PROTOCOL

IMPART - IMproving PAlliative care in Residential aged care using Telehealth

Protocol
Version: 6
Date: 21/03/2024

Author/s:
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CONFIDENTIAL

Statement of Compliance

This study will be conducted in compliance with all stipulations of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (2007 updated 2018). Australian Code for the Responsible Conduct of Research, 2018 (*the Code*) and the principles of the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

Signature Page

The undersigned confirms that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's Standard Operating Procedures (SOPs), and other regulatory requirements.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:			
Signature:		Date:	21/3/2024
Name (please print):	Kwang Lim		
Position:	Clinical Director Aged Care | Medical Director		

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1. STUDY SYNOPSIS

Title:	IMproving PAlliative care in Residential aged care using Telehealth
Short Title:	IMPART
Design:	Stepped-Wedge Cluster Randomised Controlled Trial
Lead Study Centre:	National Ageing Research Institute (NARI)
Study Aim:	To evaluate the effectiveness and cost-effectiveness of the IMPART program, which consists of 1) an interactive, needs-based end-of-life education program for senior nurses, clinical care coordinators and general practitioners (GPs) working in residential aged care facilities (RACFs), and 2) timely end-of-life support from specialist telehealth in-reach.
Primary Research Question:	Does IMPART reduce unplanned hospital admissions of aged care residents over the trial period compared to the control group?
Secondary Research Questions:	- Does IMPART reduce emergency department presentations of aged care residents over the trial period compared to the control group? - Does IMPART reduce length of stay of unplanned hospital admissions of aged care residents over the trial period compared to the control group? - Does IMPART improve end-of-life care quality over the trial period compared to the control group? - Is IMPART cost-effective to implement compared to usual care?
Inclusion Criteria:	All residents living permanently in RACFs as well as family members of residents who die during the study. GPs and RACF senior nurses and clinical care coordinators will be invited to participate.
Exclusion Criteria:	N/A
Number of Planned Participants:	2000 residents, 250 family carers, 20-50 healthcare professionals
Statistical Methods:	Statistical methods depend on the type and distribution of the outcome measures and will include, for example, descriptive analysis, mixed-effects Poisson regression models, sensitivity tests, and correlations. Statistical analyses will be conducted using Stata version 15.1. Randomisation will be conducted using Stata version 15.1 and Ralloc software.
Consumer Involvement:	Involved in all stages of the research via a consumer group that will form part of the project team and be consulted throughout the study.

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2. GLOSSARY OF ABBREVIATIONS & TERMS

Abbreviation	Description (using lay language)
C	Component
CT	Clinical trial
CVDL	Centre for Victorian Data Linkage
GCP	Good Clinical Practice
GP	General Practitioner
HREC	Human Research Ethics Committee
ICECAP	Investigating Choice Experiments for the preferences of older people CAPability
ICER	Incremental cost-effectiveness ratio
IMPART	IMproving PAlliative care in Residential aged care using Telehealth
MARC	Melbourne Ageing Research Collaboration
MBS	Medicare Benefits Scheme
NARI	National Ageing Research Institute
NHMRC	National Health and Medical Research Council
PBS	Pharmaceutical Benefits Scheme
PICF	Participant Information and Consent Form
QOL-ACC	Quality of Life – Aged Care Consumers
RAC	Residential Aged Care
RACFs	Residential Aged Care Facilities
REDCap	Research Electronic Data Capture electronic database
STATA	Software for statistics and data science
T	Time
VAED	Victorian Admitted Episodes Dataset
VEMD	Victorian Emergency Minimum Dataset

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3. STUDY SITES

3.1 STEERING COMMITTEE

The multi-disciplinary research team will form a project Steering Group that will meet three-monthly throughout the study and include consumer representatives. The steering committee will oversee all aspects of the IMPART project and consists of the following members:

Name	Affiliation
Professor Kwang Lim	NARI, Royal Melbourne Hospital
Associate Professor Kirsten Moore	NARI
Associate Professor Barbara Hayes	Northern Health
Associate Professor Brian Le	Royal Melbourne Hospital
Dr Paul Yates	Austin Health
Professor Melissa Bloomer	Griffith University
Professor Len Gray	The University of Queensland
Professor Dimity (Constance) Pond	The University of Newcastle
Dr Katrin Gerber	NARI
Dr Lidia Engel	Monash University
Mr Mark Tacey	Northern Health
Associate Professor Danny Hills	Federation University
Associate Professor Frances Batchelor	NARI
Dr Anita Goh	NARI
Dr Ross Bicknell	Royal Melbourne Hospital
Professor Debra Nestel	Monash University
Dr Christina Johnson	Monash University
Dr Steven Savvas	NARI
Ms Karen Bodna	Consumer Representative

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3.2   STUDY LOCATION/S

Site	Address	Site Principal Investigator	Phone	Email
National Ageing Research Institute	34-54 Poplar Road, Gate 4, Building 8, Royal Melbourne Hospital Victoria 3050 Australia	Dr Anita Goh	03 8387 2377	a.goh@nari.edu.au
The Royal Melbourne Hospital	City Campus, Level 6 North 300 Grattan Street, Parkville Victoria 3050	Prof Kwang Kim	03 9342 4186	kwang.lim@mh.org.au
Austin Health	Level 3, Austin Tower, 145 Studley Road, Heidelberg, PO Box 5555, Victoria, 3084	Dr Paul Yates	03 9496 5000	Paul.YATES@austin.org.au
Northern Health	1231 Plenty Rd, Bundoora VIC 3083	Dr Penny Harvey	04 0753 5629	Penelope.Harvey@nh.org.au
Monash University	Monash University 553 St Kilda Road Melbourne VIC 3004	Dr Lidia Engel	TBD	lidia.engel@monash.edu

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4. BACKGROUND

4.1 LAY SUMMARY

Sixty thousand people in Australia die every year in residential aged care facilities (RACFs) but the quality of their end-of-life care varies. The IMproving PAlliative care in Residential aged care using Telehealth (IMPART) intervention aims to improve palliative care in RACFs using a comprehensive program that includes specialist geriatric and palliative telehealth support and training to aged care staff and general practitioners (GPs). We will engage senior RACF staff and GPs in a Planning Ahead Team that will reflect on current practices and develop an action plan to improve end-of-life care planning and processes. This intervention aims to enable timely end-of-life discussions, improve documentation of care preferences, and therefore enable preference-based care, reduce unplanned hospitalisation and improve residents' quality of care at the end of life. We will evaluate the effectiveness using various measures including hospitalisation data, post-death reflections on quality of care at end-of-life by family carers and an economic analysis to examine whether the program is cost effective.

4.2 INTRODUCTION

This study will evaluate the effectiveness and cost-effectiveness of the IMPART intervention. Residential Aged Care Facilities (RACFs) have high mortality rates yet the quality of end-of-life care varies across facilities. Lack of clarity around residents' preferences is a persistent issue. There is a need to improve communication and end-of-life discussions in RACFs. There is good evidence to support the use of Goals of Care medical treatment plans in improving end-of-life discussions and planning that require ongoing education to be made available to relevant staff [1-3]. Access to specialist palliative care support is also key to supporting RACF staff. With the growing demand for and evidence to support telehealth [4-9], there is potential to improve access and clinical outcomes and reduce the cost of service delivery.

This study will implement a stepped-wedge cluster randomised controlled trial across 10 RACFs to evaluate the IMPART program. The program consists of 1) an interactive, needs-based end-of-life care education program for senior nurses, clinical care coordinators and GPs working in RACFs, and 2) timely end-of-life support from specialist telehealth in-reach. In-reach is a referral and consultation service for RACF staff and GPs providing support for residents' acute health issues, via telephone or video-conferencing. The program aims to achieve the following benefits:

- Improve communication and collaboration between residents, families, RACFs, GPs, palliative care and aged care services;
- Improve knowledge and confidence of RACF staff and GPs to provide, discuss and plan end-of-life care with residents and families;
- Increase consultation with specialist palliative and aged care services at the end of life;
- Increase frequency and quality of end-of-life care documentation, and reduced unplanned hospitalisation of residents at the end of life.

4.3 BACKGROUND INFORMATION

RACFs are a place where people live and die. In 2018-2019, 182,000 Australians lived in RACFs [10], and almost 60,000 people died there [11] with an average length of stay of 2.5 years [12]. Eighty-three percent of exits from permanent RACFs were due to death [12].

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4.3.1 End-of-life care in RACFs needs to improve

Even though RACFs are high-mortality settings, there is a known lack of clarity of residents end-of-life preferences [13, 14] and evidence that RACFs do not always provide adequate support for their dying residents [15]. The Royal Commission into Aged Care Quality and Safety found that the standard of palliative care provided in RACFs varied widely [15]. Reasons for this related to the:

- Residents' complex care needs [16], including multiple co-morbidities [16] and dementia [16-18];
- Resource issues including lack of staff [18], access to equipment and medication [1, 2, 16], access to GPs who are the primary treating doctors in RACFs [19] and availability of support for end-of-life care [1, 2, 15, 16];
- Lack of knowledge, training and confidence of RACF staff in end-of-life care discussions, recognising dying and providing end-of-life care, leading to poor communication and unclear goals of care [1-3].

The provision of palliative care is important for aged care residents due to their short life expectancy and medical, cognitive and mental health conditions, frailty and disabilities [20, 21]. This includes an approach that minimises futile treatments and burdensome care, including reducing unplanned hospital transfers. Research has shown up to 60% of hospital transfers of residents are avoidable, and often lead to poor outcomes [22]. This was highlighted in a systematic review of outcomes for residents who had an emergency transfer to hospital [22]. While up to 52% of residents died within three months of an acute hospital transfer, they had high levels of invasive procedures (e.g. blood tests: 43-80% and intravenous cannula: 40-66%) and complications (e.g. delirium: 38% and new pressure ulcers: 19%) once admitted [22].

4.3.2 The need for better end-of-life care planning and discussions

Person-centred end-of-life care relies on clear communication. Yet, end-of-life discussions and planning are often avoided by older people, families and healthcare staff including GPs or nurses, leading to sudden decision-making during medical crises [23, 24]. In RACFs, many older people lack family support for substitute medical decision-making and advocacy [25] and RACF staff and GPs often lack the resources or skills to assist with preparing advance care plans [26]. Residents' cultural backgrounds and language barriers can influence their willingness to talk about death and engage in advance care planning [27]. Research has demonstrated that older people's care preferences are poorly documented across settings including RACFs, with their preferred place of death missing in 70% of files [28]. Lack of communication and documentation can lead to frequent hospital admissions [16, 28], making the end of life a potentially disjointed and distressing experience for residents and their families [15].

4.3.3 Goals of Care support end-of-life care discussions and planning

Goals of Care medical treatment plans have been proposed as a way to address end-of-life care discussions by using shared decision-making to incorporate residents' prior advance care planning and preferences into medical treatment orders to guide future healthcare decisions when the resident is unable to express their preferences [29]. A cluster randomised controlled trial showed that these plans and discussions can be more effective in reducing non-beneficial and unwanted hospitalisation at the end of life than advance care planning alone because it not only considers the resident's own instructions, preferences and values related to healthcare but also what might be medically feasible for the resident, given their health conditions [29]. Goals of Care discussions can further improve

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end-of-life communication for residents in RACFs and enhance palliative care plans [30]. In contrast, when residents' prognoses and preferences are not discussed, they are likely to be transferred to acute care and receive a higher level of intervention than they may have wanted [31]. However, there is often lack of time and staff skills to develop these plans [26].

4.3.4 Specialist palliative care support at the end of life

Without palliative care services in RACFs being adequately and appropriately funded, the ethical, societal and economic costs are high. Palliative Care Australia report that government subsidies for palliative care services are only available for the last days of life in RACFs, with just one in 50 permanent residents (2%) receiving government-funded palliative care services [32]. Poor integration and fragmented care between hospital settings and RACFs can lead to high-cost, low-value care and poor outcomes. The intensity of care received after transfer to hospital may be inconsistent with residents' care preferences. Hence, there is a need to invest in specialist palliative care in RACFs, including support for the RAC workforce and other health professionals such as GPs to reduce unplanned hospitalisation [32]. However, the economic cost-effectiveness of education and training for RAC staff to enhance end-of-life care is rarely examined. To allocate and prioritise healthcare resources requires evaluating the impact of healthcare interventions on both costs and health outcomes [33]. Many healthcare studies use different measures of outcome to demonstrate the effect of an intervention [33]. Despite the potential financial benefits for the healthcare system of providing end-of-life care education, a recent systematic review emphasised that economic benefits have not previously been measured [34].

4.3.5 Establishing sustainable cost-effective change through telehealth

In addition to insufficient evidence that interventions create cost-effective change, sustainability is another challenge. For sustainable change, interventions for staff need to include interactive training, post-training support, offer written materials and build interventions into routine care [35]. To effectively provide such training, telehealth can be used. The International Organisation for Standardisation defines telehealth as the "use of telecommunication techniques for the purpose of providing telemedicine, medical education, and health education over a distance" [36]. The demand for telehealth has increased exponentially due to the COVID-19 pandemic [37], including its use to deliver specialist care, such as palliative care and geriatric care to RACFs. Telehealth has the potential to improve access and clinical outcomes and reduce cost of service delivery [38]. There is strong evidence to support the use of telehealth for remote monitoring of patients with chronic conditions [4], medication reviews [5] and geriatric consultations in rural hospitals and RACFs across Australia, with evident cost savings and high consumer satisfaction [6-9]. However, a recent systematic review found that the benefits of using telehealth in palliative care such as reduced need for emergency care are often being described without being adequately evaluated [39]. The review also identified only one study that was set in RAC, pointing to an urgent need for more research in this area. To address these gaps in end-of-life care in RAC, the IMPART study will involve testing and assessing a telehealth-based intervention to deliver end-of-life care training and supervision by specialist services to RAC nurses and GPs.

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5. AIM AND HYPOTHESES

5.1 AIM

To evaluate the effectiveness and cost-effectiveness of the IMPART program, which consists of 1) an interactive, needs-based end-of-life education program for senior nurses, clinical care coordinators and general practitioners (GPs) working in residential aged care facilities (RACFs), and 2) timely end-of-life support from specialist telehealth in-reach.

5.2 RESEARCH QUESTIONS AND HYPOTHESIS

Table 1 outlines the research questions and corresponding hypotheses. Unplanned hospital admissions, emergency department presentations and length of stay of unplanned hospital admissions will be measured using a rate per 1000 resident bed-days.

Table 1: IMPART Research Questions and Hypotheses

Primary Research Question	Corresponding Hypotheses
Does IMPART reduce unplanned hospital admissions of aged care residents over the trial period compared to the control group?	IMPART reduces unplanned hospital admissions of aged care residents over the trial period compared to the control group.
Secondary Research Questions	
Does IMPART reduce emergency department presentations of aged care residents over the trial period?	IMPART reduces emergency department presentations of aged care residents compared to the control group.
Does IMPART reduce length of stay of unplanned hospital admissions of aged care residents over the trial period?	IMPART reduces length of stay of unplanned hospital admissions of aged care residents compared to the control group.
Does IMPART improve end-of-life care quality over the trial period compared to the control group?	IMPART improves end-of-life care quality compared to the control group
Is IMPART cost-effective to implement compared to usual care?	IMPART is cost-effective when compared to usual care in terms of quality of life improvement units as measured by the Quality of life – Aged Care Consumer (QOL-ACC) measure

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6. STUDY DESIGN

6.1 STEPPED-WEDGE CLUSTER RANDOMISED CONTROLLED TRIAL

We will use a mixed-methods stepped-wedge cluster randomised controlled trial to assess the effectiveness and cost effectiveness of IMPART. We will recruit ten Victorian RACFs in five steps, with each step six months in duration. We will also retrospectively include the primary outcome (unplanned hospitalisations) for the 6 months prior to the trial start date to provide additional control data. Therefore we will have three years of data collection, but the trial will be active over 2.5 years (see Table 2 below). At each active step of the trial, two RACFs will be randomly allocated to start the intervention for the next six months. The intervention will be compared to usual care (control/ waiting). The first six months of the intervention will be the most active, but it is anticipated that care improvements implemented during the initial six-month active intervention period will continue into the subsequent steps of the trial. Data will be collected in each facility at the start and end of each step, therefore prior to the active intervention (pre-trial; Time 0 or T0), at baseline (T1), and at the end of Steps 1-5 (End of Step 1=T2; Step 2-T3, Step 3-T4, Step 4: T5, Step 5, T6).

Table 2: **Overview of IMPART intervention roll-out**

Year		1	1	2	2	3	3
Steps (6 month blocks):		Pre	1	2	3	4	5
Intervention roll-out 1 (2 RACFs)		Control/ waiting	Intervention	Intervention	Intervention	Intervention	Intervention
Intervention roll-out 2 (2 RACFs)		Control/ waiting	Control/ waiting	Intervention	Intervention	Intervention	Intervention
Intervention roll-out 3 (2 RACFs)		Control/ waiting	Control/ waiting	Control/ waiting	Intervention	Intervention	Intervention
Intervention roll-out 4 (2 RACFs)		Control/ waiting	Control/ waiting	Control/ waiting	Control/ waiting	Intervention	Intervention
Intervention roll-out 5 (2 RACFs)		Control/ waiting	Control/ waiting	Control/ waiting	Control/ waiting	Control/ waiting	Intervention
Key:	Intervention			Control/ waiting			

6.2 RANDOMISATION AND BLINDING

By using a stepped-wedged design, each participating RACF will eventually access the IMPART program. While they are waiting for the program to start, they will continue practice as usual. Once the 10 RACFs are determined, we will randomly select RACFs for allocation to each sequence. Considering potential variation in the size of RACFs, this process will be stratified to ensure that the largest sites are not all randomly assigned to the last roll-out block. To prevent the two largest (or vice versa, two smallest) RACFs being randomly assigned to the first or last sequence, the randomisation will be conducted in two parts. After sorting the 10 RACFs from smallest to largest in size based on number of residents, one from each of the 5 pairs (i.e. 1st-2nd smallest considered as pair 1, 3rd-4th smallest as pair 2,… etc.) will be randomly assigned to either Group A or Group B, resulting in 5 RACFs included in each group. The 2nd step will be to randomly order the 5 RACFs in Group A and assign them to stepped wedge sequences 1 to 3. The 5 RACFs in Group B will then be randomly ordered with the first RACF in Group B assigned to the remaining spot in sequence 3, and the remaining 4 RACFs assigned based on the random ordering to sequences 4 and 5. This may, by chance, result in the two largest (or smallest) being assigned to sequence 3, but it will ensure that the two largest (or two smallest) are not both assigned to sequences 1 or 5. If the size of the

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RACFs does not vary considerably, then the stratified randomisation approach will be abandoned, and simple random ordering of the 10 RACFs into the 5 clusters will be conducted. Randomisation will be completed by the project statistician, external to the research team and using Stata version 15.1 and Ralloc software. It will not be possible to blind RAC staff, external telehealth clinicians or the research staff who are implementing and analysing the intervention.

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7.   THE IMPART INTERVENTION

Prior to implementing the intervention, the research team will assess each facility's video-conferencing capacity and the need for equipment and training to enable communication via telehealth. Where IT capacity is not sufficient to participate in the trial, training will be provided to members of the Planning Ahead Team or equipment or wifi access will be purchased for 12 months to cover the active six month intervention period and the following six months.

The IMPART intervention is actively implemented over a six month period and involves five key components (C1-C5) as illustrated in Table 3 below. A detailed description of each component is described below. After this initial 6 month active part of the intervention, RACFs will be able to use the knowledge, strategies and specialist connections they established during this period and apply them for the subsequent 6 month periods of the trial and into the future. For each active 6 month intervention period, the specialist in-reach support will be funded 0.1 EFT to support engagement with the facility including participating in the needs analysis and providing training as required. We will aim to hold some meetings and workshops in person at the facility, however, we also aim to enable video-conferencing to facilitate external staff involvement.

Table 3: Timeline of IMPART components

	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6
C1	Establish Planning Ahead Team					
C2	End-of-Life Care Needs Analysis					
C3		Conduct Workshop + Develop Action Plan	Implement and Monitor the Action Plan			
C4		Apply Online Training as required				
C5		Involve Specialists in Workshop and Action Planning	Provide ongoing Specialist Telehealth In-Reach End-of-Life Support and Training			

C=Component of the IMPART intervention

7.1   COMPONENT 1: ESTABLISH PLANNING AHEAD TEAMS

In the first few weeks of the intervention, the research team will work collaboratively with a RACF to establish the facility 'Planning Ahead Team', consisting of 2-3 RAC staff. The RACF will identify appropriate staff to be involved in this team, which could include nurses with a portfolio of palliative care, clinical care coordinators, or staff who have an interest in end-of-life care. We will engage senior nurses as care champions who will be able to support other staff in palliative care discussions and processes. The lead of the Planning Ahead Team will support RAC staff and work with GPs to promote end-of-life discussions with residents and families, and document decision-making. We envisage having small Planning Ahead Teams in order to focus our full support on them and reduce

burden on RACFs. However, we aim to involve at least two RAC staff to ensure that palliative care processes will continue if someone resigns or goes on leave.

We will also engage an interested GP who has an existing visiting role at the RACF. To support GP participation, we will explore the use of case conferencing Medicare items such as item 735 for a 15-minute conference. GPs will not have a central role in all activities of the Planning Ahead Team.

7.2   COMPONENT 2: END-OF-LIFE CARE NEEDS ANALYSIS

The Planning Ahead Team (with support as required from the research team) will undertake a needs analysis in each RACF to identify areas for improvement in end-of-life care discussions, documentation and care provision. They will review current documentation in resident files using the template in Appendix 1. This recommends reviewing files of 5-10 residents for each template:

- Template 1 provides questions for reviewing current resident files to evaluate the quality of end-of-life care planning documentation (what is documented, whether resident wishes are incorporated and whether it has been recently reviewed by the resident, family and/or GP).
- Template 2 prompts evaluating documentation from 5-10 residents who have recently died (in the last 6 months). Questions include place of death, services involved, recognition of dying, whether end-of-life care was consistent with residents' wishes and end-of-life planning documentation.

These templates will be completed confidentially by the Planning Ahead Team to help them reflect on current practices in end-of-life care and documentation and will not be collected as research data. It will help inform completion of the Needs Analysis Checklist (Appendix 2) that assess the extent to which each facility's existing processes, policies and procedures enable shared-decision making, person-centred care and are responsive to cultural, language and spiritual requirements and values. This Checklist does not contain feedback regarding individual residents, but rather summaries of overall RACF processes, policies and procedures. The Needs Analysis Checklist will be completed jointly by the Planning Ahead Team with support from the research team and input from the external palliative care and aged care specialists.

The research team will invite the Planning Ahead Team to complete a short survey assessing their confidence in providing, discussing and planning for end-of-life care (Appendix 3), which is based on existing end-of-life confidence measures [40, 41]. The research team will assess the availability and confidence of RACF staff in using end-of-life related equipment such as syringe drivers, lifting machines, pressure relieving devices or catheter equipment and the availability of medication related to end of life including Imprest stock. Planning Ahead Teams will explore opportunities for obtaining resident and family input on end-of-life care planning undertaken in the facility. They will also review documented complaints and complements to the facility and see whether any relate to end-of-life care.

7.3   COMPONENT 3: WORKSHOP WITH PLANNING AHEAD TEAMS AND ACTION PLANNING

The research team will facilitate an initial workshop with the Planning Ahead Team. During this workshop, the research team will present findings from the needs analysis, highlighting strengths

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and challenges in the current end-of-life care practice. For instance, we will synthesise data from the Needs Analysis Checklist (Appendix 2) and the staff end of life care survey (Appendix 3) to reflect on practice and highlight areas where practice could be improved. This will provide a comprehensive understanding of the end-of-life care needs in the facility, incorporating views of RAC staff, external palliative care specialists and GPs. We will then discuss avenues for addressing identified needs and develop an action plan (Appendix 4). In developing the action plan, tasks will be allocated to individual staff including a timeline for completion and evaluation. This approach aims to engage facility staff with areas of practice change that they have identified and consider relevant to their practice. This ensures that solutions identified are context specific and are more likely to enable sustainable practice change through facility staff leadership and ownership of the change process.

Components 4 and 5 of IMPART will provide training and support required to address the identified needs. During the workshop, future meetings and steps for the Planning Ahead Team will be planned to monitor the action plan and outcomes. The external geriatric or palliative care specialist will contact the RACF Planning Ahead Team through a monthly telephone/video call to discuss progress, challenges and offer information and training as needed. While developing the action plan, we will identify ways of involving residents and families in implementing the action plan, e.g. by including them in future discussions about end-of-life care processes. At the end of the 6 month intervention and to evaluate the impact of the action plan on practice, we will reflect on the initial findings of the needs analysis and repeat some data collection. For example, the Planning Ahead Team may conduct another review of resident files to see whether documentation has improved (Appendix 1), repeat the staff end-of-life care survey (Appendix 3) or review policies, complaints and complements.

7.4   COMPONENT 4: IMPETUS-D PLUS ONLINE TRAINING

RACF staff will receive access to the existing 'Improving Palliative care Education and Training Using Simulation in Dementia (IMPETUS-D) validated online training package [18]. During the workshop described in Component 3, the Planning Ahead Team will review the modules available in the IMPETUS-D training set to identify which modules may be useful for staff in their facility. Depending on the goals identified in the action plan, they may choose training for all RACF staff or target training to specific staff, such as those in the Planning Ahead Team. The IMPETUS-D modules have different target audiences. For example, some modules target all RACF staff and some only target clinical staff such as GPs and nurses. It may be useful to use a section of a module or run a workshop/meeting to discuss a module and the implications for practice at that RACF. The research team will send reminders to the Planning Ahead Team to complete training as planned in the action plan.   There are 11 modules that can be completed online using a computer/laptop, tablet or smartphone. Each module takes 15-30 minutes and contains video simulation to aid learning. Topics include: recognising the end of life; engaging in Goals of Care planning and discussions; distinguishing dementia from delirium, managing symptoms including pain, breathlessness, not eating/drinking, and terminal restlessness; communicating with residents and families, and supporting staff when a resident dies. Further details are including in the Action Plan Template (Appendix 4). The training was developed for end-of-life care for people with dementia but encompasses all the skills required for end-of-life discussions for all RACF residents. In addition to the IMPETUS-D online training modules, the research team will highlight other resources that may address information needs as part of the IMPETUS-D Plus training such as advance care planning in aged care [42], recognition of dying [43], and grief support [44, 45].

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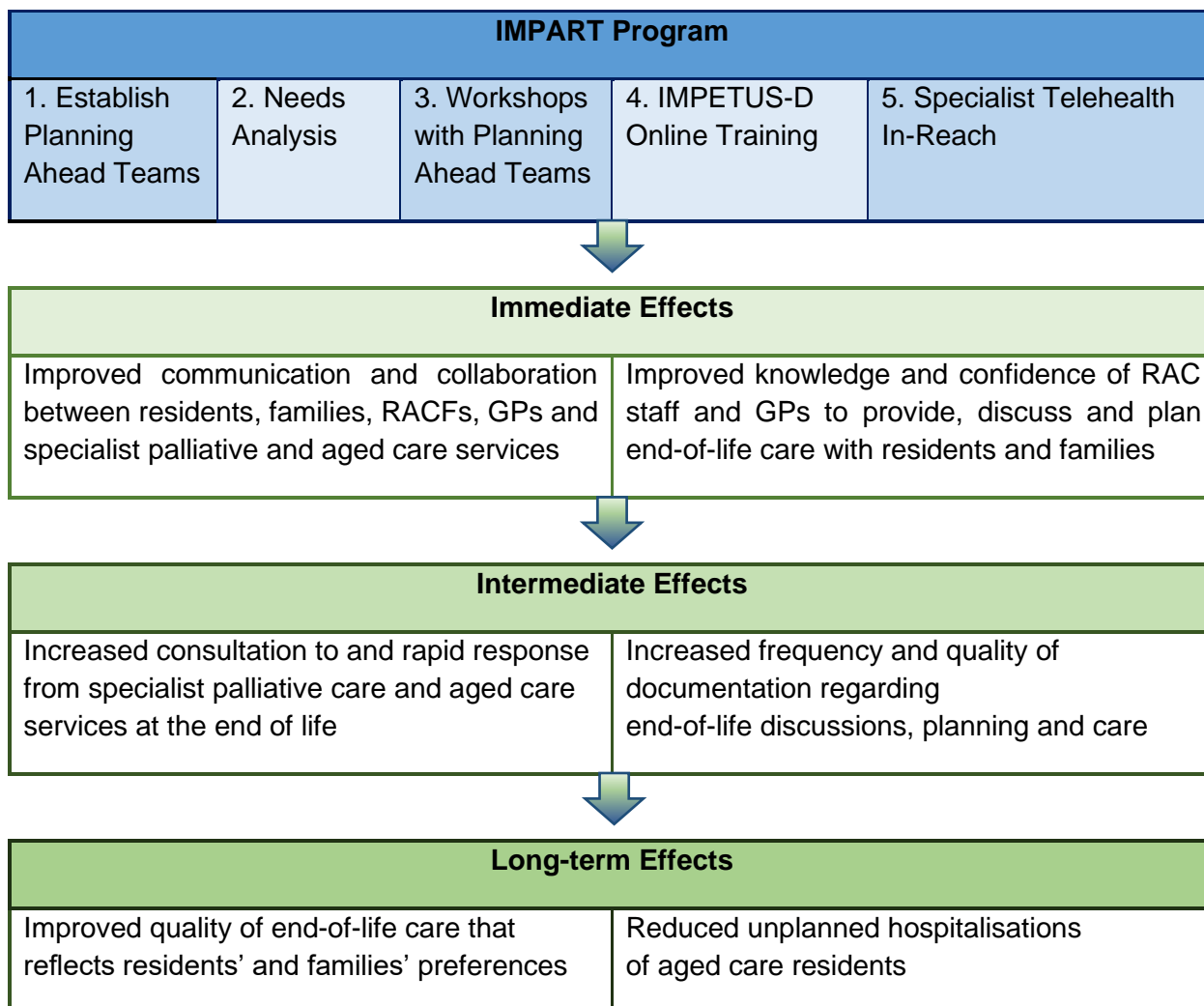
7.5   COMPONENT 5: SPECIALIST TELEHEALTH IN-REACH END-OF-LIFE SUPPORT

The local palliative care and aged care specialists will be engaged from the start of the IMPART program through their involvement in the Planning Ahead Teams in Components 1 and 3. We will work in a geographic catchment in Melbourne that contains approximately 200 RACFs and are supported by hospital and community specialist teams which are represented on our research team. The workshops with the Planning Ahead Teams will help RAC staff get to know the specialist team, establish communication channels and plan for specialists to provide training or shadowing/observations using online technology. Based on our previous work in these settings, observation of discussions can help develop clinicians' confidence [3]. An approach that may be implemented could involve the Planning Ahead Team and the GP completing IMPETUS-D modules and discussing this with the specialist team. This could be followed by a collaborative end-of life discussion between the resident and/or family member(s) with RAC staff, the GP and the specialist clinician using telehealth. This will involve immediate feedback after the case conference from the specialist clinician. While the IMPETUS-D training provides videos of professionals having these conversations, there may be additional benefits of getting direct feedback from an expert. We have also found in an evaluation of a telehealth training program across rural and metropolitan dementia advisory services that providing training fostered collaboration through 'breaking the ice' and helping clinicians feel more inclined to contact specialists at other sites for clinical advice [46]. We will use video-conferencing to foster rapid communication between RACFs and specialists. We will provide funding to specialist services to increase staff time for support and rapid response. This approach will promote sustainable collaborative working relationships beyond the completion of the study.

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7.6 IMPART Logic Model

Figure 2 outlines a process-oriented logic model of IMPART [47], illustrating the key components of the intervention and the anticipated immediate, intermediate and long-term effects.

Figure 1. **Process-Oriented Logic Model of the IMPART program**

IMPART Program				
1. Establish Planning Ahead Teams	2. Needs Analysis	3. Workshops with Planning Ahead Teams	4. IMPETUS-D Online Training	5. Specialist Telehealth In-Reach

Immediate Effects	
Improved communication and collaboration between residents, families, RACFs, GPs and specialist palliative and aged care services	Improved knowledge and confidence of RAC staff and GPs to provide, discuss and plan end-of-life care with residents and families

Intermediate Effects	
Increased consultation to and rapid response from specialist palliative care and aged care services at the end of life	Increased frequency and quality of documentation regarding end-of-life discussions, planning and care

Long-term Effects	
Improved quality of end-of-life care that reflects residents' and families' preferences	Reduced unplanned hospitalisations of aged care residents

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8. DATA COLLECTION

8.1 INTERVENTION EFFECTIVENESS

Table 4 outlines the methods of data collection that will be used to assess the primary and secondary hypotheses regarding the effectiveness of the intervention. The process for obtaining consent to access the data is described. Facility staff will be backfilled to support data collection over the duration of the trial.

Table 4: Primary and Secondary hypotheses, data collection and consent

Primary Hypothesis	Data	Consent
IMPART reduces unplanned hospital admissions of aged care residents over the trial period compared to the control group. **Secondary hypotheses:** IMPART reduces emergency department presentations of aged care residents compared to the control group. IMPART reduces length of stay of unplanned hospital admissions of aged care residents compared to the control group.	• We will ask RACFs to extract the number of unplanned hospital admissions, emergency department presentations and level of need (indicated by Australian National Aged Care Classification and the Aged Care Funding Instrument) for all permanent residents for the previous 6 months. This will be collected for the 6 months prior to the first step of the trial and then for each of the subsequent 5 steps of the stepped-wedge design. • To support the analysis of the hospitalisation data via the Centre for Victorian Data Linkage, RACF staff will extract data from residents' files, including: name, gender, date of birth, Medicare number, admission and discharge (if relevant) from the RACF. • RACF staff will be asked to submit this data to the research team once every 6 months via RedCap, a secure database which sits under strict password protection on the NARI server. • We will use this data to collect via the Centre for Victorian Data Linkage: 1) Victorian Admitted Episodes Dataset (VAED; hospital admissions, length of stay, preferred place of death, change of care phase during admission and other relevant variables) and 2) Victorian Emergency Minimum Dataset (VEMD; emergency department visits, number of deaths during transfer to hospital and other relevant variables)	We are requesting a waiver of consent for this data because 1. data collection is non-intrusive, 2. there is negligible risk for individual participants, there is no known or likely reason for thinking that participants would not have consented if they had been asked, 3. their privacy and the confidentiality of their data will be sufficiently protected 4. obtaining individual consent for this data is impractical. (further details are provided in Section 9.4.1)
IMPART improves end-of-life care	Family members of residents who die during the trial period (both in the intervention and the control/waiting arm), will be asked to complete	Family members* will be contacted 2 months after the death of a resident to

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quality compared to the control group.	three surveys 2-4-months after the resident's death (See Appendix 5). Surveys include: 1. Satisfaction with Care at End of Life [48] 2. Comfort Assessment in Dying (CAD) [48] assesses end-of-life symptoms, including discomfort, pain, restlessness, shortness of breath, choking, gurgling, difficulty swallowing, fear, anxiety, crying, moaning, serenity, peace and calm. 3. ICECAP- Close Person Measure [49] – assessing perceived quality of death and impact of end-of-life care on families 4. Semi-structured/open ended questions about the resident's end-of-life care	invite them to participate in the survey that will be completed either face to face in the facility, by telephone, or via an online survey with a researcher not employed at the facility. If conducted face to face, we will seek written consent. For surveys conducted over the telephone we will seek verbal consent and for online surveys we will seek electronic consent via REDCap e-consent.

*We will aim to recruit the Medical Treatment Decision Maker or the main family/friend carer who was most involved at the end of life (if a Medical Treatment Decision Maker was not formally appointed/identified).

8.2   ECONOMIC ANALYSIS

An economic evaluation will be undertaken to examine the cost-effectiveness of the program. We adopt a healthcare system perspective. Data collection including the hypothesis and consent processes are outlined in Table 5.

Table 5: Economic Analysis hypothesis, data collection and consent

Hypothesis	Data	Consent
IMPART is cost-effective when compared to usual care in terms of quality of life improvement units as measured by the. Quality of life - Aged Care Consumers (QOL-ACC) instrument	The costs of implementing the IMPART intervention will be recorded by the research team using process data (see Appendix 6 and section 8.3 for details) and costs of implementing the intervention (excluding any costs associated with evaluating the intervention). The Quality of life - Aged Care Consumers (QOL-ACC) instrument is a tool for use in the measurement and valuation of quality of life in aged care [53]. This measure is currently completed quarterly by RACF residents as part of the Australian Government's National Aged Care Mandatory Quality Indicator Program (QI Program). The QI Program is mandatory for all Commonwealth subsidised residential aged care providers, who are required to collect and report quality indicator data. The 'quality of life' quality indicator is measured by the QOL-ACC. This is a	QOL-ACC responses will be accessed through the RACFs with a waiver of consent (also see Section 9.4.1) We are requesting a waiver of consent for this data because: • data collection is non-intrusive and already routinely

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	six-item measure available in self-report, interviewer facilitated and proxy versions, which includes assessments of independence, mobility, pain management, emotional wellbeing, social relationships and leisure activities/hobbies on a five-point scale. We will ask RACF staff to extract item responses for all permanent residents for the previous quarter's mandatory routinely collected data. Health-related resource use (costs and cost offsets) will be collected from RACFs and also from existing data sets for residents in 6 months steps for the duration of the trial including: RACF data: • RACF resident medical record data (medical appointments and medication prescriptions) to determine medical costs and pharmaceutical costs incurred by the residents Existing data sets: • VAED (hospital admissions, length of stay, preferred place of death, change of care phase during admission and other relevant variables) • VEMD (emergency department visits, number of deaths during transfer to hospital and other relevant variables) The process for accessing VAED and VEMD data is described in Table 4 above. At the end of the trial period we will submit requests for VAED/VEMD data for all residents via the Centre for Victorian Data Linkage and MBS and PBS data from consented residents via Services Australia. Data	collected by the RACFs, • there is negligible risk for individual participants, there is no known or likely reason for thinking that participants would not have consented if they had been asked, • their privacy and the confidentiality of their data will be sufficiently protected • obtaining individual consent for this data is impractical. (further details are provided in Section 9.4.1) • this waiver simplifies the research process for the RACFs Medical appointments and medication prescriptions will be collected from RACFs with a waiver of consent (also see Section 9.4.1) • Hospital admissions, emergency minimum data, length of stay and other relevant variables will be accessed through the Victorian Centre for Data Linkage with a waiver of consent (also see Table 4 and Section 9.4.1).

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	provided by the Centre for Victorian Data Linkage will be linked to Services Australia data. Services Australia data will be linked to resident quality of life.	

8.3 PROCESS EVALUATION

We will also undertake a process evaluation to understand whether the intervention was implemented as intended [54]. It will also help us understand the mechanisms of change to test our process-oriented logic model [47] (Figure 1). We will explore:

- Were all components of the intervention delivered and how?
- Was the intervention delivered as intended and in the quantity intended?
- Did it reach those participant groups that were targeted?
- What was the mechanism of change?
- What was the impact of local and broader contextual factors?

We will record basic details about the participating facilities at baseline and at the end of each 6 month step of the trial. This will help us understand significant changes in facility operation during the study that may influence the effectiveness of the trial. We will record access to hospital-based residential in-reach services, specialist palliative care, telehealth services and other palliative care policies as well as research studies and programs (Appendix 8). This will either be completed by the research team interviewing via videoconference, telephone or in-person the facility manager or a member of the Planning Ahead Team. Alternatively, one of these members can complete the survey online.

We will record and analyse the number of accessed training modules, meetings held, RAC staff and GPs engaged, and telehealth support calls throughout the intervention, as completed in our previous work [55]. We will ask a member of the Specialist In-Reach Team and one RACF champion per facility to maintain a log of their activities relating to the IMPART intervention period over the active 6 month intervention period (Appendix 6). This will help us determine whether key components of the intervention were conducted and to estimate the time and costs of implementing the intervention (as described above, this also informs the economic evaluation). To further understand the contexts and mechanisms that influence the implementation of the IMPART intervention, a mixed methods realist process evaluation of the IMPART intervention will be conducted as part of a PhD. The PhD explores what works, for whom, how, and in what circumstances in the implementation of the IMPART program, via three phases:

In phase 1, non-participant observation will be conducted during the IMPART intervention workshops. No identifiable information will be collected during the observation. RACF staff recruited to the Planning Ahead Team will then be invited to be interviewed following the IMPART intervention workshop. They will be asked about their motivation for joining the Planning Ahead team, their perception of their readiness to implement the intervention and contextual factors that may influence the implementation of the intervention. The anticipated number of interview participants for phase 1 is 10-20 RACF staff members. **In phase 2,** RACF and In-Reach staff involved in the implementation of the intervention will be invited to be interviewed upon completion of the active 6-month intervention. These semi-structured interviews will explore perceptions of the intervention outcomes, conditions that supported and/or hindered the implementation and how this corresponds to the process-oriented logic model (Figure 1). The anticipated number of interview participants for phase 2 is 10-20 RACF staff and In-reach team members.

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In phase 3, interviews will be conducted 3 months following the completion of the IMPART intervention at each site. These interviews will investigate how sustainable and scalable the intervention. RACF staff that were involved in the implementation of the intervention will again be invited to participate. The target number of participants for phase 3 is 10-20 RACF staff members.

The interview guides for phase one (Appendix 24), phase two (Appendix 25) and phase three (Appendix 26) will evolve as data is collected and analysed to build on existing findings. Interviews will be conducted in-person, online or via telephone pending the participant's preference. The interviews will take approximately 30 minutes and be conducted, audio-recorded, de-identified and transcribed. The data collected will contribute to a student's PhD thesis. Participants will be informed of this during the recruitment and consent procedure, and all information is included on the relevant consent forms (Appendices 27, 28 & 29).

Table 6 outlines the data collection according to the different aspects of the process evaluation. We will also develop a manual to enable RACFs to independently implement the IMPART intervention which could be used in further roll-out if the intervention is found to be effective and cost-effective.

Table 6: Process evaluation hypotheses, data collection and consent

Process evaluation questions	Data	Consent
Was IMPART implemented as intended?	- Members of the specialist team and the RACF Champion will keep a log of data on any activities undertaken for the intervention including training provided/completed, meetings, consultations undertaken etc. The log will include duration and roles/positions of attendees (e.g. GP, external specialist, Planning Ahead Team, family member etc.) (Appendix 6). - The web-based IMPETUS-D training modules can record how many times modules are completed by facility and date.	This data will be aggregated at a facility level and contain no identifiable resident data. The staff (RACF or specialist team) will be providing this as members of the research team and therefore no consent is required.
Does IMPART improve existing end-of-life planning and processes in RACFs?	We will collect the completed Action Plan (Appendix 4) and Facility Information (Appendix 8) and document practice change reported at meetings. We will collect facility level evaluation data collected at the end of the six months to provide descriptive data on practice or policy change within the facility.	
Does IMPART improve senior nurses', clinical care coordinators' and GPs' working in RACFs confidence in discussing	Planning Ahead Teams and GPs will complete a confidence questionnaire at the beginning and end of the 6 month active intervention (Appendix 3).	Participating staff will provide consent on the electronic or hard copy survey.

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and planning for end-of-life care?		
What contexts and mechanisms influence the implementation of the IMPART intervention?	Non-participant observation of the IMPART intervention workshops. RACF and In-Reach staff participating in the implementation of the IMPART intervention will be invited to be interviewed (Appendices 24, 25 & 26)	Consent not required for the non-participant observation as no identifiable information will be collected. Participating residential aged care and In-Reach staff will provide signed consent.

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9.   STUDY POPULATION

Table 7 summarises the different study populations involved including the different types of data collected and the corresponding recruitment and consent processes for each. Each study population is numbered from 1-4 and these are used in the further explanations in Sections 9.1-9.4 below.

Table 7: Study Populations and recruitment and consent processes

Study Population	Summary of Data/participation (also see Tables 4-6)	Recruitment	Consent procedure
1. All permanent residents in participating RACFs at any time during the trial	Hospitalisation data for all permanent residents at participating RACFs: • Details of all residents collected from RACFs to enable identification by the Centre for Victorian Data Linkage in the Victorian Admitted Episodes Dataset and the Victorian Emergency Minimum Dataset	RACF staff will extract data from the facility database and submit this to the research team once every 6 months via RedCap. This data will be submitted to the Centre for Victorian Data Linkage using RedCap to extract VAED and VEMD data for analysis.	We are seeking a waiver of consent for this data as explained in Table 4 and 5 and Section 9.4.1.
	Resident quality of life data for all permanent residents at participating RACFs: QOL-ACC	RACF staff will extract data from the facility database for the previous quarter's mandatory routinely collected data and submit this to the research team via a secure OneDrive link.	
	Medical appointment and medication prescription data for all permanent	RACF staff will extract data from the facility database and submit this to the research team once every 6	

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Study Population	Summary of Data/participation (also see Tables 4-6)	Recruitment	Consent procedure
	residents at participating RACFs	months via a secure OneDrive link.	
2. Family members of residents who die during the active trial period and who provide consent	Family post death survey: Satisfaction with Care at End of Life, Comfort Assessment in Dying, ICECAP- Close Person Measure, semi-structured/open-ended questions(Appendix 5)	2 months after a resident dies, the RACF will send a letter of invitation to the main family member involved at end of life (Appendix 10)	If conducted face to face, we will seek written consent. For surveys conducted over the telephone we will seek verbal consent and for online surveys we will seek electronic consent via REDCap e-consent. Family members will be asked to read and sign (written or electronic) a PICF (Appendix 13) indicating their consent to completing the survey. They will have the opportunity to ask questions prior to signing.
2. Staff in the Planning Ahead Team (RACF and GPs)	Participating in the Planning Ahead Team including the needs analysis (Appendices 1 & 2) and developing and implementing the action plan (Appendix 4) during the active intervention period.	RACF managers will identify suitable skilled staff and GPs to invite them to be part of the Planning Ahead Team. If interested they will agree to be contacted by the research team.	Participant information is presented via a comprehensive intervention manual and a pre-intervention briefing. Consent is implied by staff attendance at the workshop.
	Staff confidence survey (Appendix 3)	As above	Participant information is presented at the beginning of the survey and consent is implied if staff answer the survey questions.

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Study Population	Summary of Data/participation (also see Tables 4-6)	Recruitment	Consent procedure
3. RACF and In-Reach staff	Non-participant observation of the IMPART intervention workshops. Interviews with RACF and In-Reach staff involved in implementing the intervention (Appendices 24, 25 & 26).	Participants will be identified through the Planning Ahead Team and the research team. An interview invitation letter will be sent to potential participants (Appendices 33, 34 & 35). If interested, they can contact the PhD student directly.	Consent not required for the non-participant observation as no identifiable information will be collected. Staff will be asked to read and sign a PICF (Appendices 27, 28 & 29) indicating their consent to participating.

9.1 RECRUITMENT PROCEDURE

We will engage for-profit and not-for-profit RACFs that fit within the catchments of Royal Melbourne Hospital, Northern Health, Austin Health and other areas in Melbourne.

9.1.1 Study Population 1: All permanent residents in participating RACFs at any time during the trial

As we are seeking a waiver of consent to collect resident hospitalisation data, quality of life data and medical record data, we will not be recruiting participants for this component of the research. See Section 9.4.1 for details of the justification for a waiver of consent.

9.1.2 Study Population 2: Family members of residents who die during the active trial period

For residents who die during the trial, we will aim to recruit the Medical Treatment Decision Maker or the main family/friend carer who was most involved in the final weeks towards the end of life (if an Medical Treatment Decision Maker was not formally appointed/identified) to complete the post-death interview. The relevant carer will be sent a letter inviting them to participate in a brief survey on the quality of their resident's end-of-life care (Appendix 10) along with the PICF (Appendix 13) which will be followed up by telephone calls until they are able to speak to the carer (or leave messages on up to three occasions). They will be contacted about the study by staff within the facility. Interested family members will be asked to contact the research team to learn more about the study, or interested family members can indicate their preference for completing the survey by returning the survey preference and contact details form (Appendix 36) to the research team using the provided reply-paid envelope. Alternatively, interested family members will be asked for permission for the RACF staff to pass on their name, telephone and email address for the researchers to contact them. We will use interpreters for family members who communicate in a language other than English.

9.1.3 Study Population 3: Staff in the Planning Ahead Team (RACF and GPs)

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Facility managers will approach potential RACF staff to seek expressions of interest in being involved in the Planning Ahead Team. They will also approach GPs who provide significant clinical care to residents at their facility. To avoid potential contamination, we will ensure that GPs who are engaged in the Planning Ahead Team do not also have an existing clinical role with another participating RACF.

We will approach specialist residential in-reach or palliative care services with an existing relationship with the facility if possible. We will establish service agreements with these services to fund their time to undertake project activities.

9.1.4 Study Population 4: RACF and In-Reach staff

For all three phases of process evaluation interviews, potential participants will be recruited by sending an invitation letter to the Planning Ahead Team and the In-Reach team members (Appendices 33, 34 & 35). Interested participants can then contact the PhD student as listed on the invitation to ask questions and discuss the project and PICF. If the participant consents, a time will be arranged for the interview.

For phase 1, we aim to recruit Planning Ahead Team members who are part of the active IMPART intervention to conduct the interviews after the workshop is held in month 2 of the intervention.

In phase 2, potential participants will be identified by the IMPART research team, the In-Reach teams and the Planning Ahead Team. This may include staff that participated in the phase 1 interviews or other RACF and In-Reach staff who have been involved in the implementation of the intervention. The interviews will be arranged in the month following the intervention's completion.

In the final interviews, phase 3 of the process evaluation, RACF staff that were involved in the implementation of the IMPART intervention will again be contacted. Potential participants may include interviewees from phase 1 and 2 or other eligible RACF staff identified by the research team or the Planning Ahead Team. Interviews will be conducted three months following the completion of the IMPART intervention.

9.2   INCLUSION CRITERIA
Residents: All residents living permanently in the participating RACFs will be eligible to take part in this research.

Family members or friends of eligible residents, including families of residents who die during the study and wish to take part in the post-death survey.

GPs, RACF senior nurses and clinical care coordinators liaising with or working within the participating RACFs will be eligible to participate.

RACF and In-Reach staff supporting the implementation of the intervention will be eligible to be interviewed for the process evaluation component of the study.

9.3   EXCLUSION CRITERIA
N/A

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9.4 CONSENT

The consent process differs for each study populations as described below.

9.4.1 Study Population 1: All permanent residents in participating RACFs at any time during the trial: Waiver of individual consent

To examine the primary effect of the intervention (unplanned hospitalisations), secondary measures (emergency department presentations and hospital admission length of stay) and to examine the cost-effectiveness of the program (quality of life, medical appointment and medication data). it is desirable for the data of all residents to be captured across the ten participating RACFs over the active 2.5-year trial period. Requiring consent is likely to create selection bias, impacting the results.

In accordance with the National Statement on Ethical Conduct in Human Research [56], we are seeking HREC approval for a waiver of the need for individual consent for this hospitalisation component of the trial. Data collection is non-intrusive, there is negligible risk for individual participants, there is no known or likely reason of thinking that participants would not have consented if they had been asked and their privacy and the confidentiality of their data will be sufficiently protected.

Why is it impracticable to seek individual consent?

We seek approval of a waiver for individual consent for the following reasons:

1) For a robust and representative assessment of the intervention and evaluation of the cost-effectiveness of the intervention we aim to collect hospitalisation, quality of life and medical cost data for every resident in all participating RACFs. If only a small subset of residents were recruited due to the need for individual consent, it would skew the evaluation of the effectiveness of the intervention to only represent (most likely more healthy) residents who were able to provide consent. This would negatively affect the generalisability of the intervention effect.

2) This research involves no foreseeable risk to the residents. Recruitment and data collection is nonintrusive and obtained from their RACF files and the information stored about them in the Victorian Admitted Episodes Dataset and Victorian Emergency Minimum Dataset.

3) There is a great likelihood of benefit to residents through the intervention with an expected reduction in unplanned hospitalisation and improved end-of-life care planning, discussions, quality of end-of-life care and quality of death.

4) There is likely great benefit for future aged care residents and the aged care system in testing this intervention designed to improve outcomes for residents, families and staff using education and telehealth in-reach. The likely benefits far outweigh any minimal risks to individuals.

5) There is no medication or device being tested and the intervention is non-invasive.

6) While waiting for the intervention, all control groups will receive current standard practice, not inferior care. All participating RACFs will receive the intervention at some point during the trial.

It is impracticable to seek individual consent for the following reasons:

1) There are expected to be 2000 residents in the 10 RACFs over the active 2.5-year trial period.
2) Due to the nature of health conditions which require support through residential aged care services, residents are often unavailable, absent, ill, unwell or unable to discuss participation.

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3) Many will also not have a readily available Medical Treatment Decision Maker who could provide proxy consent. This would also put undue workload on RACF staff who would be required to approach proxies for all residents who do not have capacity.

4) Unpredictable COVID outbreaks can prevent the research team from accessing the RACFs and recruiting participants.

Why is it thought that participants would have consented?

It is thought the residents would have consented to this study as:

1) There is no drug or device being tested and the intervention is entirely non-invasive as it focuses on RACF staff and on enabling them to provide better end-of-life care for residents.

2) There is no foreseeable harm.

3) There is much foreseeable benefit of the intervention for residents with RACF staff reflecting on and improving their care practice with support of in-reach telehealth specialist services.

4) This study is a quality improvement project and all participating RACFs will receive the intervention at some point during the trial.

5) There is no collection of blood/ tissue and no plan for extra follow-ups beyond the active 2.5-year trial.

6) Residents in the control group will receive current standard practice while waiting for the intervention.

7) We have multi-faceted measures in place to ensure the protection of participants' privacy and confidentiality.

How is their privacy and confidentiality protected?

To examine the primary effect of the intervention, the waiver of consent is required to collect details of residents residing in the participating facilities to enable the Centre for Victorian Data Linkage to extract relevant Victorian Admitted Episodes Dataset and Victorian Emergency Minimum Dataset data (number of hospital admissions and length of stay, emergency department presentations, changes of care phase during admission, preferred place of death, number of deaths during transfer to hospital and other relevant variables).

To enable extraction of this data, the Centre for Victorian Data Linkage requires a resident's name, suffix, date of birth, gender, Medicare number and a unique study ID. Each 6 month data collection period, RACFs will provide a database containing these details of all current permanent residents and all residents who have exited the facility in the last 6 months. RACF staff will submit this data to the research team via RedCap, a secure database which sits under strict password protection on the NARI server. RACF staff will not be able to access any data in RedCap apart from the data they are submitting.

This data will be used to submit a request to the Centre for Victorian Data Linkage for the extraction of residents' data from the Victorian Admitted Episodes Dataset and Victorian Emergency Minimum Dataset. After collecting 6 monthly data for the entire 3 years of the trial (2.5 years of the active trial, plus 6 months control level data before the active trial as illustrated in Table 2) the research team will collate this data into one dataset of residents with RACF admission and discharge dates (if

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relevant). We follow the Centre for Victorian Data Linkage advice and procedures for securely transferring resident data for the purposes of retrieving the relevant associated records.

The Centre for Victorian Data Linkage (CVDL) is an accredited Commonwealth Integrating Authority, which will provide de-identified data about residents' hospital admissions and emergency department presentations via a cloud-based, secure data access platform. Once the CVDL has extracted the hospitalization and emergency presentation data, only approved users to the dataset have access to the dataset. Access to the dataset is only via remote connection to the virtual server managed by the CVDL. All outputs (any information to be removed from the CVDL environment) derived from the dataset are vetted for potential disclosure. The data analysis will occur in a de-identified manner. Any vetted data removed from the CVDL environment will be destroyed seven years after the last publication of the project. Please see Section 12 'Data Security and Handling' for further information.

For evaluation of the cost-effectiveness of the intervention, the waiver of consent is required to access identifiable already routinely collected RACF data about residents' quality of life, medical appointments and medical prescriptions. This minimises RACF research burden and accesses only data that the RACF already collects (for administrative or mandatory regulatory purposes). Each 6 month data collection period, RACFs will provide a database containing this data of all current permanent residents and all residents who have exited the facility in the last 6 months. RACF staff will be asked to submit this data to the research team once every 6 months in a password-protected file. This password-protected file will be uploaded by each facility into a password protected online OneDrive folder that is only accessible to designated members of the RACFs and members of the research team. Once uploaded, this double protected file will be securely downloaded onto the NARI server by a member of the research team. RACF staff will not be able to access any data in OneDrive or RedCap apart from the data they are submitting.

9.4.2 Study Population 2: Family members of residents who die during the active trial period

Should a resident die during the study period, we will ask the resident's Medical Treatment Decision Maker (or if not appointed, a family member or friend who was closely involved at the resident's end of life) to complete a survey via telephone, online videoconferencing or online via REDCap to assess their satisfaction with the resident's end-of-life care, the quality of dying and experienced end-of-life symptoms. They will receive detailed information in the 'Family PICF' (Appendix 13) and will be asked to provide either verbal consent (for interviews conducted via videoconference or telephone), written consent (for interviews conducted face to face) or e-consent via REDCap for surveys completed online. Participants who opt to complete the online survey will be emailed a link to the REDCap consent form and survey. Participants will electronically sign their name and check a statement indicating that they understand that signing the form electronically is the equivalent of signing a physical document. Participants will be provided with the researcher's contact information should they have questions about the project or require assistance completing the eConsent form. Interviews completed via videoconference or telephone will be audio recorded. Participants will be informed that the interviews will be audio recorded in the PICF. We will use interpreters for family members who communicate in a language other than English. We will collect this data 2-3 months after a resident's death. We have used the time frame in previous work with bereaved families/ friend carers and found this to be an acceptable time to allow families to process the initial loss yet also close enough to the event to enable adequate recall [60].

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9.4.3 Study Population 3: Staff in the Planning Ahead Team (RACF and GPs)

Senior nurses and clinical care coordinators from each facility, plus GPs who have an existing visiting role at the RACF, will be asked to participate in the intervention by becoming a member of the Planning Ahead Team. Detailed information about their involvement will be presented to them via a comprehensive intervention manual and a pre-intervention briefing. Consent is implied by staff attendance at the workshop. At the start and end of the active six-month intervention period, we will ask staff to complete the Staff End-of-Life Care Survey (Appendix 3). Participant information is presented at the beginning of the survey and consent is implied if staff answer the survey questions.

9.4.4 Study Population 4: RACF and In-Reach staff

RACF and In-Reach staff involved in the implementation of the IMPART intervention will be invited to be interviewed as part of the process evaluation. Interested participants will be sent the participant information and consent form (Appendices 27, 28 & 29) for review prior to meeting with the interviewer and given the opportunity to ask questions. Consent will be collected in written form and verbally confirmed by the interviewer before the interview commences.

10.   PARTICIPANT SAFETY AND WITHDRAWAL

10.1   BENEFITS

There is no guarantee or promise that participants will receive any benefits from this research. However, findings from this study may help reduce unplanned hospital transfers and improve end-of-life care, planning, discussions, documentation and quality of end-of-life care in residential aged care facilities. Additional anticipated benefits include providing participants with the opportunity to reflect on the current quality of life of residents as well as end-of-life practices and experiences, and helping staff become more confident in supporting residents at the end of life. Staff participating in the process evaluation interviews will be offered a $50 Coles/Myer gift card upon completion of each interview (Phase 1, Phase 2, and Phase 3) in recognition of their involvement.

10.2   RISK MANAGEMENT AND SAFETY

For consenting participants, participation in this study is voluntary. The time taken to participate in the study may be burdensome for some participants. The time commitments are outlined in relevant PICFs. The research team will work closely with the participants to minimise any inconvenience. The advantages of taking part in this study such as improved end-of-life care outweigh any potential burden on participants.

We have aimed to minimise the burden of data collection on RAC staff, residents and families. We will reimburse RAC staff time to participate in the intervention and support the data collection.

We acknowledge that the study will explore topics that relate to end-of-life care that may cause distress to some participants. To address this, a team of highly skilled researchers experienced in aged care, end-of-life care and psychology will facilitate the data collection, needs analysis, and workshops. However, if a participant shows distress there will be an opportunity to take a break or withdraw from the study.

For staff of RACFs, dealing with death and dying is part of daily practice and, participation in the project will provide an opportunity for further support in this area. Should they experience any distress during their participation in the study, they are encouraged to talk to a colleague or a member

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of the research team. We will further provide participating staff members with a resource sheet of freely available mental health support services that they can contact (Appendix 15).

After the death of a resident, family members will be asked to complete a post-death survey to learn more about their experience and the quality of the death. This could be potentially upsetting. When doing interviews via telephone or online teleconferencing, we will respond to any distress in family members by offering basic comfort and the option to end the survey at any time. All family members will also be given a resource sheet with contact details of freely available bereavement support services such as the Australian Centre for Grief and Bereavement and GriefLine (Appendix 15). They will be encouraged to contact these services should their grief be exacerbated by answering the survey.

There is minimal risk to the researcher from the study participants. Nevertheless, care will be taken to conduct RACF visits in a safe manner if a visit is necessary. The following measures will be implemented to ensure the safety of the researcher: If at any point the researcher feels their personal safety is at risk, they will end the RACF visit and immediately leave the premises. All efforts will be made to undertake RACF visits during the day. The researcher will have a mobile phone and will notify a colleague at the National Ageing Research Institute and/or an independent person (friend or relative of the researcher) of the visit. They will inform them of where and when the RACF visit will take place and will establish contact with the contact person within one hour of the visit being completed. They will always carry a mobile phone to be able to seek help in case of an emergency. Researchers will have regular meetings with experienced palliative care researchers to debrief about their experiences of undertaking interviews about end-of-life care. They will also have additional debriefing after any specific interview they have found upsetting.

Due to the COVID-19 pandemic, special precautions need to be considered. Researchers will only enter RACFs if current governmental guidelines and restrictions and individual RACF protocols allow this. As required, researchers will follow these guidelines, which may include showing proof of their vaccination/ booster status, having evidence of a recent, negative rapid antigen test, wearing personal protective equipment such as face masks and face shields, maintaining a safe 1.5 metre distance where possible, and using hand sanitiser at the beginning, end and throughout their visit. Should COVID-19 restrictions prevent face-to-face visits to a facility, we will aim to collect data via video-conferencing, telephone or online if necessary and possible.

10.3   HANDLING OF WITHDRAWALS

Participants who have provided consent, may withdraw from the study at any time by notifying the research team or RACF staff member or completing a Withdrawal Form (Appendix 16 [resident], 17 [family], 18 [staff], 30 [phase 1 interview], 31 [phase 2 interview] and 32 [phase 3 interview]) or a Medical Treatment Decision Maker Withdrawal Form (Appendix 19). For participants who wish to withdraw after data has been collected, they will have the option of having all their data for this project to be destroyed or whether data collected to date can be retained.

Hospitalisation data, quality of life data and medical record data that is collected through the waiver will not have participant consent and therefore will not be subject to withdrawal if the resident withdraws from completing surveys.

11.   STATISTICAL METHODS

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11.1 SAMPLE SIZE ESTIMATION & JUSTIFICATION

Table 8 provides details of the sample size estimation for each study population.

Table 8: Sample size estimation for each study population

Study Population	Summary of Data/participation (also see Tables 4-6)	Sample Size Estimation
1. All permanent residents in participating RACFs at any time during the trial	Hospitalisation data (VAED and VEMD), quality of life data (QOL-ACC), medical record data (medical appointments and medication prescriptions)for all permanent residents at participating RACFs (waiver of consent)	We will include all permanent residents at the 10 participating facilities over the 3 years of the trial (6 months pre-trial and 2.5 years active trial), likely to be approximately 2000 residents.
2. Family members of residents who die during the active trial period	Family post death survey: Satisfaction with Care at End of Life, Comfort Assessment in Dying, ICECAP- Close Person Measure, semi-structured/open-ended questions (Appendix 5)	We will seek to recruit 250 family members to take part in the post-death surveys. We anticipate that approximately 20% of RACF residents die during a 6 month period and that we will be able to recruit 5-10 bereaved family members per facility during each five steps of the active trial.
3. Staff in the Planning Ahead Team (RACF and GPs)	Needs analysis (Appendices 1 & 2) and developing and implementing the action plan (Appendix 4) during the active intervention period. & Staff confidence survey (Appendix 3)	The Planning Ahead Team at each facility will consist of 4-5 members consisting of 3-4 RACF staff and one GP, with a total of up to 50 staff involved across the 10 facilities.
4. RACF and In-Reach staff supporting the implementation of the intervention.	Process evaluation phase 1 interviews (Appendix 24) Process evaluation phase 2 interviews (Appendix 25) Process evaluation phase 3 interviews (Appendix 26)	Up to 20 RACF staff recruited to the Planning Ahead Teams across the participating RACFs to complete phase 1 interview. Up to 20 RACF and In-Reach staff involved in the implementation of the IMPART intervention across the participating RACFs to complete phase 2 interviews. Up to 20 RACF staff involved in the implementation of the IMPART intervention

Study Population	Summary of Data/participation (also see Tables 4-6)	Sample Size Estimation
		across the participating RACFs to complete phase 3 interviews

11.2 POWER CALCULATIONS

11.2.1 Primary outcome – unplanned hospitalisations (waiver of consent)

Our power calculation and statistical approach were developed by a biostatistician experienced in health service evaluation. Whilst the primary outcome will consider the rate of unplanned hospitalisations per 1000 resident bed-days, the sample size calculation was determined considering the proportion of residents having a transfer over the study duration of 6 months, as the estimate of the intraclass correlation coefficient could more readily be estimated. The inputs to the stepped wedge cluster trial were primarily drawn from the study by Martin et al, [29] which indicated a baseline proportion of approximately 30% of residents with at least one hospital transfer. This study indicated a between cluster standard deviation of 0.081 and a within-cluster standard deviation of 0.458, thus estimating an intraclass correlation coefficient of 0.031. Martin et al [29] also informed the coefficient of variation of 0.3 in the variation in residents per RACF.

It is uncertain how correlated the measures that guide the power and sample size calculation (i.e. proportion with at least one transfer or total hospitalisations) will be to the primary measure for our study (i.e. the number of unplanned admissions). However, based on transfers from RACFs to Northern Health, we expect the rate of unplanned (emergency) admissions as a proportion of total admissions to be approximately 50-60%. The minimum sample size per cluster considered in the sample size calculations was n=50 per cluster per sequence/step, but under the waiver of consent scenario, we are expecting the sample size for the consideration of our hospitalisation outcome measures to be approximately double this estimate, and closer to 100 residents per cluster. This will offset the potential for the number of unplanned admissions to be lower than the overall admissions.

Based on a significance level of α=0.05, with 80% power (β=0.2), and an expected average cluster size of 90 residents, a stepped wedge trial design of 2 clusters per sequence with 5 sequences (i.e. one baseline period of 6 months and 5 steps) will provide sufficient power to detect a minimum reduction of 20% in the rate per 1000 bed days of residents with at least one transfer [61, 62]. Thus, a total of 10 RACFs will be recruited for this study.

11.2.2 Post death surveys completed by family members

Based on the trial design and sample size of 10 RACFs, the secondary measure of the ICECAP-Close Person Measure, will be powered at a minimum level of 86% to detect a difference in means of 0.08 (on a 0 to 1 scale) which is representative of a clinically significant difference, assuming an intraclass correlation coefficient of 0.1, and a standard deviation within clusters of 0.15, and a cluster size of 5 residents per 6 month period per RACF.

11.3 STATISTICAL METHODS TO BE UNDERTAKEN

11.3.1 Intervention effectiveness

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Descriptive analysis will be prepared to illustrate the effect of the intervention on the rate per 1000 bed-days of residents with unplanned hospitalisations to address the primary outcome of the study. The analytical methods will utilise mixed-effects Poisson regression models [63]. We will conduct sensitivity tests to assess the effect of correlation structures on the results of the trial [64]. The assumed correlation structure will be exchangeable, with time-decaying correlation structures explored via the sensitivity analysis. Suitable analyses will also be conducted to address the set of secondary outcomes considered (quality of life, confidence of staff in providing and discussing end-of-life care, and post-death measures of carer satisfaction with end-of-life care, perceived quality of death and comfort at end of life), depending on the format and distribution of these outcome measures (continuous: normally distributed or skewed; or categorical). The effects of time will be accounted for by an assessment of the effect of secular trends over time as proposed by Hussey and Hughes [63]. The primary analysis will consider the same underlying secular trend over time for each RACF/cluster, with sensitivity tests conducted to test the effects of considering different underlying secular trends by RACF or cluster, by considering treatment by strata and/or cluster interactions as proposed by Hemming, Taljaard [64]. Statistical analysis will be conducted using Stata version 15.1, with a two-sided p-value of less than 0.05 indicating statistical significance.

11.3.2 Economic analysis

A micro-costing approach will be performed to assess the economic costs of the IMPART program that will involve detailed data collection on resources utilized and assignment of unit costs. A cost-utility analysis framework will be used for the economic analysis, based on the QoL ACC [53] as the outcome. Medical appointment and medication prescription data for all permanent residents at participating RACFs will be extracted from the facility records. We will estimate adjusted incremental (differential) total costs and adjusted incremental effects to derive the incremental cost-effectiveness ratio (ICER). Multilevel regression modelling will be used to account for time, clustering and correlation between costs and outcomes. Uncertainty in the data will be assessed using nonparametric bootstrapping from the distribution of the observed cost/effect pairs (1,000 simulated replications) to determine confidence intervals and presented in a cost-effectiveness plane along with a cost-effectiveness acceptability curve. To explore robustness, sensitivity analyses will be carried out..

11.3.3 Process evaluation analysis

Qualitative analysis of the interview transcripts, non-participant observations and documentation (Appendices 4, 6 & 8) will occur concurrently with data collection for the course of the project. NVivo software (NVivo 14) will assist this process. Analysis will begin as the intervention begins and continue throughout, cycling through the hypothesising and testing of causal pathways. Coding will be done independently, then collectively verified in iterative cycles; interpretations will be cross-checked within the data, with existing literature and relevant program theories.

A combined inductive and deductive content analysis approach will be used. Thematic analysis will be performed initially using codes based on the Consolidated Framework for Implementation Research domains and theories developed from the literature. Following this a deliberative and inductive process of searching for causal patterns that link 'intervention activity', 'context', 'mechanism' and 'outcome' will be undertaken.

Findings will be presented as intervention activities-Context-Mechanisms-Outcomes configurations formed as middle range theories. Results will be compared to the original goals and objectives of IMPART to determine if the program was successful in achieving its intended outcomes, and results will be incorporated back into a logic model using the Implementation Research Logic Model

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template. This analysis will be used to help identify areas for improvement in the program and to support the development of a framework to guide future implementation of the IMPART intervention.

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12. DATA SECURITY & HANDLING

12.1 DETAILS OF WHERE RECORDS WILL BE KEPT & HOW LONG WILL THEY BE STORED

Signed participant information and consent forms; surveys, action plans, needs analysis forms, activity logs, interview recordings and de-identified transcripts: Hard copy data will be stored in locked filing cabinets at NARI. Electronic data will be stored in a password-protected, electronic database in a de-identified format. All data will be destroyed seven years after the last publication of the project.

VAED and VEMD datasets: This data, held by the Centre for Victorian Data Linkage are only accessed via a secure remote access platform, and no datasets can be removed from the virtual platform. This platform is known as the Victorian data Access Linkage Trust (VALT), and allows approved users to undertake analysis of de-identified data through virtual machines, allowing the dataset to remain secure in the CVDL environment. The platform used by the CVDL is the Azure cloud environment, and is certified up to "Protected" by the Information Security Registered Assessors Program (IRAP) of the Commonwealth.

QOL-ACC data and medical record data: Once RACFs have securely provided the data to NARI, NARI will apply participant IDs and securely store the data on the NARI server as described above.

12.2 CONFIDENTIALITY AND SECURITY

Information collected during the needs analysis, workshops and process evaluation as well as survey data, information extracted from residents' files and the Centre of Victorian Data Linkage, will be de-identified by assigning a participant code, which will be kept separately from the data. Hard copies of any identifiable information such as signed PICFs will be securely stored in locked filing cabinets at NARI or by Services Australia as described in Section 12.1. Digital files will be stored under strict password protection on the NARI server. VAED and VEMD data will be stored and accessed via the Victorian data Access Linkage Trust (VALT) as described in Section 12.1

The privacy of participants and non-participants in any notes and/or publications will be protected. Any field notes will be de-identified using ID codes e.g. for participating aged care facilities. Publications will only present data in aggregated or de-identified form.

12.3 ANCILLARY DATA

Photos or videos of the research project may be taken for promotional materials. We will avoid photos/videos of residents who do not have capacity to consent. Any identifiable individual in the photo/video will be asked to sign a photo/video release form to provide consent for its use in promotional materials.

13. CONSUMER INVOLVEMENT

Underlying our approach is person-centred care, prioritising residents' values, preferences and goals to inform all end-of-life care planning [65]. To ensure consumer engagement, we have involved a community representative, who has lived experience in caring for someone who moved into a RACF and will play a key role in the project Steering Group, and have read and provided feedback on all

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resident and carer facing documents (PICFs, letters of invitation, questionnaires and advertising flyers). The community representative is a volunteer biographer in the Palliative Care Biography Program of Cabrini Hospital and has worked for the Victorian Department of Education and Training. We will further involve representatives from peak policy and advocacy organisations for older Australians in the project Steering Group, such as a member of the Council on the Ageing (COTA) and Carers Victoria. These advocacy groups and consumer representatives will provide input on the IMPART program and the interpretation of research findings.

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14. LIST OF APPENDICES

Document Name	Version	Date
Appendix 1: Template to support Planning Ahead Team file audit	1	30/3/2022
Appendix 2: Needs analysis checklist	1	30/3/2022
Appendix 3: Staff End of Life Care Survey	2	21/4/2022
Appendix 4: Action Plan Template	1	30/3/2022
Appendix 5: Family proxy post death survey	3	21/3/2024
Appendix 6: IMPART Activity Log	1	30/3/2022
Appendix 7a: Resident assessment of quality of life	1	30/3/2022
Appendix 7b: Family proxy assessment of resident's quality of life	1	28/4/2022
Appendix 7c: Staff proxy assessment of resident's quality of life	1	28/4/2022
Appendix 8: RACF Information	1	30/3/2022
Appendix 9: Advertising study flyer	3	04/10/2023
Appendix 10: Invitation letter for bereaved families	4	21/3/2024
Appendix 11: Resident PICF	2	26/4/2022
Appendix 12: Medical Treatment Decision Maker PICF	2	26/4/2022
Appendix 13: Family PICF (Post-death survey)	4	21/3/2024
~~Appendix 14: Staff PICF~~ REMOVED	2	26/4/2022
Appendix 15: Mental health support resource sheet	2	26/4/2022
Appendix 16: Resident Withdrawal form	2	26/4/2022
Appendix 17: Family Withdrawal form	2	21/4/2022
Appendix 18: Staff Withdrawal form	2	26/4/2022
Appendix 19: Medical Treatment Decision Maker Withdrawal form	2	26/4/2022
Appendix 20: Services Australia Participant Information Document	1	30/3/2022
Appendix 21: Services Australia Participant Consent Form	1	30/3/2022
Appendix 22: Services Australia Participant Withdrawal Form	1	30/3/2022
Appendix 23: Invitation letter for Medical Treatment Decision Maker	2	26/4/2022
Appendix 24: Phase 1 interview guide	1	1/5/2023

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Appendix 25: Phase 2 interview guide	1	1/5/2023
Appendix 26: Phase 3 interview guide	1	1/5/2023
Appendix 27: Phase 1 PICF interview	1	1/5/2023
Appendix 28: Phase 2 PICF interview	1	1/5/2023
Appendix 29: Phase 3 PICF interview	1	1/5/2023
Appendix 30: Phase 1 interview withdrawal form	1	1/5/2023
Appendix 31: Phase 2 interview withdrawal form	1	1/5/2023
Appendix 32: Phase 3 interview withdrawal form	1	1/5/2023
Appendix 33: Phase 1 interview invitation letter	1	1/5/2023
Appendix 34: Phase 2 interview invitation letter	1	1/5/2023
Appendix 35: Phase 3 interview invitation letter	1	1/5/2023
Appendix 36: Post-death survey preference and contact details form	1	21/03/2024

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