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## Evaluating the provision of Further Enabling Care at Home (FECH+) for informal caregivers of older adults discharged home from hospital – protocol for a multicentre randomised controlled trial

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**Title**

Evaluating the provision of Further Enabling Care at Home (FECH+) for informal caregivers of older adults discharged home from hospital – protocol for a multicentre randomised controlled trial

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## ABSTRACT

### Introduction

There are personal and societal benefits from caregiving; however caregiving can jeopardise caregivers' health. The Further Enabling Care at Home (FECH+) program provides structured nurse support, through telephone outreach, to caregivers of older adults following discharge from acute hospital care to home. The trial aims to evaluate the effectiveness of the FECH+ program on caregivers' health-related quality of life (HRQOL) after care recipients' hospital discharge.

### Methods and analysis

A multi-site, parallel-group, randomised controlled trial with blinded baseline and outcome assessment and intention-to-treat analysis, adhering to CONSORT guidelines will be conducted. Participants (N=925 dyads) comprising informal home caregiver (18 years or older) and care recipient (70 years or older) will be recruited when the care recipient is discharged from hospital. Caregivers of patients discharged from wards in three hospitals in Australia (one in Western Australia, two in Queensland) are eligible for inclusion.

Participants will be randomly assigned to one of two groups. The intervention group receive the FECH+ program, which provides structured support and problem solving for the caregiver after the care recipient's discharge, in addition to usual care. The control group receives usual care. The program is delivered by a registered nurse and comprises six 30 to 45-minute telephone sessions over six months. The primary outcome is caregivers' HRQOL measured using the AQOL-8D. Secondary outcomes include caregiver preparedness, strain and distress, and use of health care services. Changes in HRQOL between groups will be

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3 compared using a mixed regression model that accounts for the correlation between repeated  
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5 measurements.  
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### 8 9 **Ethics and dissemination**

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12 Participants will provide written informed consent. Ethics approvals have been obtained from  
13  
14 Sir Charles Gairdner and Osborne Park Health Care Group, Curtin University, Griffith  
15  
16 University, Gold Coast Health Service, and government health data linkage services.  
17  
18 Findings will be disseminated through presentations, peer-reviewed journals and conferences.  
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### 25 **Trial Registration number**

26  
27 Australian New Zealand Clinical Trials Registry, ACTRN12620000060943  
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### 32 **Keywords**

33  
34 Patient discharge, caregivers, randomised controlled trial, dyad, aged, aged 80 and over,  
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36 telephone-based intervention  
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### Strengths and limitations of this study

- The study uses a multi-centre randomised design with blinded baseline and outcome assessment.
- Follow-up time points of six and 12 months allow robust evaluation of the effect of the FECH+ program on caregivers' outcomes as well as the use of health services.
- Evaluating secondary outcomes, including caregiver distress and preparedness to care will provide further insight into the intervention effect.
- Participants cannot be blinded to receiving the intervention.
- The study population is older and frail, therefore mortality and hospital readmission may affect the recruitment or retention of participants.

## INTRODUCTION

In Australia, an estimated 2.65 million people provide informal care, 32% as primary caregivers, of whom over 60% provide support for a spouse or parent.[1] The proportion of older adults (aged 65 years and over) across the world is expected to double from 12% in 2020 to 22% by 2050[2] and in Australia older people expect to continue to live at home, with less than 5% of older people living in Residential Aged Care (RAC) accommodation.[1] Hence informal caregivers are critical in supporting older people to live at home for as long as possible.[3]

Caregivers, however, report significant personal costs associated with care, including serious financial, social and health problems.[4,5] Caregivers repeatedly report lower levels of wellbeing than the general population.[5] Mental health risks are particularly severe, with caregivers reporting significantly higher levels of loneliness, anxiety, depression and stress than the general population.[4-7] A systematic review found evidence of a negative impact of caregiving on both the mental and physical health of the informal caregiver.[8] Rising levels of caregiver stress are known to predict premature admission of the care recipient to RAC.[9]

There is evidence that providing supportive programs can reduce the adverse consequences of caregiving for older adults.[10-13] However, one in five caregivers in the UK report receiving no support.[4] Ensuring that resources and services are used by those who need them is problematic, with identified barriers including cost, having no one to talk to, not knowing what is available and caring responsibilities taking priority.[4,5] Older adults discharged from hospital are at high risk of functional decline, unplanned hospital readmissions and injurious falls.[14-16] This transition can be particularly problematic for older adults who receive care support and their caregivers. Lack of continuity of care and

1  
2  
3 inadequate communication and discharge plans during this time of transition can increase  
4 caregiver burden even further.[17-19]  
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10 There is limited evidence about how to effectively support caregivers of older adults when  
11 they are discharged from hospital, including what interventions can sustain and improve  
12 caregivers' health and wellbeing.[19-21] A recent meta-analysis of 23 trials found low  
13 quality evidence that informal caregiver interventions provided after hospital discharge may  
14 reduce caregiver burden and anxiety in stroke populations. However, they did not change  
15 health related quality of life (HRQOL), anxiety, or health resource use.[20] Over 90% of the  
16 included trials were conducted in stroke populations thereby providing limited  
17 generalisability. Another systematic review of 21 trials found that telephone interventions  
18 providing support for caregivers may slightly reduce anxiety and improve preparedness to  
19 care, but did not significantly improve other caregiver outcomes.[21] None of the included  
20 trials in the review measured changes in HRQOL.[21] Both reviews recommended further  
21 high-quality trials in caregiver populations.  
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40 We conducted an RCT evaluating the Further Enabling Care at Home (FECH) program,  
41 delivered to caregivers when the frail, older adult they cared for was discharged from  
42 hospital.[11] The program significantly reduced caregiver strain and distress and increased  
43 preparedness to care.[11] Caregivers also reported high levels of satisfaction with the  
44 program.[22] The FECH program had some limitations. We limited caregiver support to  
45 receiving three telephone contacts over three weeks after discharge and did not take an  
46 approach that assisted caregivers to develop and implement problem-solving skills. The trial  
47 was conducted in a single hospital ward and 141 dyads provided data at all timepoints.  
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49 Therefore we aim to increase the duration and intensity of the program (FECH+) and conduct  
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3 a multi-centre RCT to evaluate whether the FECH+ program may improve caregivers'  
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5 HRQOL. Since the original FECH program improved caregiving preparedness, we also seek  
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7 to examine if the FECH+ program results in improvements in care, and therefore in care  
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9 recipients' levels of independence and symptoms of distress.  
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### 14 **Aims and hypotheses**

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17 The primary aim of the trial is to evaluate the efficacy of participation in the FECH+ program  
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19 in addition to usual discharge care on HRQOL of caregivers of older adults discharged home  
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21 from hospital, compared to receiving usual discharge care alone. The secondary aims are to  
22  
23 evaluate the efficacy of participation in the FECH+ program in addition to usual discharge  
24  
25 care on: i) caregiver preparedness to care, self-efficacy and levels of strain and distress; ii)  
26  
27 care recipient outcomes of symptoms of distress and level of independence, compared to  
28  
29 usual discharge care alone.  
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36 The primary hypothesis is that caregivers participating in the FECH+ program in addition to  
37  
38 receiving usual hospital discharge care (intervention group) when compared with caregivers  
39  
40 receiving usual discharge care alone (control group), will report improved HRQOL.  
41

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43 Secondary hypotheses are that the: i) intervention group will report improved caregiving  
44  
45 preparedness, decreased strain and distress, and improved self-efficacy compared to the  
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47 control group; and ii) care recipients in the intervention group will experience decreased  
48  
49 symptom distress and improved independence compared to the control group.  
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55 A separate process evaluation will be conducted to explore how caregiving is impacted by  
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57 participating in the FECH+ program and identify aspects of implementation that particularly  
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3 contribute to effectiveness. A subsequent trial-based economic evaluation will evaluate the  
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5 effectiveness of the intervention using the framework of a within-trial, cost-utility analysis.  
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## METHODS AND ANALYSIS

### Design

The trial is a multi-centre parallel two-group RCT with 1:1 dyad allocation to the intervention (FECH+ program in addition to usual care) group or the control (usual care alone) group. The study will adhere to the Consolidated Standards of Reporting Trials (CONSORT) guidelines (see **Figure 1**).<sup>[23]</sup> This protocol is reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 Statement (see **Additional file 1**).<sup>[24]</sup> The trial is registered through the Australian New Zealand Clinical Trials Registry (ACTRN12620000060943).

### Participants

Participants will be enrolled as dyads (caregiver and care recipient). To be eligible for the study caregivers must be: a) aged 18 years or older; b) providing unpaid support as a caregiver to a patient (care recipient) aged 70 years or older when this care recipient is discharged home from a ward included in the study; care recipients must be: c) discharged home from a ward included in the study. Exclusion criteria are that care recipients are discharged to a setting other than home (such as to a nursing home or another hospital) or undertake a hospital in the home program. Based on a definition of a caregiver used in an Australian study investigating the support of frail older people,<sup>[25]</sup> caregivers are defined as family members or friends providing unpaid care and support to older people. The support must be regular (at least weekly) ongoing, home-based and can be physical and/or emotional care.

### Setting

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3 The trial will be conducted at three public hospitals in Australia. In Western Australia (WA),  
4 the site is Sir Charles Gairdner Hospital, a metropolitan tertiary hospital with approximately  
5 600 beds. In Queensland (QLD), the two hospitals are Robina Hospital (approximately 400  
6 beds) and Gold Coast University Hospital (approximately 600 beds). Wards included in the  
7 trial admit medical patients, of whom large numbers are aged over 70 years.  
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### 17 **Randomisation and Blinding**

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19 The WA Health Translation Network's Clinical Trials and Data Management Centre  
20 (CTDMC) will administer the randomisation process. The allocation list has been generated  
21 prior to trial commencement by the CTDMC using computer-generated random numbers and  
22 organised such that recruitment to the two study arms (WA and QLD) occurs at an  
23 approximately equal rate. The treatment allocation list is stored as a password protected file  
24 at Curtin University and is only accessible to the trial's CTDMC administrators. The research  
25 assistants (RAs) enter all baseline data directly into a secure online database. Completion of  
26 baseline data entry automatically triggers the allocation of the dyad (caregiver and care  
27 recipient) to the next number in the sequence and triggers an alert to the project manager,  
28 who contacts the FECH+ nurse if the dyad is allocated to the intervention group.  
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45 The investigators on the trial team are not involved in recruitment or data collection and all  
46 investigators, including the statistical team, are blinded to group allocation until after  
47 analyses are completed. RAs who enrol patients and conduct baseline and outcome  
48 assessments are blinded to group allocation throughout the study. The project manager is the  
49 only team member to see the group allocation as she manages the trial procedure. The nurses  
50 who deliver the intervention know which participants receive the intervention, but are not  
51 involved in baseline or outcome data collection. Hospital staff who organise discharge  
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3 services remain blinded to participants' enrolment into the study. Participants are not  
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5 specifically informed of their group allocation but cannot be blinded to the intervention they  
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7 receive. Participants will be instructed at enrolment and during monthly phone calls not to  
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9 divulge their allocation to research staff. RAs who conduct baseline and outcome assessments  
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11 are based in the hospitals while the nurses who deliver the intervention are located at the  
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13 Universities, to maintain blinding of staff.  
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### 19 **Intervention**

20  
21 Participants allocated to the intervention receive the FECH+ program in addition to usual  
22  
23 care. A summary of the FECH+ program is presented in **Table 1** using the Template for  
24  
25 Intervention Description and Replication (TIDieR) checklist.[26] The FECH+ program is a  
26  
27 telephone-based, post-hospital-discharge intervention delivered to the caregiver by one or  
28  
29 more specially trained 'FECH+' nurses. These registered nurses have acute gerontological  
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31 nursing care experience, have substantial knowledge on how to navigate the home care  
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33 system, and receive training in the FECH+ intervention.  
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**Table 1.** Summary of the FECH+ program (TIDieR checklist).

1. Brief name	Further Enabling Care at Home (FECH+) for informal caregivers of older adults discharged home from hospital.
2. Why	The FECH+ program offers a problem-solving, caregiver-focussed approach to improve outcomes for the caregiver and care recipient that is complementary to usual discharge care. It is designed to provide caregivers with timely health professional support and training to use the resources available in the community. It aims to develop problem-solving skills and address the caregiver's identified needs.
3. What- materials	The caregiver completes the CSNAT[27] with support provided by the FECH+ nurse. A standard operating procedures manual is used by the nurse delivering the intervention. Resources relevant for individual caregivers, such as contacts for organisations, are emailed or mailed to participants as required. Caregivers are provided with an initial booklet and an individualised summary sheet after the final phone call.
4. What- procedures	The FECH+ nurse facilitates caregivers to (a) reflect upon the current caregiving situation, (b) identify and prioritise new or ongoing support needs, and (c) implement a problem-solving approach to address these support needs. Caregivers are guided to address three prioritised needs using problem-solving techniques and goal setting. The first phone call explores the caregiver's understanding of discharge information. During subsequent phone calls caring responsibilities are discussed, using the CSNAT[27] to identify problems. The program aims to facilitate the development of caregivers' problem-solving skills to

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3 continue without support from the FECH+ nurse after the intervention  
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5 is completed. Each contact point provides an opportunity to reinforce  
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7 the problem-solving skills learnt.  
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- 10 5. Who provided Registered nurses experienced in gerontological nursing and who have  
11  
12 received training in delivering the FECH+ program.  
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14
- 15 6. How The FECH+ program is delivered via telephone to the caregiver after  
16  
17 the care recipient is discharged from hospital.  
18
- 19 7. Where Delivered directly to the caregiver in their home.  
20
- 21 8. When and how Six telephone calls by the FECH+ nurse after the care recipient's  
22  
23 much discharge from hospital. *Call 1*) during the first week after discharge  
24  
25 (15 minutes); *Call 2*) at two weeks after discharge (approximately 45  
26  
27 minutes); *Calls 3 to 6*) at 1, 2, 4, and 6 months respectively after  
28  
29 discharge, (each approximately 30 minutes).  
30  
31
- 32 9. Tailoring The intervention is tailored to the needs of each caregiver, using a  
33  
34 problem-solving approach to identify, prioritise, and address the top  
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36 three support needs. Individual resources are provided to participants  
37  
38 according to problems or needs identified.  
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- 41 10. Modifications to be reported at study conclusion  
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- 43 11. Fidelity to be reported at study conclusion  
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- 45 12. Adherence to be reported at study conclusion  
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49 *Notes:* CSNAT = Carer Support Needs Assessment Tool  
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5 The original FECH program[11] has been expanded (FECH+) to encourage and build the  
6 caregiver's use of problem-solving skills, through instruction and role modelling, that they  
7  
8 can continue to use after the intervention period. Problem-solving is a practical step-by-step  
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10 approach typically involving identifying and defining the problem, understanding it, setting  
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12 goals and generating solutions, implementing a course of action, and evaluating its  
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14  
15 efficacy.[28]  
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## 22 Training

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24 The FECH+ nurses undertake three days face to face training. This includes how to assess the  
25  
26 caregiver's understanding of discharge information, how to use the Caregiver Support Needs  
27  
28 Assessment Tool (CSNAT)[27] to facilitate the caregivers' identifying and prioritising  
29  
30 support needs, and assisting the caregiver to undertake a problem-solving approach. The  
31  
32 CSNAT has 14 items with Likert-type response options that rate needs for support in two  
33  
34 domains: enabling the caregiver to care for the care recipient at home and enabling support  
35  
36 for the caregiver in their caring role.[27] Training materials include the resources associated  
37  
38 with the online CSNAT toolkit[29] and an electronic manual that provides information for  
39  
40 caregivers related to care provision for older people in Australia, as well as a manual tailored  
41  
42 for each state that outlines the problem-solving approach.[22]  
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## 49 Usual Care

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51 All participants in both intervention and control groups will receive usual discharge care.  
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53 Usual discharge care includes providing the care recipient and/or caregiver with a copy of the  
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55 discharge letter, medications or prescriptions, outpatient appointments and home care  
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3 programs organised by the hospital team. Social work input for caregivers is not routine but  
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5 may occur when prioritised by the ward social worker during admission.  
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## 10 **Outcome Measures**

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12 The primary outcome is caregivers' HRQOL at six months after hospital discharge measured  
13  
14 using the 35-item Assessment of Quality of Life – 8 dimensions (AQoL-8D).[30,31] It has  
15  
16 established validity and reliability, and good psychometric properties which capture psycho-  
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18 social as well as physical health domains.[31] Australian norms have been established for the  
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20 AQoL-8D.[32]  
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26 Secondary outcomes are:

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28 1. Caregivers' HRQOL at 12 months after hospital discharge measured using the 35-  
29  
30 item AQoL-8D.[30,31]  
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32

33 Other secondary outcomes evaluated at six and 12 months after hospital discharge include:

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35 2. Caregivers' self-rated preparedness for caregiving, measured using the Preparedness  
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37 for Caregiving Scale (PCS).[33] This 8-item scale has five response options (0=not at all  
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39 prepared, 4=very well prepared) and is designed for use with caregivers of older adults  
40  
41 receiving homecare/experiencing care transitions. The construct validity for the PCS has been  
42  
43 established in older adults.[34] Testing in patients with life-threatening illness confirmed  
44  
45 satisfactory internal consistency, reliability and stability, and unidimensionality.[35]  
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48  
49 3. Caregivers' self-efficacy measured with the 21-item Caregiver Inventory (CGI).[36]

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51 This questionnaire has four sub-scales confirmed by factor analysis: Cronbach's alpha for the  
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53 scale was 0.91 in a sample of caregivers of patients for whom the main diagnoses were  
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55 cancer, chronic obstructive pulmonary disease, stroke, chronic heart failure, and dementia.  
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58 Responses are provided using a five-point Likert scale.  
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3 4. Caregivers' strain and distress measured by the corresponding sub-scales of the  
4 Family Appraisal of Caregiving Questionnaire- Palliative Care (FACQ), for which good  
5 internal consistency, reliability and construct validity are confirmed.[37] Responses are  
6 provided using a five point Likert scale.  
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12 5. Care recipients' level of independence reported by caregivers using the Barthel  
13 Activities of Daily Living Index (BADLI), which has established reliability and validity,  
14 including for telephone administration.[38, 39]  
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19 6. Care recipients' symptoms measured using the Symptom Assessment Scale  
20 (SAS).[40] Seven symptoms are each scored from 0 (not at all) to 10 (worst possible). Scores  
21 can be totalled, and caregiver proxies can complete responses. Adequate internal consistency  
22 reliability and test-retest reliability and concurrent validity have been demonstrated in older  
23 populations.[40, 41]  
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33 Demographic data collected for caregivers and care recipients at baseline are age, gender,  
34 country of birth, number of prescription medications taken by caregiver and care recipient's  
35 length of stay in hospital. Information about the type, duration, and amount of care provided  
36 by the caregiver, types of services received by the caregiver/care recipient and caregiver/care  
37 recipient health (number, type of health conditions) will also be collected.  
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## 47 Procedure

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49 The study procedure is summarised in **Table 2**. Participant dyads will be enrolled in the trial  
50 by the RAs within 24 hours of discharge from hospital. Baseline (timepoint 1) assessment,  
51 including demographic data collection, is completed during the first week after hospital  
52 discharge. Questionnaires are administered by phone by the RAs. Data collection at  
53 timepoints 2, 3, and 4 will be prompted by the project manager sending an alert to the RAs  
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through the database and completed by phone for both intervention and control groups. This strategy ensures that FECH+ program completion occurs prior to timepoint 3 data collection and maintains the RAs blinding to group allocation.

**Table 2. Overview of procedure**

Timepoint	Time After Discharge	Measurement tools administered
T1 (baseline) data collection	1-4 days	AQoL-8D*, CGI, PCS, FACQ, SAS, BADLI, Demographic data
<b><i>Intervention group only: FECH+ Nurse Contacts 1-4: one week, two weeks, 1 month, 2 months after discharge</i></b>		
T2 data collection	3 months	AQoL-8D, PCS, FACQ, SAS, BADLI
<b><i>Intervention group only: FECH+ Nurse Contacts 5-6: 4months, 6 months after discharge</i></b>		
T3 data collection	6 months	AQoL-8D, CGI, PCS, FACQ, SAS, BADLI, Qualitative Interview (subset)
T4 data collection	12 months	AQoL-8D, CGI, PCS, FACQ, SAS, BADLI, Qualitative Interview (subset)
<p><i>Notes:</i> CGI= Caregiver Inventory, PCS= Preparedness for Caregiving Scale, FACQ= Family Appraisal of Caregiving Questionnaire- Palliative Care, SAS= Symptom Assessment Scale, BADLI= Barthel Activities of Daily Living Index</p> <p>*AQoL-8D measures health-related quality of life [30]</p>		

### Statistical analysis plan

Characteristics of the groups will be summarised using descriptive statistics (frequencies and percentages for categorical variables; means, standard deviations, medians and ranges for variables measured on a continuous scale). Differences in demographic and baseline health status variables between groups at baseline will be compared using Chi-square, t-tests or non-parametric Wilcoxon two-sample tests as appropriate. Changes from baseline in the AQoL-8D score for the caregiver will be calculated to each time point and tested for normality using the Shapiro-Wilk statistic; if not normally distributed, a Box-Cox transformation will be applied to the measure before further analysis. Comparison of the changes in AQoL-8D scores between control and intervention groups will be performed using a mixed regression model with the caregiver group identified as a random effect. This model takes into account the correlation between repeated measurements on each individual. An interaction term between time and group will be introduced into the model to test whether rates of change in the outcome differ between groups. If differences between the groups are evident at baseline, these will be included in the model as covariates so that adjustment can be made before examining differences between groups in outcomes.

In our preliminary work,[11] there was <20% missing data. Missing data will be managed using multiple imputation methods informed by a sensitivity analysis to manage this, creating 25 or more data sets. Two analyses will be performed, namely: an analysis using only the observed data, and secondly, after missing value substitution, where necessary. Data will be analysed using an intention-to-treat approach. Secondary outcomes will be analysed in a similar manner to the primary outcome. Statistical analyses will be conducted using STATA 16 software (Stata Statistical Software, College Station, TX: StataCorp LLC)) and a p-value <0.05 will be taken to indicate statistical significance.

## Sample size

The primary outcome is the change in total score on the AQoL-8D[30] for the caregiver at 6 months post-discharge. A very small effect size of 0.06 has been described as being of clinical importance.[42] However, we anticipate a larger effect size, based upon: a) our assessment of changes in health, measured using the SF12 [43] during our preliminary study,[11] in which we obtained a positive change in physical health (0.17) and mental health (0.22) from baseline until immediately post-intervention; b) that the AQoL-8D is a more appropriate outcome measure as psychosocial components of health are emphasised more; and c) that we are now implementing an expanded intervention with longer follow up. Therefore, we designed this study with 80% power to detect an effect size of 0.22. This would require 648 caregiver dyads (324 in each of the control and intervention groups), determined using the G\*Power sample size calculator.[44] We anticipate 30% attrition during the 12-month post-discharge period so our recruitment target to address the primary outcome variable is 925 dyads. Based upon preliminary work, this sample size will also allow 80% power to detect meaningful differences in the secondary outcomes for caregiver preparedness, strain and distress, and hospitalisation costs for patients.[11]

## Process evaluation

A process evaluation will assist in understanding the mechanism of the trial results. The process evaluation uses the framework recommended by the Medical Research Council for evaluating complex interventions.[45] Caregivers' and nurses' feedback on aspects of program implementation will be evaluated. A purposive sample (estimated 25-40) of caregivers from WA and QLD who have completed participation in the FECH+ program will be selected immediately after program conclusion for inclusion in qualitative interviews.



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3 Sample selection will ensure maximum variation (e.g., gender, age, relationship, caregiving  
4 duration), until data saturation.[46] Qualitative, digital, audio-recorded and transcribed semi-  
5 structured telephone interviews (estimated 10-20 minutes) will be scheduled at two time  
6 points (at the end of the intervention and six months later) to explore how the FECH+  
7 program has influenced caregiving and caregiver experiences during and after the program.  
8 FECH+ nurses will also be asked to record their reflections on each FECH+ Program contact.  
9 This includes identifying barriers to, or facilitators of, the effectiveness of the FECH+  
10 program.  
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24 Program implementation will be examined by addressing fidelity, safety, adaptations, reach,  
25 and dose.[45] Data to be collected by the FECH+ nurses as they deliver the intervention  
26 include:  
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- 30 a) adherence to or deviation from planned FECH+ processes including any safety concerns and  
31 how addressed;  
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33 b) information provided to caregivers and the extent to which caregivers engaged with  
34 resources provided;  
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36 c) time taken to implement processes, including duration and frequency of sessions.  
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44 Qualitative data will be analysed using thematic analysis.[46] Strategies to enhance the  
45 trustworthiness of findings will include verbatim transcriptions of audio-recorded interviews  
46 and an audit trail.[46] Quantitative data will be presented using the framework of the process  
47 evaluation and where appropriate triangulated with qualitative data to assist in clarifying  
48 complex causal pathways.[45]  
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## 58 **Economic analysis**

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3 The economic analysis plan will be published separately. Briefly, cost effectiveness of the  
4 intervention will be measured using a within-trial cost-utility analysis evaluating the mean  
5 incremental cost and quality-adjusted life years (QALYs) according to intervention status. A  
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10 12-month time horizon will be used, taking a health system perspective.  
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### 14 **Data Management**

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17 Data management will be overseen by a data management committee comprising a  
18 representative from the CTDMC, the WA and Qld State Managers and trial leaders from WA  
19 (AMH) and QLD (WM). The committee will undertake regular monthly monitoring and  
20 auditing of data entry procedures and guide all data management. Data security is primarily  
21 addressed by the use of REDCap, an online application that provides for secure data entry,  
22 storage, and transfer. (<https://www.project-redcap.org/>) The CTDMC administers REDCap  
23 and all data are stored in WA. Administrative data (which include names and dates of birth)  
24 that are accessed via the database for merging with the health data will be locked down prior  
25 to creating a merged dataset and are only accessible to a CTDMC administrator. De-  
26 identified datasets will be uploaded through the University's encrypted system and stored on  
27 a password protected drive (at Curtin University). All data will be securely managed and  
28 stored at Curtin University as per National Health and Medical Research Council Australia  
29 guidelines, State data linkage services and Services Australia guidelines. Following the  
30 completion of the study analyses, a de-identified dataset will be made available on reasonable  
31 request after ongoing secondary analyses are conducted and pending ethics approval from  
32 existing and requesting institutions and approval from all investigators.  
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### 56 **Trial Status**

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3 Recruitment commenced in August 2020 and is expected to be completed by approximately  
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5 April 2022 with final follow up occurring in April 2023. Primary data analyses will be  
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7 completed, followed by the process evaluation. Final health data linkage will be undertaken  
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9 in the 12 months after final follow up. Health economic analyses will then be completed.  
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### 14 **Trial Management**

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16 Any amendments required to the study will be agreed on by the trial management committee  
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18 consisting of all Chief Investigators (AMH, WM, RM, KH, NW, SS, CB, SA), and submitted  
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20 to all ethics committees for approval prior to being commenced. The trial management  
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22 committee will monitor the trial in accordance with the currently approved protocol, which  
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24 includes submitting annual ethics reports detailing trial progress and any adverse events to all  
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26 ethics committees. Each of the named investigators on the grant shall be eligible to have  
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28 authorship.  
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### 35 **Patient and Public Involvement**

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37 Two consumer advocates are members of the trial team. This study was developed with  
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39 caregiver input from Carers WA and the WA Consumer and Community Health Research  
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41 Network, prior to submitting the application for funding. The consumer input assisted to  
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43 ensure the appropriateness of the intervention and study processes. This included assisting  
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45 with wording of documents for the trial and aspects of procedure and intervention delivery.  
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47 The two consumer advocates are ongoing members of the trial team and continue to inform  
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49 and give feedback about the study procedure. Both consumer organisations will contribute to  
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51 the dissemination of results and future presentations and translation projects.  
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## ETHICS AND DISSEMINATION

The study has been approved by hospitals (the Sir Charles Gairdner Osborne Park Health Care Group, Gold Coast Health Care Group) and universities (Curtin and Griffith) human research ethics committees. Approvals for linked health data for economic evaluation have been obtained from the Data Linkage Branches of WA Health, QLD Health, and Services Australia (for national health administered data). All caregivers will provide written, informed consent to participate in the trial. Care recipients will also provide written, informed consent to participate in the trial. Cognitive impairment may occur in a care recipient who forms part of the dyad. A waiver of consent has been approved in WA for these care recipients to be included in the study. If these care recipients are encountered in QLD, we will seek consent from the appropriate substitute decision-maker.

To disseminate findings, Carers WA and Carers QLD, (two peak organisations who provide carer advocacy and support) will be asked to publicise the study completion and findings on their website. Our consumer advocates will provide advice and assistance to maximise engagement strategies through established state and national consumer networks. Papers will be published in peer-reviewed journals, and abstracts submitted to relevant conferences. Practitioner and consumer forums will be held in participating hospitals and State health districts. Study participants will be provided with a summary of study findings upon request.

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## COMPETING INTERESTS

The authors have no conflicts to declare.

## AUTHORS CONTRIBUTION

AMH and WM led manuscript drafting. AMH is the lead investigator on the National Health and Medical Research Council of Australia grant and all authors are named applicants on the grant. AMH, WM, RM, KH, SS, CB, NW and SA contributed to trial design and will assist with monitoring trial procedure. AMH leads the trial with support from WM, LG and AK. CB, SS, SA, KH, LG, WM and AMH contribute to intervention design and delivery. MB and AMH lead the statistical analysis plan. AK and LG lead the management of the trial sites. MBr, CR, SM, (WA) TC and CJ (QLD) contribute to trial procedure, including management at the sites. RM leads the economic analyses. All authors provided critical evaluation and approval of the final submitted manuscript.

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4  
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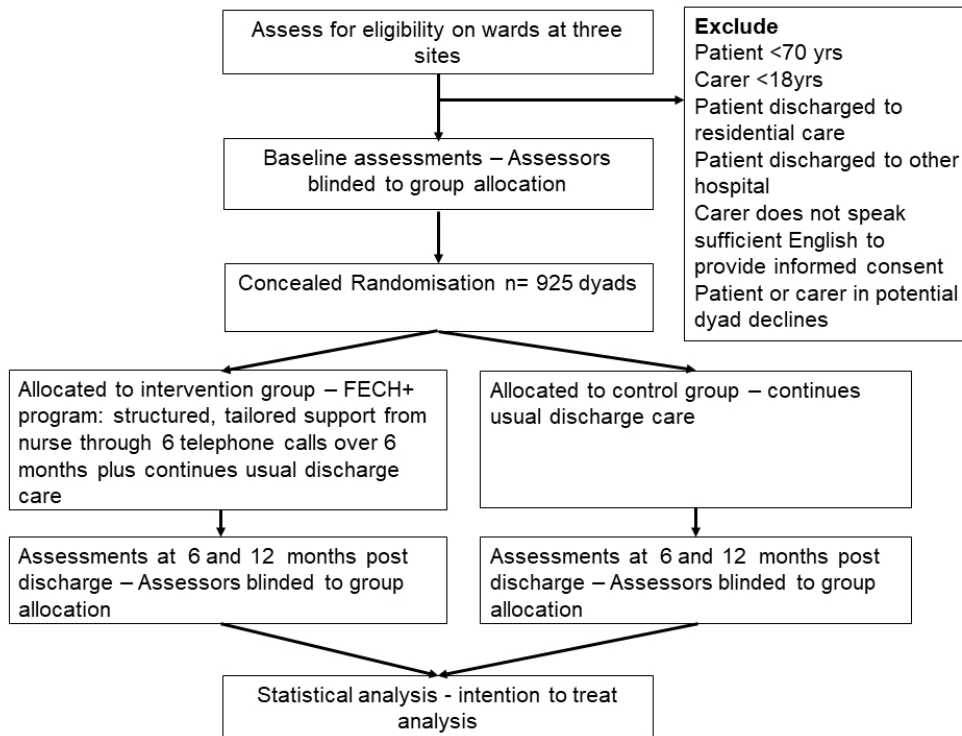
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3 **FIGURE LEGENDS**  
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5 **Figure 1.** Participant flow through the study  
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For peer review only



Participant flow through the study.

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STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

**Hill et al, 2020: Evaluating the provision of Further Enabling Care at Home (FECH+) for informal caregivers of older adults discharged home from hospital – protocol for a multicentre randomised controlled trial**

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents\*

Section/item	Item No	Description	Addressed on page number
<b>Administrative information</b>			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	4
	2b	All items from the World Health Organization Trial Registration Data Set	Yes - see ANZCTR trial registry page link in manuscript page 10
Protocol version	3	Date and version identifier	Published version is final
Funding	4	Sources and types of financial, material, and other support	25 – Funding statement
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Title page and page 25

	5b	Name and contact information for the trial sponsor	25 –Funding statement
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	25 – Funding statement
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	22-23
<b>Introduction</b>			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	6 -8
	6b	Explanation for choice of comparators	N/A
Objectives	7	Specific objectives or hypotheses	8
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	10
<b>Methods: Participants, interventions, and outcomes</b>			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	11
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	10
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	12, 15, Table 1



	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Refer protocol ANZCTR online registry link on page 10
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	16
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Table 2 – p 18
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	19
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	19
<b>Methods: Assignment of interventions (for controlled trials)</b>			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	11
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	11

1	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	11-12
2	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	11-12
3		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
4	<b>Methods: Data collection, management, and analysis</b>			
5	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	16-17,
6		18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	21
7	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	22
8	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	19
9		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	19
10		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	19
11	<b>Methods: Monitoring</b>			
12	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	22

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	23
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	23
<b>Ethics and dissemination</b>			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	24
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	23
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	11, 17
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	22
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	22
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	25
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	n/a
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a

1 2 3 4	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	24
5 6		31b	Authorship eligibility guidelines and any intended use of professional writers	23
7 8		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	21
9 10	<b>Appendices</b>			
11 12 13 14	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Available on request
15 16 17	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

18 \*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items.  
 19 Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons  
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# BMJ Open

## Evaluating the provision of Further Enabling Care at Home (FECH+) for informal caregivers of older adults discharged home from hospital – protocol for a multicentre randomised controlled trial

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Secondary Subject Heading:	Geriatric medicine, Nursing
Keywords:	GERIATRIC MEDICINE, INTERNAL MEDICINE, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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**Title**

Evaluating the provision of Further Enabling Care at Home (FECH+) for informal caregivers of older adults discharged home from hospital – protocol for a multicentre randomised controlled trial

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## ABSTRACT

### Introduction

There are personal and societal benefits from caregiving; however, caregiving can jeopardise caregivers' health. The Further Enabling Care at Home (FECH+) program provides structured nurse support, through telephone outreach, to informal caregivers of older adults following discharge from acute hospital care to home. The trial aims to evaluate the efficacy of the FECH+ program on caregivers' health-related quality of life (HRQOL) after care recipients' hospital discharge.

### Methods and analysis

A multi-site, parallel-group, randomised controlled trial with blinded baseline and outcome assessment and intention-to-treat analysis, adhering to CONSORT guidelines will be conducted. Participants (N=925 dyads) comprising informal home caregiver (18 years or older) and care recipient (70 years or older) will be recruited when the care recipient is discharged from hospital. Caregivers of patients discharged from wards in three hospitals in Australia (one in Western Australia, two in Queensland) are eligible for inclusion. Participants will be randomly assigned to one of two groups. The intervention group receive the FECH+ program, which provides structured support and problem solving for the caregiver after the care recipient's discharge, in addition to usual care. The control group receives usual care. The program is delivered by a registered nurse and comprises six 30 to 45-minute telephone support sessions over six months. The primary outcome is caregivers' HRQOL measured using the AQOL-8D. Secondary outcomes include caregiver preparedness, strain and distress, and use of health care services. Changes in HRQOL

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3 between groups will be compared using a mixed regression model that accounts for the  
4 correlation between repeated measurements.  
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### 8 9 **Ethics and dissemination**

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12 Participants will provide written informed consent. Ethics approvals have been obtained from  
13 Sir Charles Gairdner and Osborne Park Health Care Group, Curtin University, Griffith  
14 University, Gold Coast Health Service, and government health data linkage services.  
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17 Findings will be disseminated through presentations, peer-reviewed journals and conferences.  
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### 25 **Trial Registration number**

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27 Australian New Zealand Clinical Trials Registry, ACTRN12620000060943  
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### 32 **Keywords**

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34 Patient discharge, caregivers, randomised controlled trial, dyad, aged, telephone-based  
35 intervention  
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### Strengths and limitations of this study

- The study uses a multi-centre randomised design with blinded baseline and outcome assessment.
- Follow-up time points of six and 12 months allow robust evaluation of the effect of the FECH+ program on caregivers' outcomes as well as the use of health services.
- Evaluating secondary outcomes, including caregiver distress and preparedness to care will provide further insight into the intervention effect.
- Participants cannot be blinded to receiving the intervention.
- The care recipients are older and therefore mortality and hospital readmission may affect the recruitment or retention of participants.

## INTRODUCTION

In Australia, an estimated 2.65 million people provide informal care, 32% as primary caregivers, of whom over 60% provide support for a spouse or parent.[1] The proportion of older adults (aged 65 years and over) across the world is expected to double from 12% in 2020 to 22% by 2050[2] and in Australia older people expect to continue to live at home, with less than 5% of older people living in Residential Aged Care (RAC) accommodation.[1] Hence informal caregivers are critical in supporting older people to live at home for as long as possible.[3]

Caregivers, however, report significant personal costs associated with care, including serious financial, social and health problems.[4, 5] Caregivers repeatedly report lower levels of wellbeing than the general population. Mental health risks are particularly severe, with caregivers reporting significantly higher levels of loneliness, anxiety, depression and stress than the general population.[4-7] A systematic review found evidence of a negative impact of caregiving on both the mental and physical health of the informal caregiver.[8] Rising levels of caregiver stress are known to predict premature admission of the care recipient to RAC.[9]

There is limited evidence that providing supportive programs, such as face to face training, telephone support or online digital programs, can reduce the adverse consequences of caregiving for older adults.[10-13] In addition to problems faced by caregivers in providing ongoing care, there is limited evidence about how to effectively support caregivers of older adults when they are discharged from hospital, including what interventions can sustain and improve caregivers' health and wellbeing.[14-16] Older adults discharged from hospital are at high risk of functional decline, unplanned hospital readmissions and injurious falls.[17-19] This transition can be particularly problematic for older adults who receive care support and

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2  
3 their caregivers. Lack of continuity of care and inadequate communication and discharge  
4 plans during this time of transition can increase caregiver burden even further.[20, 21] A  
5 recent meta-analysis of 23 trials found low quality evidence that informal caregiver  
6 interventions provided after hospital discharge may reduce caregiver burden and anxiety in  
7 stroke populations. However, they did not change health related quality of life (HRQOL),  
8 anxiety, or health resource use.[15] Over 90% of the included trials were conducted in stroke  
9 populations thereby providing limited generalisability. Another systematic review of 21 trials  
10 found that telephone interventions providing support for caregivers may slightly reduce  
11 anxiety and improve preparedness to care, but did not significantly improve other caregiver  
12 outcomes.[16] None of the included trials in this review measured changes in HRQOL[16]  
13 and both reviews recommended further high-quality trials in caregiver populations. Recent  
14 qualitative research conducted with caregivers of older adults discharged from hospital  
15 indicated that negative impacts of caregiving at this time can stem from feelings of  
16 uncertainty exacerbated by gaps in formal support, the strain of balancing caregiving with  
17 other life demands and a sense of helplessness.[22] Therefore further trials that design and  
18 evaluate interventions to support caregivers when the older adult they care for is transitioning  
19 from hospital to home are required.  
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45 We conducted an RCT evaluating the Further Enabling Care at Home (FECH) program, a  
46 telephone-based intervention delivered to caregivers when the older adult they cared for was  
47 discharged from hospital.[11] Telephone interventions are part of a suite of expanding  
48 telehealth technologies that demonstrate early evidence for providing support for caregivers  
49 and families.[23] A brief intervention of seven CBT 60-minute telephone sessions for  
50 caregivers of adults with dementia resulted in improved caregiver emotional wellbeing,  
51 decreased exhaustion and reduced depressive symptoms.[24] Caregivers asked to rate their  
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3 preferences for telehealth technologies rated telephone as the highest preferred form of  
4 technology compared to videoconferencing, facebook, email and other technologies and  
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6 telephones have the advantage of being usable for those without access to suitable technology  
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8 and internet.[25] A review of telephone and computer delivered interventions for caregivers  
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10 of people living with dementia found that these intervention have potential to improve  
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12 caregiver wellbeing, in particular those that incorporated various elements of psycho-  
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14 education, peer support, skills training and health assessments but that further high quality  
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16 trials were required.[26] The FECH telephone program provided support for caregivers in a  
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18 timely and convenient manner in their own home. It was tailored to address the caregivers'  
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20 identified support needs by providing immediate information and resources.[11] In contrast to  
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22 previous studies providing caregiver support,[15, 16] the FECH program delivered promising  
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24 results when piloted with caregivers of older patients following hospital discharge. The  
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26 program significantly reduced caregiver strain and distress and increased preparedness to  
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28 care.[11] Caregivers also reported high levels of satisfaction with the program.[27] While the  
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30 program achieved a moderate effect size that was clinically significant,[11] the FECH  
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32 program had some limitations. Caregiver support was limited to receiving three telephone  
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34 contacts over three weeks after discharge and did not take an approach that assisted  
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36 caregivers to develop and implement problem-solving skills. The trial was conducted in a  
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38 single hospital ward and 141 dyads provided data at all timepoints. Since it is evident that  
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40 caring frequently results in a significant negative impact across mental, physical, social and  
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42 emotional health of caregivers,[4, 5] we seek to measure the impact of the intervention by  
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44 using a HRQOL tool. These tools are patient reported outcome measures and therefore  
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46 capture the individuals own perception of their health and wellbeing in a broad sense  
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48 including their quality of life.[28] Therefore we aim to increase the duration and intensity of  
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50 the program (FECH+) and conduct a multi-centre RCT to evaluate whether the FECH+  
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3 program may improve caregivers' HRQOL. Secondary aims will assist to explore potential  
4 causal mechanisms (such as reduction in caregiver distress and improved caregiver self-  
5 efficacy) by which participation in the FECH+ program in addition to usual discharge care  
6 may improve caregiver HRQOL. Since the original FECH program improved caregiving  
7 preparedness, we also seek to examine if the FECH+ program results in improvements in  
8 care, and therefore in care recipients' levels of independence and symptoms of distress.  
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### 19 **Aims and hypotheses**

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21 The primary aims of the trial are to i) evaluate the efficacy of participation in the FECH+  
22 program in addition to usual discharge care on HRQOL of caregivers of older adults  
23 discharged home from hospital, compared to receiving usual discharge care alone: ii)  
24 evaluate the cost-effectiveness of the intervention using the framework of a within-trial, cost-  
25 utility analysis. The secondary aims are to evaluate the efficacy of participation in the  
26 FECH+ program in addition to usual discharge care on: i) caregiver preparedness to care,  
27 caregiver self-efficacy and levels of strain and distress; ii) care recipient outcomes of  
28 symptoms of distress and level of independence, compared to usual discharge care alone.  
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42 The primary hypothesis is that caregivers participating in the FECH+ program in addition to  
43 receiving usual hospital discharge care (intervention group) when compared with caregivers  
44 receiving usual discharge care alone (control group), will report improved HRQOL.  
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49 Secondary hypotheses are that the: i) intervention group will report improved caregiving  
50 preparedness, decreased strain and distress, and improved caregiver self-efficacy compared to  
51 the control group; and ii) care recipients in the intervention group will experience decreased  
52 symptom distress and improved independence compared to the control group.  
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3 A separate process evaluation will be conducted to explore how caregiving is impacted by  
4 participating in the FECH+ program and identify aspects of implementation that particularly  
5 contribute to effectiveness. A subsequent trial-based economic evaluation will evaluate the  
6 cost-effectiveness of the intervention using the framework of a within-trial, cost-utility  
7 analysis.  
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For peer review only

## METHODS AND ANALYSIS

### Design

The trial is a multi-centre parallel two-group RCT with 1:1 dyad allocation to the intervention (FECH+ program in addition to usual care) group or the control (usual care alone) group. The study will adhere to the Consolidated Standards of Reporting Trials (CONSORT) guidelines (see **Figure 1**).[29] This protocol is reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 Statement (see **Additional file 1**).[30] The trial is registered through the Australian New Zealand Clinical Trials Registry (ACTRN12620000060943).

### Participants

Participants will be enrolled as dyads (caregiver and care recipient). To be eligible for the study caregivers must be: a) aged 18 years or older; b) providing unpaid support as a caregiver to a patient (care recipient) aged 70 years or older when this care recipient is discharged home from a ward included in the study; care recipients must be: c) discharged home from a ward included in the study. Exclusion criteria are that care recipients are discharged to a setting other than home (such as to a nursing home or another hospital) or undertake a hospital in the home program. Based on a definition of a caregiver used in an Australian study investigating the support of frail older people,[31] caregivers are defined as family members or friends providing care and support to older people. The support must be regular (at least weekly) ongoing, home-based and can be physical and/or emotional care. In Australia unpaid care and support is provided by family and friends on a voluntary basis as compared to paid caregivers who provide personal and home care services through aged care organisations.

## Setting

The trial will be conducted at three public hospitals in Australia. In Western Australia (WA), the site is Sir Charles Gairdner Hospital, a metropolitan tertiary hospital with approximately 600 beds. In Queensland (QLD), the two hospitals are Robina Hospital (approximately 400 beds) and Gold Coast University Hospital (approximately 600 beds). Wards included in the trial admit medical patients, of whom large numbers are aged over 70 years.

## Randomisation and Blinding

The WA Health Translation Network's Clinical Trials and Data Management Centre (CTDMC) will administer the randomisation process. The allocation list has been generated prior to trial commencement by the CTDMC using computer-generated random numbers and organised such that recruitment to the two study arms (WA and QLD) occurs at an approximately equal rate. The treatment allocation list is stored as a password protected file at Curtin University and is only accessible to the trial's CTDMC administrators. The research assistants (RAs) enter all baseline data directly into a secure online database. Completion of baseline data entry automatically triggers the allocation of the dyad (caregiver and care recipient) to the next number in the sequence and triggers an alert to the project manager, who contacts the FECH+ nurse if the dyad is allocated to the intervention group.

The investigators on the trial team are not involved in recruitment or data collection and all investigators, including the statistical team, are blinded to group allocation until after analyses are completed. RAs who enrol patients and conduct baseline and outcome assessments are blinded to group allocation throughout the study. The project manager is the only team member to see the group allocation as she manages the trial procedure. The nurses

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2  
3 who deliver the intervention know which participants receive the intervention, but are not  
4 involved in baseline or outcome data collection. Hospital staff who organise discharge  
5 services remain blinded to participants' enrolment into the study. Participants are not  
6 specifically informed of their group allocation but cannot be blinded to the intervention they  
7 receive. Participants will be instructed at enrolment and during monthly phone calls not to  
8 divulge their allocation to research staff. RAs who conduct baseline and outcome assessments  
9 are based in the hospitals while the nurses who deliver the intervention are located at the  
10 Universities, to maintain blinding of staff.  
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### 24 **Intervention**

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26 Participants allocated to the intervention receive the FECH+ program in addition to usual  
27 care. A summary of the FECH+ program is presented in **Table 1** using the Template for  
28 Intervention Description and Replication (TIDieR) checklist.[32] The FECH+ program is a  
29 telephone-based, post-hospital-discharge intervention delivered to the caregiver by one or  
30 more specially trained 'FECH+' nurses. These registered nurses have acute gerontological  
31 nursing care experience, have substantial knowledge on how to navigate the home care  
32 system, and receive training in the FECH+ intervention.  
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**Table 1.** Summary of the FECH+ program (TIDieR checklist).

1. Brief name	Further Enabling Care at Home (FECH+) for informal caregivers of older adults discharged home from hospital.
2. Why	The FECH+ program offers a problem-solving, caregiver-focussed approach to improve outcomes for the caregiver and care recipient that is complementary to usual discharge care. It is designed to provide caregivers with timely health professional support and training to use the resources available in the community. It aims to develop problem-solving skills and address the caregiver's identified needs.
3. What- materials	The caregiver completes the CSNAT[33] with support provided by the FECH+ nurse. A standard operating procedures manual is used by the nurse delivering the intervention. Resources relevant for individual caregivers, such as contacts for organisations, are emailed or mailed to participants as required. Caregivers are provided with an initial booklet and an individualised summary sheet after the final phone call.
4. What- procedures	The FECH+ nurse facilitates caregivers to (a) reflect upon the current caregiving situation, (b) identify and prioritise new or ongoing support needs, and (c) implement a problem-solving approach to address these support needs. Caregivers are guided to address three prioritised needs using problem-solving techniques and goal setting. The first phone call explores the caregiver's understanding of discharge information. During subsequent phone calls caring responsibilities are discussed, using the CSNAT[33] to identify problems. The program aims to facilitate the development of caregivers' problem-solving skills to

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2  
3 continue without support from the FECH+ nurse after the intervention  
4  
5 is completed. Each contact point provides an opportunity to reinforce  
6  
7 the problem-solving skills learnt.  
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- 10 5. Who provided Registered nurses experienced in gerontological nursing and who have  
11  
12 received training in delivering the FECH+ program.  
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14
- 15 6. How The FECH+ program is delivered via telephone to the caregiver after  
16  
17 the care recipient is discharged from hospital.  
18  
19
- 20 7. Where Delivered directly to the caregiver in their home.  
21  
22
- 23 8. When and how Six telephone calls by the FECH+ nurse after the care recipient's  
24  
25 much discharge from hospital. *Call 1*) during the first week after discharge  
26  
27 (15 minutes); *Call 2*) at two weeks after discharge (approximately 45  
28  
29 minutes); *Calls 3 to 6*) at 1, 2, 4, and 6 months respectively after  
30  
31 discharge, (each approximately 30 minutes).  
32  
33
- 34 9. Tailoring The intervention is tailored to the needs of each caregiver, using a  
35  
36 problem-solving approach to identify, prioritise, and address the top  
37  
38 three support needs. Individual resources are provided to participants  
39  
40 according to problems or needs identified.  
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- 43 10. Modifications to be reported at study conclusion  
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- 46 11. Fidelity to be reported at study conclusion  
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- 49 12. Adherence to be reported at study conclusion  
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Notes: CSNAT = Carer Support Needs Assessment Tool

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5 The original FECH program[11] has been expanded (FECH+) to encourage and build the  
6 caregiver's use of problem-solving skills, through instruction and role modelling, that they  
7 can continue to use after the intervention period. Problem-solving is a practical step-by-step  
8 approach typically involving identifying and defining the problem, understanding it, setting  
9 goals and generating solutions, implementing a course of action, and evaluating its  
10 efficacy.[34]  
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## 22 Training

23 The FECH+ nurses undertake three days face to face training in a group setting. This includes  
24 how to assess the caregiver's understanding of discharge information, how to use the  
25 Caregiver Support Needs Assessment Tool (CSNAT)[33] to facilitate the caregivers'  
26 identifying and prioritising support needs, and how to assist the caregiver to undertake a  
27 problem-solving approach.[34] The CSNAT has 14 items with Likert-type response options  
28 that rate needs for support in two domains: enabling the caregiver to care for the care  
29 recipient at home and enabling support for the caregiver in their caring role.[33] Training  
30 materials include the resources associated with the online CSNAT toolkit[35] and an  
31 electronic manual that provides information for caregivers related to care provision for older  
32 people in Australia, as well as a manual tailored for each state that outlines the problem-  
33 solving approach.[27] It is envisaged that two to three nurses will be employed at each site.  
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49 Regular meetings for nurses to consolidate training procedures and to assist to monitor  
50 fidelity of intervention delivery will be conducted by the project manager and trial leaders  
51 (AMH, CB, SS, LG). The project manager will also monitor data entry for intervention  
52 delivery through the online database.  
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## Usual Care

All participants in both intervention and control groups will receive usual discharge care.

Usual discharge care includes providing the care recipient and/or caregiver with a copy of the discharge letter, medications or prescriptions, outpatient appointments and home care programs organised by the hospital team. Social work input for caregivers is not routine but may occur when prioritised by the ward social worker during admission.

## Outcome Measures

The primary outcome (primary aim i) is caregivers' HRQOL at six months after hospital discharge measured using the 35-item Assessment of Quality of Life – 8 dimensions (AQoL-8D).[36, 37] The AQoL-8D captures psycho-social as well as physical health domains (Independent Living, Happiness, Mental Health, Coping, Relationships, Self-Worth, Pain, Senses) and can be administered by telephone. The focus on psychosocial domains makes this instrument appropriate for our study since the dominant factor affecting choice of a multi-attribute utility instrument (MAUI) is its ability to capture facets of health states relevant to the research question.[38] It has established validity and reliability, and good psychometric properties which capture psycho-social as well as physical health domains.[37] Australian norms have been established for the AQoL-8D.[39]

Secondary outcomes are chosen to understand possible causal mechanisms of the intervention effect. For example, improved preparedness to care and reduction of caregiver strain and distress may improve caregivers HRQOL. Better prepared caregivers may in turn more effectively manage care recipients' symptoms and functional limitations. The PCS, FACQ, SAS and BADLI assessment instruments were previously evaluated in our pilot trial as being feasible to administer to caregivers over the telephone.[11] Secondary outcomes are:



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3 1. Caregivers' HRQOL at 12 months after hospital discharge (primary aim i: secondary  
4 timepoint) measured using the 35-item AQoL-8D.[36, 37]  
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7 Other secondary outcomes evaluated at six and 12 months after hospital discharge include:  
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10 2. Caregivers' self-rated preparedness for caregiving (secondary aim i), measured using  
11 the Preparedness for Caregiving Scale (PCS),[40] which covers multiple domains of  
12 caregiving including preparedness to provide physical, emotional and instrumental care along  
13 with managing the stress of caregiving. This 8-item scale has five response options (0=not at  
14 all prepared, 4=very well prepared) and is designed for use with caregivers of older adults  
15 receiving homecare/experiencing care transitions. The construct validity for the PCS has been  
16 established in older adults.[41] Testing in patients with life-threatening illness confirmed  
17 satisfactory internal consistency, reliability and stability, and unidimensionality.[42]  
18

19  
20 3. Caregivers' self-efficacy (secondary aim i), measured with the 21-item Caregiver  
21 Inventory (CGI).[43] Self-efficacy is built through a mastery of tasks and ability to persist  
22 and has been shown to improve caregiver wellbeing.[7] This questionnaire has four sub-  
23 scales confirmed by factor analysis: Cronbach's alpha for the scale was 0.91 in a sample of  
24 caregivers of patients for whom the main diagnoses were cancer, chronic obstructive  
25 pulmonary disease, stroke, chronic heart failure, and dementia. Responses are provided using  
26 a five-point Likert scale.  
27

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29 4. Caregivers' strain and distress [secondary aim i], measured by the corresponding  
30 sub-scales of the Family Appraisal of Caregiving Questionnaire- Palliative Care (FACQ), for  
31 which good internal consistency, reliability and construct validity are confirmed.[44]  
32 Responses are provided using a five point Likert scale.  
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44 5. Care recipients' level of independence (secondary aim ii), reported by caregivers  
45 using the Barthel Activities of Daily Living Index (BADLI), which has established reliability  
46 and validity.[45]  
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6. Care recipients' symptoms (secondary aim ii), measured using the Symptom Assessment Scale (SAS).[46] Seven symptoms are each scored from 0 (not at all) to 10 (worst possible). Scores can be totalled, and caregiver proxies can complete responses. Adequate internal consistency reliability and test-retest reliability and concurrent validity have been demonstrated in older populations.[46, 47]

Demographic data collected for caregivers and care recipients at baseline are age, gender, country of birth, number of prescription medications taken by caregiver and care recipient's length of stay in hospital. Information about the type, duration, and amount of care provided by the caregiver, types of services received by the caregiver/care recipient and caregiver/care recipient health (number, type of health conditions) will also be collected.

### Procedure

The study procedure is summarised in **Table 2**. Participant dyads will be enrolled in the trial by the RAs within 24 hours of discharge from hospital. Baseline (timepoint 1) assessment, including demographic data collection, is completed during the first week after hospital discharge. Questionnaires are administered by phone by the RAs. Data collection at timepoints 2, 3, and 4 will be prompted by the project manager sending an alert to the RAs through the database and completed by phone for both intervention and control groups. This strategy ensures that FECH+ program completion occurs prior to timepoint 3 data collection and maintains the RAs blinding to group allocation.

**Table 2. Overview of procedure**

Timepoint	Time After Discharge	Measurement tools administered
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T1 (baseline) data collection	1-4 days	AQoL-8D*, CGI, PCS, FACQ, SAS, BADLI, Demographic data
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***Intervention group only: FECH+ Nurse Contacts 1-4: one week, two weeks, 1 month, 2 months after discharge***

T2 data collection	3 months	AQoL-8D, PCS, FACQ, SAS, BADLI
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***Intervention group only: FECH+ Nurse Contacts 5-6: 4months, 6 months after discharge***

T3 data collection	6 months	AQoL-8D, CGI, PCS, FACQ, SAS, BADLI, Qualitative Interview (subset)
T4 data collection	12 months	AQoL-8D, CGI, PCS, FACQ, SAS, BADLI, Qualitative Interview (subset)

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*Notes:* CGI= Caregiver Inventory, PCS= Preparedness for Caregiving Scale, FACQ= Family Appraisal of Caregiving Questionnaire- Palliative Care, SAS= Symptom Assessment Scale, BADLI= Barthel Activities of Daily Living Index

\*AQoL-8D measures health-related quality of life[36]

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### **Statistical analysis plan**

Characteristics of the groups will be summarised using descriptive statistics (frequencies and percentages for categorical variables; means, standard deviations, medians and ranges for variables measured on a continuous scale). Differences in demographic and baseline health status variables between groups at baseline will be compared using Chi-square, t-tests or non-parametric Wilcoxon two-sample tests as appropriate. Changes from baseline in the AQoL-8D score for the caregiver will be calculated to each time point and tested for normality using the Shapiro-Wilk statistic; if not normally distributed, a Box-Cox transformation will be applied to the measure before further analysis. Comparison of the changes in AQoL-8D scores between control and intervention groups will be performed using a mixed regression

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3 model with the caregiver group identified as a random effect. This model takes into account  
4 the correlation between repeated measurements on each individual. An interaction term  
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6 between time and group will be introduced into the model to test whether rates of change in  
7  
8 the outcome differ between groups. If differences between the groups are evident at baseline,  
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10 these will be included in the model as covariates so that adjustment can be made before  
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12 examining differences between groups in outcomes.  
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19 In our preliminary work[11] there was <20% missing data. Missing data will be managed  
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21 using multiple imputation methods informed by a sensitivity analysis to manage this, creating  
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23 25 or more data sets.[48] Two analyses will be performed, namely: an analysis using only the  
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25 observed data, and secondly, after missing value substitution, where necessary. Data will be  
26  
27 analysed using an intention-to-treat approach. Secondary outcomes will be analysed in a  
28  
29 similar manner to the primary outcome. Statistical analyses will be conducted using STATA  
30  
31 16 software (Stata Statistical Software, College Station, TX: StataCorp LLC). All hypothesis  
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33 tests will be 2-sided and p values of <.05 considered statistically significant.  
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#### 40 Sample size

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42 The primary outcome is the change in total score on the AQoL-8D[36] for the caregiver at 6  
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44 months post-discharge. A very small effect size of 0.06 has been described as being of  
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46 clinical importance.[49] However, we anticipate a larger effect size, based upon: a) our  
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48 assessment of changes in health, measured using the SF12[50] during our preliminary  
49  
50 study,[11] in which we obtained a positive change in physical health (0.17) and mental health  
51  
52 (0.22) from baseline until immediately post-intervention; b) that the AQoL-8D is a more  
53  
54 appropriate outcome measure as psychosocial components of health are emphasised more;  
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56 and c) that we are now implementing an expanded intervention with longer follow up.  
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3 Therefore, we designed this study with 80% power to detect an effect size of 0.22. This  
4 would require 648 caregiver dyads (324 in each of the control and intervention groups),  
5  
6 determined using the G\*Power sample size calculator.[51] We anticipate 30% attrition during  
7  
8 the 12-month post-discharge period so our recruitment target to address the primary outcome  
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10 variable is 925 dyads. Based upon preliminary work, this sample size will also allow 80%  
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12 power to detect meaningful differences in the secondary outcomes for caregiver  
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14 preparedness, strain and distress, and hospitalisation costs for patients.[11]  
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### 23 **Process evaluation**

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25 A process evaluation will assist in understanding the mechanism of the trial results. The  
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27 process evaluation uses the framework recommended by the Medical Research Council for  
28  
29 evaluating complex interventions.[52] Caregivers' and nurses' feedback on aspects of  
30  
31 program implementation will be evaluated. A purposive sample (estimated 25-40) of  
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33 caregivers from WA and QLD who have completed participation in the FECH+ program will  
34  
35 be selected immediately after program conclusion for inclusion in qualitative interviews.  
36  
37 Sample selection will ensure maximum variation (e.g., gender, age, relationship, caregiving  
38  
39 duration), until data saturation.[53] Qualitative, digital, audio-recorded and transcribed semi-  
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41 structured telephone interviews (estimated 10-20 minutes) will be scheduled at two time  
42  
43 points (at the end of the intervention and six months later) to explore how the FECH+  
44  
45 program has influenced caregiving and caregiver experiences during and after the program.  
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47 FECH+ nurses will also be asked to record their reflections on each FECH+ program contact.  
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49 This includes identifying barriers to, or facilitators of, the effectiveness of the FECH+  
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51 program.  
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3 Program implementation will be examined by addressing fidelity, safety, adaptations, reach,  
4 and dose.[52] Data to be collected by the FECH+ nurses as they deliver the intervention  
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6  
7 include:

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10 a) adherence to or deviation from planned FECH+ processes including any safety concerns and  
11 how addressed;  
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13 b) information provided to caregivers and the extent to which caregivers engaged with  
14 resources provided;  
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17 c) time taken to implement processes, including duration and frequency of sessions.  
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24 Qualitative data will be analysed using thematic analysis.[53] Strategies to enhance the  
25 trustworthiness of findings will include verbatim transcriptions of audio-recorded interviews  
26 and an audit trail.[53] Quantitative data will be presented using the framework of the process  
27 evaluation and where appropriate triangulated with qualitative data to assist in clarifying  
28 complex causal pathways.[52]  
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### 35 36 37 **Economic analysis**

38 The economic analysis plan will be published separately. Briefly, cost effectiveness of the  
39 intervention (primary aim ii) will be measured using a within-trial cost-utility analysis. We  
40 shall evaluate the mean incremental cost and quality-adjusted life years (QALYs) according  
41 to the two randomized groups, taking an intention to treat perspective. A 12-month time  
42 horizon will be used, taking a health system perspective.  
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### 53 **Data Management**

54 Data management will be overseen by a data management committee comprising a  
55 representative from the CTDMC, the WA and Qld State Managers and trial leaders from WA  
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3 (AMH) and QLD (WM). The committee will undertake regular monthly monitoring and  
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5 auditing of data entry procedures and guide all data management. Data security is primarily  
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7 addressed by the use of REDCap, an online application that provides for secure data entry,  
8  
9 storage, and transfer. (<https://www.project-redcap.org/>) The CTDMC administers REDCap  
10  
11 and all data are stored in WA. Administrative data (which include names and dates of birth)  
12  
13 that are accessed via the database for merging with the health data will be locked down prior  
14  
15 to creating a merged dataset and are only accessible to a CTDMC administrator. De-  
16  
17 identified datasets will be uploaded through the University's encrypted system and stored on  
18  
19 a password protected drive (at Curtin University). All data will be securely managed and  
20  
21 stored at Curtin University as per National Health and Medical Research Council Australia  
22  
23 guidelines, State data linkage services and Services Australia guidelines. Following the  
24  
25 completion of the study analyses, a de-identified dataset will be made available on reasonable  
26  
27 request after ongoing secondary analyses are conducted and pending ethics approval from  
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29 existing and requesting institutions and approval from all investigators.  
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### 38 **Trial Status**

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40 Recruitment commenced in August 2020 and is expected to be completed by approximately  
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42 April 2022 with final follow up occurring in April 2023. Primary data analyses will be  
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44 completed, followed by the process evaluation. Final health data linkage will be undertaken  
45  
46 in the 12 months after final follow up. Health economic analyses will then be completed.  
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### 51 **Trial Management**

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53 Any amendments required to the study will be agreed on by the trial management committee  
54  
55 consisting of all Chief Investigators (AMH, WM, RM, KH, NW, SS, CB, SA), and submitted  
56  
57 to all ethics committees for approval prior to being commenced. The trial management  
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3 committee will monitor the trial in accordance with the currently approved protocol, which  
4 includes submitting annual ethics reports detailing trial progress and any adverse events to all  
5 ethics committees. Each of the named investigators on the grant shall be eligible to have  
6 authorship.  
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### 15 **Patient and Public Involvement**

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17 Two consumer advocates are members of the trial team. This study was developed with  
18 caregiver input from Carers WA and the WA Consumer and Community Health Research  
19 Network, prior to submitting the application for funding. The consumer input assisted to  
20 ensure the appropriateness of the intervention and study processes. This included assisting  
21 with wording of documents for the trial and aspects of procedure and intervention delivery.  
22  
23 The two consumer advocates are ongoing members of the trial team and continue to inform  
24 and give feedback about the study procedure. Both consumer organisations will contribute to  
25 the dissemination of results and future presentations and translation projects.  
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## ETHICS AND DISSEMINATION

The study has been approved by hospitals (the Sir Charles Gairdner Osborne Park Health Care Group, Gold Coast Health Care Group) and universities (Curtin and Griffith) human research ethics committees. Approvals for linked health data for economic evaluation have been obtained from the Data Linkage Branches of WA Health, QLD Health, and Services Australia (for national health administered data). All caregivers will provide written, informed consent to participate in the trial. Care recipients will also provide written, informed consent to participate in the trial. Participant information and consent forms are provided as online supplementary files (**see Additional file 2**). Cognitive impairment may occur in a care recipient who forms part of the dyad. A waiver of consent has been approved in WA for these care recipients to be included in the study. If these care recipients are encountered in QLD, we will seek consent from the appropriate substitute decision-maker.

To disseminate findings, Carers WA and Carers QLD, (two peak organisations who provide carer advocacy and support) will be asked to publicise the study completion and findings on their website. Our consumer advocates will provide advice and assistance to maximise engagement strategies through established state and national consumer networks. Papers will be published in peer-reviewed journals, and abstracts submitted to relevant conferences. Practitioner and consumer forums will be held in participating hospitals and State health districts. Study participants will be provided with a summary of study findings upon request.

## ACKNOWLEDGEMENTS

Authors thank and acknowledge the contributions of Adjunct Associate Professor Christine Toye (Curtin University) who led the trial of the original FECH program, made a substantial contribution to the trial design, led the grant application to obtain the funding for the trial and completed ethics applications, and Dr Richard Parsons who contributed to the trial design, grant application and preparation of the statistical analysis plan.

## COMPETING INTERESTS

The authors have no conflicts to declare.

## AUTHORS CONTRIBUTION

AMH and WM led manuscript drafting. AMH is the lead investigator on the National Health and Medical Research Council of Australia grant and all authors are named applicants on the grant. AMH, WM, RM, KH, SS, CB, NW and SA contributed to trial design and will assist with monitoring trial procedure. AMH leads the trial with support from WM, LG and AK. CB, SS, SA, KH, LG, WM and AMH contribute to intervention design and delivery. MB and AMH lead the statistical analysis plan. AK and LG lead the management of the trial sites. MBr, CR, SM, (WA) TC and CJ (QLD) contribute to trial procedure, including management at the sites. RM leads the economic analyses. All authors provided critical evaluation and approval of the final submitted manuscript.

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3 **FIGURE LEGENDS**  
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5 **Figure 1.** Participant flow through the study  
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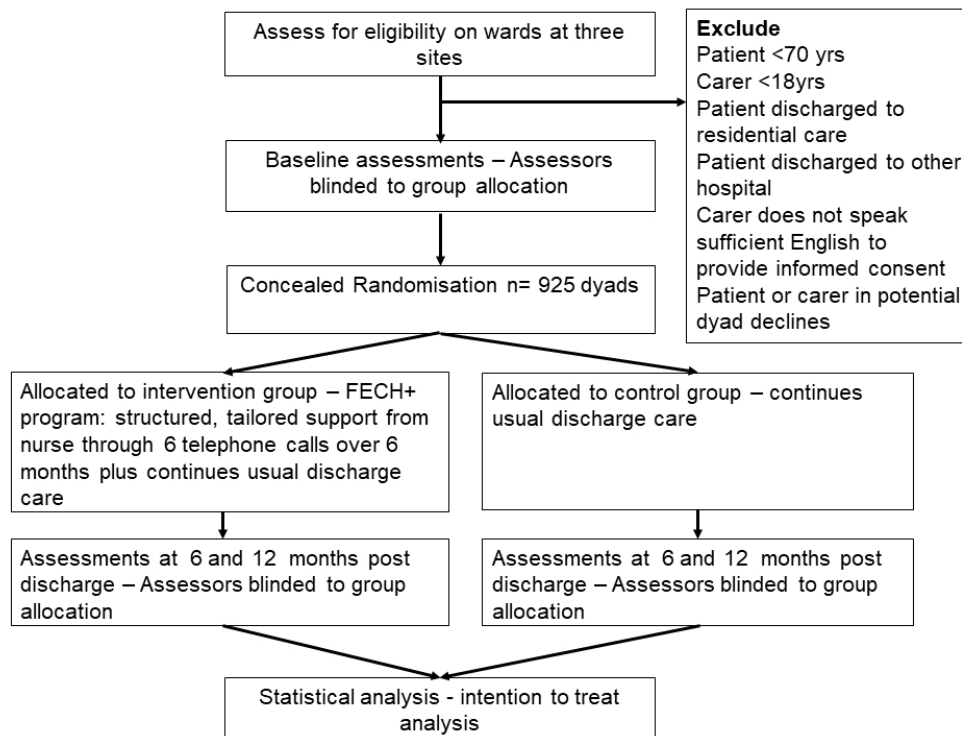


Figure 1. Participant flow through the study

81x60mm (300 x 300 DPI)



**Hill et al, 2020: Evaluating the provision of Further Enabling Care at Home (FECH+) for informal caregivers of older adults discharged home from hospital – protocol for a multicentre randomised controlled trial**

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents\*

Section/item	Item No	Description	Addressed on page number
<b>Administrative information</b>			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	4
	2b	All items from the World Health Organization Trial Registration Data Set	Yes - see ANZCTR trial registry page link in manuscript page 10
Protocol version	3	Date and version identifier	Published version is final
Funding	4	Sources and types of financial, material, and other support	25 – Funding statement
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Title page and page 25

1	5b	Name and contact information for the trial sponsor	25 –Funding statement
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4	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	25 – Funding statement
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8	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	22-23
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15	<b>Introduction</b>		
16			
17	Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention
18			6 -8
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20		6b	Explanation for choice of comparators
21			N/A
22	Objectives	7	Specific objectives or hypotheses
23			8
24	Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)
25			10
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28	<b>Methods: Participants, interventions, and outcomes</b>		
29			
30	Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained
31			11
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33	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)
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36	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
37			12, 15, Table 1
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	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Refer protocol ANZCTR online registry link on page 10
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	16
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Table 2 – p 18
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	19
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	19
<b>Methods: Assignment of interventions (for controlled trials)</b>			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	11
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	11

1	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	11-12
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4	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	11-12
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7		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
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10	<b>Methods: Data collection, management, and analysis</b>			
11				
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13	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	16-17,
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19		18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	21
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22	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	22
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27	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	19
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30		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	19
31				
32		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	19
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35	<b>Methods: Monitoring</b>			
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38	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	22
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	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	23
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	23
<b>Ethics and dissemination</b>			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	24
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	23
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	11, 17
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	22
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	22
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	25
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	n/a
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a

1 2 3 4	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	24
5 6		31b	Authorship eligibility guidelines and any intended use of professional writers	23
7 8		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	21
9 10	<b>Appendices</b>			
11 12 13 14	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Available on request
15 16 17	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

\*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons [“Attribution-NonCommercial-NoDerivs 3.0 Unported”](https://creativecommons.org/licenses/by-nc-nd/3.0/) license.

## **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

<b>Title</b>	Multicentre randomised controlled trial: caregiver, patient, and system outcomes from a program supporting informal caregivers of older people discharged home from hospital
<b>Short Title</b>	Evaluating the Further Enabling Care at Home (FECH) post-discharge program as a way to support carers of older hospital patients.
<b>Protocol Number</b>	APP1157834 Version 6 May 14 2020
<b>Project Sponsor</b>	Curtin University
<b>Coordinating Principal Investigator/ Principal Investigator</b>	Professor Anne-Marie Hill
<b>Chief Investigator(s)</b>	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
<b>Location</b>	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:

- 1 ■ Understand what you have read.
- 2 ■ Consent to take part in the research project.
- 3 ■ Consent to take part in the assessments and program that are described.
- 4 ■ Consent to the use of your personal and health information as described.

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

### 6 **Your withdrawal from the study**

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

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

## 16 **2 What is the purpose of this research?**

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

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

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

## 28 **3 What does participation in this research involve?**

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

35 The study is seeking to determine how a particular type of additional support for family carers may  
36 provide benefits for them and the patients for whom they provide care – and any costs or cost savings  
37 that the health system may incur as a result. To achieve this, some family carers will receive existing  
38 support and some will receive existing support plus additional support. You will be randomly allocated,  
39 like tossing a coin, to either receive usual post-discharge support, or to receive usual post-discharge  
40 support plus the FECH program. If you take part in the FECH program, the details you have provided  
41 about yourself, the care you provide, and the older person's health plus their care and support needs  
42 will also be provided to the nurse who delivers that program. This is so that the program can take  
43 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 31<sup>st</sup> 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.



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

### 12 ***Storage, retention and destruction of your information***

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

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

28 Results of this research project will be published and/or presented in a variety of forums. In any  
29 publication and/or presentation, information will be provided in such a way that you cannot be identified.  
30 All health results will be presented as group data, meaning individuals cannot be identified. Any quotes  
31 from interviews that are presented will be identified only with the study number used to describe the  
32 carer (eg, Carer 1, Carer 2). The processes that have been approved for this study ensure that the  
33 data we access from State and Federal Departments are de-identified prior to inclusion in the study  
34 analyses and cannot thereafter be re-identified. Furthermore, these data will be provided to us via the  
35 secure methods determined by these Departments.

36 After the study is completed, non-identifiable questionnaire data may be used again by our research  
37 team (for example when additional testing of the Further Enabling Care at Home program is  
38 undertaken) but the data obtained from your health records, including that provided by the Department  
39 of Health of Western Australians and/or Services Australia will not be used in any future or unspecified  
40 research outside of the approved study and will only be disclosed with your permission, except as  
41 required by law. Any information obtained for the purpose of this research project that can identify you  
42 will be treated as confidential and securely stored. It will be disclosed only with your permission, or as  
43 required by law.

### 44 ***Accessing your information***

45 In accordance with relevant Australian and/or Western Australian privacy and other relevant laws, you  
46 have the right to request access to your information collected and stored by the research team. You  
47 also have the right to request that any information with which you disagree be corrected. However, the  
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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](mailto: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](mailto: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

✂.....

#### 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**

<b>Title</b>	Multicentre randomised controlled trial: caregiver, patient, and system outcomes from a program supporting informal caregivers of older people discharged home from hospital
<b>Short Title</b>	Evaluating the Further Enabling Care at Home (FECH) post-discharge program as a way to support carers of older hospital patients.
<b>Protocol Number</b>	APP1157834 Version 6 May 14 2020
<b>Project Sponsor</b>	Curtin University
<b>Coordinating Principal Investigator/ Principal Investigator</b>	Professor Anne-Marie Hill
<b>Chief Investigator(s)</b>	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
<b>Location</b>	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.

1 I have had an opportunity to ask questions and I am satisfied with the answers I have received.

2  
3 I freely agree to participate in this research project as described and understand that I am free to  
4 withdraw at any time during the study without affecting my future health care.

5  
6 I understand that I will be given a signed copy of this document to keep.

7  
8 I understand that Curtin University is not part of the Sir Charles Gairdner Hospital or the Government  
9 of Western Australia and health professionals involved in the conduct of this study do so in a private  
10 capacity and not as employees of the hospital or the State.  
11

12			
13 Full name of Participant (please print first, middle, and last IN FULL)			
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17 Date of birth			
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22 Home (street) address (including suburb and postcode)			
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27 Email address			
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31 Telephone number			
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Signature		Date	
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43 **Declaration by Researcher**

44 I have given a verbal explanation of the research project, its procedures and risks and I believe that  
45 the participant has understood that explanation.

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47	
48 Name Researcher (please print) _____	
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51 Signature _____ Date _____	
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54 Note: All parties signing the consent section must date their own signature.	
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**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](mailto: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.**