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| protocol  |
| IMPART - IMproving PAlliative care in Residential aged care using Telehealth |
| Protocol Version: 2Date: 21/04/2022 |
| **Author/s:**Professor Kwang Lim, Associate Professor Kirsten Moore, Dr Katrin Gerber, Sarah Carr, Kayla Lock, Kerry Hwang, Sue Williams**Sponsor/s:**National Ageing Research Institute**Funding:**National Health and Medical Research Council (NHMRC) APP2006121 |
| **CONFIDENTIAL**This document is confidential and the property of Royal Melbourne Hospital and the National Ageing Research Institute. No part of it may be transmitted, reproduced, published, or used without prior written authorisation from the institution.**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.

|  |
| --- |
| C:\Users\MifsudRu\Desktop\Signatures\Kwang Lim - Electronic Signature (002) (002).jpg**Chief Investigator:** |
| Signature:  |  | Date:  | 21/04/2022 |
| Name (please print): | Kwang Lim |
| Position:  | Clinical Director Aged Care | Medical Director |

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# 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.  |

# 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 |
| 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 |

# Study Sites

### 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  |

### 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 | A/Prof Kirsten Moore | 03 8387 2596 | k.moore@nari.edu.au |
| The Royal Melbourne Hospital | City Campus, Level 6 North300 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 University553 St Kilda RoadMelbourne VIC 3004 | Dr Lidia Engel | TBD | lidia.engel@monash.edu |

# Background

### 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.

### 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.

### 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].

#### 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 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.

# Aim and Hypotheses

### 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.

### 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 ICECAP-Supportive Care Measure. |

# Study Design

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

### 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 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.

# 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*

### 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.

### 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.

### 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 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.

### 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].

### 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.

### 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 |

# Data Collection

### 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. | * 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 because1. 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)
 |
| **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. |
| IMPART improves end-of-life care quality compared to the control group. | Family members of residents who die during the trial period (both in the intervention and the control/waiting arm), will be asked to complete 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
 | Family members\* will be contacted 2 months after the death of a resident to 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.  |

\*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).

### 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 ICECAP-Supportive Care Measure. | 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 ICECAP-Supportive Care Measure is a validated tool for use in economic evaluation conducted in end-of-life settings [50-52]. ICECAP stands for ‘Investigating Choice Experiments for the preferences of older people CAPability’. This measure will be completed by the resident or the ICECAP-Supportive Care Measure Proxy Version by the family member (Appendix 7a, b, c). This will be completed at baseline and every 6 months face to face or by telephone by the research team. This is a 7-item measure available in a self-report and proxy version, which includes assessments of choice, care, freedom from physical suffering and emotional suffering, dignity, being supported and being prepared on a 4-point scale. Health-related resource use (costs and cost offsets) will be collected from existing data sets for residents in 6 months steps for the duration of the trial including:* Medicare Benefits Schedule (MBS) data to identify medical costs incurred by the resident
* Pharmaceutical Benefits Scheme (PBS) data to identify pharmaceutical costs incurred by the resident
* 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 provided by the Centre for Victorian Data Linkage will not be able to be linked to Services Australia data. Services Australia data will be linked to resident quality of life.  | * MBS and PBS data will require signed consent from the resident or from a legal representative using the Services Australia Participant Information and Consent Forms and processes (Appendix 20-22)
* Residents (Appendix 11) or their proxy (Appendix 19) will provide consent for completion of the ICECAP-Supportive Care Measure
* 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).
 |

### Process Evaluation

We will also undertake a process evaluation to understand whether the intervention was implemented as intended [53]. 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 [54]. 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). 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 and planning for end-of-life care? | 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.  |

# 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 Section 9.4.1. |
| 1. Residents who provide consent (or a proxy who provides consent)
 | Resident quality of life: ICECAP-Supportive Care Measure completed at T1-T6 (Appendix 7a, b, c). | Posters in the facility (Appendix 9), RACF staff introducing residents or family to the researchers, letters to family members (Appendix 23) | Residents who have capacity will sign a consent form (Appendix 1). For residents who don’t have capacity, their Medical Treatment Decision Maker will be invited to complete the proxy version and sign a Medical Treatment Decision Maker PICF (Appendix 12) |
| Medical services and medications obtained from Services Australia (MBS and BPS data) | As above | Residents who have capacity or their Medical Treatment Decision Maker if they don’t have capacity will consent to collection of MBS and PBS data. They will be provided the Services Australia Participant Information Document (Appendix 20) and asked to sign the Services Australia consent form (Appendix 21).  |
| 1. 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 (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.Family members will be asked to read and sign a PICF (Appendix 13) indicating their consent to completing the survey. They will have the opportunity to ask questions prior to signing. |
| 1. 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.  | Staff members will be asked to read and sign a PICF (Appendix 14) indicating their consent to participating. |
| 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. |

###

### 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.

#### 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, 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: Residents who provide consent (or a proxy who provides consent)

Within each of the ten RACFs, we aim to recruit residents to complete the quality of life measure (Appendix 7a, b, c) and for data for MBS and PBS data for the economic evaluation. We aim to recruit as many residents as possible, but a sample of approximately 10-15% of the sample of 2000 residents (i.e. 200-300), should be adequate for extrapolating costs. A range of strategies will be used to reach potential participants. A member of the research team will visit each facility to give a presentation to residents and family about the study and answer questions. We will put up study flyers in the facility for general promotion of the study to potential participants (Appendix 9). We will ask staff to help with resident recruitment by asking residents with decision-making capacity or their Medical Treatment Decision Maker if they would be interested to learn more about the study. We will use interpreters for residents who communicate in a language other than English. For residents who do not have capacity to consent, we will seek completion of the quality of life measure by a family as a proxy. They will either be approached by facility staff or receive a letter from the facility (Appendix 23). We will only approach residents or family after being introduced to them by staff with their permission. At each 6 month step we will repeat this process to target new residents who have moved into the facility in the previous 6 months.

#### 9.1.3 Study Population 3: 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 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.

#### 9.1.4 Study Population 4: Staff in the Planning Ahead Team (RACF and GPs)

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.

### 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.

### Exclusion Criteria

N/A

### Consent

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

#### 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) and secondary measures (emergency department presentations and hospital admission length of stay), 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 [55], 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, we aim to collect hospitalisation 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.
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?**

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 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.

#### 9.4.2 Study Population 2: Residents who provide consent (or a proxy who provides consent)

We will verbally explain to interested residents what the study involves, what the risks and benefits are, and that participation is voluntary. They further have the opportunity to access this information in written form in the detailed ‘Resident PICF’ (Appendix 11). We will use interpreters for residents who communicate in a language other than English. The resident may also have their Supportive Person (appointed or informal) present. As outlined by the decision-making capacity procedure of the Office of the Public Advocate, we will assess residents’ ability to provide informed consent by asking them to repeat the key elements as well as risks and benefits of the study participation back to the researcher to identify whether they understand, retain and weigh up the study information and are able to communicate their decision. Research staff will assess whether a resident fully understands the implications of participating in research. Decision-making capacity must be assessed in relation to a specific decision, in this case involvement in this research. Thus, in accordance with the Medical Treatment Decision Making Act [56], capacity to provide consent will be determined by whether the potential participant:

* Understands the information relevant to the decision whether or not to participate and the effect of the decision;
* Retains that information to the extent necessary to make the decision;
* Uses or weigh that information as part of the process of making the decision;
* Communicates the decision and the person's views and needs as to the decision in some way, including by speech, gestures or other means.

The potential participant will be asked to explain the details of the research program back to the researcher. This approach is recommended by Dementia Collaborative Research Centres, as cognitive decline can be specific to one or more cognitive processes and a general cognitive screen may not be the best way to judge a person's capacity to give consent to participate in research [57]. This approach is considered less invasive than conducting a formal cognitive test with someone who may not have capacity to consent to the test or involving the potential participant’s medical practitioner.

Residents with capacity will be asked to provide consent for the research team to access their healthcare data (MBS, PBS) and conduct short interviews about their current quality of life approximately every six months. Residents with the ability to give informed consent will be asked to sign the PICF and will be given a copy to keep. For each 6 monthly assessment we will briefly review their capacity, remind them of the study details and check that they are still happy to complete the short quality of life questionnaire. If they have do not have capacity at any 6 month interview, we will seek consent from the medical treatment decision maker as described below.

***Residents who lack capacity:*** For those residents who lack capacity to provide informed consent, we will seek consent from the person’s medical treatment decision maker as per the National Statement on Ethical Conduct in Human Research, the Guardianship and Administration Act 1986 and the Medical Treatment Planning and Decision Act 2016 using the Medical Treatment Decision Maker PICF (Appendix 12) [58]. This could include the resident’s spouse, primary carer, adult child, parent or sibling. If neither resident nor their Medical Treatment Decision Maker are available for the quality of life interview, we will ask RAC staff who worked closely with the resident to complete the interview on their behalf. This will also be explained to the resident to the extent they are able to understand.

#### 9.4.3 Study Population 3: 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 or online videoconferencing 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) or written consent (for interviews conducted face to face). 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 [59].

#### 9.4.4 Study Population 4: 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 in form of a ‘Staff PICF’ (Appendix 14) and written consent will be obtained. 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.

# Participant Safety and Withdrawal

### 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.

### 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 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).

For residents and their families, trained researchers will collect quality of life measures directly from residents or their proxy. This should take no more than ten minutes of their time. Should a participant become upset distressed during the interview or immediately thereafter, the researcher will provide basic comfort, identify and contact family members/friends if the participant so desires. Basic comfort here means an empathetic response (e.g. providing tissues, sitting with them, giving them a glass of water) and does not involve any form of counselling. With resident’s permission, we will further inform a RAC staff member when a resident becomes distressed and ask them to check in on them to make sure they are OK.

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. As this will be done 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. 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. 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.

We hope most data collection will be possible in person/ face-to-face. Yet, 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 possible.

### 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] and 18 [staff]) 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 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.

There is a separate withdrawal form to withdraw from the MBS and PBS data collection (Appendix 22). This form asks participants to indicate whether they want all data from Services Australia for this project to be destroyed or whether data collected to date can be retained. Signing this withdrawal form (Appendix 22) indicates that information already analysed and/or included in a publication may not be able to be destroyed.

### Replacements

Should residents die or withdraw their consent during the study period, we will seek to recruit another resident to avoid data attrition. The power analysis relies on having a consistent sample size in each step of the intervention, so if we do not replace residents who die during the study, the final steps may not contain sufficient numbers of residents for analyses.

# Statistical Methods

### 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) 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. |
| 1. All residents who provide consent (or a proxy who provides consent)
 | Resident quality of life: ICECAP-Supportive Care Measure completed at T1-T6 (Appendix 7a, b, c). | We anticipate that gaining consent for a large number of residents will not be possible. We will aim for as many as possible but estimate that obtaining consent from 10-15% of residents (ie 200-300) may be possible and will enable weighting of the sample to reflect the overall cohort. |
| Medical services and medications obtained from Services Australia (MBS and BPS data) | This will be a similar population to those completing the ICECAP-Supportive Care Measure. However, as the requirement for proxy consent for Services Australia data requires supplying a legal document of evidence, there may be some participants who lack capacity and have someone who can act as a proxy, but who may not have a legal document to support consent for MBS and PBS data collection. Therefore we estimate 100-200 residents for this component. |
| 1. 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 (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.  |
| 1. 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. |

### 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 [60, 61]. 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.

### Statistical Methods To Be Undertaken

#### 11.3.1 Intervention effectiveness

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 [62]. We will conduct sensitivity tests to assess the effect of correlation structures on the results of the trial [63]. 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 for all consenting residents, 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 [62]. 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 [63]. 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 Quality of Life ICECAP-Supportive Care Measure [50-52] as the outcome. 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. To adjust for the smaller sample size for the economic data we will compare the characteristics of the residents we have consent for MBS/PBS data with the overall sample and weight the sample to reflect the overall cohort. Subgroup analysis will be undertaken to examine the impact of proxy versus self-report of the ICECAP-SCM.

# Data Security & Handling

### 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, and activity logs:** 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.

**MBS and PBS data:** For consenting residents, personal information and the signed Services Australia consent form will be sent securely to Services Australia to authorise the release of Services Australia information to NARI. Services Australia will retain consent forms for the life of the study as a record of consent. A copy of the Services Australia consent form will also be retained by NARI for the life of the study. Once Services Australia information has been securely provided to NARI, NARI will apply participant IDs and securely store the data on the NARI server as described above.

### 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, and MBS/PBS data 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.

### 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.

# Consumer Involvement

Underlying our approach is person-centred care, prioritising residents’ values, preferences and goals to inform all end-of-life care planning [64]. 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 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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