that Curtin University is not part of the Sir Charles Gairdner Hospital or the Government of Western Australia and health professionals involved in the conduct of this study do so in a private capacity and not as employees of the hospital or the State.

Full name of Participant (please print first, middle, and last IN FULL)		
Date of birth		
Home (street) address (including suburb and postcode)		
Email address		
Telephone number		
Signature		Date

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.

Name Researcher (please print) _____
Signature _____ Date _____
Note: All parties signing the consent section must date their own signature.

PARTICIPANT WITHDRAWAL OF CONSENT FORM

Multicentre randomised controlled trial: caregiver, patient, and system outcomes from a program supporting informal caregivers of older people discharged home from hospital

Please cross out the non-applicable statements and tick the appropriate box

I wish to WITHDRAW my participation entirely from this study, effective from the date below and request that the study handles the information they have collected about me in the following way (choose one option):

DESTROY all information collected about me so it can no longer be used for research

RETAIN all information collected about me so it can continue to be used for research

I understand that:

1. no further information about me will be collected for the study from the withdrawal date;
2. information about me that has already been analysed and/or included in a publication by the study, may not be able to be destroyed; and
3. choosing to withdraw from the study will not affect my access to Health Services or Government benefits.

.....
Signature

.....
Date

..... **Please print full name**

Hospital where you first learned of the study

This form should be forwarded by email to: anne-marie.hill@curtin.edu.au.

**Alternatively, forms can be posted to:
Professor Anne-Marie Hill,
School of Physiotherapy and Exercise Science,
Curtin University, GPO Box S1512, Perth WA 6845.**