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Implementation and evaluation of Goals of Patient Care
medical treatment orders in residential aged care facilities;
a mixed methods study.

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Submitted in total fulfilment of the requirements of the degree

of

Doctor of Medical Science

September 2017

Faculty of Medicine, Dentistry & Health Sciences

The University of Melbourne

Abstract

Background

Systematic reviews demonstrate that Advance Care Planning has many positive effects for residents of residential aged care facilities, including decreased hospitalisation. The proposed residential aged care facility “Goals of Patient Care” form uses shared decision-making to incorporate a resident’s prior Advance Care Planning into medical treatment orders. Where no written Advance Care Plan exists it captures residents’ known values and preferences. This documentation guides healthcare decision-making at a time of clinical deterioration.

Method

A mixed methods study design was used incorporating (i) a cluster randomised controlled trial and (ii) an explanatory descriptive study.

The cluster randomised controlled trial took place in three pairs of residential aged care facilities over twelve months in 2015-2016. In Intervention facilities Goals of Patient Care discussions and forms were completed by a Medical Practitioner, following a shared decision making process, incorporating Advance Care Plans or preferences. In Control facilities residents had usual care, which frequently included an Advance Care Plan. The primary hypothesis was that the Goals of Patient Care process was superior to standard Advance Care Planning alone leading to decreased hospitalisation due to clearer documentation of residents' medical treatment plans. The primary outcome was the effect seen on Emergency Department attendances and emergency admissions at six months.

Secondary outcomes included change in hospitalisation rates at three and twelve months, total hospital bed days and In-RACF and In-hospital mortality rates.

The explanatory descriptive study took place in the Intervention facilities alone twelve months post Goals of Patient Care implementation. Focus groups and semi-structured interviews were conducted to evaluate both Advance Care Planning and Goals of Patient Care from a healthcare professional's point of view. Open and axial coding of themes was used to analyse this data.

Results

Over 70% of patients participated. The facilities were pooled for analysis with 181 residents were randomised to Intervention and 145 to Control. In the cluster randomised controlled trial the primary outcome of a 40% reduction in Emergency Department attendances and emergency admissions compared with Control facilities at six months was not attained with Incident Rate Ratio of 0.74, 95% CI: 0.49–1.14, $p=0.170$. There was a near 50% change in Cluster 3, but not in Cluster 1 and 2. In the Intervention group 11/61 (20.4%) Emergency Department attendances did not result in admission while in the Control group a significantly higher, 20/54 (32.7%) did not result in hospital admission. There was no difference seen in mortality in the groups at six or twelve months

In terms of secondary outcomes the Intervention resulted in a 40% reduction in Emergency Department attendances and emergency admissions at twelve months with IRR=0.62, 95% CI 0.39-0.99, $p=0.043$. There was a trend toward decreased total hospital bed days in Intervention versus Control facilities. Mortality rates at all time-points show increased likelihood of dying in the facility rather than hospital, which was the preference for our participants. This was statistically significant at six months with RRR 2.21, $p=0.008$ 95% CI 1.23-3.98.

Qualitative analysis identified four major themes; Completing an Advance Care Plan; Activating an Advance Care Plan; End-of-life; GOPC. Both ACP and GOPC was seen as a valuable addition to improve patient care and help residents engage with their own preferences. Barriers to successful ACP included poor health literacy, mistrust, ambivalence to activate the plan by family and varying involvement from General Practitioners.

Conclusions

Goals of Patient Care medical treatment orders were not effective in reducing Emergency Department attendances and emergency admissions at six months post intervention. Secondary outcomes did find that Goals of Patient Care medical treatment orders were more effective than standard Advance Care Planning for decreasing hospital transfers and decreasing likelihood of dying outside the facility. The shared decision making process results in medical treatment plans that take better account of both: the resident's values and preferences; and the medical interventions suitable for their care. Barriers to successful completion and activation of plans still exist and education of all stakeholders would help address these issues.

Declaration

This thesis comprises only my original work toward the degree of Doctor of Medical Science.

The thesis is fewer than the maximum word limit in length, exclusive of tables, maps, bibliographies and appendices.

A handwritten signature in black ink on a light gray background. The signature is stylized, starting with a large, loopy 'R' followed by a series of connected loops and a final sharp upward stroke.

Ruth Martin

Preface

This thesis was carried out with myself as the principal researcher and with four supervisors, Professor Wen Kwang Lim, Dr Barbara Hayes, Professor Anastasia Hutchinson and Dr Paul Yates. Their contribution to the published papers was mainly in an editorial role. Dr Barbara Hayes was also involved in the three qualitative focus groups. The proportion of my input to all aspects was more than 90%. All work is original. The Northern Hospital Foundation provided a small research grant to fund the study.

Acknowledgements

I would like to acknowledge all those who helped me complete this research degree. Firstly, I would like to thank my supervisors. To Ana for all the great advice and helping me access the grant for the study. To Paul for all your assistance especially in organising my presentation in Austin Health. To Barbara for all the education about Advance Care Planning as well as the endless editing of my work and for developing the process my research was based on. To Kwang for not only giving me the research opportunity but assisting me both in my scholarship applications and staying gainfully employed to allow me both stay in the country and survive my research years.

I would like to thank also Mark Tacey for all his statistical work and support as well as education over the last two years.

I would like to thank my family for all their support during these years completing my research.

I would like to thank my Dad for reviewing my thesis- ironic after all these years that one of the last theses he edits would be mine.

Lastly without being welcomed by both facility staff and residents as well as their families this research would never have been possible so a special thanks to all those who gave me their time.

Table of Contents

Abstract	iii
Declaration	vi
Preface	vii
List of Abbreviations	xv

Chapter 1 Introduction 1

1.1 Background	1
1.2 Goals of Patient Care	4
1.3 Victorian Legal Framework for Advance Care Planning	6
1.4 Study Objectives	7
1.5 Introduction to Study Design	8
1.6 Limitations of study design	8
1.7 Thesis Structure	9

Chapter 2 Literature review..... 11

2.1 Introduction	11
2.2 Methods	13
2.2.1 Design.....	13
2.2.2 Search Strategy.....	13
2.2.3 Selection Criteria	14
2.2.4 Data Extraction	14
2.2.5 Data Synthesis	15
2.3 Results	15
2.3.1 Study Characteristics.....	15
2.3.2 Quality of the studies	16
2.3.3 Hospitalisation and costs.....	16
2.3.4 Place of Death	17
2.3.5 Consistency with patient's wishes	17
2.3.6 Use of Life-sustaining treatments.....	18
2.3.7 Quality of Life and satisfaction	18
2.3.8 Mortality	18
2.3.9 In-patient Hospice and Community Palliative Care	19

2.3.10	Do-Not-Resuscitate orders and interventions	19
2.3.11	Relevant Prior Systematic Reviews	19
2.3.12	Advance Care Planning studies 2015-2017	20
2.3.13	Advance Care Planning from the healthcare professional's point of view	21
2.4	Discussion	22
2.4.1	Interventions	22
2.4.2	Outcomes; hospitalisation and mortality.....	22
2.4.3	Outcomes; consistency with patient's wishes	23
2.4.4	Outcomes; place of death, palliative care and hospice	23
2.4.5	Outcomes; quality of life	24
2.4.6	Outcomes; Do-Not-Resuscitate orders	24
2.4.7	Outcomes; Advance Care Planning from healthcare professional's point of view	25
2.5	Conclusion	25
Chapter 3 Methodology.....		27
3.1	Introduction	27
3.2	Study Design	27
3.2.1	Introduction to Study Design	27
3.2.2	Study registration.....	28
3.2.3	Study Objectives.....	28
3.2.4	Outcome Measures	28
3.2.5	Study timeline	29
3.3	Methods for the cluster randomised controlled trial	30
3.3.1	Introduction	30
3.3.2	Study population.....	31
3.3.3	Inclusion Criteria.....	31
3.3.4	Exclusion Criteria.....	32
3.3.5	Consent	32
3.3.6	Intervention	33
3.3.7	Usual Care.....	34
3.3.8	Baseline Characteristics and Assessments	34
3.3.9	Investigational Plan	35
3.3.10	Ethical Considerations.....	38
3.3.11	Internal and External Validity.....	39
3.4	Methods for the qualitative study	40
3.4.1	Introduction	40
3.4.2	Study population.....	40

3.4.3	Inclusion Criteria.....	41
3.4.4	Exclusion Criteria.....	41
3.4.5	Consent	41
3.4.6	Intervention.....	41
3.4.7	Usual Care.....	41
3.4.8	Investigational Plan	42
3.4.9	Data transcription	43
3.4.10	Data coding and thematic analysis.....	43
3.4.11	Ethical considerations.....	46
3.4.12	Qualitative Validity and Reliability	46
3.5	Conclusion	46

Chapter 4 Randomised Controlled Trial Data Analysis and Findings..... 47

4.1	Introduction	47
4.2	Section one	47
4.2.1	Recruitment of facilities	47
4.2.2	Screening of facilities.....	48
4.2.3	Residential Aged Care Facility characteristics	48
4.3	Section two.....	49
4.4	Patient recruitment	49
4.4.1	Baseline Characteristics	50
4.4.2	Baseline Assessments	51
4.5	Section three	53
4.5.1	Results of the Goals of Patient Care process and form completion	53
4.6	Section four	55
4.7	Results of Emergency Department attendances and emergency admissions.....	56
4.7.1	Primary outcome	56
4.8	Summary.....	58

Chapter 5 Data Analysis and Findings of Qualitative Study... 60

5.1	Introduction	60
5.1.1	Participant characteristics.....	60
5.2	Results: Thematic analysis.....	61
5.3	Completing an Advance Care Plan	63

5.3.1	Timing of Advance Care Plan completion	64
5.3.2	Roles in Advance Care Plan completion	65
5.3.3	The effect of cultural differences and health literacy on uptake and understanding of ACP	67
5.3.4	Changes in Advance Care Planning completion overtime	68
5.4	Activating an Advance Care Plan	69
5.4.1	Advance Care Planning as a guide to decision making	69
5.4.2	Family members' ambivalence about following the Advance Care Planning.....	69
5.4.3	Mistrust	71
5.4.4	Best interest of the patient.....	72
5.5	End-of-life	73
5.5.1	Difficulty predicting time of death	73
5.5.2	Palliative care provision.....	73
5.5.3	Family Issues.....	75
5.5.4	Residential-In-Reach support (Outreach and Residential Care Intervention Program in the Elderly [RECIPE] namely)	76
5.6	Goals of Patient Care	76
5.6.1	Attitudes to Goals of Patient Care	77
5.6.2	Confusion about Goals of Patient Care and Advance Care Planning.....	78
5.7	Summary.....	78
Chapter 6 Discussion and Conclusions.....		80
6.1	Introduction	80
6.2	Discussion of the cluster randomised controlled trial results	80
6.2.1	Residential aged care facility matching and recruitment.....	80
6.2.2	Residential aged care facility characteristics.....	81
6.2.3	Baseline characteristics and assessments.....	82
6.2.4	GOPC form choices.....	85
6.2.5	GOPC effect on primary outcome	86
6.3	Discussion of Explanatory Descriptive Study results.....	89
6.3.1	Completing an Advance Care Plan	89
6.3.2	Activating an Advance Care Plan.....	90
6.3.3	End-of-Life	91
6.3.4	Goals of Patient Care	92
6.3.5	Relationship between Advance Care Plans and residential aged care facility Goals of Patient Care	92
6.4	Discussion of combined results.....	92
6.5	Conclusion	93

6.6	Strengths and limitations	95
6.6.1	Strengths	95
6.6.2	Limitations	96
6.7	Implications	97
6.7.1	Implications for clinical practice	97
6.7.2	Implications for policy	97
6.7.3	Implications for research	98
References		99
Appendices		107
Appendix 1	Goals of Patient Care RACF Sample form	107
Appendix 2	Secondary Outcomes	110
Appendix 3	Strategy used to identify published studies on ACP suitable for our analysis	120
Appendix 4	GRADE criteria applied to systematic review included studies	121
Appendix 5	A summary of the GRADE approach to the grading of quality of evidence for each	122
Appendix 6	Results Table Systematic Review	123
Appendix 7	Email invitation to RACF managers.....	126
Appendix 8	CONSORT participant flow diagram.....	127
Appendix 9	Patient Information Consent Form Manager	128
Appendix 10	Patient Information Consent Form Resident	137
Appendix 11	Patient information and consent forms Substitute Decision Maker	146
Appendix 12	Baseline assessments	155
Appendix 13	Patient Information Consent Form Healthcare professional.....	162
Appendix 14	Question Guide for focus groups.....	171
Appendix 15	Question guide for Medical Practitioner interviews	172
Appendix 16	Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist	173
Appendix 17	Summary table on 'Completing an Advance Care Plan', describing the numbers of quotes and sources on the 6 subthemes outlined.....	175
Appendix 18	Summary table on 'Activating an Advance Care Plan'	176
Appendix 19	Summary table on 'End-of-life'	177
Appendix 20	Summary table on 'Goals of Patient Care'	178
Appendix 21	JAMDA publication	179
Appendix 22	BMJ Open publication	191

List of Figures

Figure 1.1	GOPC Options	5
Figure 3.1	Study Methodology	27
Figure 3.2	Study Timeline	30
Figure 3.3	Data Analysis in Qualitative Research.....	45
Figure 4.1	GOPC choices	54
Figure 5.1	Thematic Analysis Results of Qualitative Analysis	62

List of Tables

Table 3.3.8	Baseline Characteristics and Assessments.....	35
Table 4.1	Baseline Characteristics and Assessments.....	52
Table 4.2	Results RACF prior ED event rates, study participant numbers, primary and secondary outcomes; separate facilities.....	55
Table 4.3	Six month outcome results for ED attendances and emergency admissions and mortality	57

List of Abbreviations

ACP	Advance Care Planning
ED	Emergency Department
GOPC.....	Goals of Patient Care
GP	General Practitioner
GRADE.....	Grading of Recommendations, Assessment, Development and Evaluations
IRR	Incident Rate Ratio
PICF	Patient information and consent forms
POLST.....	Physicians Orders for Life Sustaining Treatment
PRN.....	Pro Re Nata (as required)
RACF.....	Residential Aged Care Facility
RRR.....	Relative Risk Ratio
SDM	Substitute Decision Maker
USA	United States of America

Chapter 1 Introduction

1.1 Background

Advance Care Planning is a process by which people document their preferences and values for healthcare, planning for a time when they are not able to speak for themselves. The process is centred on patient autonomy and the idea that this autonomy should extend to situations where a person's capacity is impaired. In Australia although Advance Care Planning has been present to a degree for the past three decades, it has become a much greater focus of healthcare in the last ten years. Palliative medicine within Australia has championed its development due to its association with improved end-of-life care. It is supported by policy, which differs between Australian states but was supported nationally by the *National Palliative Care Strategy* in 2015. In Victoria, Australia, where this study took place, *Medical Treatment Planning and Decisions Act 2016* will give new legal standing of Advance Care Plans when it comes into effect in March 2018.

Within Australia recent figures show that in 2016 there were 199,249 places in residential aged care. This equates to 113.2 places in aged care for every 1,000 people aged 70 years. Most aged care services are run by not-for-profit organisations (65%). Most privately-owned aged care services are in cities, and government services are predominant in remote area (1). Internal governance varies between organisations but standards of quality are accredited nationally by the Department of Health. The northern metropolitan area of Melbourne, the catchment in which the study took place, has 9593 aged care beds with a mix of all organisation types. This is comparable with all the metropolitan areas in Australian cities. Within this northern metropolitan area all facilities included were within 13 km of public and private hospitals with admitting Emergency Departments. This contrasts to rural areas in Australia in which distances to local hospitals both public and private can be vast.

Despite this, Advance Care Planning has not shown the efficacy one would expect in Australia (2). Although it has shown some positive effects in terms of quality of life and decreasing family

distress (3) it has not always in terms of hospitalisation rates (2). In residential aged care facilities in the United States of America medical treatment orders such as the Physicians Orders for Limitations of Treatment (POLST) were first introduced to address shortcomings they found with Advance Care Plans, including difficulty with their interpretation (4-8) and not being in a format of orders that ambulance staff could follow (9). Studies in the United States of America have shown more appropriate treatment choices for residents with the introduction of the medical treatment forms such as the Physician Orders for Life Sustaining Treatment and others adapted from it (10) over their prior Advance Care Plans. Current issues exist here in Australia with both the clarity of the Advance Care Plan completed (11) and the activation of this plan when residents become unwell.

The residential aged care facility Goals of Patient Care process was developed to deal with the shortcomings seen by clinicians working in residential aged care facilities and hospitals in Australia with current Advance Care Plans. The Goals of Patient Care process involves reviewing a patient's medical history as well as current health trajectory with healthcare professionals providing care to them. The main factors being reviewed including oral intake, cognitive and functional status as well as recent hospitalisations. A Goals of Patient Care form is then completed. This is a medical treatment order that incorporates aged care residents' Advance Care Plans or preferences. It is completed by the Medical Practitioner following this patient review and discussion with the patient and their substitute medical decision maker or interested parties. The form helps guide healthcare decisions made on behalf of patients in planned and emergency situations. It was developed to try and improve healthcare decisions made for patients of residential aged care facilities.

Systematic review has shown that Advance Care Planning initiatives can many positive effects on residents of aged care facilities, including decreasing unwanted hospitalisation (12). Prior research in Australia has shown that standards of Advance Care Plans in residential aged care facilities are inconsistent and variable in quality (11). The POLST intervention, like our Goals of Patient Care process, was developed to help ensure the wishes of individuals with advanced illness or frailty were honoured by documenting their preferences as medical treatment orders (13). Studies in the United States of America have shown that patients with such orders were

less likely to receive unwanted interventions including hospitalisation (14-16) and intravenous fluids (16), than those with traditional Advance Care Plans (16).

The incidence of transfers from the residential aged care facilities to the Emergency Department (ED) has been measured at greater than 30 transfers per 100 bed days (17) but is variable depending on facility and location. Hospitalisation can be burdensome for residential aged care facility patients (2, 4) and many, when asked, would prefer to be treated in their residential aged care facility where possible (18). Given their frailty, high incidence of dementia and multi-morbidity residential aged care facility patients have an increased incidence of acute illness compared with the ambulatory population. This is reflected by a high incidence of acute healthcare utilisation (19). Up to 48% of these hospital transfers are thought to be avoidable (4, 5). Interventions targeting these admissions, according to a recent systematic review (6) include, improving palliative care provision(20-22) improving Advance Care Planning interventions(23, 24), improving treatment of pneumonia and chronic obstructive pulmonary disease within facilities (25-27) and providing ambulatory geriatric care through Geriatrician reviews in residential aged care facilities (18, 28-30) .

Dementia, estimated to affect over 50% of residential aged care facility patients (18, 31, 32), hinders the decision making capacity of the patients, especially at times of acute illness. The introduction of the Goals of Patient Care medical treatment orders will make the preferences of frail patients' clearer and with the authority of their treating Medical Practitioner. When patients are reviewed by staff that do not know them well, such as after-hours locum Medical Practitioners or agency nurses, this document completed by their treating or usual Medical Practitioner should give them increased confidence in following the treatment plan. We hypothesise that for these reasons Goals of Patient Care will be superior to current Advance Care Plans and its implementation will result in medical decisions being more congruent with patients' preferences, and more appropriate for their care. Studies examining medical treatment orders in residential aged care facilities have not been conducted in Australia and we intend to show that such innovations are translatable to our target population. We hypothesise that the introduction of the this medical treatment order will lead to decreased acute healthcare

utilisation as compared with usual care by improving communication of the residents wishes to all healthcare staff leading to more appropriate healthcare decisions.

1.2 Goals of Patient Care

The Goals of Patient Care, [appendix 1], is a document used to record medical treatment plans for patients in residential aged care facilities in event of clinical deterioration. It takes into account the current medical condition as well as patients' preferences and any prior Advance Care Planning. As it is specifically for patients in residential aged care facilities it identifies whether patients are open to hospital transfer for treatment escalation.

There is little Australian research from within residential aged care facilities to advise us on current processes of Advance Care Planning completion, although some research has taken place giving advice on the necessary steps to facilitate Advance Care Plan completion (33). It is known that the process is varied between residential aged care facilities (11) and it was hypothesised based on clinical experience of the investigators that Medical Practitioners also had varied input. Without this input disease trajectory would not always be discussed at time of completion. At times these Advance Care Plans are completed with no facilitation at all and thus the clarity of the document is fully dependent on health literacy of those individuals involved. This leads to suboptimal Advance Care Plan completion.

GOAL A: FOR TREATMENT OF ALL REVERSIBLE ILLNESSES	
☐ FOR CPR and appropriate life-sustaining treatments	→ FOR TRANSFER TO HOSPITAL (if required treatment cannot be provided in the facility)
GOAL B: FOR TREATMENT OF REVERSIBLE ILLNESS WITH FOLLOWING LIMITATIONS	
☐ NOT FOR CPR or INTUBATION - but is for other appropriate life-sustaining treatments	→ FOR TRANSFER TO HOSPITAL (if required treatment cannot be provided in the facility)
GOAL C: FOR TREATMENT OF REVERSIBLE ILLNESS ABLE TO BE MANAGED WITH SIMPLE, NON-BURDENSOME TREATMENT. GOOD SYMPTOM MANAGEMENT NOT FOR CPR or INTUBATION	
☐ - is for treatment of illness if this can be done without causing excessive distress. For hospital treatment if required.	→ Aim to provide care in the facility but TRANSFER TO HOSPITAL if necessary
OR ☐ - is for trial of treatment at the facility, if this can be done without causing excessive distress. If deteriorates, is for comfort measures only.	→ NOT FOR TRANSFER TO HOSPITAL if condition deteriorates - unless symptom cannot be managed in facility eg fracture
OR ☐ - NOT for life-prolonging treatment of new illness / deterioration. All treatment is aimed at comfort and relieving symptoms.	→ NOT FOR TRANSFER TO HOSPITAL unless symptom cannot be managed in the facility eg fracture
GOAL D: COMFORT DURING DYING – TERMINAL CARE (prognosis is assessed to be hours or days)	
☐ All treatment is aimed at relieving symptoms and supporting the resident / patient and their family / important others	→ Commence End-of-Life Plan → NOT FOR TRANSFER TO HOSPITAL unless symptom cannot be managed in the facility eg fracture pain

Figure 1.1 GOPC Options

The Goals of Patient Care document has six Goal options as seen in [figure 1]. Goal A identifies residents for cardiopulmonary resuscitation (CPR) and all life sustaining treatments. Goal B identifies residents for hospital transfer and treatment but who should not receive cardiopulmonary resuscitation or intubation. Goal C1 identifies residents for trial of treatment at facility and for hospital transfer if required. Goal C2 identifies residents for trial of treatment at facility but not for hospital transfer in the event of deterioration. Goal C3 identifies residents who are not for further treatments of new illnesses, and who are opting for symptom management only. Goal D identifies residents who are in the terminal stage of illness (last hours and days of life).

The Goals of Patient Care document relates to Advance Care Planning as it plays a role in future healthcare planning for patients. An Advance Care Plan is usually regarded as a communicate between patients or their substitute decision maker and staff, and is completed by the patient/substitute decision maker. The Goals of Patient Care, however, is a communicate

between staff and is completed by their Medical Practitioner. It translates the Advance Care Plan into clinical language and guides healthcare professionals in their treatment choices for that patient. It is particularly helpful when a patient is being reviewed by a Medical Practitioner or nurse who is unfamiliar with that person, their values or their treatment plans. Additionally, the language is unambiguous and directive in nature.

1.3 Victorian Legal Framework for Advance Care Planning

Currently residential aged care facilities in Victoria engage with Advance Care Planning to variable degrees. Sometimes patients and their substitute decision maker fill in the forms alone, sometimes with support of facility staff and sometimes also with the support of their visiting Medical Practitioner. We envisage that most patients recruited will have been invited to complete Advance Care Plan. However we hypothesize, from prior experience, that the quality of the Advance Care Plans at times will be low and open to interpretation leading to difficulty basing medical decisions on them.

In 2016 the Victorian Parliament passed the *Medical Treatment Planning and Decisions Act 2016* (34). Victorians, with decision making capacity, will be able to create a legally binding advance care directive that will allow them to:

- Make an instructional directive (which will provide specific directives about treatment a person consents to or refuses).
- Make a values directive (which will describe a person's views and values. A medical treatment decision maker and health practitioners will be required to give effect to a values directive).
- Appoint a medical treatment decision maker (who will make decisions on behalf of a person when they no longer have decision making capacity).
- Appoint a support person (who will assist a person to make decisions for themselves, by collecting and interpreting information or assisting the person to communicate their decisions).

In this Victorian framework the Substitute Decision Maker is the term used to refer to the person appointed to make decisions for an individual lacking capacity. The framework also refers to 'Activation' rather than 'Following' an Advance Care Plan which is the terminology used in this thesis. Of note there is no provision for people without capacity to make an Advance Care Plan in this legislation at present.

1.4 Study Objectives

The primary objective in this study was to show that the introduction of the Goals of Patient Care medical treatment orders would lead to decreased Emergency Department attendances and emergency admissions for residential aged care facility patients at six months post implementation as compared with usual care. Emergency Department attendances were taken as any transfer of the patient to any public or private Emergency Department. Admissions were taken as any emergency hospital admissions for more than 24 hours, planned admissions were excluded.

The qualitative objectives investigated were:

- A change in facilitation of healthcare decision making for all staff
- Process evaluation and comparison of Advance Care Planning and Goals of Patient Care in residential aged care facilities

This research study aimed to demonstrate the effectiveness of Goals of Patient Care medical treatment orders in the Australian residential aged care facility setting, as has previously been done in USA (35). If the study does show decreased hospitalisation and increased death within the facility, which was the preferred choice for the participants, then it will prove itself superior to current Advance Care Planning in place and this would support the use and dissemination of Goals of Patient Care medical treatment orders across Victorian Health Services. This tool is specifically focussed on the residential aged care facility population but in the future the Goals of Patient Care document may be adapted for community dwelling individuals in Australia also.

1.5 Introduction to Study Design

The study is an Explanatory Sequential Mixed Methods study (36). This mixed methods study design used incorporates (i) a cluster randomised controlled trial and (ii) an explanatory descriptive study. The main objective of the study was to implement and examine the effects of Goals of Patient Care medical treatment orders in residential aged care facilities through quantitative and qualitative research methods. Baseline characteristics and assessments were recorded from all patients. The Goals of Patient Care discussion and form was completed with patients in the Intervention residential aged care facilities as compared with usual care in Control residential aged care facilities. The quantitative analysis was performed at three, six and twelve months in both Intervention and Control residential aged care facilities from 2015 to 2016. The qualitative analysis was completed at twelve months in the Intervention residential aged care facilities alone. The COnsolidated criteria for REporting Qualitative research (COREQ) Checklist (37) has been used to report the qualitative component of the study and is available in appendix 14.

1.6 Limitations of study design

The research study commenced with a systematic review looking at the effects of Advance Care Planning, including medical treatment orders, on patients of residential aged care facilities. A systematic review is a process of reviewing all available high quality data addressing a specific question, analysing outcomes from a range of studies to increase the strength of evidence on healthcare interventions (38). Limitations associated with this research method include:

1. The assumption that the evaluation methods are consistent across studies
2. Difficulty in located all relevant studies
3. Unknown bias in the statistical methods used in individual studies
4. Inconsistent coding of variables limiting their utilisation for detecting heterogeneity
5. Difficulty in detecting interactions and trends if all the data is not consistent and available (39)

A cluster randomised controlled trial is the research method used for the analysis of the quantitative component of the mixed methods study. The unit of inference for each cluster is the

individual residential aged care facility. Limitations are recognised with this study design including:

1. The study was unblinded leading to possible introduction of bias
2. Clustering itself leads to issues with design choice, the choice of the unit of inference and the degree to which clusters must be matched at baseline
3. Clustering substantially reduces statistical efficiency
4. Clustering can lead to an imbalance between the two arms
5. There is increased selection bias identified in these types of studies
6. Effects from these studies are not definitely generalisable to other populations (40)

An explanatory descriptive study is the research method being used for the analysis of the qualitative arm of the mixed methods study. Qualitative studies have their own limitations, some of which are unique to this type of research method, including:

1. Rigour of study design leading to issues with validity and reliability
2. Results can be very dependent on the skill of the researcher
3. Researchers presence can affect the responses of interviewees
4. Volume of data to be analysed can be time consuming
5. Qualitative research is not as well understood quantitative research
6. Bias is easily introduced at time of data collection, analysis and interpretation
7. Issues with generalisability to other populations (41)

These limitations were acknowledged and addressed by the investigators to improve the validity and reliability of the results found and conclusions drawn.

1.7 Thesis Structure

The thesis is divided into six chapters: Chapter One, this introduction. Chapter Two discusses in more detail the current literature on this topic. Chapter Three introduces the methodology and ethical considerations for the study. Chapter Four presents the quantitative outcomes from the randomised controlled trial implementing the residential aged care facility Goals of Patient Care discussion and form in three cluster pairs of residential aged care facilities. Chapter Five

presents the qualitative outcomes from focus groups and in-depth interviews held with healthcare professionals working in the Intervention residential aged care facilities where the form had been implemented for twelve months. Chapter Six discusses the outcomes and conclusions from the research study.

Chapter 2 Literature review

2.1 Introduction

Due to significant advances in medicine and technology the proportion of people reaching older age is increasing globally. In 2013 the proportion of older persons over 80, “the oldest old”, was 14% and this is projected to reach 19% by 2050 (42). Unfortunately, not all are maintaining their functional independence to live in the community, leading to larger numbers requiring care in residential aged care facilities (43). The population in residential aged care facilities are increasingly frail with multiple comorbidities. This is reflected by the high incidence of acute healthcare utilisation (5) with the incidence of hospital admission of residential aged care facility population reported to be patient up to three times that of community dwellers (44). A systematic review by Arendts et al, including two Australian studies, has shown the range of Emergency department transfers to be 0.2-1.5 transfers per residential aged care facility bed per year (2) with large variations existing not just between but within geographical areas. Although it is acknowledged that a high number of the patients have high acuity (2) , a high percentage of the transfers, up to 48% are felt to be avoidable in international studies (3, 4). In Australia one large multicentre study found that 1 in 4 patients attending were discharged directly from the Emergency Department with 35% being triaged according to the Australasian Triage Scale as a category 4-5 indicating less urgent issues(2) . A single centre study, in Western Australia, found the up to 13% of admissions were avoidable (45) .

The residential aged care facility population has the unique characteristic of 24 hour access to nursing or support staff care. Despite the increasingly large ratio of patients to staff, this still enables care delivery in the facility that would be difficult to give in the community. Knowing how detrimental unnecessary hospital admissions can be to patients (4, 18) and that research has shown both patients and families have a preference for treatment in the facility (19) ,interventions to reduce hospital transfer from residential aged care facilities are common.

Advance Care Planning has been one of these targeted interventions with legislation or policy supporting it since the 1990s, including the United States *Patient Self Determination Act 1990* and the United Kingdom *Mental Capacity Act 2005*. In Victoria, Australia as mentioned, a new *Medical Treatment Planning and Decisions Act 2016* will be implemented in March 2018. There are many different types of Advance Care Plans used in residential aged care facilities, some of which are specific to the facility or group of facilities. Advance Care Planning may also be included within medical treatment orders that plan for future deterioration, such as Do-Not-Resuscitate orders, Do-Not-Hospitalise orders and the newer Physician Orders for Life Sustaining Treatments. However, if these medical treatment orders are unilateral decisions made by physicians, or do not explicitly capture and describe the preferences and values of the person, they would not be in keeping with the ethos of Advance Care Planning, which is regarded as recording the 'voice of the patient' (46).

A systematic review by Sharp et al has shown that the majority of older people welcome the chance to discuss end of life care, with most perceiving the risk of leaving it too late (47). A recent article described the 'Goldilocks phenomenon' with regards to the timing of Advance Care Planning: not too early as people's preferences tend to vary over time; not too late at time of crisis; but trying to find the 'just right' time to engage. The author suggested better prognostication to be the key to finding this optimal time (48).

Advance Care Planning allows people to have a voice in their healthcare decisions should they lose the capacity to be involved in these conversations in the future. Loss of capacity may be transient, at times of acute illness or delirium, or permanent and progressive due to dementia. Dementia is estimated to affect between 50 – 80% of residential aged care facility patients (18, 31, 32), impairing their decision-making capacity, which highlights the relevance and importance of Advance Care Planning for this group. Some large international studies have failed to show a significant impact on care with Advance Care Planning in the ambulatory population (49) due to shortcomings including difficulty with Advance Care Planning interpretation (4-7, 49) and the orders not being in a format that ambulance staff can follow (9). However, other studies both Australian and international have shown positive outcomes with Advance Care Planning for

patients and families (3), specifically in residential aged care facility populations (24, 25) thus supporting their on-going prioritisation for health care services (50) .

Heterogeneity of studies, for both the Advance Care Planning interventions and their outcome measures, leads to some difficulty in their interpretation and application (15). In the United States of America the Advance Care Planning focus since the late 1990's has been on POLST. These medical treatment orders and their permutations are said to be now in use, or in development, in 41 American states (10). With POLST, research has shown that residential aged care facility patients are less likely to receive unwanted interventions including hospitalisation (14, 16) and intravenous fluids (16). These medical treatment orders are completed by Medical Practitioners, in consultation with patients or their substitute medical decision-makers, taking into account the patients' preferences for care as well as their current health status. They were developed to deal with the shortcomings of original Advance Care Planning completed by a person with capacity for themselves. In countries outside the United States of America the types of Advance Care Planning, and the terminology referring to the different directives, are very varied (51).

Although there have been systematic reviews in the area of Advance Care Planning no reviews have focussed on the residential aged care facility population. It was felt important to do a systematic investigation to collate the findings of the effects of Advance Care Planning on this unique population as the effects found in other populations may not be generalisable to this population.

2.2 Methods

2.2.1 Design

This systematic review was prospectively registered with PROSPERO (52).

2.2.2 Search Strategy

In April 2015 a comprehensive literature search was conducted using the following four electronic databases Embase, Medline, PsychINFO and CINAHL with no limits on year or

language. The search strategy is available for review in appendix 3. The search yielded 4,654 titles. There were no restrictions by study design at this time so as to allow identification of all studies related to the question. Hand-searching of citations in these articles to identify additional relevant studies was performed, as well as searching of grey literature.

A further literature review was performed in August 2017 to update the review with any recent high quality studies and to review exploratory studies looking at Advance Care Planning from the health care professional's point of view.

2.2.3 Selection Criteria

Inclusion criteria were studies examining an effect of Advance Care Planning on residential aged care facility patients. Residential aged care facilities were defined for this review as permanent residences providing care for older people also including nursing homes, long term care units, and skilled nursing facilities or care homes. Advance Care Planning was defined as any advance discussions or directives, including medical treatment orders, with effect on residential aged care facility patients. Having reviewed all the articles for relevance, articles pertaining to randomised controlled trials, controlled trials, pre/post study design trials and prospective trials were assessed, with thirteen studies fitting all the inclusion criteria in appendix 2, including one study taking place in Australia. Exclusion criteria included all other types of studies including retrospective studies, studies focussed solely on implementation of Advance Care Planning or medical treatment orders rather than examining effects. Also none of these studies involved appointment of a medical substitute decision-maker as the sole element of Advance Care Planning. A further five systematic reviews were also identified as partially relevant and are discussed separately.

2.2.4 Data Extraction

Data was extracted using Grading of Recommendations Assessment, Development and Evaluation (GRADE) (53). As with other systems for data extraction it is based on the rigour of the study design. The systematic approach suggested by the GRADE working group was followed (53, 54) and categorisation of the studies into four groups according to a judgement on

their evidence was performed; high, moderate, low and very low. As per the GRADE protocol, randomised controlled trials start as high quality evidence and observational studies start as low evidence. They then moved up or down categories depending on the robustness of their study design according to GRADE criteria (53) as seen in appendix 4 and 5. Two reviewers appraised each study with high levels of agreement. Disagreements were resolved through discussion with a third reviewer.

2.2.5 Data Synthesis

It was not possible to perform a meta-analysis on the pooled results due to the heterogeneous nature of the both the interventions and results. For this reason a detailed narrative synthesis has been compiled.

2.3 Results

All results found in studies that fit inclusion criteria are reported in the following section.

Tabulation of results can be found in Appendix 6.

2.3.1 Study Characteristics

Seven of the studies took place in the United States of America (USA), one took place in Australia, one in Hong Kong, one in Canada, one in the United Kingdom, one in Singapore, and one in The Netherlands. The intervention in five studies was an educational programme. For two of these, the Advance Care Planning education was provided just to healthcare staff (55, 56) while in the other three, education was provided to healthcare staff, patients and families (24, 25, 57). Five studies involved introduction or evaluation of a new Advance Care Planning form in the facility, although none identified whether this new form was a change in forms or the first introduction of Advance Care Planning (13, 16, 58-60). Two studies involved introduction of an Advance Care Planning programme together with a palliative care initiative (61, 62) and one study involved observation of the effect of Do-Not-Resuscitate orders on the medical treatments of patients with lower respiratory infections (63).

2.3.2 Quality of the studies

The overall quality of the study methodologies was assessed as low as can be seen in appendix 6. Only one study was of high quality and two of moderate quality, using GRADE criteria. The majority, eight of the studies, were of low quality, with two being of very low quality.

2.3.3 Hospitalisation and costs

Hospital utilisation is a frequent measure used across the included studies (13, 24, 25, 59-63).

In the residential aged care facility population, Advance Care Planning has been shown to decrease hospitalisation rates from between 9% and 43%. Mott et al in their inter-group comparison found a decrease in admissions of 77% between their Group 1 (opting for full medical management) and Group 4 (opting for comfort measures only) (59). Associated healthcare costs were less frequently studied with results reported from Canada and Singapore. In Canada it was found by Molloy et al that there was a significant decrease in both the hospital costs reported in Canadian Dollars, intervention home \$1772 v control home \$3869 per patient $p=0.003$ and total healthcare costs, intervention home \$3400 v control home \$5239 per patient $p=0.01$ (24).

In Singapore, Teo et al showed significant reduction in total health costs in both the last three months and last month of life associated with decreased hospitalisation in the Advance Care Planning group versus control. They found per-patient cost savings in Singapore Dollars (SGD) \$7129 over the last three months of life (US \$1-SGD\$1.3) and per-patient cost savings SGD\$ 3703 over the last one month of life (62). Caplan et al in an Australian study, showed a decrease in hospital bed use by 26% in the intervention v control facilities from which one can safely deduce a decrease in hospital costs but cannot presume a decrease in overall healthcare costs (25). In the American setting Mott et al showed a decrease of 79% in hospital bed days from their group for active intervention compared to their group for comfort measures only (64), with an associated decrease in hospital costs but not necessarily a reduction in overall healthcare costs while Levy et al found no significant change in length of stay in those hospitalised 5.17 v 3.33 days (61).

2.3.4 Place of Death

Place of death is another important studied effect of Advance Care Plan. The studies found significant increases in the number of patients dying in their residential aged care facility both nationally and internationally (25, 56, 60, 61, 64) by 29-40% compared with control. Some studies compare this effect between groups according to stated wishes in their Advance Care Plan; for example Mott et al found that there was an increase from 55% to 85% of patients dying in their facility between Group 1 (opting for full medical management) to Group 4 (opting for comfort measures only) (59). This difference reflects an effective Advance Care Plan. It also reflects the influence the type and specificity of the Advance Care Plan can have on the approach to the patient's care. Caplan et al found that in their Australian study, of the 32 patients in the Advance Care Plan intervention group who died, 100% of them died in their preferred place as specified in their Advance Care Plan (25).

2.3.5 Consistency with patient's wishes

Actions being consistent with patients' wishes are outcome measures in many of the studies (13, 55, 56, 58). The range of increase in effect is 13-29% in the Intervention compared with Controls across these studies. However, when the Advance Care Plan is broken down into different components it becomes apparent that some directives are easier to follow than others and some Advance Care Planning outcomes are easier to measure. For example studies show Advance Care Planning with regard to cardiopulmonary resuscitation can be up to 100% effective (13, 16). In contrast the guidance of Advance Care Planning with regard to the administration of antibiotics was found to be ineffective (16). Danis et al investigated variables associated with consistency and found that when treated in hospital rather than treated in the residential aged care facility the ACP was more consistent with their expressed wishes 87% v 46% $p = 0.00003$, as most inconsistencies tended towards under-treatment and they felt the approach to medical care was less aggressive in the residential aged care facility (58). This study did not assess how appropriate the Advance Care Plan wishes were.

2.3.6 Use of Life-sustaining treatments

Use of life-sustaining treatments is another outcome measure of Advance Care Planning studies, which overlaps with the outcome measure of a patient's care being consistent with their Advance Care Planning wishes. It is addressed in two of the included studies (16, 64). Hickman et al found that those opting for 'Comfort Measures Only' were significantly less likely to receive life-sustaining medical treatment than those with Advance Care Plans for full active management, those with Do-Not-Resuscitate orders and those with For Resuscitation orders (16). In a sample of patients who were only for hospitalisation in the event of unmanageable symptoms, four of twenty-four hospitalisations were for the purpose of life-sustaining treatments (13) showing it is possible for even the most specific Advance Care Plan to be ignored.

2.3.7 Quality of Life and satisfaction

Perceived improvements in quality of life of the patient and satisfaction of the family, although difficult to measure, were studied in two of the included articles (57, 60). Van Soest-Poortvliet et al (60) found that establishing baseline comfort goals for patients was associated with more satisfaction with end-of-life care $p=0.03$. The effect, however, was significant only when patients were living in the residential aged care facility for less than six months before they died. Chan et al 2010 found with introduction of Advance Care Planning there were statistically significant improvements in overall Quality of Life $p=0.034$, physical discomfort $p=0.017$ and existential distress $p=0.038$ for patients (65).

2.3.8 Mortality

Mortality associated with Advance Care Planning has been measured in two of the included studies (24, 25). Both studies showed that Advance Care Planning was not associated with increased mortality. In fact, Caplan et al in their Australian study found no significant change in mortality except for the third year of their study when the mortality rate rose in the control residential aged care facilities by 10% rather than the intervention homes, 30.4 v 41.6 per 100 beds; $P=0.0425$ (25). Similarly Molloy et al in their Canadian study found no significant difference in death rate between the Intervention and Control groups 24% v 20% $p=0.2$ despite lower hospitalisation in the intervention group (24).

2.3.9 In-patient Hospice and Community Palliative Care

Although many Advance Care Planning studies look at in-patient hospice and community palliative care referral in association with Advance Care Planning, most are of a retrospective observational nature and so are not included in this analysis. Only one of the studies included investigated these effects and they found no change in in-patient hospice referrals pre and post implementation of their intervention but community palliative care referrals increased by 23.7% $p=0.02$ following the Advance Care Planning intervention (61). Mean Length of Stay in hospice did not differ significantly with 24.3 days pre versus 32.7 post Advance Care Planning intervention. The mean number of days however in the community palliative care programmes did increase, from one day to 13.8+/- 25.9 days, but did not reach significance, $p=0.09$ (61). No difference was found in end-of-life symptom assessment or management between those with and those without Advance Care Plans in the one study in which it was examined (16).

2.3.10 Do-Not-Resuscitate orders and interventions

One study showed no difference in medical interventions, including hospitalisation, between patients who are for cardiopulmonary resuscitation and patients with Do-Not-Resuscitate orders (16). A second large study investigating the effect of Do-Not-Resuscitate orders on hospitalisation of patients with lower respiratory infection found 23% of those with Do-Not-Resuscitate orders, and 32% of those without Do-Not-Resuscitate orders, were hospitalised (63).

2.3.11 Relevant Prior Systematic Reviews

The literature search yielded five systematic reviews of partial relevance to this review. One had performed a meta-analysis while the others reported a narrative synthesis. Houben et al conducted a meta-analysis on concordance between patient preferences for end-of-life care and end-of-life care delivered. They included three studies evaluating the effect of an Advance Care Planning intervention versus control, and found in favour of intervention (66). Of note, only one of these included studies involved residential aged care facility patients. In another systematic review, Brinkman et al examined the effect of Advance Care Planning on end-of-life care. Of the 113 studies included, they found 95% of were observational, many were

retrospective in design, and 32% included residential aged care facility populations. They found Advance Care Planning was associated with decreased use of life sustaining treatments, decreased hospitalisations and increased use of in-patient hospice and community palliative care (67). Kirolos et al examined interventions to improve in-patient hospice and community palliative care referral and five of the six included studies demonstrated an increase in in-patient hospice referral (68). Only one of their studies included an Advance Care Planning intervention and thus was included in our analysis. This study did not show an increase in in-patient hospice referrals but did show an increase in community palliative care referrals (61).

Robinson et al studied the effectiveness of Advance Care Planning interventions for people with pre-existing cognitive impairment and dementia. They identified two studies that showed decrease in hospitalisation and one that showed increase in in-patient hospice use (69). Their conclusion was that the residential aged care facility is too late for Advance Care Planning conversations with only 36% of patients having capacity. Arendts et al examined the interface between a residential aged care facility and the Emergency Department and found a complex interplay of factors influencing hospitalisation from facilities including the type of facility, the functional and clinical status of patients, and individual facility transfer policies- two Australian studies were included in their analysis. They did find that Advance Care Planning is helpful and compliance with it is generally good (2).

2.3.12 Advance Care Planning studies 2015-2017

Since the review was completed in 2015 and published (12), there has been a further randomised controlled trial, in the dementia population of residential aged care facilities, studying the effects of Advance Care Planning on family carers. This study found Advance Care Planning was effective in reducing family carer decision-making uncertainty concerning the care of their family member and also in improving perceptions of quality of care in residential aged care facilities (70). A further randomised controlled trial looked at the patient's Goals of Care elicited in a family meeting, again in those with dementia in residential aged care facilities. It was found that hospitalisation was decreased in Intervention facilities versus Control, adjusting for person-days at risk, patients in the Intervention group with Goals of Care completed were

half as likely to experience hospital transfers (0.078 vs 0.163 transfers per 90 person-days). The Goals of Care decision aid intervention was also effective to improve quality of communication about end-of-life care for residential aged care facility patients with advanced dementia (71). One further systematic review which was of partial relevance looked at Advance Care Planning in randomised controlled trials in older adults (72). It referred to just two studies conducted in residential aged care facility populations (24, 56) which are already included in this study.

2.3.13 Advance Care Planning from the healthcare professional's point of view

Studies on Advance Care Planning from a health care professional's point of view identify that Advance Care Planning is mainly judged in a positive light (73-77). However its implementation in practice presented them with significant challenges including whether current service provision for end of life care, could meet patient wishes (76). Effective communication was also seen as a barrier to good Advance Care Planning with one author suggesting that the verbal aspect of Advance Care Planning should be given greater significance, with a move away from the over-reliance on a tangible document (74). The many and varied documents in use was also a strong theme, with the consensus being that they lead to confusion and that standardisation would improve the process and outcomes (69). Improved education around Advance Care Planning and end of life care for health care professionals was felt to be necessary for improvements in both the Advance Care Planning process and end of life care, particularly in patients with dementia (73, 78-81). Family issues were also reported to be a significant barrier to effective Advance Care Planning (47); both the family dynamics influencing the perspectives and behaviour of staff; and staff concerns about whether the views of family were truly reflective of the wishes of the person (73). Interestingly in relation to activation of an Advance Care Planning it was found in one study that 78% of relatives felt Advance Care Planning would always be followed, as opposed to 44% of the medical staff (75). One Australian study found that registered nurses felt that Advance Care Planning helped them practice patient centred care but they found family issues and the fact that death and dying was a taboo subject, led to resistance to initiate Advance Care Planning on their part (82).

2.4 Discussion

2.4.1 Interventions

Findings from this review show beneficial effects for Advance Care Planning interventions in the residential aged care facility population but the evidence supporting the findings is of generally low quality. The variability in the interventions was considerable, but over 75% could be classified broadly into two categories: (i) educational programmes; or (ii) introduction and evaluation of a new Advance Care Plan in the facilities. Five of the thirteen studies took either an educational approach for staff or an educational approach for staff, families and patients; the most multifaceted of which included education of staff outside facilities including Medical Practitioners and Emergency Department staff (24, 25, 55, 57, 80). In the literature, the Advance Care Planning term is often used as an umbrella term describing both: a document completed by a person expressing preferences and values; or a document completed by a clinician in discussion with the person or their substitute decision maker, and which captures that person's preferences and values. Five of the thirteen studies introduced or evaluated what was identified as a new Advance Care Planning document in the facility, all of which were in the format of medical treatment orders (13, 16, 58-60). Two of these involved POLST (13, 16) and three were individual to the facility (58, 60, 64). These two categories of Advance Care Planning interventions along with a third, the examination of other medical treatment orders including Do-Not-Resuscitate and Do-Not-Hospitalise, were the most common interventions included in the area of Advance Care Planning study. Comparing the types of interventions in this review is difficult as the grading of the studies was more focussed on the study design than their proven outcome effects. The studies using educational programmes were more (61) robust generally in their design but there is insufficient evidence to conclude that educational programmes are better than introduction of new Advance Care Plans in facilities.

2.4.2 Outcomes; hospitalisation and mortality

This review found that Advance Care Planning reduces hospitalisation of residential aged care facility patients. These decreases were in the range of 9-26%, with Caplan's Australian study showing the greatest decrease (13, 24, 25, 60, 62-64) and could lead to considerable hospital

savings. It is difficult to say whether this always translates to overall healthcare savings but Molloy et al (24) and Teo et al (62) did demonstrate this outcome internationally. Interestingly, where studied, mortality wasn't decreased by hospitalisation (24, 25); an outcome that further supports treatment of residential aged care facility patients within the facility and avoiding hospitalisation where possible.

2.4.3 Outcomes; consistency with patient's wishes

The studies showed that actions are highly consistent with patient's wishes when their Advance Care Planning is completed (13, 55, 56, 58) and lead to decreased usage of unwanted life sustaining treatments (16, 64). This is not at a level of 100% compliance, as unwanted admissions and life-sustaining treatments are still recorded, but at much lower levels (13). In some areas, such as antibiotics, Advance Care Planning is less helpful (16); perhaps because antibiotics can also be given as part of "comfort measures" to alleviate discomfort, secretions and delirium, three of the prevalent symptoms of infection that may occur at the end of life.

2.4.4 Outcomes; place of death, palliative care and hospice

The evidence shows that patients with Advance Care Planning have a higher incidence of dying in their preferred place for death, which was more often, in the residential aged care facility (25, 56, 61, 64). In the included Australian study 100% of patients died in their specified location. Increased knowledge and experience of residential aged care facility staff in palliation at end-of-life has been identified as necessary to facilitate good dying. Advance Care Planning was found to lead to increased and earlier community palliative care referrals (61), which may indicate earlier recognition of the end-of-life phase and provision of care. However another study found no difference in symptom assessment or management with Advance Care Planning versus controls (16). Referral to in-patient hospice was not affected by Advance Care Planning in the one study that looked at this outcome measure (61) but prior systematic reviews have shown an increase in in-patient hospice referrals with Advance Care Planning (67, 68). In the United States of America cost neutrality or savings was a policy goal of the Medicare hospice benefit at its onset (83). A recent publication now shows that provision of in-patient hospice care did not reduce overall health-costs (84). This is of concern, as its provision, which is proven to improve

quality of care (84), could be at risk if it is only regarded as a money-saving exercise.

Communication about end-of-life care was improved for patients for whom 'Goals of Care' discussion and documentation had been completed (71).

2.4.5 Outcomes; quality of life

Quality of life and satisfaction with the dying process were rarely measured in the studies reviewed but, when they were, Advance Care Planning was found to improve both in certain circumstances (57, 60). In patients residing in the residential aged care facility for less than six months, establishing goals of care was found to improve family satisfaction with the death but was not significant in those present for longer periods making it less generalisable to the entire residential aged care facility population (60). The one study looking at Quality of Life found improvements with Advance Care Planning and this extended to improvements in existential distress also (57). Again, given this is the result from one small study it would require further research to support its findings. This effect has been studied in the general population in Australia (3), and the findings consistent with that of the review, but not in the residential aged care facility population.

2.4.6 Outcomes; Do-Not-Resuscitate orders

The effect of Do-Not-Resuscitate orders on medical treatment was addressed in two studies with conflicting results (16, 63). One found no difference in the medical treatments provided to patients with For Cardiopulmonary Resuscitation v Do-Not-Resuscitate orders (63). The second found those with Do-Not-Resuscitate orders were less likely to be hospitalised than those without (63). The latter is more in keeping with both general consensus and systematic review of the area (67). A Do-Not-Resuscitate and Do-Not-Hospitalise order is often taken as a proxy for a path towards less aggressive care, whether that was the original intention of the directive or not. Given the conflicting results from our review we can draw no conclusions from this area.

2.4.7 Outcomes; Advance Care Planning from healthcare professional's point of view

Advance Care Planning is described as being a positive process from the viewpoint of health care professionals but with limitations (73-77). One limitation is that numerous advance care plan forms are in use which can cause confusion (69).

A second limitation is that due to lack of resources available at a residential aged care facility there are times when the staff cannot honour the patient's documented Advance Care Plan and must transfer them to hospital (76). Education is identified as the most important change required to improve the Advance Care Planning process (73, 78-81). It was felt this education should pertain to Advance Care Planning, end-of-life care and dementia. Family issues were referred to as being a barrier to effective Advance Care Planning (47).

2.5 Conclusion

The data on Advance Care Planning interventions shows beneficial effects in residential aged care facility populations; the most important of which include actions being consistent with the person's wishes, and avoidance of unwanted hospitalisation and life sustaining treatments. The available evidence for residential aged care facility populations is generally not of high quality. Most studies in this area use retrospective designs and, hence, many such studies were excluded from this review. One such Australian study describes shorter lengths of stay in patients with Advance Care Plans versus those without and also a higher probability of cognitively impaired patients having a completed Advance Care Plan (85).

Over 24% of those aged 85 and over in Australia are living in residential aged care facilities (86). Advance Care Planning is important for these frail older people where the likelihood of developing cognitive impairment and losing decision-making capacity is high. With such high rates of dementia, estimated to be over 52% in Australia in 2016 (87) and decreased capacity in residential aged care facility populations (69), it does feel like the opportunity for true Advance Care Planning here has been lost. Most often the Advance Care Plan is completed with substitute medical decision-makers who do not always make the same decisions that the

patient would have (88). This highlights the need for earlier commencement of the Advance Care Planning process.

This review found that Advance Care Planning can have important effects in the residential aged care facility population but the effect measurements are being derived from very few studies. Only one Australian study fit the inclusion criteria. Further high quality studies especially examining the Australian context, are required to support the reported outcomes and to help identify the types of Advance Care Planning interventions that are most effective and beneficial for this population.

Key Points

- The residential aged care facility population has unique characteristics for Advance Care Planning
- Advance Care Planning has beneficial effects for the residential aged care facility population
- Advance Care Planning leads to actions being more consistent with patients wishes
- Advance Care Planning decreases unwanted medical interventions including hospitalization, use of life sustaining treatments, and increases probability of dying in the residential aged care facility
- Advance Care Planning may decrease health care costs
- The effects found are mainly from pooled low quality studies due to lack of high quality experimental studies in the area
- Further studies describing the Australian context are required

Chapter 3 Methodology

3.1 Introduction

This chapter explains the research methodology for this proposed study. It outlines the study design and rationale for the chosen study methods given the aims and setting of the research. The study is an Explanatory Sequential Mixed Methods study (36). This mixed methods study design incorporates (i) a cluster randomised controlled trial and (ii) an exploratory descriptive study [figure 3.1]. The main objective of the study was to implement and examine the effects of the Goals of Patient Care medical treatment orders in residential aged care facilities through quantitative and qualitative research methods.

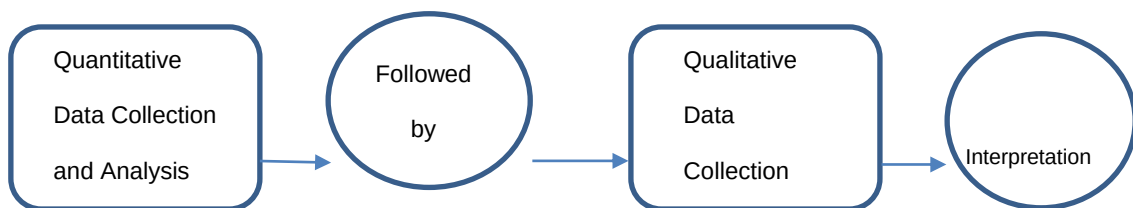


Figure 3.1 Study Methodology

3.2 Study Design

3.2.1 Introduction to Study Design

The mixed methods study design incorporates both quantitative and qualitative research methods. The quantitative data collection and analysis took place followed by a qualitative analysis. The use of both closed ended (quantitative) and open ended (qualitative) questions helped enrich the analysis of the data collected and formation of a more complete understanding of the effects of the intervention. The explanatory sequential mixed methods

design was chosen to give a more in-depth understanding of quantitative results in the residential aged care facility environment (89).

3.2.2 Study registration

Registration took place with the Australia and New Zealand Clinical Trial Registry (Trial ID: ACTRN12615000298516) prior to study commencement.

3.2.3 Study Objectives

The primary objective of the randomised controlled trial was to show that the introduction of the Goals of Patient Care medical treatment orders led to decreased Emergency Department attendances and emergency hospital admissions, for residential aged care facility patients, at six months post implementation as compared with usual care. The Goals of Patient Care document clearly documents whether people are open to escalation of treatment in hospital or would prefer treatment in the facility and wish to avoid hospital transfers. It is this fact along with the discussions about current healthcare issues and disease trajectory that could lead to more appropriate usage of acute hospital care.

In addition the following qualitative objectives were measured:

- A change in facilitation of healthcare decision making for all staff
- A comparison of Advance Care Planning and Goals of Patient Care in residential aged care facilities.

3.2.4 Outcome Measures

The predicted primary outcome measure was that providing patients with a Goals of Patient Care medical treatment order would result in a 40% decrease in Emergency Department attendance and emergency hospital admission at six months.

The qualitative outcome measures included:

- The healthcare professionals' opinions on use of Advance Care Planning and Goals of Patient Care in residential aged care facilities
- The healthcare professionals opinions on effect of Goals of Patient Care on healthcare decision making

3.2.5 Study timeline

The timeline for the study is seen below in figure 3.2. The study commenced with ethics application. In each facility the roll out of the study took up to two weeks in the Control facilities and up to four weeks in the Intervention facilities. The study commenced on completion of the roll out of the study with each resident in each facility. The study continued for twelve months from the time of commencement. The Focus Groups took up to ninety minutes each and occurred on just one occasion in each of the Intervention facilities. The semi-structured interviews took between 20- 40 minutes. One took place at a Medical Practitioner's private clinic. Two took place at the residential aged care facility they attended.

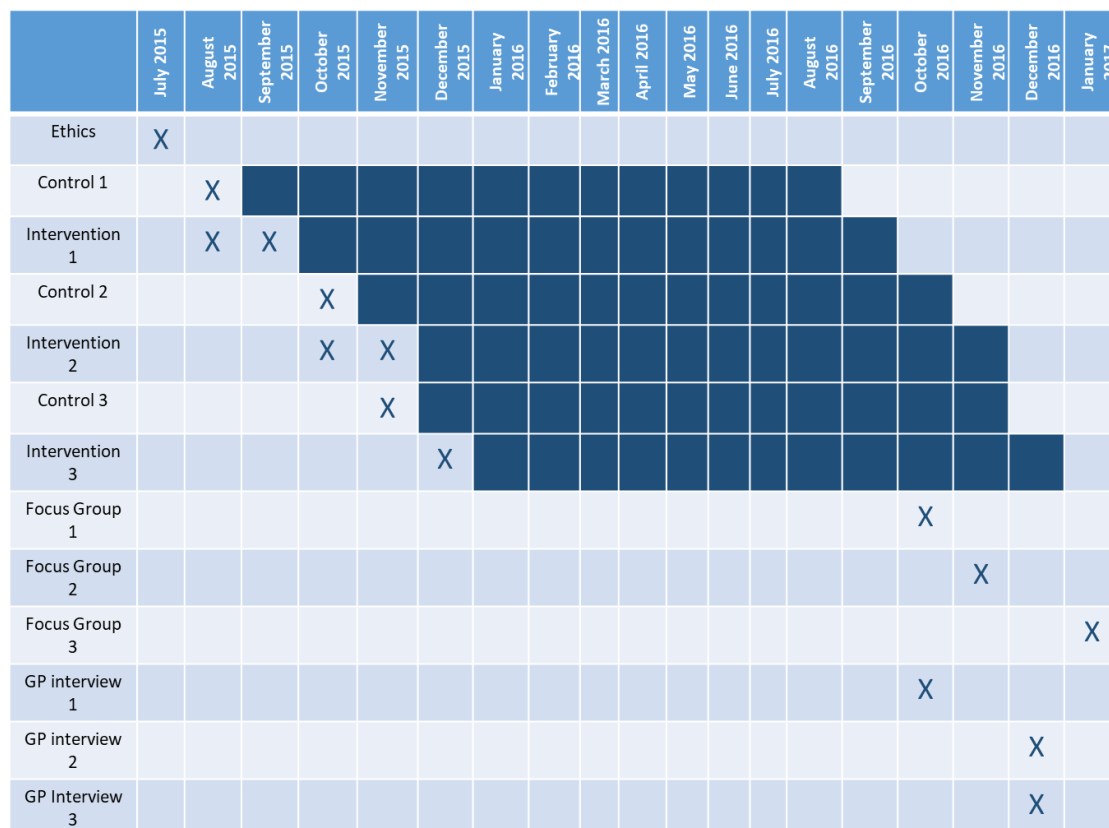


Figure 3.2 Study Timeline

X = Commencement date  = Study ongoing

3.3 Methods for the cluster randomised controlled trial

3.3.1 Introduction

The quantitative study employed was a prospective cluster randomised controlled trial evaluating the effects of the implementation of the Goals of Patient Care medical treatment orders for residential aged care facility patients. Randomisation helped to reduce selection bias in the studied population (90). Clustering allowed for randomisation at facility level to minimise contamination between patients within the same facility (91). A prior study in the area adopted similar design (92) with noteworthy outcomes. Facilities were organised into cluster pairs based on key baseline characteristics. Facilities were blinded to the random allocation prior to

agreeing to participate. Once randomisation has taken place using the add-in random allocation program 'ralloc' available in Stata version 12.1 (StataCorp LP, Texas, USA), no further blinding was undertaken.

3.3.2 Study population

The study population was all patients of the six participating residential aged care facilities for whom written informed consent could be obtained. An email was sent to 45 local facility managers and clinical care co-ordinators describing the project and inviting them to participate. The residential aged care facilities were all in a catchment within a 13 km radius of the Northern Hospital in the northern metropolitan area of Melbourne, Victoria to which the principal researcher was associated. A follow up phone call and meeting took place with all interested facility managers further explaining the study and providing samples of the Goals of Patient Care form to be used. Written informed consent was then obtained, for facility participation and to gain access to the local health care services for the facility's prior twelve month acute healthcare utilisation rates in non-identifiable format. Three pairs of residential aged care facilities were then selected, matched on key characteristics, the most important being this prior twelve month event rate for Emergency Department attendance and admission. The facility pairs were then randomised to receive either the Goals of Patient Care Intervention or to be the Control. Individual recruitment of patients and their substitute decision-makers then took place in each participating facility.

In appendix 7 there is a copy of the email sent to facility managers

3.3.3 Inclusion Criteria

All the patients in the aged care facilities participating in the study, together with their substitute decision maker, were invited to participate. Those for whom written informed consent could be taken were included. Only patients present at time 0 (zero) were included. New patients were not recruited to the study.

3.3.4 Exclusion Criteria

Patients who lacked capacity to provide written informed consent were excluded from participating in the study, unless they had a substitute decision maker who was able to participate in the study in conjunction with, or on behalf of, a patient lacking medical decision-making capacity.

3.3.5 Consent

Participation in the study by individual patients, substitute decision makers and healthcare professionals was voluntary. Participation Consent and Information Forms were individualised for: (i) residential aged care facility managers, (ii) patients and (iii) substitute decision makers. Participation Consent and Information Forms were distributed to residential aged care facility managers and written informed consent was obtained from the management of the residential aged care facilities involved at the first stage of recruitment as seen in appendix 8,9 and 10.

Recruitment of patients and substitute decision makers commenced with an invitation letter giving information about the study and explaining what involvement entailed for each patient/ substitute decision maker. A Participation Consent and Information Form and a sample Goals of Patient Care form were sent with the invitation to all substitute decision makers or next of kin registered for each patient in intervention facilities. In control facilities the Participation Consent and Information Form was sent but the Goals of Patient Care form was omitted to avoid any confusion about the need for its completion. A follow up phone call was placed, by the investigator, to each substitute decision maker or next of kin to explain the study further, one week following Participation Consent and Information Form distribution. The Participation Consent and Information Form and sample Goals of Patient Care form was distributed by hand to the patients in the facility and the study was further explained in person at this time.

Following distribution of Participation Consent and Information Form, written informed consent was obtained from all patients/ substitute decision makers wishing to participate in the intervention and control group. In event of decreased or a definite lack of capacity co-signing/substitute signing of the consent form by the substitute decision maker was obtained.

Telephone consent was obtained from those substitute decision makers that could not attend in person, anticipating frailty issues with partners of patients, but who wished to be involved. Telephone consents were witnessed by a second person not directly involved in the study.

At the time of notification about the study a meeting was planned where possible to meet with those substitute decision makers or family members wishing to be present at the time the baseline assessments were carried out. For those substitute decision makers who wished to complete the Goals of Patient Care form, a meeting time was planned for those who could attend in person, for those unable to attend in person a time was planned to re-contact by telephone.

3.3.6 Intervention

The interventions to be compared were that of the new Goals of Patient Care medical treatment order form and usual care. The principal investigator, a consultant Geriatrician, reviewed all patients' medical notes as well as discussing their disease trajectory and general well-being with the healthcare staff directly involved in their care. The principal investigator then arranged family meetings with all those who could attend in person to be with the patient at the time of discussing the Goals of Patient Care form. This occurred in over 66% of cases. On only one occasion was a second family meeting required. Family meetings took in general up to 30 minutes but discussion with at least one family member and distribution of the form had taken place prior to the meeting. In a further 25% of cases the choice for each patient was conveyed back to their substitute decision maker, with permission of the patient.

The medical treatment orders on the Goals of Patient Care form indicate the preferred course of action in the event of clinical deterioration. It was placed in the patient's notes in the section on Advance Care Planning. It was subsequently available to all healthcare professionals reviewing the patient and a copy was to transfer with them to the Emergency Department with their residential aged care documentation. In case of computerised medical notes the document was scanned on to the system in the Advance Care Planning section.

3.3.7 Usual Care

'Usual Care' included the current processes in use within the individual residential aged care facilities. For many patients this included an Advance Care Plan which should be present in their paper or computerised notes. It is known from the original contact with the facilities that Advance Care Plans were sometimes completed by the patient and/or their substitute decision maker alone, without input from health professionals. In some facilities the residential aged care facility staff were involved in the Advance Care Plan discussion and form completion. In others, the Medical Practitioners were either required to be involved in the discussion or simply to sign the completed form. In no facilities were medical treatment orders in use, as they were not being used anywhere in these health services. Not all patients were expected to have an Advance Care Plan but it was expected that all would have been invited to complete an Advance Care Plan at some stage since admission to the residential aged care facility.

3.3.8 Baseline Characteristics and Assessments

Baseline characteristics and assessments were documented for all participants as listed below in table 3.3.8. Assessments used can be seen in appendix 11. These included age, sex, English-speaking status, comorbidities, presence of a life-limiting illness (excluding dementia) and medications. A cognitive screen was undertaken using the Mini Mental State Exam (MMSE) (93) and also correlated with a known diagnosis of dementia and use of medical treatments for dementia. A functional assessment screen used the Barthel Index (94). Depression was screened for using the Geriatric Depression Scale (95). Frailty was assessed with Clinical Frailty Scale (96). The presence of a prior instructional Advance Care Plan and/or appointment of a medical enduring power of attorney was recorded, if copies of these documents were available in the facility notes.

Table 3.3.8 Baseline Characteristics and Assessments

Baseline Characteristics	Baseline Assessments
Sex	Mini Mental State Exam
Age	Barthel Index of function
Co-morbidities	Clinical Frailty Scale
Presence of Life-limiting Illness	Geriatric Depression Scale
Diagnosis of Dementia	
Dementia Treatment	
Regular Medications	
PRN Medications	
English As first Language	
Advance Care Plan	
Medical Power Of Attorney	
Evidence Medical Power Of Attorney	

3.3.9 Investigational Plan

Hospital utilisation for each facility was evaluated, prior to randomisation, by accessing local hospital records to calculate a baseline event rate for this three, six and twelve months prior to commencement of the study. The information accessed was only from local public health services for which ethical approval was given to access facility information. Facility usage of private hospitals was not included in this calculation for any of the six facilities. Hence, it was known that this baseline event rate was under-estimated for all six facilities. This data was used to match facilities into cluster pairs, but it was not used to make 'before and after' comparisons for each facility's event rates as it was known not to be completely accurate.

Prior to Goals of Patient Care discussions the principal investigator thoroughly reviewed each patient, including review of facility notes, completion of baseline characteristics and assessments, review of any prior advance care plans they have completed, discussion of

current health status with healthcare staff and discussion with the patient about their healthcare values and preferences, where possible. The Goals of Patient Care form was then completed with the patient or substitute decision maker.

The following data was collected at three, six and twelve months for included participants: acute healthcare utilisation including Emergency Department attendances, emergency hospital admissions, and total hospital bed days. Death rates and place of death was also recorded. The facilities recorded this information on a document provided to them by the investigator on a ward level. The investigator reviewed all facility patients' notes to confirm the validity of this data at three, six and twelve months.

Statistical methods

3.3.9.1 Sample Size

The sample size was calculated for the outcome of Emergency Department attendances and emergency admissions. On calculation for individual randomisation for this study, the sample size required was $n = 157$ persons per period for both Intervention and Control arms. This was given a significance of 0.05 and 80% power. On calculation for cluster randomisation an anticipated event rate of 0.5 (emergency department attendances and emergency admissions/6months/facility bed) in Control and 0.3 in Intervention facilities was used as seen in a prior randomised controlled trial on ACP in residential aged care facilities (24). This was with an assumed intra-cluster correlation (p) which was a combination of within cluster variance of 0.01. The estimated number of clusters required per intervention and control strata was 3.5. On testing feasibility of three clusters, it was found to be feasible if the number of clusters (k) was greater than $n (157) \times p (0.011)$. Therefore three cluster pairs was taken as the sample size.

3.3.9.2 Quantitative statistical analysis methods

The data for this study was collated in Microsoft Excel with all statistical analysis conducted using Stata version 14.0 (StataCorp, College Station, Texas, USA). Descriptive statistics, the discipline of quantitatively describing the main features of information collected (97) was used to conduct the assessment of the effects of the study. This initially included a comparison of

healthcare utilisation rates at baseline to demonstrate the consistency of health care utilisation between the intervention and control arms prior to the study intervention. Appropriate analysis was then conducted to assess the differences in the primary and other secondary outcomes, between the Intervention and Control arms at the three, six and twelve month follow-up time-points. Results were presented as counts and frequencies for categorical variables, with chi-squared tests used to compare across groups for categorical and appropriate parametric and non-parametric continuous data statistical tests were used to evaluate the effectiveness of the intervention for the secondary outcomes. Descriptive statistics were also reported at baseline to demonstrate the consistency of health care utilisation between the Intervention and Control arms prior to the study intervention.

Multi-level Poisson regression models were established to account for the intra-class correlation within each residential aged care facility when assessing the primary outcome of health care utilisation rates. As the Poisson model was used for this assessment, the statistical measurement used for comparison between the Control and Intervention groups for Emergency Department attendances and emergency admissions was the Incident Rate Ratio. The Incident Rate Ratio reflects the ratio in the incident rate for the intervention group compared to the control. Thus, an Incident Rate Ratio <1 suggests that the intervention has reduced the rate when compared to the Control group. It has also been used in other randomised controlled trials to show results (98).

The Poisson model is used to model count outcome data. That is, the number of Emergency Department attendances and emergency admissions over the six-month period. These outcome variables tended to be right-skewed with a high proportion of cases with lower counts extending out to a few cases with extreme values. The zero-inflated Poisson regression model extension has thus been applied to account for the high proportion of patients not having any admissions. It has been used in prior studies on hospital admissions (99). The modelling took into account the fact that in each time period patients that had died could no longer have further Emergency Department attendances and emergency admissions and thus only those that were alive at the three, six and twelve month time-point were included in that time-point analysis.

3.3.10 Ethical Considerations

The trial was approved by the Northern Health Human Research Ethics Committee; HREC/15/NH/6. For retrieval of baseline hospital utilisation rates two further ethics approvals were sought. Approval was given by the Austin Health Human Research Ethics Committee; LNR 15/ Austin/169. Approval was also given by the Melbourne Health Quality Assurance section of the Ethics Committee; QA2016047.

The issues of consent have been previously discussed but the associated ethical aspects are discussed here. Due to less than 50% of patients having capacity to consent to participation, there was considerable involvement of substitute decision makers and families in this study. As the study took place in residential aged care facilities, adherence to facility policies of informing all next of kin listed about the study, took place. A letter of invitation together with the Patient Information and Consent Form, and in intervention facilities the sample Goals of Patient Care form, was thus sent by post to those on the facility next of kin mailing list. Follow up phone calls one week later were made. In effect verbal consent or assent was taken from nearly all substitute decision makers or interested family members, as if the substitute decision maker or family did not want the patient approached, as per the residential aged care facility request, the patient was not involved. For those patients with whom no follow up phone call was achieved with their listed substitute decision maker or next of kin, only patients that it was felt by facility staff may have capacity were approached by the investigator for consent to perform baseline assessments including a capacity assessment.

Due to this recruitment process some patients with capacity to participate may have missed the opportunity but it was felt this number was very small. Most families who refused participation did so as they felt the review would be bothersome or distressing to their relative. It was felt it was important to abide by facility regulations and not have the study cause distress or problems for patients, families or staff.

It was felt that the possibility to cause harm was minimal in this study. It was highlighted on each form in writing that the Goals of Patient Care form was to guide healthcare decisions in conjunction with discussion with substitute decision makers/families. The form does not replace

the need for discussion between healthcare professionals and families in times of clinical decline, which is a possible harm for patients and substitute decision makers. It is possible, as with all Advance Care Plans, that a patient could be denied care they actually want at a later stage due to them changing their mind. However with family involvement at times of clinical decline this was hopefully minimised. Blank Goals of Patient Care forms were left at the facility with both ward staff and Medical Practitioners in case of their need for updating during the study period or afterwards.

3.3.11 Internal and External Validity

The proposed research design as a cluster randomised controlled trial was a key component to maintaining internal validity. All of the residential aged care facilities involved had access to the same external services for patients: regular and locum Medical Practitioners; Residential-In-Reach services with ambulatory geriatricians and nurses attending the facilities; Hospital in the Home providing treatment such as intravenous fluids and antibiotics; out-patient clinics; and acute hospitals. All were located within 13km of public and private hospitals with admitting Emergency Departments. Thus all had the same options for treatment escalation when patients became unwell. There had been some palliative care initiatives in Victoria in recent times, including introduction of the Palliative Care Toolkit and education, and a new 24 hour Palliative Care Advice line for aged care. These were all available to all residential aged care facilities and so should not have affected any changes found. All residential aged care facilities were similar in the fact that some prior Advance Care Planning had been offered to all patients of participating facilities; so none were more familiar with the process than others. Thus, the only difference between the facilities should have been the introduction of this new Goals of Patient Care medical treatment orders and it should have been the only effective change.

By using patients' facility notes review as the means of collating hospital attendances and emergency admissions, the chance of missing any Emergency Department attendances and emergency admissions was minimised, increasing the validity of the study outcomes. The clustering of residential aged care facilities into pairs involved matching them on their event rates for Emergency Department attendances admissions over the prior twelve months. This

allowed for facilities as similar as possible to be matched at baseline for better comparison from the prospective data.

The randomisation proposed for this study helped with its external validity and the potential for the study to be generalised to other facilities in other settings. An important factor to consider was available treatment options for unwell patients. Similar treatment options and treatment settings were available across most health services within the developed world and so the introduction of this medical treatment order is expected to have similar effects in residential aged care facilities in other locations.

3.4 Methods for the qualitative study

3.4.1 Introduction

The qualitative study proposed was an exploratory descriptive study taking place with healthcare staff in the Intervention facilities only, at twelve months. It examined the areas of Advance Care Planning and Goals of Patient Care from healthcare professional's perspective.

3.4.2 Study population

Healthcare professionals were invited to take part in focus groups. Invitations were distributed through the facility managers twelve months after the Goals of Patient Care form has been implemented. Healthcare professionals across a range of positions within the facilities were invited to participate although as only nurses were involved decision making based on Advance Care Planning and Goals of Patient Care, other healthcare professionals did not participate.

The focus groups involved endorsed nurses, registered nurses, clinical care co-ordinators and facility managers. The focus groups took place at the hand over time between the morning and afternoon shifts to try and involve as many participants as possible in each facility in the study.

Medical Practitioners were invited to be part of the study by both email and phone contact. The contact details were accessed through the facilities. One Medical Practitioner visiting each facility was thought to be sufficient for the data collection. The interviews took place at a time

and place convenient for the Medical Practitioner, either at the aged care facility visited by the Medical Practitioner or their private practice.

3.4.3 Inclusion Criteria

All healthcare staff involved in Advance Care Planning and Goals of Patient Care in the Intervention residential aged care facilities were eligible to participate in the focus groups. All visiting Medical Practitioners to the Intervention facilities were eligible to partake in the semi-structured interviews. A convenience sample of those Medical Practitioners who agreed to partake was taken.

3.4.4 Exclusion Criteria

Healthcare professionals in Control facilities were not eligible to take part as the data collection related to experiences of using both Advance Care Planning and Goals of Patient Care; the latter of which those within the Control would have had no exposure to.

3.4.5 Consent

Participation in the study by individual staff was voluntary. Participation Consent and Information Forms, as seen in appendix 12, was developed specifically for healthcare professionals were available. For those healthcare staff who agreed to participate in the study, the Participation Consent and Information Form was distributed, and written informed consent was obtained, prior to participation in a focus group or individual interview.

3.4.6 Intervention

See 3.3.5

3.4.7 Usual Care

See 3.3.6

3.4.8 Investigational Plan

The principal investigator was a Medical Practitioner with specialty in Geriatric Medicine and an associate researcher, with a PhD in qualitative methodology and a Medical Practitioner with specialty in Palliative Medicine, (BH), facilitated the focus groups in a room on site in each facility. At the time of the study the principal investigator was a research student undertaking a research doctorate and the associate researcher was the Clinical Lead in Advance Care Planning in the northern metropolitan area of Melbourne. Both researchers had experience in facilitating Advance Care Plan completion with patients. Only the associate researcher had prior experience in qualitative research. The principal investigator had been visiting the residential aged care facility for over twelve months intermittently so the participants knew her and the research project she was conducting for her university doctorate. The associate researcher had developed the Goals of Patient Care form that was being reviewed. The participants were not aware of this fact.

Focus groups and in-depth interviews were used for the data collection. Focus groups provide a “rich and detailed set of data about perceptions, feelings and impressions” of those involved in the groups (100) and thus enabled the study to explore and evaluate the effects of Advance Care Planning and Goals of Patient Care on those working closely with both. Focus groups encourage people to partake that would not like to be interviewed on their own, whether they feel uncomfortable or feel they have little to add (101). The focus groups were conducted in each of the three Intervention facilities at least twelve months post implementation of the Goals of Patient Care medical treatment orders intervention. Healthcare professionals were invited verbally through their management to take part; participation was voluntary. Participant Information and Consent Forms were provided to the participants and brought signed to the focus group or interview. The focus groups were organised at handover time in the residential aged care facilities to gain a convenience sample from the morning and afternoon shifts. The same question guide (appendix 13) was used with each focus group and unanticipated themes were also explored as they arose, and in subsequent focus groups/interviews. The questions were mainly open ended; some dichotomous questions were asked which led onto more open

ended questions depending on responses. Focus group interviews were audio-recorded on two separate recording devices to ensure no loss of data

In addition, one-to-one semi-structured interviews were conducted with Medical Practitioners who visited each intervention facility. Prior studies have found that individual interviews can “elicit information about the meanings and interpretations of events” for the participants (102) and provide even greater understanding about an individual’s experiences than with the focus groups (103). The interviews took place in the facilities or in the Medical Practitioners practice depending on individual preference. It was not possible to bring the Medical Practitioners together for a separate focus group or for all to come to the focus groups organised for the other healthcare professionals in each Intervention facility, thus semi-structured interviews were conducted. The same question guide (appendix 14) was used with each interview and unanticipated themes were subsequently explored. Again the questions were mainly open ended with some dichotomous questions asked which led onto more open ended questions depending on responses.

Focus groups and in-depth interviews have been found to be particularly useful when gathering stakeholder experiences with services and quality of care (104) as this study was. While focus groups use group dynamics to generate qualitative data, one on one interviews explore the personal views and beliefs of the interviewee (105).

3.4.9 Data transcription

Focus groups and semi-structured interviews were audio-recorded and transcribed verbatim as has been advocated by many as the preferable method employed (102, 106). The texts were then copied into a qualitative software program, Nvivo. The coding of the data took place within this software program. Field notes were not made.

3.4.10 Data coding and thematic analysis

The coding commenced with reading of all the transcribed texts. Drawing on aspects of Grounded Theory, initial themes were identified within all the texts and a list of these themes created. By the end of the last text no new themes were being identified. Related initial themes

were then grouped together under major theme categories. An associate researcher, (BH) present at the focus groups reviewed the transcripts and coding to help validate it and ensure no further themes were identified. Qualitative description is used for the thematic content analysis for assessing the interventions of Advance Care Planning and Goals of Patient Care (107). Figure 3.3 represents the sequencing of the analysis.

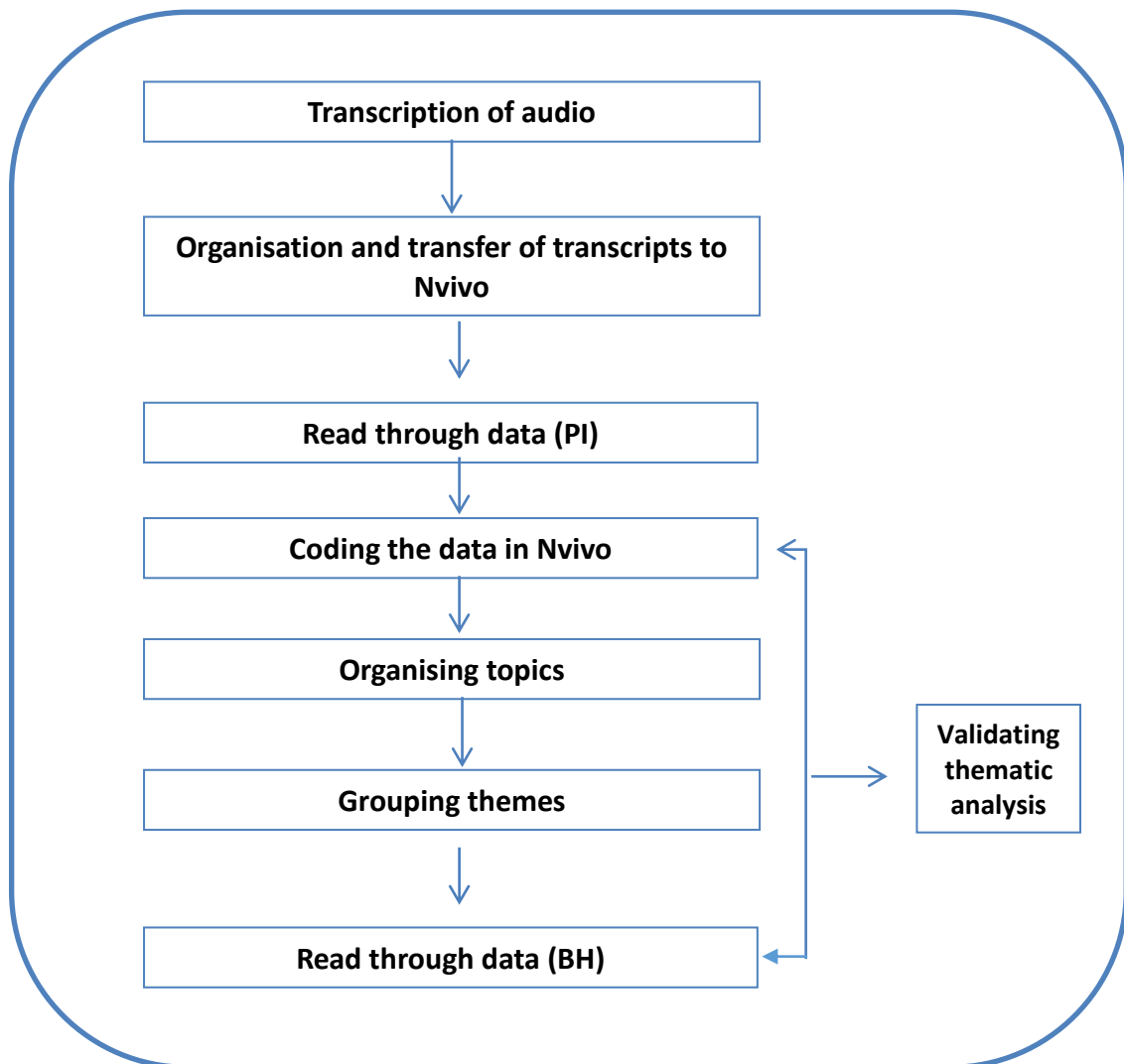


Figure 3.3 Data Analysis in Qualitative Research,(108)

PI Principal Investigator, BH Barbara Hayes

3.4.11 Ethical considerations

An important ethical consideration in the qualitative study was maintaining confidentiality and anonymity of both the individual participants and of the facilities. This was essential so that participants could feel confident to discuss matters that were specific to their facility without being identified at a later stage. Anonymising of participants and of the facilities was described in the Participation Consent and Information Forms and verbally addressed again at the commencement of each focus group and interview. The qualitative reporting uses anonymous

3.4.12 Qualitative Validity and Reliability

Qualitative validity and reliability in the study was achieved by numerous methods. Triangulation of the data and themes was achieved by seeking information from staff working in a variety of roles within the aged care facilities and also from visiting Medical Practitioners (108). The principal investigator spent an extended amount of time in the facilities so as to develop an in-depth understanding of the facility context in which the intervention took place. Validity was further achieved by crosschecking of the transcripts and the thematic analysis by a second coder with inter-coder agreement.

3.5 Conclusion

The study proposed is to implement and evaluate the new residential aged care facility Goals of Patient Care medical treatment orders using an Explanatory Sequential Mixed Methods study incorporating: (i) a cluster randomised controlled trial; and (ii) an exploratory descriptive study as outlined above. Participation was voluntary and only those providing written informed consent were involved. Baseline characteristics and assessments were gathered in both Intervention and Control facilities with the Goals of Patient Care process and form being completed with patients in the Intervention group only. The primary outcome was Emergency department attendances and emergency admissions at six months. Quantitative and qualitative research methods were used to evaluate the data and draw conclusions.

Chapter 4 Randomised Controlled Trial Data Analysis and Findings

4.1 Introduction

In this chapter the quantitative data analysis and findings are presented. The aims of the data collection were to evaluate the implementation of the Goals of Patient Care process and subsequent form completion and the analysis of our primary and qualitative outcomes.

The results are presented in four sections. Section one presents the results of the recruitment process in the residential aged care facilities, their screening results and randomisation. Section two describes the baseline characteristics of the participants involved in the residential aged care facilities. It also includes their baseline assessment data. Section three outlines the implementation of the intervention – the Goals of Patient Care discussions and results of the choices made on the Goals of Patient Care form. Section four presents the results of the primary outcome. Secondary outcome results are available in appendix 2.

4.2 Section one

4.2.1 Recruitment of facilities

At study commencement 45 residential aged care facilities in northern metropolitan Melbourne were invited to take part. Twelve facilities expressing an interest in participation and the principal researcher held a meeting with them, giving a more in-depth explanation of the study. These meetings involved the facility managers and clinical care co-ordinators as well as those leaders in advance care planning within the facility where they existed. The sample residential aged care facility Goals of Patient Care form was shown and the process of its completion explained as well as the follow up required over the twelve months post implementation. The fact that each facility would not know whether they were randomised to Intervention or Control groups until time of study commencement was also explained.

The goal had been to recruit as many facilities as possible, organise them into cluster pairs based on key baseline characteristics, and choose the pairs most similar for the study. They would then be randomised within their cluster pair to intervention and control. The closer the similarity of baseline characteristics in cluster pairs the lower the intra-cluster co-efficient, which measures variability, and thus the lower the adjustment for clustering effect would be at time of analysis. This would also affect sample size calculations as the smaller the intra-cluster co-efficient, the lower the number of cluster pairs required to gain significance. The sample size calculation, as described in section 3.3.9.1, found feasibility in the use of three facility pairs.

Initially eight facilities were recruited, however only six went on to sign informed consent and were organised into three cluster pairs. Although there was interest in the study from the excluded two facilities, their interstate senior management declined to partake.

4.2.2 Screening of facilities

The key baseline characteristics identified were Emergency Department attendances and emergency admissions at three, six and twelve months as this was the major outcome being investigated. The facilities kept no record of this information themselves. It was known that attendances and emergency admissions to private hospitals would be missed but this would be the case for all six of the facilities and was unavoidable. It was estimated that the number of Emergency Department attendances and emergency admissions would therefore be under calculated retrospectively but all captured in the subsequent prospective data.

Event rates represent the number of Emergency Department attendances and emergency hospital admissions per facility patient per time period. They were then matched and randomised into Control and Intervention 1, 2 and 3 depending on their cluster pair. The event rates leading to this match can be seen in table 4.5.

4.2.3 Residential Aged Care Facility characteristics

Of the six residential aged care facilities, four were private and two were not-for-profit. There were two private and one not-for-profit facilities in both the Intervention and Control groups. None were stand-alone facilities, all were owned by an aged care professional with multiple

facilities both within the Victoria and interstate. Management policies for all were handled by the aged care professional rather than having a focus on local policies. In terms of staffing, five facilities had division one registered nurses working by day with a range of three to five in the mornings and one to three in the afternoons, with one division one registered nurse working on site overnight. In Control 3 however, there was only two division one registered nurses during the morning, one during the afternoon and at times there was no division one registered nurse at night but an endorsed nurse, with less training, would cover the night shift on rotation, with a division one registered nurse, the facility manager, on call from home.

One facility, Intervention 3 used a General Practitioner practice that provided their own locum Medical Practitioners to cover out of hours calls. Another facility, Intervention 2 used their regular visiting Medical Practitioners at times out of hours but not always.

None of the facilities had specific hospital transfer policies. In all the decision was based on clinical review at the time of deterioration. In emergency situations the nursing staff would contact ambulances by calling 000. Where possible the patient was reviewed by a Medical Practitioner prior to hospital transfer. Instruction for transfer could be given by Medical Practitioners following clinical review or by phone advice. There was no variation on this between Intervention and Control groups.

4.3 Section two

4.4 Patient recruitment

In each facility individual written informed consent from patients was obtained as described in 3.3.4. Participation rates varied between 65 % and 80% with a mean participation of 74% across the six facilities exceeding expectations. The CONSORT participant flow diagram can be seen in appendix 8.

In total, at study commencement, there were 145 participants in the Control Group and 181 in Intervention Group. The difference was more reflective of the facility patient numbers than willingness to participate.

4.4.1 Baseline Characteristics

The Control and Intervention Groups were combined for analysis. The complete baseline characteristic and assessment results with appropriate statistical test comparison and result can be seen in table 4.1.

No difference was found in the median age for participants in both groups, it was 88 years. Female gender was comparable in both groups, in the Control Group it was 102 (70%) and 138 (76%) in the Intervention Group. Relatively equal numbers of co-morbidities were seen across the groups with 10.9 and 10.8 respectively for Control and Intervention groups.

The percentage of patients with a documented dementia diagnosis was low with only 67 (46%) in the Control Group and 92 (51%) in the Intervention Group. Only a documented diagnosis was accepted, a diagnosis of 'Short Term Memory Loss' was not accepted. The number of these patients with a documented diagnosis of dementia being on treatment for dementia was extremely low at 10 (7%) in the Control Group and 15 (8%) in the Intervention Group.

There was a statistical difference seen in the presence of life-limiting illness with n=27 (15%) in the Intervention group and n= 12(8 %) in the Control group. Life limiting illness was taken to be any end stage organ failure or active cancer diagnosis. Dementia was excluded as a life-limiting illness as it was taken into account separately due to high levels known to exist in the residential aged care facility population.

There was a preponderance for English speaking background in the Control group 124 (86%) and 139 (77%) in the Intervention group and a statistical difference between as seen in table 4.1.

The number of patients with an Advance Care Plan was 88 (61%) in the Control Group and was 123 (67%) in the Intervention Group. Importantly there was no statistical difference between the groups. However the number of patients naming a Medical Enduring Power of Attorney was 68 (47%) in the Control Group and 113 (63%) in the Intervention Group. There was a significant statistical difference between these two groups which could indicate greater involvement in the

Advance Care Planning process in our Intervention Group. Yet when it came to evidence of said Medical Enduring Power of Attorney there was only 32 (22%) with documentation in the Control Group and 57 (21%) in the Intervention Group without any statistically significant difference.

The only other characteristic which showed a statistically significant difference between Intervention and Control facilities was the number of as required/PRN medications. In the Control Group there was a median of four medications, a range of two to five medications. In the Intervention Group there was a median of five, with a range of three to eight. There was a statistical difference between these two groups with $p < 0.0001$. The importance of the number of as required medications is minimal and is unlikely to have any further effect on the differences between the Control and Intervention Groups.

No other baseline characteristics varied between the two groups with all statistical tests showing p values > 0.05 as shown in table 4.1.

4.4.2 Baseline Assessments

There were no statistically significant differences in the baseline assessment scores between the Intervention and Control groups. In terms of cognition, impairments were tested with the mean Mini Mental State Exam. The median MMSE score was 20/30 in both groups. This indicates mild dementia overall however both groups had a wide interquartile range representative of the diverse range of cognitive ability in those present in the residential aged care facilities.

The median Barthel Index out of 11/20 was 11 with a range of 6-15 and in Control and 5-16 in the Intervention Group. This again while showing overall two severely dependent groups demonstrates a considerable range in functional ability as one would expect.

The median Geriatric Depression Scale score was 2/15 in both groups. A score of eight or more indicates possible depression indicating that the study results showed overall low levels of probable depression.

The median Clinical Frailty Scale was 7/9 in both groups. Within the scale six indicates moderately frail, seven severely frail, eight very severely frail and nine terminally ill. So our results showed two groups who were equally moderately to severely frail in table 4.1.

Table 4.1 Baseline Characteristics and Assessments

	Intervention (n=181)	Control (n=145)	P-value
Age (years): Median with IQR	88 IQR 83-92	88 IQR 85- 91	0.464 ^(a)
Sex (female) n (%)	138 (76.2)	102 (70.0)	0.3 ^(c)
English 1 st Language n(%)	139 (77)	124 (86)	0.031 ^(c)
Comorbidities: Mean $\pm$ SD	10.8 $\pm$ 3.4	10.9 $\pm$ 4.2	0.680 ^(b)
Life-limiting Illness n(%)	27(15)	8 12(8)	0.061 ^(c)
Dementia Diagnosis n(%)	92(51)	67(46)	0.407 ^(c)
Regular Meds: Mean $\pm$ SD	9.6 $\pm$ 4.6	9.7 $\pm$ 3.8	0.600 ^(b)
PRN Meds: Median with IQR	5 IQR 3-8	4 IQR 2-5	<0.0001 ^(a)
Dementia Meds n(%)	15(8)	(10(7)	0.681 ^(c)
*MMSE (/30): Median with IQR	20 IQR 10-27	20 IQR 7.75-26.25	0.826 ^(a)
Barthel (/20):	11 IQR 5-16	11 IQR 6-15	0.794 ^(a)

Median with IQR			
*Geri Depression Scale (/15):	2 IQR 0-4	2 IQR 0.75-5	0.287 ^(a)
Median with IQR			
Clinical Frailty Scale (/9):	7 IQR 7-7	7 IQR 6-7	0.095 ^(a)
Median with IQR			
Advance Care n (%)	123(67)	88(61)	0.172 ^(c)
Medical Power of Attorney n(%)	115(63)	68(47)	0.005 ^(c)
Evidence MPOA n(%)	21 (n=57)	22 (n=32)	0.104 ^(c)

(a) = Mann Whitney U test, (b) = Independent t-test, (c) = Chi-Square test

4.5 Section three

4.5.1 Results of the Goals of Patient Care process and form completion

The Goals of Patient Care discussions took place as described in 3.3.8 with the principal investigator plus varying combinations of patients and/or their family members/substitute decision makers present. The discussion resulted in completion of the GOPC form with choices A, B, C1, C2, C3, or D for each participant as seen on the sample form in appendix 1. The Goals were assigned as is shown in figure 4.1 below. 163(90%) of patients were assigned Goal C1 and C2 indicating a preference for treatment in their facility but while 109 (60%) still remained open to hospital transfer, for 56 (30%) the decision was made not for further hospital transfers even if deteriorating and not responding to treatment.

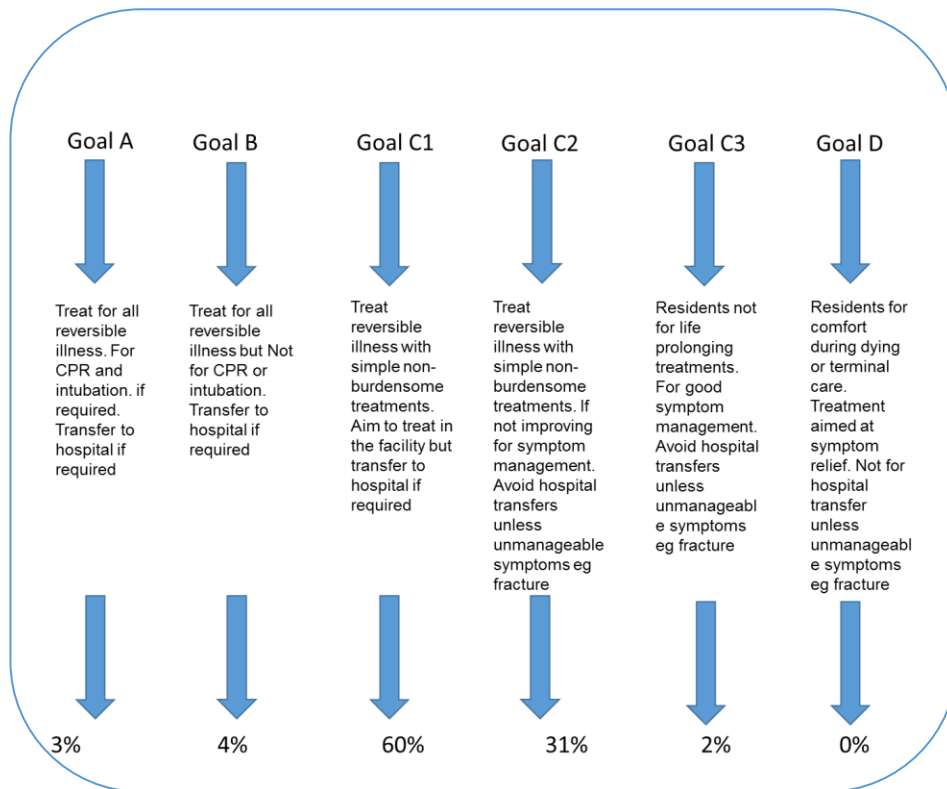


Figure 4.1 GOPC choices

4.6 Section four

Table 4.2 Results RACF prior ED event rates, study participant numbers, primary and secondary outcomes; separate facilities

	Control 1	Intervention 1	Control 2	Intervention 2	Control 3	Intervention 3
Prior 12 month ED event rate	1.23	1.1	0.75	0.63	1.4	1.27
RACF Participants						
Full Capacity	90	90	63	90	55	95
Total residents (T0)	90	68 (20TCP)	56	87	49	95
Participants (T0)	63	44	43	65	39	72
Participants (T+3/12)	60	36	39	61	35	68
Participants (T+6/12)	56	32	38	56	32	62
Participants (T+12/12)	48	27	30	44	27	53
ED attendances and admissions						
T+3/12 n(rate*)	12(0.2)	7 (0.19)	5 (0.13)	5 (0.08)	13 (0.38)	13 (0.19)
T+6/12 n(rate*)	29 (0.52)	17 (0.53)	10 (0.26)	14 (0.25)	22 (0.7)	23 (0.37)
T+12/12 n(rate*)	52 (1.08)	31 (1.15)	24 (0.8)	19 (0.43)	42 (1.56)	38 (0.72)
Total Hospital Bed Days						
T+3/12 n(rate*)	21 (0.35)	13 0.36)	3 (0.08)	10 (0.16)	72 (2.11)	49 (0.7)
T+6/12 n(rate*)	48 (0.86)	25 (0.78)	23 (0.6)	74 (1.32)	108 (3.48)	77 (1.24)
T+12/12 n(rate*)	216 (4.5)	70 (2.59)	77 (2.57)	90 (2.05)	196 (7.25)	194 (3.66)
Mortality T12/12						
In RACF n(%)	11 (18)	12 (27)	13 (28)	18 (29)	5 (13)	18 (26)
In Hospital n (%)	1 (2)	1 (2)	0 (0)	1 (3)	6 (15)	0 (0)

*= rate of facility patient per event per time period

20 TCP= 20 patients admitted in this facility through the acute hospital Transition Care Program

i.e. not permanent residents and not eligible for inclusion

4.7 Results of Emergency Department attendances and emergency admissions

4.7.1 Primary outcome

The primary outcome from the study was investigating Emergency Department attendances and emergency admissions at six months as it was felt three months would be too short a time period to show a significant change and that the mortality rate at twelve months might be too great as to affect the number of participants remaining for evaluation. The information was obtained as described in 3.3.8 from a combination of facility recorded information and a full review of patients' facility notes. All patients alive and present in the facility at the end of each time-point were included in that time-point analysis. All those who died prior to that time-point were excluded from that time-point analysis but not from prior analyses.

The study aim was for the intervention to result in a 40% decrease in Emergency Department attendances and emergency admissions between Intervention and Control groups at six months. Total number of attendances and emergency admissions is seen in table 4.3.

Event rates were initially calculated for each individual facility as seen in table 4.2. The groups were then pooled into Control and Intervention for statistical analysis. The study sought to evaluate whether the null hypothesis could be rejected by the intervention causing a statistically significant effect, or whether the intervention made no difference and the null hypothesis could not be rejected, or in fact if the intervention had a deleterious effect. The statistical measurement used for comparison between the Control and Intervention groups was the Incident Rate Ratio. The Incident Rate Ratio reflects the ratio in the incident rate of the Emergency Department attendances and emergency admissions. An Incident Rate Ratio of <1 suggests that the intervention has reduced the rate of admissions when compared to the Control group.

The Incident Rate Ratio was 0.74, 95% CI: 0.49–1.14, $p=0.170$. Thus the primary outcome showed that although overall the results did show reduced rate of admissions in favour of intervention as the result was less than one, it did not reach statistical significance at six months and thus the null hypothesis could not be rejected. A divergence in results within the cluster

pairs is only seen in Cluster 3 where the event rate in Control 3 was 0.7 and in Intervention 3 was 0.37, so a near 50% difference was seen. In Cluster 1 and Cluster 2 no such difference was seen in the event rates for this outcome. The large effect in Cluster 3 leads to the Incident Rate Ratio being favourable in terms of the primary outcome but is not indicative of changes found elsewhere.

Table 4.3 Six month outcome results for ED attendances and emergency admissions and mortality

	Intervention n=181	Control n=145	P value
ED attendances not resulting in admission 6/12 n(% of total attendances and admissions)	11(20.4)	20(32.7)	0.018 ^(a)
Total ED attendances and admissions n(rate*) 6/12	61(0.48)	54(0.36)	0.170 ^(b)
Mortality n(%) 6/12	23(12.71)	11(7.59)	0.133 ^(a)

(a) Chi square test (b) Incident Rate Ratio

(b) *=rate of ED attendances and emergency admissions per facility resident per time period

In the Intervention 11/61 (20.4%) Emergency Department attendances did not result in admission while in the Control facility a significantly higher, 20/54 (32.7%) did not result in hospital admission. Control 1 had 14/20, Control 2 had 2/20 and Control 3 had 4/20 attendances not resulting in admission over 24 hours. Intervention 1 had 7/11, Intervention 2 had 1/11 and Intervention 3 had 3/11 attendances not resulting in admission over 24 hours. Despite this difference there was no significant difference in mortality seen between the two groups with n=23 (12.71%) in Intervention group over six months n=11 (25%) in the Control group as seen in table 4.3..

No harms were reported during the time of study completion or analysis or since and there was no significant excess mortality in the Intervention group, thus the intervention did not cause any deleterious effect.

The exact timing of admissions was not recorded in the study. The reason for admission was not recorded for every patient as it was not presumed accurate unless a discharge summary was present in the patients' files outlining what was found on review and admission. In those where both the reason for transfer in the patients notes and the actual discharge diagnosis were compared significant discrepancies were seen so total accuracy could not be guaranteed. However, it was noted by the principal investigator that overall the reason for hospital transfer was most frequently falls, followed by lower respiratory chest infection, followed by urinary tract infection.

4.8 Summary

The results of the cluster randomised controlled trial showed high participation rates with a mean of 74% of eligible patients in the six residential aged care facilities participating. Despite the fact that the Control and Intervention groups were matched on facility characteristics, by clustering, rather than individual characteristics, the groups were statistically similar in many categories. The Intervention group had a statistically higher proportion of patients with a life-limiting illness and non-English speaking background, presence of a Medical Enduring Power of Attorney and a higher number of PRN (as required) medications.

The baseline assessments revealed two groups with significant cognitive and functional impairments and evidence of severe frailty and dependence. There was a low level of definitively diagnosed dementia given the median MMSE score was only 20. The investigators found that a majority of patients had a diagnosis of 'Short term memory loss' not attributed to any definitive diagnosis.

Facility characteristics were similar in the Control and Intervention groups in terms of organisational type. However there was a difference in the staffing in terms of the presence of an on-site division one registered nurse working overnight. In Control 3 there was not always such a nurse working, at times it would be an endorsed nurse with a division one registered nurse on call from home.

The primary outcome of a decrease in Emergency Department attendances and emergency admissions of 40% between Intervention and Control groups was not statistically significant at six months. Instead there was a large effect seen in Cluster 3 and no difference seen in Cluster 1 and 2. There was no difference in mortality between the two groups. The Control group were more likely to have Emergency Department attendances that did not result in an admission. The study was not found to have any deleterious effects but the null hypothesis could not be rejected as it did not achieve the 40% change in Emergency Department attendances and emergency admissions required for a statistically significant result at six months.

Chapter 5 Data Analysis and Findings of Qualitative Study

5.1 Introduction

Within the three Intervention residential aged care facilities, where the Goals of Patient Care medical treatment orders were completed, focus groups were formed with healthcare professionals. The aim of this qualitative component of the study was to better understand, from the perspective of healthcare professionals, how Advance Care Planning and use of the residential aged care facility Goals of Patient Care were understood and experienced.

This chapter will present details of the participants who were involved in the focus groups and individual interviews. Findings from these focus groups and interviews will then be presented. Interview data has been de-identified in order to protect confidentiality of individual participants and their participating residential aged care facilities.

5.1.1 Participant characteristics

The healthcare professionals participating in the focus groups included endorsed nurses, registered nurses, clinical care co-ordinators and facility managers. Experience ranged between two and twenty years with a mean of nine years. Each of the three focus group had between three to eight participants (total of 18 participants). Written informed consent was taken from each participant prior to commencement. The same question guide (appendix 12) was used with each focus group and unanticipated themes including the effects of health literacy on Advance Care Planning, mistrust between the stakeholders and barriers to provision of good end-of-life care were also explored in subsequent interviews. In addition, one-to-one semi-structured interviews were conducted with Medical Practitioners who visited each intervention facility. Three Medical Practitioners were recruited for interviews. No other non-participants attended the focus groups or interviews. The same question guide (appendix 13) was used with each of the individual interviews and unanticipated themes were also explored in subsequent interviews.

The focus groups and individual interviews took place with staff providing care to the Intervention facilities only, as the intent of the interviews was to gather information about both standard Advance Care Planning and Goals of Patient Care medical treatment orders. It was estimated that the 21 participants recruited would be sufficient to provide saturation of themes for analysis and, at the time the final interviews and focus groups were being completed, no new themes were emerging. The transcripts were read independently and coded by an associate researcher (BH) and no further themes were identified. The transcripts were not returned to participants for comment or correction.

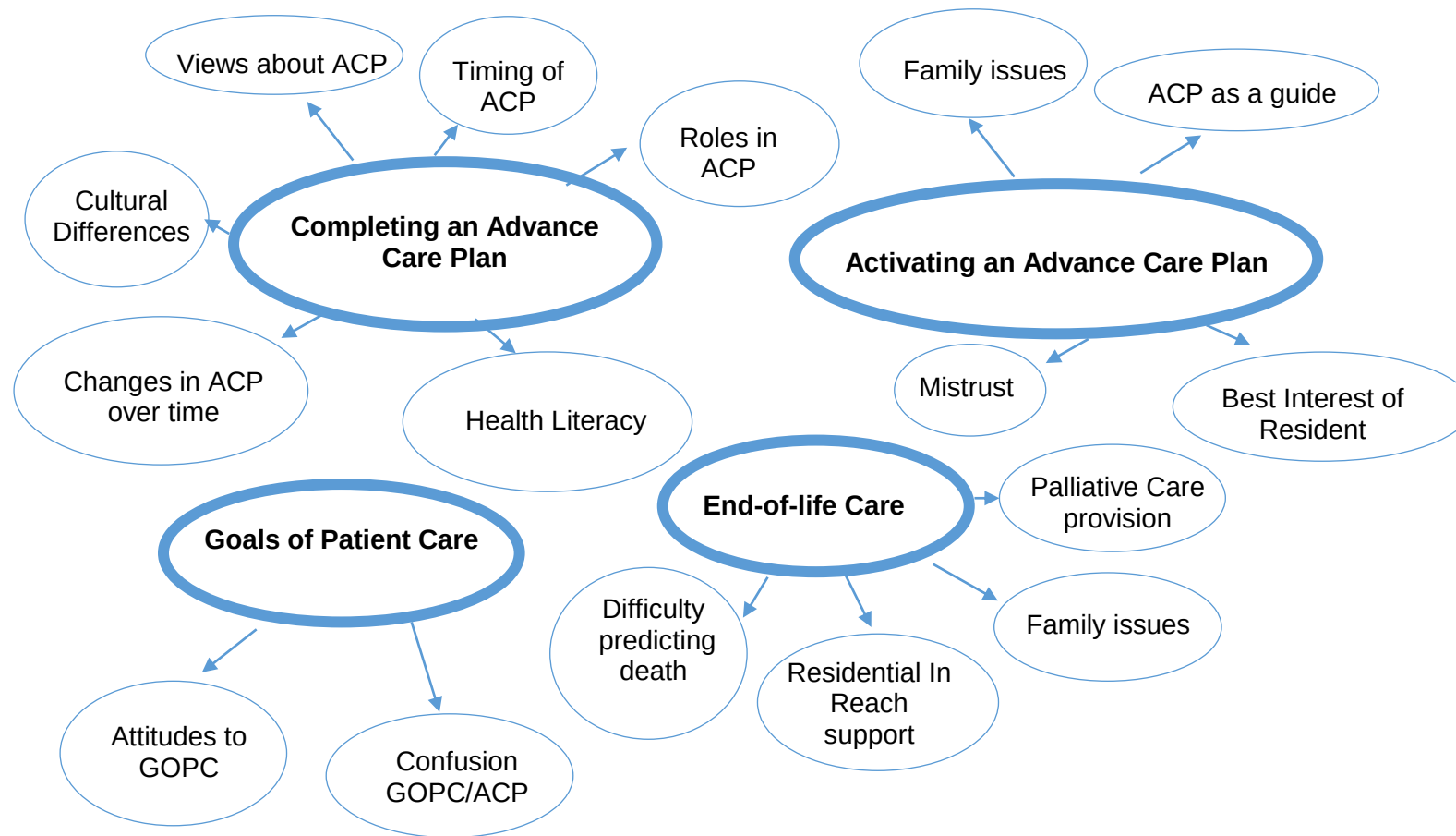
5.2 Results: Thematic analysis

As described in section 3.1 the study performed was an explanatory sequential mixed methods descriptive study. This research method has previously been used to assess healthcare staff (109). The main research questions being investigated in this exploratory qualitative part of the study were whether the intervention would result in: (i) in improved communication of the patients' preferences; and, (ii) improved healthcare decision making for patients by the staff. The exploration of these questions and valuation of Advance Care Planning and Goals of Patient Care in residential aged care facilities took place from the perspective of healthcare staff only. Patients and families were not interviewed as although a valuable source of information this aspect was outside the scope of this study.

Staff reported in-principal support for Advance Care Planning as a good idea but also went on to discuss many issues related to Advance Care Planning. They also reported issues that related to providing end-of-life care within residential aged care facilities and the use of the Goals of Patient Care to guide patient management. The following section will present the findings under four main themes as seen in figure 5.2.

1. Completing an Advance Care Plan
2. Activating an Advance Care Plan
3. End-of-life
4. Goals of Patient Care

Figure 5.1 Thematic Analysis Results of Qualitative Analysis



5.3 Completing an Advance Care Plan

This theme will be discussed under five subthemes; Views about Advance Care Planning; Timing of Advance Care Plan completion; Roles in Advance Care Plan completion; Cultural differences and Effect of Health Literacy on Advance Care Plan completion; Changes in Advance Care Plan completion over time. Appendix 17 presents a summary table describing the numbers of quotes and sources on the five subthemes outlined.

5.3.1 Views about Advance Care Planning

Overall Advance Care Planning was described by nursing staff and medical staff as a valuable resource when making treatment decisions especially in terms of hospital transfers. One nursing participant from Focus Group 1 illustrated this saying,

'It is very helpful especially in time of whether we have to send them to the hospital'.

From the following quote (from Focus Group 3), it can also be inferred that it had helped improve patients' treatment, ensuring that they received more appropriate care at the end-of-life,

'It's allowing people to die with privacy and dignity now where a lot of people before weren't allowed to die with dignity.'

The Medical Practitioners interviewed also highlighted the value of Advance Care Plan as Medical Practitioner 3 illustrated,

'Advance care planning is clearly something that is very important'.

It became evident from many references that staff felt the Advance Care Planning often allowed family members to voice their own preferences for the patients' care in terms of healthcare decisions, rather than the families articulating what the patients themselves had wanted, as illustrated by a nursing participant in Focus Group 2,

'I know a lot of family members say, this is what mum wanted but when mum has deteriorated or dad has deteriorated [and] they can no longer advocate for themselves its more what they [the family] want'.

5.3.1 Timing of Advance Care Plan completion

The benefits of completing Advance Care Planning at a time when patients had the capacity to be involved in the conversation was identified by a number of participants. The point was illustrated by this quote from a nurse in Focus Group 1,

'I think my big take [on Advance Care Planning] would be that we should try and involve the patient as much as possible because they have the right [to make their own decisions] and I think that should be their say whether I want this or not. So try to do it when they're in good health'.

Another participant from Focus Group 3 further supported this opinion saying,

'This person is fine now and can make decisions but what if he had a CVA he might not be able to participate then'.

Participants stated that the best timing for completion of an advance care plan was at admission to the residential aged care facility, as indicated by this nurse in Focus Group 3,

'I think advance care planning paperwork should be in the admission pack so that it can be discussed as a family unit before they even come in. It can always be changed but I think it would be easier if that was already in your admission pack'.

Although some participants felt it was a difficult topic to broach at the same time with new patients with one participant from Focus Group 1 describing Advance Care Planning as a,

'Very sensitive topic, especially when they are new in the facility'.

He went on to describe the fact that at times people both patients and families find it confronting,

'When they just show up with their relatives in the facility they don't want to talk about it'.

Another participant from Focus Group 3 agreed more with this aspect describing Advance Care Planning again in this manner saying,

'A lot of people feel daunted by that conversation'.

The fact that patients were now typically entering residential aged care facilities in a much frailer condition than previously was a common theme, and this was said to be leading to Advance Care Plan being addressed at an earlier stage in the admission process. One nursing participant from Focus Group 2 commenting,

'They come in and we bypass the initial assessment period and start with advance care planning first, just to make sure and usually it's the right decision'.

5.3.2 Roles in Advance Care Plan completion

The roles of nurses and Medical Practitioners in the completion of Advance Care Planning was spoken about in all focus groups and interviews. In all the facilities involved it was the nursing staff primarily who completed Advance Care Plans with the patients and families. There was a difference between the three facilities in terms of the involvement of the Medical Practitioners. In Intervention 1 the nursing staff completed the Advance Care Plans without Medical Practitioner's input,

'We sort of have a family conference and then based on what information we get then it's transcribed onto our [Advance Care Plan] form without the doctors [input]'.

The Medical Practitioner was only involved if a palliative approach was chosen as a nursing participant noted,

'If we make a decision that the patient is not for CPR or not for transfer definitely then we get the GP, GP decides it'

Or if the family are judged to be difficult,

'Or if it's a tricky family.....we get the doctor to give them more explaining'.

In Intervention 2 the Medical Practitioners always review and sign the Advance Care Plans as was indicated by a nursing participant in Focus Group 2,

'They always sign them'.

Again if the family was judged to be anxious then the Medical Practitioner was more involved,

'Sometimes the family is very anxious and we have to have a meeting to discuss everything and then it's all signed by the relative and the doctor'.

In Intervention 3 the Medical Practitioners review the ACP and again sign off on them and become more involved in time of clinical deterioration or if the Advance Care Plan is not in keeping with how the healthcare staff felt it should be as was illustrated by Medical Practitioner 3,

'In the facilities we go to we sign them off'.

In Focus Group 1 nursing participants commented on the suitability of nurses completing the Advance Care Plan as they had a good rapport with the patient and the family, with one participant from Focus Group 1 saying,

'As nurses we are more empathetic, we spend time with them, we know how the family is'.

In contrast the same group felt that Medical Practitioners had variable levels of suitability to be completing Advance Care Planning with patients and families and that this depended on their

personality traits and communication skills, as illustrated by the same nursing participant who stated,

'It depends on how compassionate that GP is'.

The participants at this facility did not however feel that this was the preferable approach to Advance Care Planning, indicating that a team approach was often preferable. This is illustrated by statements from another participant from the Focus Group 1, who compared their current experience to working in a prior residential aged care facility where a more collaborative, shared decision making approach was used.

'In my old facility where I used to work, with care planning end of life there is always the GP, the family and the nurse, the three of us will do the meeting all the time. That's the way it should be'.

The Medical Practitioners described theirs as a more supervisory role in relation to Advance Care Planning completion. Medical Practitioner 1 commented,

'I always look over it and see if I feel it's appropriate'.

They also said that they would ring the families to clarify any issues if they felt the Advance Plan wasn't appropriate as illustrated by Medical Practitioner 2,

'Sometimes I don't feel that the family have gotten the gist of it or there are extra questions. Then I ring the family and clarify a few issues before I sign it off'.

5.3.3 The effect of cultural differences and health literacy on uptake and understanding of ACP

Cultural differences affect the willingness of patients to engage with advance care planning as is illustrated by both nursing and doctor participants. Europeans and Catholics were mentioned as groups where culture affected their engagement with Advance Care Planning discussions.

Medical Practitioner 1 illustrated this saying,

'The resistant groups are the Catholics and the southern Mediterranean Catholics'.

'Yes the Europeans they want everything.....well certain Europeans.... their mother has to go to hospital no matter what'.

The issue of health literacy was mentioned in a few contexts in the focus groups one of which was the completion of ACPs. Nursing participants from Focus Group 3 felt there was a considerable lack of understanding about the purpose of ACP completion due to poor health literacy with families and patients saying,

'I think it's an unawareness, it's a knowledge, and they're not educated',

And describing the need to address this,

'I think there should be more education in the community, I think everyone, all us even should have our wishes known.'

5.3.4 Changes in Advance Care Planning completion overtime

The changes in Advance Care Planning completion rates seen over time is a theme reported on by many participants, all commenting on an increased uptake of Advance Care Planning by patients of residential aged care facilities as described by Medical Practitioner 1,

'The penetration rate, we've increased dramatically. Whereas you used to be trying to make decisions at crisis time'.

Changes to the format of the Advance Care Planning documentation so that it had more relevance to patient choices was also highlighted as important, making the process more consumer focused, as described by a participant in Focus Group 2 ,

‘Advance Care Planning, It has progressed to be more comprehensive and more a formal process. Become more person centred ‘

5.4 Activating an Advance Care Plan

This theme will be discussed under four subthemes: Advance Care Planning as a guide, Family members’ ambivalence about following the Advance Care Plan, Mistrust, and Best Interests of Patient. Appendix 18 presents a summary table on ‘Activating an Advance Care Plan’, describing the main numbers of quotes and sources on the four subthemes outlined

5.4.1 Advance Care Planning as a guide to decision making

It was clear from all the discussions that Advance Care Planning was seen as a guide to healthcare decisions rather than defining treatment decisions. This is illustrated by a quote from a nursing participant in Focus Group 3,

‘I think we like them cause its gives us the direction, direction which way we’re going’.

It did not however replace the need to confer with family when a situation of clinical deterioration arose as a participant from Focus Group 2 illustrated,

‘A phone call in accordance plays still a big part on the day when they are unwell’.

5.4.2 Family members’ ambivalence about following the Advance Care Planning

The issue of families changing their minds and not following the Advance Care Plan was a strong theme throughout all the interviews and focus groups. This is illustrated well by the following quote from a nursing participant in Focus Group 3, who describes a personal experience,

‘I did send a man.... to hospital recently but his advance care directive said no more hospital transfers but at the time the family said, “No send him to hospital”’.

A participant from Focus Group 2 illustrated how this ambivalence about following the Advance Care Plan decreases the documents usefulness saying,

'I find even though you've got all of these and how beautifully completed they are, at the end of the day people still change their minds last mind and are wanting to go to hospital'.

Reasons were given for deviating from instructions on an Advance Care Plan. One reason reported was that the decision was easy to make in advance but difficult to follow through on at a time of deterioration. This is described by a participant from Focus Group 3,

'Like now to hand a form and say can you fill this in is easier to when you get to the actual point of time, it [the situation] can change quite dramatically'.

Also, many participants reported that they believed feelings of guilt to be a reason Advance Care Plans are not always followed by families. This is described in regards to a patient's wife by Focus Group 1,

'For her to decide whether I'm [patient's wife] doing the right thing or not, it's very hard on them and they feel so guilty about it'.

Internal conflict for family members was also reported to play a role in whether Advance Care Plans were followed as one participant from Focus Group 1 described,

'She is still not in acceptance with what is happening to her husband so she still in her mind feels that she hasn't done enough'.

Participants described that the Advance Care Plan becomes more about the family's wishes than the patient's as they want their loved ones to live as long as possible; sometimes ignoring their quality of life,. A typical quote that illustrate this view comes from Focus Group 3 saying family members feel,

‘Very confronted..... as they all [the families] want their loved ones to be here forever. There’s no compromise on stopping any care even though if it was my father I would have stopped it but for her it’s totally inappropriate ‘.

Another factor mentioned by many participants in relation to the family’s decision making, was their lack of recognition or acknowledgement of clinical deterioration in their loved one. This is illustrated by the following the response from a participant from Focus Group 1 who stated,

‘It’s more so when the families are in denial’.

Medical Practitioner 2 illustrated how families can misunderstand the purpose of ACP with the following example,

‘They’ll say, “No I don’t want her to go no, don’t send her to hospital”. And then they’ll add at the end, “Unless she gets any worse”. And that’s the thing that gets me all the time. I have to say, “Hang on hang on. Let’s go back to the drawing board here”.’

5.4.3 Mistrust

Mistrust amongst clinicians and families was a theme that transcended many other themes in the interviews and focus groups. One participant from Focus Group 3 illustrated families’ mistrust of Advance Care Planning saying,

‘I think relatives are just a bit nervous if I fill that in , then does that mean they’re not going to look after mum anymore’.

Medical Practitioner 2 described their own mistrust of the Advance Care Plans saying,

‘If it’s a nurse that’s filled it out, the doctors won’t follow what nurses have done. Not just necessarily locums. They won’t take that as gospel’.

Issues regarding certain staff groups not following Advance Care Plans was frequently discussed, namely agency nurses and locum Medical Practitioners. Mistrust of ACP by these

health professionals was again highlighted as a strong reason for unwillingness to follow the instructions on an Advance Care Plan, as is illustrated by the following quote from a nursing participant in Focus Group 2 in regards locum Medical Practitioners ...

'I often have them [Locum Medical Practitioners] still say, "Send them to hospital"....with an Advance Care Plan to the contrary'.

5.4.4 Best interest of the patient

From all of the interviews and focus groups it was evident that everyone seemed to be working with the best interest of the patient in mind as was nicely illustrated by a nursing participant from Focus Group 3,

'Not that we want anyone to die but if we are in that situation at least [we] make sure they die with peace and dignity and make sure they're pain free'.

But it was also clear that the participants and families' opinions about what was best for the patients conflicted at times. This is reported by the nursing participant from Focus Group 1,

'You know there is a little bit of conflict in you know getting the goal to achieve our care, what is best for the patient'.

When Advance Care Planning is completed for patients by their families, participants felt that the wishes documented were more frequently those of the families than the patients themselves as one nursing participant from Focus Group 2 illustrated,

'I know a lot of family members say, "This is what mum wanted" but when mum has deteriorated or dad has deteriorated they can no longer advocate for themselves its more so what they [the family] want'.

An inference can be made from this statement that the staff member lacked trust in the family member to make a decision consistent with the best interests of the patient.

5.5 End-of-life

The theme of end-of-life emerged from all discussions. It will be discussed under the following four subthemes: Difficulty predicting time of death; Palliative Care provision; Family issues; and Residential In-Reach support. Appendix 19 presents a summary table on 'End-of-life', describing the main numbers of quotes and sources on the four subthemes.

5.5.1 Difficulty predicting time of death

The fact that dying can be difficult to predict across healthcare settings was described by Medical Practitioner 1, reflecting on an outcome in which the family became very angry,

'[The patient was] virtually comatose so we withdraw everything.....and then things got better and the husband abused me for getting it wrong'.

The outcome of poor prediction by acute health care clinicians of when patients are likely to die, had led to patients dying during transfer between the hospital and residential aged care facilities was also highlighted by a nursing participant from Focus Group 1,

'We didn't think they needed to be sent back to us, they were under palliative care or whatever and one died two hours after they arrived and the other one dies on the way'.

Deterioration in health and death was described as a difficult thing for families to accept as was illustrated by a nursing participant in Focus Group 2,

'There's still a lot of attitudes from families and sometimes staff members, people aren't allowed to die'.

5.5.2 Palliative care provision

Palliative care provision in the residential aged care facilities was a strong theme across facilities, with most indicating improvements especially in the area of palliative medication prescribing as was reported by the following nurse participant in Focus Group 2.

'I find most GPs now, since we've been on our band wagon of advance care planning, they're very prepared, so they already have a lot of palliative care medication and plans, treatment plans prepared, once we've had family conversations and they are discussed'

Facility staff showed confidence in their ability to look after palliative patients. An example was described from Focus Group 1 with a nursing participant saying,

'We can look after palliative patients, we can look after pain management and everything'.

Nevertheless, participants also reported that issues still exist with providing palliation in the residential aged care facilities. Facility staff have found that locum doctors are not keen to commence people on a palliative pathway. One nursing participant from Focus Group 2 saying,

'He wanted to die here and the locum kept sending him to the hospital

He kept saying, "I don't want to go to hospital" but the locum wouldn't write him up for anything and this poor man actually died in pain before we could even get him a morphine order so it was quite horrific '.

Locum doctor's concern about prescribing palliative medications in the setting of acute deterioration is described by a participant in Focus Group 3,

'Most of the locums, they're not confident writing the morphines'.

Another participant from Focus Group 3 described the reasoning behind this rather that the doctors were practising defensive medicine saying,

'They're all thinking if someone dies and it goes to the coroners, they want to offload that responsibility onto the hospital'.

Agency nurses were also described as not following Advance Care Plans due to a different focus of care rather than concern with palliation as illustrated by a participant in Focus Group 2,

'The agency [nurse] is more focussed on acute care so they want to send everyone off to hospital regardless of what the Advance Care Plan says'.

Poor communication about the fact that patients are returning from the hospital to the facility for palliation, and issues surrounding this handover of information, was referred to by many participants. Lack of communication about patients returning in a palliative state was highlighted by one participant in Focus Group 3,

'She came back and she was actually unconscious and in the last stages, she was palliative, but they hadn't told us that she was palliative and lucky Dr was here. Even on the discharge summary they mentioned that they had discussed palliative care with the family but I called the son and son didn't know anything'.

5.5.3 Family Issues

Misconceptions by families about the use of morphine to ensure patients had good symptom control at the end of their lives were raised. In regards to the use of morphine one participant from Focus Group 1 recounted an experience saying,

'Then she [the daughter] told me and the doctor and the Recipe [Residential In-Reach] team. I'm not killing my mother, you can do it if you want. That morphine will kill mum and [she believes] we're trying to kill her mum, and so that up to the last day she dies without morphine'.

Participants felt that these misconceptions by family members were a barrier to providing good palliation. In terms of morphine use one participant from Focus Group 3 said,

'Not that we want anyone to die, but if we are in that situation at least make sure they die with peace and dignity and make sure they're pain free'.

5.5.4 Residential-In-Reach support (Outreach and Residential Care Intervention Program in the Elderly [RECIPE] namely)

Residential-In-Reach provision of support in palliative decision making was commented on positively by nursing participants in Focus Group 1 and 3,

‘Outreach and the RECIPE teams are fabulous..... and I’ve used them, I use them a lot to bring the family around [to the understanding] that this is palliative.

They’ll often sit the family down and the person will be palliative from that point on..... [they provide] the extra layer of authority.’

Their assistance with palliative care provision to patients was also mentioned by both nursing and Medical Practitioner participants in various interviews and focus groups. A typical example was given by a nursing participant in Focus Group 2,

‘Yes RECIPE it’s really good and they’re out pretty much as soon as you [call] them. They’d be a same day service. ‘We always have very good (palliative) support from the Northern Hospital (Residential-In-Reach)’.

The participants reported that the support of Residential-In-Reach was particularly useful when families were not in agreement with treatment plans thought most suitable by facility staff and their visiting Medical Practitioner. Medical Practitioner 2 described the situation of a Residential-In-Reach registrar visiting saying,

‘So when the doctor and sometimes it’s only a junior registrar—when they come in and say there’s nothing we can do and there’s nothing we can do in hospital they believe them[as they are] not just the GP ’.

5.6 Goals of Patient Care

The theme of Goals of Patient Care will be discussed under the following two subthemes:

1.Attitudes to Goals of Patient Care and 2. Confusion about Goals of Patient Care and Advance

Care Planning. Appendix 20 presents a summary table on 'Goals of Patient Care', describing the main numbers of quotes and sources on the two subthemes.

5.6.1 Attitudes to Goals of Patient Care

The Goals of Patient Care form was discussed at all focus groups and interviews. A participant from Focus Group 1 described the Goals of Patient Care form as improving communication of patient's healthcare wishes of and focussing on key information,

'Our form, there is a lot of information, and a lot of detail whereas with this one you've got the key things in there'.

Another participant from Focus Group 3 felt that it helped with healthcare decision making for patients by being more suitable for people with lower levels of health literacy as the information was presented in a more accessible format.

'It gives you tick boxes to give you a choice of what would be acceptable and that's what I find helpful for a lot of people who have no background with health literacy'.

Some participants described referring to the Goals of Patient Care form when making healthcare decisions. An example being from a nursing participant in Focus Group 3 saying,

'Obviously this has played an important role'.

Medical Practitioner 1 described referring to the forms when making healthcare decisions,

'I have referred to these at times'.

The potential benefit of adding a free text area was referred to by a Medical Practitioner and by focus group participants. The following quote is from Medical Practitioner 2,

'If I'm sorting it out with them I can write in about what treatment they want and I can bring up the examples of you know, a free text area on the back that allowed you to document those things would be useful'.

5.6.2 Confusion about Goals of Patient Care and Advance Care Planning

Confusion about the different purposes and authorities between an Advance Care Plan and a Goals of Patient Care form was a recurrent theme. One nursing participant from Focus Group 3 illustrated it saying,

'I find it a little bit confusing because we have an [facility name] one and then this one and I wasn't sure whether we copy that information onto [facility name] or vice versa'

Some participants saw no difference between their facility Advance Care Plan and the Goals of Patient Care medical treatment orders, one nursing participant from Focus Group 1 illustrated this saying,

'It's pretty much similar to what we have on our assessments on admissions with the advance care planning'.

Another participant mentioned the fact that regardless of the presence of a completed Goals of Patient Care they still are required to fill out the facility's Advance Care Plan. An example from Focus Group 2 being,

'They said oh no we did one with the doctor but we needed them to complete our form also.'

An inference from the preceding quote is that there is a strong facility imperative to have an Advance Care Plan completed.

5.7 Summary

Despite some confusion among residential aged care facility staff about the relative place and roles of Advance Care Planning and Goals of Patient Care findings from the qualitative

component of this study suggest that Goals of Patient Care and Advance Care Planning help healthcare staff in making medical treatment decisions for patients. Goals of Patient Care medical treatment orders may improve communication of patients' wishes and be a clearer guide for healthcare staff to follow.

Adherence to Advance Care Planning was reduced by a number of issues including how much the Advance Care Plan could be trusted by both familiar and unfamiliar clinicians. Due to the fact that the Advance Care Plan often had to be activated by clinicians unfamiliar with the patient, such as locum Medical Practitioners and agency nurses, adherence was regularly affected. Misunderstanding about the purpose of Advance Care Planning also affected adherence by family; participants felt that making critical healthcare decisions in advance, was difficult for families to stick to at times of crisis such as when the patient had an episode of clinical deterioration. Additionally, the purpose of Advance Care Planning is to reflect the patients' values and wishes but participants have suggested that these documents were sometimes written more from the viewpoint of relatives rather than patients.

End-of-life care was a strong theme with all highlighting improvements that have been happening in palliative management in residential aged care facilities. Despite planning some issues still exist. Nursing participants felt strongly that locum Medical Practitioners were not happy to commence patients on a palliative pathway should they deteriorate outside of normal hours, which was negatively affecting their ability to look after patients well in their final hours to days. Lower health literacy of family members was also described as leading to poor end of life experiences for patients; as family members misunderstood the role that medications could play in ensuring that their family member had a comfortable death. This could result in patients being denied adequate pain management at the end of life as family members were concerned that opioids could hasten their relative's death. These findings highlight the need to provide patients and families with culturally sensitive information so that they had a better understanding of end of life care.

Chapter 6 Discussion and Conclusions

6.1 Introduction

In this chapter the main findings in regards to the research questions are summarised and conclusions drawn. The chapter is be split into six sections; 1. Discussion of the cluster randomised controlled trial results including the primary outcome; 2. Discussion of the explanatory descriptive study results; 3. Conclusions; 4. Strengths and limitations; 5. Implications.

6.2 Discussion of the cluster randomised controlled trial results

6.2.1 Residential aged care facility matching and recruitment

On study commencement, invitations to residential aged care facilities in the healthcare services involved in the study, resulted in interest from just over 25%, in meeting the principal investigator. It was known from the statistical analysis as described in 3.3.9.1 that a sample size of three pairs of facilities was felt to suffice. The mean of 74% of patients consenting to participate exceeded our expectations. With such high numbers of participants we hoped to negate the risk of selection bias in those choosing to participate as much as possible.

Statistically for powered analysis three pairs of residential aged care facilities was judged to be sufficient. This was achieved, however the hope had been to recruit more facilities so that they could be matched in terms of facility size, facility staffing and other characteristics. This was not possible so instead the facilities were organised into cluster pairs based solely on their twelve month prior event rates for Emergency Department attendances and emergency admissions and other facility characteristics were not considered. In terms of the prior event rate considered, it was known that only information from the public health services the facility patients attended and not private hospitals could be accessed and so it was going to be an underestimation in all facilities involved. All facilities were in close proximity to both public and private hospitals with admitting Emergency Departments so it was known these would be

missed. The main effect of this would be seen in the statistical analysis as the closer the facilities within each pair were at baseline the lower the intra-cluster co-efficient would be. This intra-cluster co-efficient affects the number of facility pairs required to provide a statistically significant result, the closer it is the less cluster pairs required.

6.2.2 Residential aged care facility characteristics

In terms of management structure as there was a similar breakdown of private and not-for-profit facilities in the Intervention and Control groups so this should not have impacted on the results. In terms of staffing our focus was on the availability of senior nursing staff in the staffing mix of endorsed nurses and personal care assistants. It is acknowledged that staff turnover is a considerable factor also to be addressed in terms of quality of care in residential aged care facilities (110) but to monitor staff turnover over the twelve months was beyond the scope of this study.

All six facilities have division one registered nurses working by day, and all but one have a division nurse registered nurse on site overnight. It was noted that the highest event rate for Emergency Department attendances and emergency admissions occurred in this facility, Control 3. The time of day of Emergency Department transfers was not recorded in this study due to concerns with accuracy, but this difference in staffing could impact significantly on the results from this facility. Prior research has shown that it is not necessarily the numbers of nursing staff but factors such as experience that affect quality of care in residential aged care facilities (111) so the presence of senior nursing staff on site is important. There has been a decrease in the numbers of division one registered nurses working at residential aged care facilities in Australia since the 1990s (112) with a preference for endorsed nurses who receive less training and whose pay grade is less than that of a division one registered nurse (113). Lack of senior nursing onsite is a concern for the standard of care provided in residential aged care facilities (114) and Australian studies have found that when standards of care slip there is a tendency for greater use of emergency hospital services (115). .

There was no variation in the presence of hospital transfer policies between Intervention and Control groups. The fact that the visiting Medical Practitioners from Intervention 3 provide their

own locum service out of hours could impact on Emergency Department transfers compared with the other facilities who were using locum services with doctors unfamiliar with their facility, staff and patients. Intermittently the Medical Practitioners at Intervention 2 provided their own locum advice but not all Medical Practitioners for patients in this facility were involved in this initiative. These were not new initiatives and pre-dated the study intervention.

The matching of facility pairs took place on Emergency Department attendance and admission data in residential aged care facilities where the staffing differences described above were already established. No new staffing changes took place during the prospective study time period.

6.2.3 Baseline characteristics and assessments

Despite the fact that the Intervention and Control groups were matched on facility rather than individual patient characteristics the groups were statistically quite similar in many categories of baseline characteristics.

The first difference seen was in the presence of a life-limiting illness. There was a greater percentage of patients in the Intervention group with a life-limiting illness. This did not translate to a higher mortality rate in the group over the study period. Dementia, although a life-limiting illness in itself was separately addressed due to the high percentage of disease presence seen in residential aged care facilities. As there was no difference in mortality the impact of this difference is not thought to be significant.

The second difference seen is the presence of more patients with a non-English speaking background in the Intervention group. There has been Australian research showing that patients from non-English speaking backgrounds were significantly less likely to have prior knowledge of Advance Care Planning (116). This difference in knowledge and engagement with Advance Care Planning was perceived from our qualitative study to be related more to certain cultural differences. Internationally, however, it has been shown that it was more health literacy rather than culture that causes this difference (117). This fact could have negatively impacted on the effect of the Goals of Patient Care Intervention, however these patients were still open to

involvement in the research study which shows an openness to future healthcare planning. It was important to the study to involve non-English speaking patients with interpreters used, as this is representative of the clientele in the northern metropolitan area of Melbourne and to exclude based on language would have led to misrepresentation of the population.

The third difference in baseline characteristic was in the number with a nominated Medical Power of Attorney with the Intervention group having a higher percentage of patients over the Control group. This could indicate a greater involvement in the Advance Care Planning process with these patients. However when it came to evidence of this Medical Power of Attorney with the legal documentation present in the patients file there was no statistical difference between the groups. This could be explained by a few scenarios. Firstly that the formal appointing of the Medical Power of Attorney had not actually taken place, and when asked a patient or family member gives a name for the Medical Power of Attorney and so no document had ever been made but a name has been recorded. Secondly that a copy of the legal document was not given to the residential aged care facility for filing in the patient's chart. Thirdly that the document had been given but was not filed in such a manner as it was accessible to those reviewing the chart.

This difference between the groups that may indicate the patients in the Intervention group were more invested in Advance Care Planning at baseline that they were more likely to complete and follow any prior Advance Care Planning regardless of the addition of the Goals of Patient Care which could negate its effect. However, given that there was no significant difference in the percentages of participants with existing Advance Care Plans, 67% in the Intervention and 62% in the Control group it makes it less likely.

The last difference seen was the number of 'as required' or PRN medications prescribed. The significance of this is not felt to be great. This could be simply down to prescribing practice of the physicians attending different residential aged care facilities. The number of regular medications could be indicative of a frailer population but as these were similar in both Intervention and Control groups it is unlikely that the medications in general would be indicative of an important difference between the groups.

The percentage of patients with a formal dementia diagnosis was low in both Intervention and Control groups at 51 and 46% respectively. This contrasts with the MMSE scores, showing median MMSE scores of 20, indicating impairment of cognition (93). This indicates a disparity between with cognitive impairments observed and the formal diagnosis of dementia which had been given to participants. It was noted that instead of a diagnosis of dementia, a diagnosis of 'Short term Memory Loss' or STML was given. Reasons for this may include the visiting Medical Practitioners not being confident in diagnosing dementia or feeling that following residential aged care admission its relevance to the patient decreases. Participant and family factors may also play a role as the stigma surrounding the dementia leads to patients and at times families not wanting a formal diagnosis as international research has shown (118). This does not change the analysis in any way but just under-represents the number of participants with dementia included in the study.

Without a formal diagnosis of dementia participants would not be prescribed treatment. In terms of dementia treatments, it was treatment for stabilisation with cholinesterase inhibitors or Memantine rather than antipsychotic medications for pure behavioural management that were considered. This would clearly impact on the low numbers of patients on dementia treatment, 7% in the Control Group and 8% in the Intervention Group. This may also be affected by the fact that stabilisation in cognition is not always achieved with these agents and the side effect profile (119), as well as this lack of proven stabilisation required for on-going Pharmaceutical Benefits Scheme (PBS) subsidisation (120), may lead to their withdrawal. Prior usage was not recorded.

As expected with the baseline assessments of function and frailty the groups in general were found to be dependent and frail. The Barthel Index of function showed a median of 11 out of 20 in each group indicating two overall severely dependent groups (94). A wide range of 6-15 in the control and a range of 5-16 in the intervention Group represented the range in function expected in residential aged care facilities. The Clinical Frailty Scale with a score of 1-9, increasing in score with increasing frailty was used to evaluate the frailty of participants. The median score was seven in both groups. Within the scale seven indicates severely frail patients

that are dependent in terms of function and cognition (96) so our results showed two groups who were equally severely frail.

6.2.4 GOPC form choices

The GOPC form choices are as seen in figure 1. The principal researcher had in-depth discussions leading to the completion of these forms. For only a tiny percentage, 3%, was no treatment limitation chosen as is likely appropriate considering the levels of dependence and frailty identified in both groups of patients. More than 90% of patients preferred to be treated in the facility if they became unwell rather than immediate transfer to hospital. While 60% of them were still open to hospital transfer if not improving, for 30% the choice was not to go to hospital even if not improving from facility based treatment.

In completion of the discussions of the different goals of care and explanation about Cardiopulmonary Resuscitation and Intubation was given to all. Most patients, due to their frailty and dependence levels, felt this limitation was appropriate, thus leading to few patients having Goal A documented. In terms of wanting all life prolonging treatments with the limitations of 'Not for Cardiopulmonary Resuscitation or Intubation', i.e. Goal B, patients wanting all treatment if unwell with immediate transfer to hospital opted for this option. These patients had no issue with hospital transfer for treatment or escalation of treatment.

In terms of Goal C1, the most popular option by far, patients having a preference for avoiding hospital transfer and preferring treatment in the residential aged care facility had this goal chosen. This cohort was still open to hospital transfer for treatment escalation if they were not improving but had a definite preference for a trial treatment in the facility if possible.

In practice the principal researcher found that Goal B and Goal C1 were thought similar by patients and families. The difference was to be that patients with Goal B wanted limitations of no cardiopulmonary resuscitation and intubation but wanted immediate hospital transfer if unwell. However in reality all patients wanted any treatment they could have at the facility but this did not mean they didn't want hospital transfer also if needed.

Patients for whom Goal C2 was chosen were again open to any treatment that could be provided in their residential aged care facility including Residential-In-Reach teams visiting from the local health services but they wanted no further hospital transfers. Many had very strong feelings about avoiding hospital transfers. This cohort was generally frail and dependent on nursing staff for much assistance. Goal C3 was rarely chosen on the forms but was indicative of very frail participants that no longer wanted life prolonging treatments. Many in this cohort had advanced dementia or other medical conditions.

There were no patients for whom Goal D was chosen, for the last hours and days of life. Potential patients in this group chose not to partake in the research study. Due to the fact that the first analysis point was at three months, no participants would have been included in the analysis even if they had chosen to partake.

6.2.5 GOPC effect on primary outcome

The primary outcome for the intervention was that the introduction of Goals of Patient Care medical treatment orders would result in a 40% decrease in Emergency Department attendances and emergency admissions between intervention and control groups at six months. Prior studies in the area have shown effective interventions in this area (13, 24, 25, 59, 61-63) and one prior study demonstrated this 40% decrease over an 18 month period (24). This outcome was examined at three, six and twelve months. The reason that six months was chosen for the primary outcome was that it was thought that three months would be too short to see an effect and that by twelve months the attrition rate due to deaths in this frail population might be so great as to negate any effect. The results showed that at six months although there was a trend towards decreased Emergency Department attendance and emergency admissions it did not reach statistical significance. .

The three Control and Intervention residential aged care facilities were grouped for analysis. On review of the three separate cluster pairs the results were variable. As seen in table 4.2, there was little change seen between Control 1 and Intervention 1. A reason proposed for this is that within Intervention 1, a 90 bed facility 20 beds were used as Transition Care beds from a local health service and so did not contain permanent patients. These patients were thus ineligible to

participate in the study. In turn only 50% of the patients in this facility took part in the study at baseline and only 36% were still available for analysis at six months. A reason that the intervention was less effective here than in other facilities may have been due to the low percentage of participants involved. The intervention may have been unable to exact a change in culture amongst patients and healthcare staff. Changing the culture in residential aged care facilities has been found instrumental in exacting change both in Australia (121) and internationally (122). In the qualitative component of the study it was found that the Medical Practitioners in Intervention 1 were less involved in Advance Care Planning than those in Intervention 2 and 3. This impact this has on the facilities approach to Advance Care Planning and use of future planning documents in general could affect this outcome. This has been found in prior International studies where it has been shown that Medical Practitioners at times don't act on perceptions of nurses and relatives wishes of the patient even when documented in an Advance Care Plan due to their focus on curative treatment (123).

In Cluster 2 again there was no difference in Emergency Department attendances and emergency admissions at six months between Intervention and Control facilities. The nursing staff reported varying input from the Medical Practitioners with Advance Care Planning. They also spoke about 'Agency' nurses and 'Locum' doctors not following the future planning in place. At times the Medical Practitioners attending Intervention 2 provided their own locum service but they also used outside locum services. Medical Practitioner 2 demonstrated the trust issues that that were seen recurrently in the qualitative focus groups and interviews, saying that she wouldn't trust any future planning document completed by another clinician be it a nurse or doctor and her belief that this underpins why locum and agency staff don't follow these plans. Not alone was the distrust seen in terms of healthcare professionals' activation of future planning but also patients and families not following the plans as illustrated by nursing participants in our focus groups. Although trust has not been highlighted by prior studies as a reason that future planning documents are not activated, the investigators from this study find it has a significant effect on healthcare professionals' views and usage of both their standard Advance Care Planning and the Goals of Patient Care medical treatment orders. The lack of trust in Advance Care Plans was a common description and reported to be a reason why health

professionals could be unwilling to take them into account and thus affected outcomes from the intervention in this facility.

In Cluster 3 a big divergence was seen between Intervention and Control facilities in terms of Emergency Department attendances and emergency admissions with a near 50% difference at six months. This is despite the facilities having a similar prior twelve month event rate for this variable at 1.4 admissions and attendances per facility resident per time period for Control and 1.27 for Intervention. As previously discussed in the facility characteristics Control 3 was the only facility without a definite division one registered nurse on site overnight. It is of no doubt that this lack of senior leadership could have affected this result but this was not a new change and had been similar the year prior to study commencement. Intervention 3 was the only facility who's Medical Practitioners all hailed from the one practice and provided their own locum service. Again this was not a new intervention in the facility, it predated the study commencement but was a significant different to the other Intervention facilities. It also did not stop the healthcare professionals from giving examples of when the locum medical practitioners did not follow their patient's known wishes in terms of hospitalisation. These two differences could have impacted on this difference seen between Intervention and Control facilities as well as the Goals of Patient Care discussion and form completion.

Although there was not a statistically significant change between Intervention and Control facilities in terms of total Emergency Department attendances and emergency admissions there was in terms of Emergency Department attendances not resulting in admission over 24 hours. In the Control group there were 20/54 (32.7%) of Emergency department attendances that did not result in admission versus 11/61 (20.4) in the Intervention group. This was a statistically significant difference as seen in table 4.3. There was a spread of these attendances across the three Control and Intervention groups but Control 1 and Intervention 1 had more than twice as many as the other facilities. In the Intervention group with the Goals of Patient Care document complete there was clear indication that 90% of resident had a preference for treatment in the facility and 60% were opting for transfer only if they were not improving from treatment. This clear documentation about hospital transfer and preferred place of treatment for Intervention

patients would help stop transfers for less serious conditions and thus help reduce Emergency Department attendances not resulting in admissions as was demonstrated..

It has been reported in Australian data that up to 40% of Residential aged care facility attendances to the Emergency Department are not admitted (2, 124). Less serious cases are often discharged immediately back to the residential aged care facility with international literature noting that falls and injuries are most commonly discharged from the Emergency Department compared with respiratory tract infections or neurological changes being much more likely admitted (125). Our qualitative research found that dying patients were also being sent directly back from the Emergency Departments, with reference in Focus Group 1 and 3 but in this case this wouldn't account for these Emergency Department attendances as these were for patients who were all alive at subsequent time points for analysis. It is reasonable to conclude that the Control facilities sent a significantly higher proportion of patients to the Emergency Department with issues not requiring on-going hospital care. One could conclude that the Goals of Patient Care had an effect on decreasing Emergency Department transfers for less serious issues.

6.3 Discussion of Explanatory Descriptive Study results

6.3.1 Completing an Advance Care Plan

Advance Care Planning was regarded to be a helpful addition to the care of residential aged care facility patients by all healthcare staff leading to more appropriate medical care as has been seen in prior studies (16, 64). The general consensus was that although it is felt a difficult topic to broach, the frailty of patients at their time of entry forced its completion soon after admission. Also when discussing the time frame for completion, some touched on the true value of Advance Care Planning, completing it at a time when the patient can be involved in the conversation rather than their families making decisions on their behalf. It was also noted from the discussions that staff felt at times the Advance Care Plan was more reflective of what family members wishes than the person themselves.

The roles of those facilitating completion varied between facilities with nursing staff always being involved but Medical Practitioners having the most variation and Residential-In-Reach services also assisting at times. In Intervention 1 the Medical Practitioners had the least involvement. This facility was one in which there was no effect on Emergency Department attendances and emergency admissions over the time period and may have influenced this finding. The overriding theme was that Medical Practitioners had increased involvement if the family was perceived as being tricky, if the Advance Care Plan was not in keeping with what healthcare staff felt appropriate or if there was a definitive palliative path being chosen. The growing importance of Advance Care Planning over time was also highlighted with both better penetration rates described as well as the process itself becoming more patient centred.

Cultural differences and health literacy were mentioned as barriers to effective Advance Care Planning completion. Prior studies in the United States of America have shown that it is health literacy more than culture that impacts on the Advance Care Planning process (117). Whether in fact it is more the non- English speaking background affecting health literacy here in Australia rather than in fact the culture of the people from these backgrounds that affects advance care planning would be an interesting area to study further. The interaction of the two issues was not alluded to in any of the focus groups or interviews but the increased number of patients of non- English speaking background in our Intervention group may have affected the outcomes seen.

6.3.2 Activating an Advance Care Plan

It was clear that the substitute decision maker and families were most influential on activating an Advance Care Plan. The Advance Care Plan was seen as a guide certainly, but one that was discussed with the families or SDM at every clinical deterioration. In all discussions it was highlighted that substitute decision makers often don't activate the Advance Care Plan but make decisions contrary to it at crisis times, generally in favour of active treatment and hospital transfer as prior studies (126) have shown substitute decision makers alone were not seen as a barrier to Advance Care Plan activation but also Locum Medical Practitioners and Agency nurses were highlighted as other groups that tend not to follow the Advance Care Plan. A strong

theme found was that all groups felt they were working in the best interest of the patient but views on what this would entail varied significantly.

Mistrust was a theme seen underlying all aspects of the process of Advance Care Planning from patients/ substitute decision makers mistrusting the completion of the form for fear it would impact on treatment they want, to healthcare staff not trusting the decisions made on the Advance Care Plan, to healthcare staff not trusting each other in regards following the plan. It is likely with education about the process of advance care planning some of this trust could be negated but it seems this education would be required for all the stakeholders in the process.

The new Victorian legislation will create an obligation on all health practitioners to seek out and follow Advance Care Directives. It will also create an obligation for the substitute medical decision maker to make medical treatment decisions that are as close as possible to the decision that the person would make for themselves. Education will be required to make both health practitioners and community members aware of their obligations, which should help to address some misunderstandings about current Advance Care Planning and consent that were identified in this research.

6.3.3 End-of-Life

End-of-life was a strong theme across all focus groups and interviews. Both the fact that at times end of life is difficult to predict, even for healthcare staff, and for families to recognise, makes it a hard for all involved. Palliative care provision has certainly improved in residential aged care facilities and the confidence with which healthcare staff approach end of life was illustrated. However a barrier to this, as with advance care planning itself, was locum doctors not agreeing with facility staff to start patients on a palliative pathway, an issue described in a prior Australian study (127). Confidence and fear of litigation were two issues raised as reasons for this. Health literacy again was seen to cause misconceptions with family members about morphine usage and thus interfered with good palliation of patients in the end of life phase.

The support that Residential-In-Reach provide in optimising end of life care was appreciated by all healthcare staff. It was felt that the extra layer of authority given by the service helped

families to trust that palliation was the right option. Their provision of support was able to be provided at short notice, regularly the same day as requested illustrating how crisis situations needing urgent palliation are still often required despite improved planning within the residential aged care facilities.

6.3.4 Goals of Patient Care

The Goals of Patient Care form was seen to improve the communication of patients' wishes as compared with the standard Advance Care Plans in the residential aged care facilities. It was seen to address some of the issues with health literacy outlined throughout the discussions. It was referred to as playing an important role in healthcare decisions. Some areas for improvement were highlighted by staff including provision of a free text area to outline specific discussion points at the times of the meeting and form completion.

However the overall feeling from the interviews and focus groups was that the difference between the Advance Care Plans and medical treatment orders was not really seen. In fact, having the two forms present was seen as confusing and one form preferable at times of decision making.

6.3.5 Relationship between Advance Care Plans and residential aged care facility Goals of Patient Care

The focus group and individual interviews provided some insights into Advance Care Planning and the residential aged care facility Goals of Patient Care. An interesting report by participants was that it is not unusual for Advance Care Plans to document and reflect what appeared to be more in the nature of consensus decisions made at a family meeting. Such descriptions may help to explain why Advance Care Plans were described by some participants as being the same as the residential aged care facility Goals of Patient Care process and form.

6.4 Discussion of combined results

The combination of the quantitative and qualitative analysis gave the study a broad review of Advance Care Planning and the intervention Goal of Patient Care process under examination. During the initial randomised controlled trial the principal investigator spent time in each

residential aged care facility before commencement introducing the study to healthcare workers and organising recruitment. This was followed by visits over twelve months following. This led to an understanding of culture of the facilities. A review of current Advance Care Planning processes in each residential aged care facilities led to knowledge of some of the issues faced by healthcare workers in the area. The completion of all the Goals of Patient Care discussions gave insights into the issues with Advance Care Planning from the patients and families' points of view. The standard of the Advance Care Plans in place was seen to be variable both within the residential aged care facilities themselves and between the facilities. These Advance Care Plans often contributed to the Goals of Patient Care discussions and affected choices of different goals.

The process and experience of the quantitative study informed the development of the qualitative component of the study. The qualitative study provided further insights into the analysis of the Goals of Patient Care process from the point of view of healthcare workers leading to further understanding of the quantitative outcomes while concurrently providing information not just about the new Goals of Patient Care process but also Advance Care Planning in general in residential aged care facilities. The explanatory descriptive study helped give depth to the main outcomes seen from the cluster randomised controlled trial

6.5 Conclusion

The primary outcome of Goals of Patient Care medical treatment orders being more effective than Advance Care Planning alone for decreasing hospital transfers was not shown. There was a trend toward this decrease but it did not reach statistical significance at this time-point. A prior randomised controlled trial in the area ran their study for 18 months with statistically significant outcomes. It is felt that the study time period was too short at six months to show such an effect and a longer time period may have led to a different primary outcome. At six months a difference between Intervention and Control facilities was only seen in Cluster 3. The studies secondary outcomes, seen in Appendix 2, expand on this theory.

However an interesting difference was seen in the numbers of Emergency Department attendances not resulting in admission being higher in the Control group which could indicate

less patients with less serious conditions not requiring admission being transferred to the Emergency Department in those without Goals of Patient Care discussions and forms. .

Adherence to Advance Care Planning/ Goals of Patient Care was reduced by a number of issues around how much to trust the document. This was largely affected by understanding the purpose of Advance Care Planning process. The Advance Care Plan often needed to be activated by unfamiliar clinicians-including Locum Medical Practitioner s and Agency nurses which affected its activation also. This is concerning for the near future when Advance Care Plans will hold the same authority as refusal of treatment orders and the knock on effects this will have. Education to all stakeholders, namely the people completing the forms, residential aged care facility staff, regular and locum Medical Practitioner s and hospital staff will be paramount to ensure both Advance Care Plans and Goals of Patient Care are completed appropriately and activated in accordance.

This study is particularly relevant as health services target residential aged care facility admissions in attempts to reduce pressure on Emergency Departments (128). In Victoria, Australia where the study took place it is estimated to cost up to \$1800 per hospital transfer (129) so in terms of health economics the effect considerable. As mentioned previously Advance Care Planning not only improves patients care (57, 60) and makes health care decisions more in keeping with patients wishes (55) but also is an effective way to decrease hospitalisation from residential aged care facilities (13, 24, 25). As with previous studies examining medical treatment orders, it was found that they were superior to Advance Care Plans alone (10, 13). The Goals of Patient Care medical treatment order is not intended to replace Advance Care Planning but, rather, to complement prior Advance Care Planning. It is also a mechanism for capturing known preferences and values that have not been documented in a written Advance Care Plan.

In Australia prior research has shown a decrease in hospitalisation of Residential Aged Care Facility patients with combined introduction of the 'Let Me Decide' Advance Care Planning framework and hospital in the residential aged care facility (25) in a similar manner to the Goals of Patient Care medical treatment orders used in this study. A study into the standard of

Advance Care Planning in 2013 found that Advance Care Planning was inconsistent and variable in quality (11). Improvements in current practice are still found by this study to be necessary, as when comparing the effects of the intervention versus usual care significant inconsistencies are evident in terms of both hospitalisations in relation to patients' wishes.

In both parts of the study it was clear that many residential aged care facility patients no longer have capacity to complete the Advance Care Plan independently. The new Victorian legislation coming into effect in March 2018 only provides framework for people with capacity to complete an Advance Care Plan. It is likely medical treatment orders, such as the Goals of Patient Care process, will become increasingly important for patients without capacity to be involved in their future healthcare planning. For this to take place it will require a shift in the practice identified by the qualitative study in the role of Medical Practitioners in future planning. If medical treatment orders are to indeed become the common form of future planning for patients without capacity the Medical Practitioners and Geriatricians rather than nursing facilitators alone will need to be involved in these discussions and complete, rather than just review, the forms required.

This study is the only one of very few in the last 15 years examining effects of ACP or medical treatment orders in RACFs through a randomised controlled trial and thus its outcomes are very important to all those working in the areas of Advance Care Planning, Geriatric Medicine and Health Service Planning.

6.6 Strengths and limitations

6.6.1 Strengths

The study examines the effects of a new medical treatment order form, Goals of Patient Care, specifically designed for residential aged care facility patients.

The study design is a major strength of this study. The cluster randomised controlled trial gives the best evidence of the impact of the intervention. The explanatory descriptive study allows a more in-depth analysis of the results from the randomised controlled trial as well as adding

other insights about the process evaluation of Advance Care Planning and Goals of Patient Care in residential aged care facilities.

This study is the first to introduce medical treatment orders in residential aged care facilities in Victoria providing original outcome measures of their effects.

6.6.2 Limitations

The sample size was six facilities which is a small number in terms of the residential aged care facilities in each Victorian health service. Interest in partaking in the study was limited to these six facilities. This may have led to selection bias as in those residential aged care facilities that had a greater interest in Advance Care Planning may have chosen to partake. As only six facilities took part it did not allow for full facility screening and matching of facilities that were similar in more than just their prior twelve month event rate for ED attendances and emergency admissions.

The study was un-blinded and this may have led to introduction of bias.

In the quantitative study the intervention was performed by the principal investigator, a geriatrician with a particular interest in Advance Care Planning and Goals of Patient Care, and not the Medical Practitioners for each patient, as would be expected for future Goals of Patient Care discussions. This may have impacted on the discussions and choices made by patients and families. Particularly the discussion of illness trajectory should be included in all Advance Care Planning discussions but this is not known to definitely occur. In the discussions on completion of the Goals of Patient Care form however, it took place every time. This may have led to changes in the choices on the Goals of Patient Care form. It may have also influenced decisions when activation of the form was proposed in times of clinical deterioration of patients. The possible effects that this had on the outcome, if any, remain unknown until further tested.

In the qualitative arm of the study the principal investigator led the focus groups and interviews. There may have been selection bias in that those healthcare workers who choose to participate may have had a particular interest in the topic of Advance Care Planning. Also the presence of

the principal investigator, known to most participants due to presence in the facility for the prior twelve months of the research study, may have influenced responses leading to response bias.

A further limitation to the qualitative study is that transcripts were not sent back to participants for comments or corrections, although the associate researchers present at the focus groups and interviews read the scripts also and found no errors.

6.7 Implications

6.7.1 Implications for clinical practice

As the Goals of Patient Care intervention did not result in decreased Emergency Department attendances and emergency admissions compared with control facilities at six months using advance care planning alone, findings from this study did not demonstrate its superiority.

The Goals of Patient Care intervention showed trends towards medical decisions being more congruent with patients' wishes and hence supports further larger studies to review its use with patients in residential aged care facilities.

What is not made clear from this study is whether completion of the Goals of Patient Care by the patient's Medical Practitioner would achieve the same outcomes as completion by a hospital Geriatrician. However, in Victoria, a common reason for referral to hospital Residential-In-Reach services is a request to undertake medical treatment planning discussions with the patient and their substitute medical decision maker. This is a process that replicates the Goals of Patient Care discussion and process, and use of the residential aged care facility Goals of Patient Care form would be recommended for documenting that discussion and medical treatment plan.

6.7.2 Implications for policy

The study identified significant deficiencies in health literacy in the area of Advance Care Planning and end-of-life care. On-going education should be provided to improve this.

With the new legislation giving Advance Care Plans the same authority as refusal of treatment orders education about the authority this Advance Care Plan holds is very important to consumers as well as health care staff.

Given the high prevalence of dementia and reduced medical decision making capacity of patients in residential aged care facilities it will be vital that provision is made for some form of future care planning for such patients. It would be expected that the use of medical treatment orders, such as the Goals of Patient Care, would help address this issue.

6.7.3 Implications for research

This small study has showed positive trends in terms of Goals of Patient Care medical treatment orders in Victorian residential aged care facilities, when used alone. Follow up with a larger study with the patients' Medical Practitioners providing the intervention would help confirm the outcomes found.

It was felt by healthcare staff that the culture of some European nations led to their lack of engagement both with advance care planning and end of life care. It had been shown in the United States of America that health literacy rather than race was the reason for this disengagement (117). It would be interesting to see if in fact it is the health literacy of these people, who in general had English as a second language, rather than their culture that leads to their medical treatment choices.

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Appendices

Appendix 1 Goals of Patient Care RACF Sample form

Residential Aged Care document

GOALS OF PATIENT CARE (MEDICAL)

For completion by Resident's doctor

Facility.....

Address.....

AFFIX PATIENT IDENTIFICATION LABEL HERE

U.R. NUMBER: _____

SURNAME: _____

GIVEN NAME: _____

DATE OF BIRTH: ____/____/____ SEX: _____

Main health problems: _____Advance Care Directive/Plan available for this resident / patient → ☐ Yes ☐ No ☐ ACP information provided

Name of Medical Enduring Power of Attorney (if appointed) _____

OR

Name of 'Person Responsible' (Legal Substitute decision-maker) _____

◆ Personal & Legal relationship to resident / patient _____

Contact phone numbers Home _____ Mobile _____

Choose ONE option from A, B, C or D --- Add further comments where required**GOAL A: FOR TREATMENT OF ALL REVERSIBLE ILLNESSES**☐ **FOR CPR and appropriate life-sustaining treatments**→ **FOR TRANSFER TO HOSPITAL**
(if required treatment cannot be provided in the facility)**GOAL B: FOR TREATMENT OF REVERSIBLE ILLNESS WITH FOLLOWING LIMITATIONS**☐ **NOT FOR CPR or INTUBATION**
- but is for other appropriate life-sustaining treatments→ **FOR TRANSFER TO HOSPITAL**
(if required treatment cannot be provided in the facility)**GOAL C: FOR TREATMENT OF REVERSIBLE ILLNESS ABLE TO BE MANAGED WITH SIMPLE, NON-BURDENSOME TREATMENT. GOOD SYMPTOM MANAGEMENT**
NOT FOR CPR or INTUBATION☐ - is for treatment of illness if this can be done without causing excessive distress. For hospital treatment if required.→ Aim to provide care in the facility but **TRANSFER TO HOSPITAL** if necessary

OR

☐ - is for trial of treatment at the facility, if this can be done without causing excessive distress. If deteriorates, is for comfort measures only.→ **NOT FOR TRANSFER TO HOSPITAL** if condition deteriorates - unless symptoms cannot be managed in facility eg fracture

OR

☐ - **NOT** for life-prolonging treatment of new illness / deterioration. All treatment is aimed at comfort and relieving symptoms.→ **NOT FOR TRANSFER TO HOSPITAL** unless symptoms cannot be managed in the facility eg fracture**GOAL D: COMFORT DURING DYING – TERMINAL CARE (prognosis is assessed to be hours or days)**☐ All treatment is aimed at relieving symptoms and supporting the resident / patient and their family / important others

→ Commence End-of-life Plan

→ **NOT FOR TRANSFER TO HOSPITAL** unless symptoms cannot be managed in the facility eg fracture pain**I have discussed above Goals of Care with** → ☐ Resident / Patient ☐ Medical EPOA or 'Person Responsible' (named above)

Others involved in discussion _____

Doctor's name (print): _____

Doctor's Designation: _____

Date: _____

Doctor's Signature: _____

CPR = Cardiopulmonary Resuscitation

ACP = Advance Care Plan / Directive



COMPLETING AND IMPLEMENTING THE GOALS OF PATIENT CARE SUMMARY

The Goals of Patient Care Summary should be completed by the General Practitioner.

It is important that any Advance Care Planning is translated into Medical Orders using this Goals of Patient Care form, so they can be followed by other clinical staff.

PHYSICIANS TO UPDATE FORM WHEN REVIEWING RESIDENT AT TIMES OF CLINICAL CHANGE

FOR ALL RESIDENTS / PATIENTS: identify and document:

- Appointment of a **Medical Enduring Power of Attorney** and/or other **Advance Care Planning** documents or requests.
- If no **Medical Enduring Power of Attorney** appointed, and the resident / patient has capacity, identify who they would wish to speak on their behalf if they became incapable of participating in medical decisions. The Resident needs to complete a **Medical Enduring Power of Attorney** if that person is not their '**Person Responsible**'.
- If the Resident is unable to nominate a substitute decision-maker, then identify the '**Person Responsible**' (see list below).

GOALS OF CARE ASSESSMENT: Clinical evaluation to determine 'Goals of Care' for this resident / patient:

■ **Management of potentially reversible illness (Goal A, B or C)**

A Treat with no treatment limitation

B Treat with some treatment limitation including not for CPR and not for intubation and ventilation

■ Limitations of medical treatment should be considered:

- if the treatment provides no potential benefit to resident / patient
- if treatment burdens far outweigh potential benefits
- if resident / patient has refused the treatment; their Medical EPOA has refused the treatment on their behalf; or if their Person Responsible states that the resident / patient would not have wanted that treatment.

C Treat with simple, non-burdensome treatment. Remember, that what is burdensome for one person may not be burdensome for another person.

- Some residents and their families will accept / request transfer to hospital if necessary for treatment
- Some residents and their families will accept treatment at the facility but decline transfer to hospital if the resident is not responding to this.
- Some residents and their families will choose comfort measures only.
- Consider if medications need to be prescribed and made available in case of potential symptoms

■ **Goal D requires diagnosis and management of dying. All treatment should be aimed at comfort and supportive measures only.** When the resident / patient is clearly dying it is important that the substitute decision-maker / family are aware of this.

- Prescribe medications that may be needed for symptoms – subcutaneous analgesic, anti-emetic, sedative and others as indicated clinically. Are regular medications required as well as PRN?

ENSURE COPIES OF THE GOALS OF PATIENT CARE SUMMARY AND THE ADVANCE CARE PLAN ACCOMPANY

THE RESIDENT IF THEY ARE TRANSFERRED TO HOSPITAL OR ARE ATTENDING A DOCTOR'S APPOINTMENT

PERSON RESPONSIBLE

Reference: [http://www.publicadvocate.vic.gov.au/file/Consent_flowchart2011\[1\].pdf](http://www.publicadvocate.vic.gov.au/file/Consent_flowchart2011[1].pdf)

When a patient is unable to consent to treatment, the practitioner can obtain consent from the Person Responsible in following order:

1. An agent - appointed with enduring power of attorney (medical treatment)
2. A person appointed by VCAT to make decisions about proposed treatment
3. A guardian - appointed by VCAT with health care powers
4. An enduring guardian - appointed with health care powers
5. A person appointed by the patient in writing to make medical & dental treatment decisions including proposed treatment
6. The spouse or domestic partner
7. The primary carer, including Centrelink paid carers but excluding all other paid carers
8. The patient's nearest relative over the age of 18: a. son or daughter, b. father or mother, c. brother or sister, d. grandfather or grandmother, e. grandson or granddaughter, f. uncle or aunt, g. nephew or niece.

(Where two relatives are in the same position, the elder will be the Person Responsible.)

Appendix 2 Secondary of Objective of the Cluster Randomised Controlled Trial

Background:

The secondary objectives of the study were to examine the effect of the Goals of Patient Care medical treatment orders on Emergency Department attendances and emergency admissions at further time-points and to expand the effects examined to total hospital bed-days and mortality outcomes. The mortality outcomes looked at overall mortality and more specifically at patients' place of death. All patients in this study said their preferred place of death was in the residential aged care facility or at home. No one had a preference for dying in the hospital.

Aims:

The secondary objectives were that the intervention would result in:

- A change in the rate of Emergency department attendances and emergency admissions at three and twelve months
- A change in total hospital bed days
- A change in in-residential aged care facility mortality rate
- A change in in-hospital mortality rate

Methods:

Statistical Methods

The model used for analysis of Emergency Department attendances and emergency admissions is explained in 3.3.10. The model used for the outcome of total hospital bed days was a zero-inflated negative binomial model. The negative binomial model is used to model count data, with the count data being the number of bed days over the three, six and twelve month periods. The negative binomial model provided a better fit to the data due to the over-dispersion or substantial skew, as some patients stayed in hospital for long periods. The zero-inflated extension to these models was also applied to account for the high proportion of patients not having any admissions and thus bed days.

With regards to the mortality outcomes, since the main hypothesis was to show that the Intervention group has a higher likelihood of in-residential aged care facility mortality rather than in-hospital mortality the analysis was structured so there are three outcomes for a patient at the six month and twelve month time-points: 1 - not deceased, 2 - deceased in residential aged care facility and 3 - deceased in hospital.

Due to this, the model structure was a multinomial logistic regression model with three potential outcomes, with cluster adjustment for the six residential aged care facilities. The reporting value was the relative risk ratio for these models. Relative risk, since the outcome was event-based, as has been used in prior mortality studies (130).

Results

The raw data for patient participation and event rates for Emergency Department attendances and emergency admissions at the three time-points, total hospital bed-days at the three time-points and mortality can be seen below in table 1.

Table 1 Results RACF prior ED event rates, study participant numbers, primary and secondary outcomes; separate facilities

	Control 1	Intervention 1	Control 2	Intervention 2	Control 3	Intervention 3
Prior 12 month ED event rate	1.23	1.1	0.75	0.63	1.4	1.27
RACF Participants						
Full Capacity	90	90	63	90	55	95
Total residents (T0)	90	68 (20TCP)	56	87	49	95
Participants (T0)	63	44	43	65	39	72
Participants (T+3/12)	60	36	39	61	35	68
Participants (T+6/12)	56	32	38	56	32	62
Participants (T+12/12)	48	27	30	44	27	53
ED attendances and admissions						
T+3/12 n(rate*)	12(0.2)	7 (0.19)	5 (0.13)	5 (0.08)	13 (0.38)	13 (0.19)
T+6/12 n(rate*)	29 (0.52)	17 (0.53)	10 (0.26)	14 (0.25)	22 (0.7)	23 (0.37)
T+12/12 n(rate*)	52 (1.08)	31 (1.15)	24 (0.8)	19 (0.43)	42 (1.56)	38 (0.72)
Total Hospital Bed Days						
T+3/12 n(rate*)	21 (0.35)	13 (0.36)	3 (0.08)	10 (0.16)	72 (2.11)	49 (0.7)
T+6/12 n(rate*)	48 (0.86)	25 (0.78)	23 (0.6)	74 (1.32)	108 (3.48)	77 (1.24)
T+12/12 n(rate*)	216 (4.5)	70 (2.59)	77 (2.57)	90 (2.05)	196 (7.25)	194 (3.66)
Mortality T12/12						
In RACF n(%)	11 (18)	12 (27)	13 (28)	18 (29)	5 (13)	18 (26)
In Hospital n (%)	1 (2)	1 (2)	0 (0)	1 (3)	6 (15)	0 (0)

Emergency Department Attendances and Emergency Admissions

The secondary outcomes included the rates of Emergency Department attendances and emergency admissions at three and twelve months. At three months the Incident Rate Ratio was 0.67, 95% CI: 0.39–1.17, $p=0.160$. At twelve months the Incident Rate Ratio was 0.62, 95% CI 0.39-0.99, $p=0.043$.

The Incident Rate Ratio of <1 , which was seen for all time-points in the results, suggests that the intervention has reduced the rate of admissions when compared to the Control group. Despite the Incident Rate Ratios all being <1.0 (between 0.62 and 0.74 for admissions), the only significant p -value is for twelve months admissions, Incident Rate Ratio 0.62, 95% CI 0.39-0.99,

p=0.043. Therefore at twelve months a statistically significant decrease in Emergency Department attendances and emergency admissions of 40% was achieved between Intervention and Control facilities.

Adjustment for clustering was included in the analysis. Without adjustment for cluster effect the result was still just significant at twelve months with Incident Rate Ratio 0.62, 95% CI: 0.44-0.86, p=0.004. Results are seen below in table 1, below.

Emergency Department attendances and emergency admissions were pooled for analysis. In total over the twelve months in the Control group there were 118 episodes of which 29 (25%) did not result in an overnight admission. In the Intervention group there were 88 episodes of which 16 (18%) did not result in an overnight admission. There was a statistical difference between the groups with Fisher's Exact test finding p=0.004. This indicates that more patients from the Control group presented to the Emergency Department for a review that did not result in an admission.

Table 2. Statistical results for Secondary Outcomes, ED attendances and emergency admissions, Total hospital bed-days and In-RACF and In-Hospital mortality

Outcome Variable	Time-point	IRR	95% CI	p-value
Admissions	3 months	0.67	0.39 - 1.17	0.160
	12 months	0.62	0.39 – 0.99	0.043
Total hospital bed-days	3 months	0.60	0.12 - 2.89	0.524
	6 months	0.85	0.34 - 2.09	0.717
	12 months	0.96	0.40 - 2.29	0.918
Outcome Variable	Time-point	RRR	95% CI	p-value
In RACF Mortality	6 months	2.21	1.23-3.98	0.008
	12 months	1.43	0.88-2.30	0.145
In Hospital Mortality	6 months	0.28	0.02- 4.84	0.382
	12 months	0.36	0.05-2.57	0.309

Total Hospital Bed-days

For each facility both in the control and intervention groups the total number of hospital bed-days was calculated three, six and twelve months post commencement of the study.

Participants alive and present in the facility at the end of each time-point were included in that time-point analysis. The admission diagnoses varied with a preponderance for infections and falls. It was not always confirmed unless a discharge summary was received and in the patients history. Information on the course of the hospital admission was not accessed.

The aim was for the intervention to result in a statistically significant decrease in total hospital bed-days between intervention and control groups. The total number of hospital bed days per facility and event rate for this is seen in table 1.

The Incident Rate Ratios was again used for the analysis as seen in table 2. This reflects the ratio in the incident rate of the total hospital bed-days. The Incident Rate Ratios of <1 , which is the case for all time-points in the results, suggests that the intervention had reduced the number of bed-days when compared to the control group. Despite the Incident Rate Ratios all being <1.0 , between 0.60 increasing to 0.96, there was no significant p-value. For length of stay at three months the Incident Rate Ratios was 0.6, 95% CI: 0.12–2.89, $p=0.524$. At six months the Incident Rate Ratios was 0.85, 95% CI 0.34–2.09, $p=0.717$. At twelve months the Incident Rate Ratios was 0.96, 95% CI: 0.4-2.29, $p=0.918$.

Adjustment for clustering was included in the analysis. Without adjustment for cluster effect the result was still statistically insignificant at all time-points.

In-RACF Mortality and In-Hospital Mortality

For each facility both in the Control and Intervention groups the In-RACF mortality and In-hospital mortality rates were calculated at two time-points six and twelve months post commencement of the study. The In-RACF mortality rate referred to the number of participants who died in the facility per total deaths per time period. The in-hospital mortality rate referred to the number of participants that died outside of their facility per total deaths per time period.

The information was obtained as described in 3.3.8 from a combination of facility recorded information and a full review of patients' facility notes. Participants that died in the two time frames were recorded along with their place of death, either in-RACF or in-hospital as seen in figure 1.

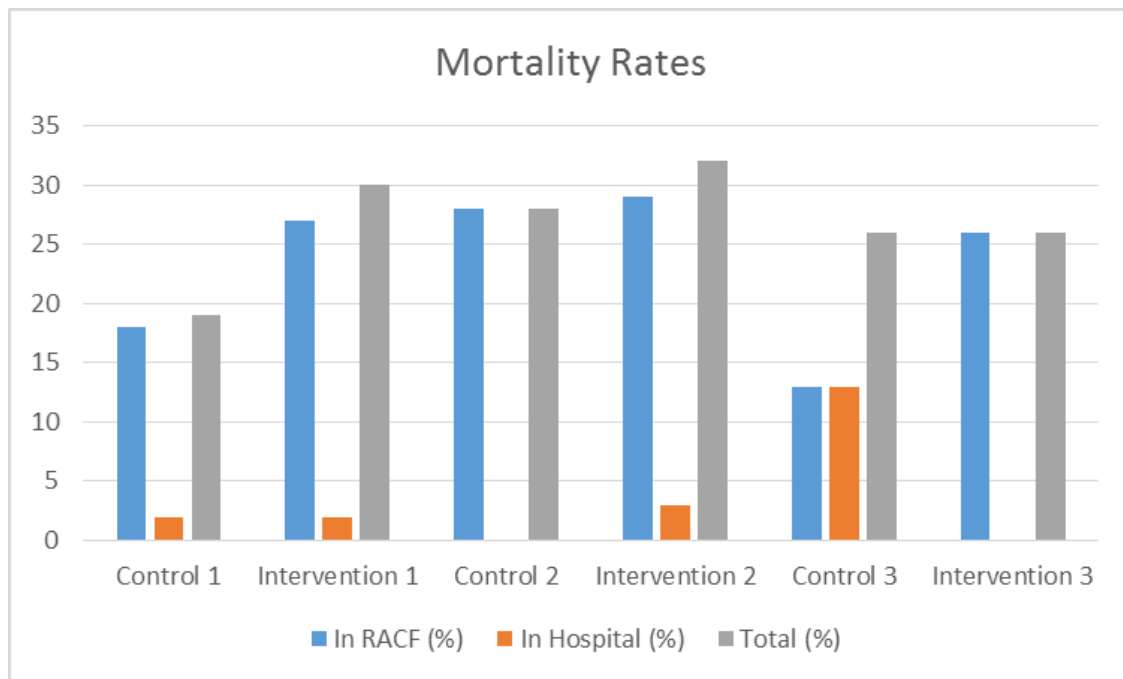


Figure 1 Mortality rates in individual facilities according to place of death

The hypothesis was that the Intervention group would have a higher likelihood of in-RACF mortality rather than in-hospital mortality. The analysis was structured for three outcomes at the two time-points, six months and twelve months: one-participants not deceased; two-deceased in-RACF; and three-deceased in-hospital. Based on this model that included cluster adjustment, there is a greater likelihood, Relative Risk Ratio 2.2, 95% confidence interval 1.23-3.98, $p=0.008$, that a participant would die in RACF when in the Intervention group when compared to the Control group at six months.

Similarly, there was a compensating reduction in the likelihood of a participant death in hospital in the Intervention group compared to the Control group, although the RRR of 0.28 was not statistically significant, $p=0.382$. At twelve months, the statistical significance is not present, however the Relative Risk Ratio maintain their trends, respectively for in-RACF and in hospital mortality. The statistical analysis outcomes are shown in table 2. Mortality between the two groups was not significantly different with 64/181 deaths in the Intervention Group and 36/145 deaths in the Control Group and analysis using Fisher's Exact test showing $p= 0.053$.

Discussion:

Goals of Patient Care effect on Emergency Department Attendances and Emergency Admissions

At three and six months the Goal of Patient Care Medical treatment orders did not result in a statistically significant change in Emergency Department attendances and emergency admissions. At twelve months, however, the Goals of Patient Care intervention did result in a statistically significant decrease in Emergency Department attendances and emergency admissions between Intervention and Control groups.

The grouped analysis showed the intervention achieved its 40% reduction in ED attendances and emergency admissions at twelve months and so the null hypothesis can be rejected and the intervention judged beneficial in terms of this outcome. A prior randomised controlled trial by Molloy et al, saw a 40% decrease in the same outcome at 18 months post study commencement. The six month time-point, used following advice from prior researchers in the area as they had previously found attrition rates in patients in aged care facilities favoured earlier outcomes. The attrition rate due to death or transfer was not exceedingly high in either the Intervention or Control groups in this study, 57 (31.5%) and 40 (27.6%) respectively. A twelve month primary outcome would have been better in this study.

Comparison of in-RACF mortality and in-hospital mortality showed that a participant would be more than twice as likely to die in their residential aged care facility when in the Intervention group, compared to the Control group, at six months. Similarly, there was a compensating reduction in the likelihood of a participant death in hospital in the Intervention group compared to the Control group, although not statistically significant. At twelve months, although the statistical differences were not maintained, the trends for, in-RACF and in-hospital mortality remained.

Control 3 was also the only facility where mortality rates in hospital was greater than those in the residential aged care facility, lack of senior nursing staff onsite, as alluded to in the main text of the thesis, 4.2.3, could have impacted on this outcome also.

Goals of Patient Care effect on Total Bed-Days

The effect of the Goals of Patient Care medical treatment orders on total bed days was a secondary outcome of the intervention. It has been shown in some prior studies that Advance Care Planning and medical treatment orders have resulted in decreased hospital bed days. In the pooled analysis there was a decrease in total bed days in intervention versus control groups at each time point in the analysis, three, six and twelve months but it did not reach statistical significance. In all facilities except one the rate of hospital bed days was low. Within the admission themselves the data was skewed with many short and some long participants' length of stays. The number of hospital attendances not resulting in admission was statistically equal in both groups.

Our intervention however was mainly aimed at preventing unnecessary and unwanted hospitalisation, to which it was effective. It was expected that by reducing hospital visits the total hospital bed days would be reduced also. The proportion of patients being admitted was statistically similar in both groups therefore it was factors beyond this that affected the length of stay per episode for each patient. It thus indicates that upon entering the hospital there are many factors affecting hospital bed days which the intervention could not affect including hospital factors, treating team factors as well as the presenting illness itself. Therefore it is likely it would require a more multi-faceted intervention including care on discharge if the admissions were to be shortened.

Goals of Patient Care effect on In-RACF and In-Hospital mortality

Another secondary outcome was that the Goals of Patient Care would result in more patients dying in their facility rather than in hospital. This has been shown with Advance Care Planning interventions. The analysis took place at two time points six and twelve months. The results showed that at six months the relative risk of In-RACF mortality was more than twice as likely in intervention versus control facilities. There was also a compensatory decrease in the likelihood of a participant dying in hospital in the intervention group. At twelve months although the trends persisted with increased likelihood of in residential aged care facility mortality and decreased in hospital mortality versus control they did not reach statistical significance. It is felt that

particularly our 30% of participants opting to avoid hospital transfer even if they were not improving from their illness would have a big effect on this in residential aged care facility and in hospital mortality rates. The evidence shows that patients with Advance Care Planning have a high incidence of dying in their preferred place of death, which was more often, in the residential aged care facility and this intervention shows similar effects.

Mortality outcomes-mixed quantitative and qualitative data

End of life care was one of the strongest themes in the qualitative study. Healthcare staff felt that the provision of end of life care in their facilities had improved leading to increased ability to look after their patients in this stage of life. Over the entire twelve month study in the cluster randomised controlled trial there were trends that patients in the Intervention group with the GOPC medical treatment orders were more likely to die in their residential aged care facility and less likely to die in hospital. At six months patients were twice as likely to die in their facility in intervention versus control. From the fact that 30% of patients opted to avoid hospital transfers even if not improving from their illness this was expected. However it was the insights from the qualitative study about end of life care in the facilities and the improved communication of patients' wishes with the Goals of Patient Care process that helped further explain the outcomes seen.

Conclusions:

Goals of Patient Care medical treatment orders were more effective than Advance Care Planning alone for decreasing hospital transfers at twelve months post implementation. The intervention also decreased the likelihood of dying outside the facility for patients.

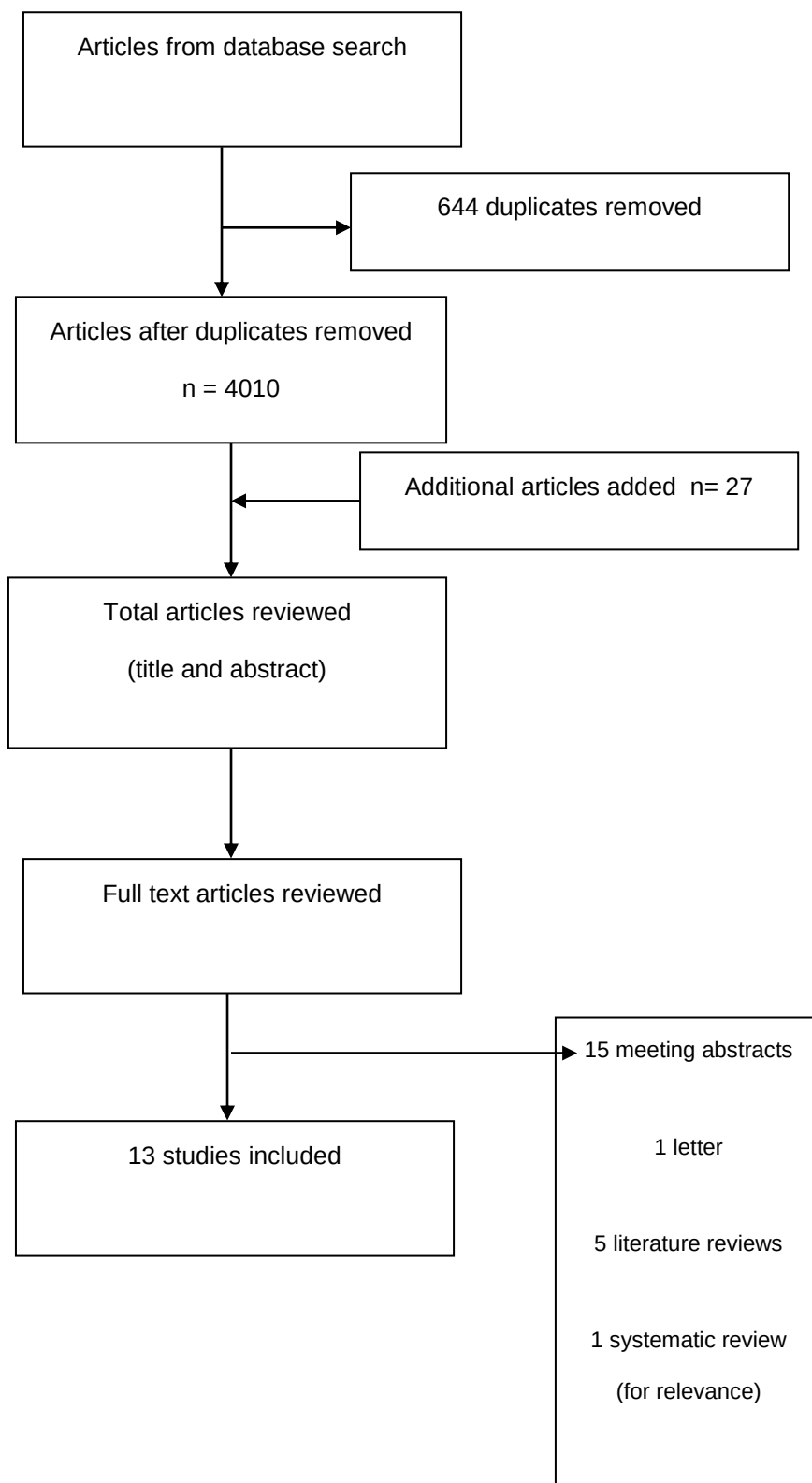
Goals of Patient Care was superior to Advance Care Planning alone for important wishes of patients, namely unwanted hospital transfers and being able to die in their home. Despite planning, end of life care in residential aged care facility is still limited by other factors including Locum and Agency staff not wanting to start the palliative pathway. End of life care was also impacted on by family members misunderstanding both the use of palliative medications and acknowledging their loved ones have entered the end of life phase.

Goals of Patient Care did not have a statistically significant effect on total hospital bed days but the intervention is not aimed at this. So many other factors interplay with this outcome that its result is not surprising.

These secondary outcomes do not take away from the fact that the primary outcome of the randomised controlled trial was not proven but they do highlight other positive results.

Further analysis with a larger study would help to prove the effectiveness of this intervention in the future.

Appendix 3 Strategy used to identify published studies on ACP suitable for our analysis



Appendix 4 GRADE criteria applied to systematic review included studies

Studies	Design	Limitations	Indirectness	Inconsistency	Imprecision	Publication Bias	Quality
Caplan 2006	Controlled trial	Minor	Little or no	Little or no	Little or no	No*	Moderate ⊕⊕⊕○
Hickman 2010	Controlled trial	Minor	Little or no	Little or no	Little or no	No*	Moderate ⊕⊕⊕○
Levy 2008	Pre-Post intervention	Minor	Little or no	Little or no	Little or no	No*	Low ⊕⊕○○
Molloy 2000	Randomised Controlled trial	Serious	Little or no	Little or no	Little or no	No*	High ⊕⊕⊕⊕
Morrison 2005	Controlled trial	Serious	Little or no	Little or no	Little or no	No*	Low ⊕⊕○○
Danis 1991	Prospective cohort	Serious	Little or no	Little or no	Little or no	No*	Low ⊕⊕○○
Zweig 2004	Prospective cohort	Serious	Little or no	Little or no	Little or no	No*	Low ⊕⊕○○
Tolle 1998	Prospective cohort	Very Serious	Little or no	Little or no	Little or no	No*	Very Low ⊕○○○
Mott 1988	Prospective cohort	Very Serious	Little or no	Little or no	Little or no	No*	Very Low ⊕○○○
Livingston 2013	Pre-Post intervention	Serious	Little or no	Little or no	Little or no	No*	Low ⊕⊕○○
Van Soest-Poortvliet 2015	Prospective cohort	Serious	Little or no	Little or no	Little or no	No*	Low ⊕⊕○○
Chan 2010	Controlled trial	Serious	Little or no	Little or no	Little or no	No*	Low ⊕⊕○○
Kelvin 2014	Controlled Trial	Serious	Little or no	Little or no	Little or no	No*	Low ⊕⊕○○

Appendix 5 A summary of the GRADE approach to the grading of quality of evidence for each

TABLE II. A summary of the GRADE approach to grading the quality of evidence for each outcome (see Online Repository 1 for details)

Source of body of evidence	Initial rating of quality of a body of evidence	Factors that may decrease the quality	Factors that may increase the quality	Final quality of a body of evidence
Randomized trials	High	1. Risk of bias 2. Inconsistency	1. Large effect 2. Dose-response	High (⊕⊕⊕⊕) Moderate (⊕⊕⊕○)
Observational studies	Low	3. Indirectness 4. Imprecision 5. Publication bias	3. All plausible residual confounding would reduce the demonstrated effect or would suggest a spurious effect if no effect was observed	Low (⊕⊕○○) Very low (⊕○○○)

Appendix 6 Results Table Systematic Review

Study Year	Population (NH residents)	Design	Country	Intervention	Outcomes	GRADE
Caplan et al 2006	45 residents for personal intervention Facility Intervention I: 1344 residents C: 523 residents	Controlled trial	Australia	Educational programme for residents, families, staff, and GPs Let Me Decide ACP and HITH in facilities surrounding two hospitals in a geographic area	Hospitalisation and costs 1. Decrease in hospitalization from the residential aged care facilities Year 1 22.7% decrease in admissions 2. Increase in hospitalization in control residential aged care facilities Year 1 by 4.2% (decrease not just due to HITH as reviews increased from just 31-37 in the year) 3. Rate of admissions higher year 1 at intervention hospitals 1.341 v 1.044 RR 1.07; 95% CI 1.03-1.11; P=0.0005, by year 3 the rate was lower at 0.865 v 1.254 RR 0.89; 95% CI 0.85-0.93; P<0.0001 4. Hospital bed use per NH bed similar in both areas at commencement 9.441 v 9.042; RR=1.01; 95% CI 0.98-1.04 p=0.442 whereas after 3 years rate was more than double in the control area 5.743 v 12.755 RR 0.74 CI 0.72-0.77 P<0.0001 5. Emergency calls to ambulance services- intervention v control -1 versus +21% p=0.0019 Place of death 1. Place of death 32 (71%) died, 100% in their preferred place specified Mortality 1. No significant change in mortality except for the third year when the rate rose in the control residential aged care facilities 30.4 v 41.6 per 100 beds; P=0.0425	Moderate ⊕⊕⊕○
Molloy et al 2000	I: 444 C: 374	Randomised Controlled trial	Canada	Educational ACP programme, Let Me Decide, included educating staff in local hospitals and residential aged care facilities, residents and families about advance directives Offering competent residents or next-of-kin an advance directive which offered choices for life-threatening illness, cardiac arrest and nutrition	Hospitalisation and costs 1. Lower risk of hospitalisation in intervention homes 0.27 v 0.48 mean per pt p=0.001 2. Lower mean no of hospital days in intervention group 2.61 v 5.86 p=0.01 3. Mean hospital cost for intervention homes was \$1772 v \$3869 p=0.003 4. Total healthcare cost for intervention group was \$3400 v \$5239 p=0.01 Mortality 1. Death rate similar between both groups 24% v 20% p=0.2 despite lower hospitalization in the intervention group	High ⊕⊕⊕⊕
Chan et al 2010	I: 59 C: 62	Controlled trial	Hong Kong	Educational ACP programme, Let me Talk, four themes life stories, illness narratives, life views and end of life care, 4 sessions 1hr/session	Quality of Life / Satisfaction 1. Statistically significant improvements in overall QOL p=0.034, physical discomfort p=0.017 and existential distress p=0.038	Low ⊕⊕○○
Morrison et al 2005	I: 49 C: 96	Controlled trial	USA	Educational ACP programme for residential aged care facility social workers randomised to intervention or control. Structured approach to completion and review of ACP with residents and other healthcare staff.	Actions consistent with wishes 1. 2/49 (5%) of intervention residents received a treatment in conflict with their prior stated wishes v 17/96 (18%) controls p=0.04 2. OR 5.06 re treatments being consistent with wishes 95% CI 1.12-22.87 (Houben 2014)	Low ⊕⊕○○
Livingston et al 2013	Pre: 63 Post: 49	Pre-Post intervention	UK	Educational programme on ACP and end of life care- 10 sessions for residential and senior care workers and general nurses	Place of death 1. Significant increase in residents with dementia dying in the care home from 47% to 76% Chi squared test = 5.3, p=0.02 Actions consistent with wishes 1. Where recorded (n=20) end of life care was consistent residents with dementias wishes 71% to 100% p=0.04	Low ⊕⊕○○
Van Soest-Poortvliet et al 2015	I: 148	Prospective cohort	The Netherlands	New ACP completion: Establishing "Goal of Care" with residents within 8 weeks after admission. Measuring outcome with End Of Life in Dementia –	Quality of life / Satisfaction 1. Significant interaction between LOS and baseline comfort goal for family satisfaction with care and quality of dying p=0.03	Low ⊕⊕○○

Study Year	Population (NH residents)	Design	Country	Intervention	Outcomes	GRADE
				Satisfaction With Care scale (EOLD-SWC)	2. Only significant for Families where residents were in NH <6 months	
Danis et al 1991	I: 175	Prospective cohort	USA	New ACP completion: Prospective interview of residents with documentation of their preferences with respect to hospitalization, intensive care, cardiopulmonary resuscitation, artificial ventilation, surgery and tube feeding in event of critical illness, terminal illness or permanent unconsciousness	Actions consistent with wishes 1. In 96 events- medical treatment was consistent with the directive in 75% of cases 2. 24/96 (25%) events were inconsistent with stated wishes 3. Consistency with patients wishes occurred less often when the AD was in the chart p=0.045 4. Consistency with patients wishes more often when the patient remained competent p=0.014 5. Consistency with patients wishes more likely when even occurred in hospital rather than the residential aged care facility 59/68 v 13/28 p=0.00003	Low ⊕⊕○○
Mott et al 1988	I: 110	Prospective cohort	USA	New ACP completion: Medical treatment orders form filled by practice physicians looking after the facility, four levels of care – Maximum Care (all), Intermediate Care (hospitalisation but to avoid surgery or intensive care if possible), Intermediate, less active care (avoid hospital but using antibiotics when indicated), Comfort care only (avoid hospitalization, antibiotics and IV fluids except for comfort)	Use of Life-sustaining treatments 1. Those in the less aggressive treatment groups Group 1 58 admissions per 1000 person months compared with 13 admissions per 1000 person months in group 4 p<0.001 2. 774 hospital bed days v 162 hospital bed days, p<0.001 (G1 v G4) Place of death 1. Deaths occurring in residential aged care facility, group 1 55% v group 4 85% p<0.0001	Very Low ⊕○○○
Tolle et al 1998	I: 180	Prospective cohort	USA	New ACP evaluation: Effect of Physician Orders for Life Sustaining Treatment form	Hospitalisation 1. Low rates of hospitalization 13% (n=24), 2/24 died in hospital 2. 15% of hospitalisations were to extend life contrary to POLST (n=4), 85% for comfort 3. Of 24 hospitalised 85% had DNR order, no one received CPR nor ICU Actions consistent with wishes 1. Los hospitalization rates, 85% of hospitalization for symptom control as POLST advised	Very Low ⊕○○○
Hickman et al 2010	I: 817 C: 894	Controlled trial	USA	New ACP evaluation: Effect of Physician Orders for Life Sustaining Treatment form	Use of life-sustaining treatments 1. CPR usage only 1 in POLST and 4 in non-POLST, too small to comment, tube feeding was similar- too little usage to analyse 25 POLST (3.4%), 62 non-POLST (6.9%) 2. No difference in use of medical interventions b/n residents with DNR orders and traditional full code orders OR 1.4, 95% CI 0.91-2.14, P=0.12 3. POLST had no effect on use of antibiotics regardless of whether choices specifies 4. POLST forms for comfort measures only were significantly less likely to receive life-sustaining medical treatment than those with POLST full tx, DNR and For resuscitation orders Palliative Care and Hospice 1. No difference in symptom assessment or management on logistic regression for those with and without POLST forms	Moderate ⊕⊕⊕○
Levy et al 2008	I: 45 C: 27	Pre-Post intervention	USA	Making Advance Care Planning a Priority- a program designed to 1) identify residents at high risk of death , 2) inform the attending physician of the resident's mortality risk 3) obtain palliative care or hospice consultation 4) improve advance care planning documentation	Hospitalisation 1. No change in Length of Stay LOS in those hospitalized 5.17 v 3.33 post p=0.42 Place of death 1. Fewer residents died in hospital post intervention 48.2% pre and 8.9% post p<0.0001 2. Significance persists when covariates taken into consideration in regression Palliative Care / Hospice 1. Mean no of days in palliative care programs in the pre-implementation was 1 day, this increased to 13.8 +/-25.9 days p=0.09	Low ⊕⊕○○

Study Year	Population (NH residents)	Design	Country	Intervention	Outcomes	GRADE
					2. No change in percentage of residents referred to hospice but pall care referral increased by 23.7% p=0.02 3. Mean LOS in hospice didn't differ significantly 24.3 v 32.7 days post implementation	
Zweig et al	I: 1031 residents C: 3000 residents (approx)	Prospective cohort	USA	Observational study to determine the effect of DNR orders on the treatment of residential aged care facility residents with Lower Respiratory Infection	Hospitalisation 1. Less likely to be hospitalized with DNR order 23% v 32% without p <0.003 2. Even with other characteristics which make you more likely to be hospitalised	Low ⊕⊕○○
Kelvin et al 2014	145 residents	Case control study	Singapore	Project CARE was introduced in seven residential aged care facilities to provide advance care planning and palliative care for residents identified to be at risk of dying within 1 year	Health care costs 1. Per-resident cost savings of SGD\$7129 (confidence interval: SGD\$4544–SGD\$9714) over the last 3 months of life and SGD\$3703 (confidence interval: SGD\$1848–SGD\$5557) over the last month of life (US\$1 = SGD\$1.3).	Low ⊕⊕○○

Appendix 7 Email invitation to RACF managers

 Goals of Patient Care	AFFIX PATIENT IDENTIFICATION LABEL HERE ID NUMBER
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Dear,

We would like to invite your aged care facility to take part in a Northern Health project that is specifically looking at residential aged care facilities in the northern region of metropolitan Melbourne.

We are hoping to introduce our Goals of Patient Care form, which is a medical treatment order filled out by doctors, to try and improve healthcare decisions made by staff on behalf of their residents.

The form, based on their advance care plan or wishes, serves to improve communication and help guide healthcare decisions in times when residents become clinically unwell.

We wish to support and enhance the innovations, such as the palliative approach toolkit, that are already in place.

We feel this will benefit not just the facility residents and staff, but the organisation as a whole. From a quality perspective we want to engage a sustainable change that works within your current systems. We will be engaging with facility staff, your residents or their representatives, and your visiting GPs (both regular and locum).

If you would like to take part please reply to this email and our principal investigator, Dr Ruth Martin, will come and meet your team, at your convenience, with our protocol to discuss further. We would then approach all residents and their families individually for their permission to take part in the project.

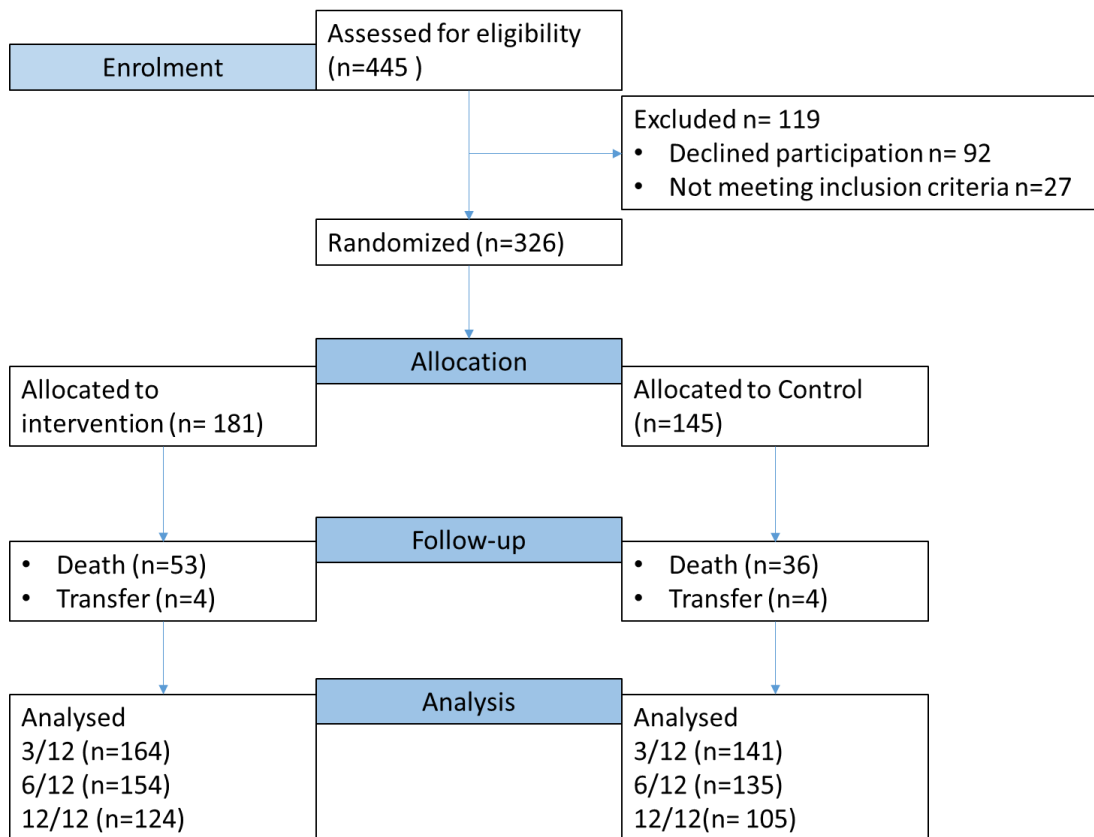
If you have any questions or queries, please don't hesitate to contact me.

Email: ruth.martin@nh.org.au or phone (03)84052463

Kind regards,

Dr Ruth Martin, Dr Barbara Hayes, Prof Anastasia Hutchinson, Dr Paul Yates and Prof Kwang Lim "Goals of Patient Care" Implementation Team

Appendix 8 CONSORT participant flow diagram



Appendix 9 PICF Manager

PARTICIPANT INFORMATION & CONSENT FORM (PICF)

Project Name: Implementation of “Goals of Patient Care” medical treatment orders in residential aged care facilities

NH HREC No:

Principal Investigator: Dr Ruth Martin, Advanced Trainee in Aged Care Medicine

Participant’s Involvement in project –

Start Date: 01/05/2015

Finish Date: 01/10/2016

Participant Information:

The residential aged care facility “Goals of Patient Care” form is a medical treatment order incorporating prior Advance Care Planning and wishes. It is based on a medical assessment of each individual. The form serves as a communication tool about the individual's healthcare decisions for staff in the aged care facility, visiting doctors (regular or locum GPs), ambulance staff and Emergency Department staff. The form helps guide these decisions made on behalf of the resident in both planned and emergency situations. The form is filled in by a doctor in discussion with the resident, or substitute medical decision maker. We are trialling the form in pairs of aged care facilities, with one facility using the form and its pair not using it. This way we can examine its effect.

Part 1 What does my participation involve?

1 Introduction : RACF manager

You are invited, on behalf of you residential aged care facility (RACF), to take part in this research project. We are conducting a research project to improve the care of residents in RACFs. The research project is testing a new medical treatment order form. This is called a "Goals of Patient Care" form.

This Participant Information Sheet and Consent Form tell you about the research project. It explains the intervention involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with your visiting GPs.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to taking part in the research project
- Consent to your residents and staff having the tests and interventions that are described
- Consent to the use of the facilities' health information as described.

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

2 What is the purpose of this research?

Our project is looking at the effect of the Goals of Patient Care medical treatment order on the hospital usage of residents in aged care facilities. We feel that the introduction of this form, which indicates the treatment preferences of residents, will lead to healthcare decisions being more in line with the wants and needs of residents. As a result of this we feel that it will be easier for healthcare staff to make healthcare decisions about the residents especially in times of acute deterioration.

Currently there are no medical treatment orders in use in Victorian aged care facilities and we feel by investigating the effect of this type of form we will contribute to the care provided in aged care facilities. These types of forms have been thoroughly researched and are in place in other countries and have been well received.

We hope to bring this form to Northern Health and make it available to other facilities to help guide healthcare decisions made on behalf of residents in our catchment. The results of this research will be used by the study doctor, Dr Ruth Martin, to complete a research doctorate (MD) degree.

A research grant has been applied for from the Northern Health small research grant fund.

3 What does participation in this research involve?

The type of project the participants will be involved with is called a cluster randomised controlled research project. Sometimes we do not know which treatment is best for participants. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each facility is put into a group by chance (random). The chance of receiving the investigational form is 1 in 2.

Consent forms will be signed prior to any study assessments being performed. The commitment required by the RACFs involved will be; to allow the research team approach residents or their substitute medical-decision makers and healthcare staff individually for written informed consent to take part in the study and to allow the research team access to facility medical records.

The Manager or delegate of the Facility must ensure that residents who are participating have a signed consent form. A copy of each signed consent form will be provided to the Manager by the research team.

We will gather information about all participants' characteristics including age, sex, English speaking status, medical problems, medications, prior 12 month hospital attendance, presence of Advance Care Plan, use of palliative care.

We will conduct a short memory test with all participants. We will fill out the Goals of Patient Care form with all residents in the participating facilities randomised to the Goals of Patient Care intervention or with their substitute medical decision-maker. We will calculate a measure of participants' independence with daily activities with the staff looking after them. We will follow up the participants' hospital usage for 12 months.

We will approach healthcare workers for written informed consent to take part in 1-2 surveys and either a focus group or brief interview.

The research will be monitored at 3-monthly intervals. All issues between these times will be communicated from the facility/or participant/ or substitute medical-decision maker directly by phone or email to Dr. Ruth Martin.

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

There are no additional costs associated with participating in this research project, nor will you or the participant be paid. All tests and medical care required as part of the research project will be provided to the participant free of charge.

If you decide to take part in this research project, the study doctor will inform your visiting Medical Practitioner s (GPs).

4 What do I have to do?

The participant and their substitute medical-decision maker will have to:

1. Permit the research team to approach staff and residents for informed consent
2. Allow staff to take part in focus group or interview on Advance Care Planning and the Goals of Patient Care form (if they are in a intervention facility)
3. Permit access to healthcare records of all consenting participants 12 months pre and post the commencement of the study

5 Other relevant information about the research project

Overall we will be conducting the study in 6 residential aged care facilities in Northern Health catchment area. Three facilities will use the form and three will not use the form. There are five researchers involved in the project, all working within the departments of Aged Care and Advance Care Planning.

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

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project upon notification of the research team, the participants and the substitute medical decision-makers.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether you take part or not take part, or take part and then be withdrawn, will not affect your relationship with Northern Health.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that participants will receive any benefits from this research; however, possible benefits include the introduction of medical treatment orders which help facilitate healthcare decision making for residents especially in times of acute deterioration. We also hypothesise that it will help guide healthcare decisions when the resident is being reviewed by a healthcare worker who doesn't know them well.

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

The main risk that we foresee is that the form may not reflect participants' wishes fully and healthcare decisions made about them that are not be in keeping with their preferences.

A disadvantage is that some time will be required from staff members in completion of the surveys, focus groups or interviews for the surveys 5-10 minutes, the interview 10-15 minutes, and the focus group 20-30 minutes.

What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team and the participants and their substitute medical-decision makers. We will stop recruitment and not gather any further information from the facility.

11 What happens when the research project ends?

When the research project ends the results will be analysed to see the effect the Goals of Patient Care form has had on residents and healthcare workers. If it is found to be successful it will be offered for continuation in the facilities it is in and GPs in the other facilities will be given education about its use and access to it for residents. If it is not deemed beneficial, it will be withdrawn and facilities will continue with Advance Care Planning already in place or can be referred to the Advance Care Planning department in Northern Health for further ACP advice.

The results from the study will be made available to every facility involved following completion of the project, by October 2016. Healthcare workers, residents and substitute medical-decision

makers will have access to these results from their facility. A copy of all publications from the study will be made available to each facility also.

Part 2 How is the research project being conducted?

12 What will happen to information about the participant?

By signing the consent form you consent to Dr Ruth Martin, an advanced trainee in Aged Care Medicine and relevant research staff collecting and using personal information about your residents and healthcare staff for the research project following their individual consent. Any information obtained in connection with this research project that can identify them or the facility will remain confidential. It will be kept on computer file with password to access it. Paper

documentation will be kept in a locked cabinet within an office locked when unattended in Northern Health. Only the five team members will be able to access the information at any time.

The data will be stored in this format for the duration of the study and for 7 years post. At this stage it will be securely destroyed. The participant's information will only be used for the purpose of this research project and it will only be disclosed with their permission, except as required by law.

Information about your residents may be obtained from their health records held at this and other health services for the purpose of this research. By signing the consent form they agree to the study team accessing their health records if they are relevant to participation in this research project

It is anticipated that the results of this research project will be published in academic journals and presented at conferences and medical meetings. In any publication and/or presentation, information will be provided in such a way that neither the facility nor the participant can be identified, without their permission. The information will be grouped and not individualised for this process.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional information from your facility, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the team up to the time you withdraw will form part of the research project results.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the study team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify the participant will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

13 Complaints

If you suffer any problems as a result of this research project, you should contact the study team or your GP as soon as possible and you will be assisted.

14 Who is organising and funding the research?

This research project is being conducted by Dr Ruth Martin on behalf of Northern Health

15 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the Human Research Ethics Committee, Northern Health Ph: (03) 8405 2918 or ethics@nh.org.au.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

16 Further information and who to contact in case of adverse events

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project, you can contact the principal study doctor on (03) 8405 2463 or ruth.martin@nh.org.au. In the case of any serious adverse events you can contact Dr Penelope Harvey an external advisor on the project at Penelope.Harvey@nh.org.au or 0407535629. If you have any concerns or complaints regarding the way the research is or has been conducted, you can contact the Ethics Officer, Human Research Ethics Committee, Northern Health Ph: (03) 8405 2918 or ethics@nh.org.au.

Consent Form – RACF Manager providing own consent

Title	Implementation of “Goals of Patient Care” medical treatment orders in residential aged care facilities.
Protocol Number	[Protocol Number]
Project Sponsor	Northern Health Small Research Grant
Coordinating Principal Investigator	Dr Ruth Martin
Associate Investigator(s)	Professor Kwang Lim, Professor Anastasia Hutchinson, Dr Paul Yates and Dr Barbara Hayes
Location	Northern Health

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

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

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

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

Name of Facility and Manager (please print)	_____
Signature _____	Date _____

Name of Witness* to Participant's Signature (please print)	_____
Signature _____	Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†

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

Name of Study Doctor/
Senior Researcher[†] (please print)

Signature _____ Date _____

[†] A senior member of the research team must provide the explanation of, and information concerning, the research project.

Form for Withdrawal of Participation – RACF Manager providing own consent

Title	Implementation of “Goals of Patient Care” medical treatment orders in residential aged care facilities.
Protocol Number	[Protocol Number]
Project Sponsor	Northern Health Small Research Grant (applied for)
Coordinating Principal Investigator	Dr Ruth Martin
Associate Investigator(s)	Professor Kwang Lim, Professor Anastasia Hutchinson, Dr Paul Yates and Dr Barbara Hayes
Location	Northern Health

Declaration by Participant

I wish to withdraw my facility from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Northern Health

Name of Participant (please print) _____	
Signature _____	Date _____

Description of Circumstances

Declaration by Study Doctor/Senior Researcher[†]

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/ Senior Researcher [†] (please print) _____	
Signature _____	Date _____

[†] A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date

Appendix 10 PICF Resident

PARTICIPANT INFORMATION & CONSENT FORM (PICF)

Project Name: Implementation of “Goals of Patient Care” medical treatment orders in residential aged care facilities

NH HREC No:

Principal Investigator: Dr Ruth Martin, Advanced Trainee in Geriatric Medicine

Participant’s Involvement in project –

Start Date: 01/05/2015

Finish Date: 01/10/2016

Participant Information:

The residential aged care facility “Goals of Patient Care” form is a medical treatment order incorporating prior Advance Care Planning and wishes. It is based on a medical assessment of each individual. The form serves as a communication tool about the individual's healthcare decisions for staff in the aged care facility, visiting doctors (regular or locum GPs), ambulance staff and Emergency Department staff. The form helps guide these decisions made on behalf of the resident in both planned and emergency situations. The form is filled in by a doctor in discussion with the resident, or substitute medical decision maker. We are trialling the form in pairs of aged care facilities, with one facility using the form and its pair not using it. This way we can examine its effect.

Part 1 What does my participation involve?

1 Introduction : Resident

You are invited to take part in this research project. This is because you are a resident in an aged care facility that has agreed to take part in the project. This research is testing a new medical treatment order form, called a "Goals of Patient Care" form.

This Participant Information Sheet and Consent Form tell you about the research project. It explains the intervention involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not you can take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to taking part in the research project
- Consent to having the tests and interventions that are described
- Consent to the use of your personal and health information as described.

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

2 What is the purpose of this research?

Our project is looking at the effect of the Goals of Patient Care medical treatment order on the hospital use of residents' aged care facilities. We feel that the introduction of this form, which indicates the treatment preferences of residents, will lead to healthcare decisions being more in line with the wants and needs of residents. As a result of this we feel that the number of unhelpful transfer of residents' to hospitals will decrease.

Currently there are no medical treatment orders in use in Victorian residential aged care facilities and we feel by investigating the effect of this type of form we will contribute to the care provided in aged care facilities. These types of forms have been thoroughly researched and are in place in other countries and have been well received.

We hope to bring this form to Northern Health and make it available to other facilities to help guide healthcare decisions made on behalf of residents in our catchment. The results of this research will be used by the study doctor, Dr Ruth Martin, to complete a research doctorate (MD) degree.

A research grant has been applied for from the Northern Health small research grant fund.

3 What does participation in this research involve?

Consent forms will be signed prior to any study assessments being performed by Dr Ruth Martin. All residents that can sign the consent form, or for whom the consent form can be signed by their substitute medical-decision maker will be invited to participate.

For each pair of facilities, the participants in one facility will have the Goals of Patient Care form completed while participants in the paired facility will not fill the form. We will examine the effect

the form has on participants' use of hospital care. We will compare this with participants in the paired residential aged care facilities where the form is not available.

We will gather information about your characteristics including age, sex, English speaking status, medical problems, medications, prior 12 month hospital attendance, presence of Advance Care Plan, use of palliative care.

We will conduct a short memory test and depression screen with you.

If you are in the intervention facility (using the form) we will fill out the Goals of Patient Care form with you or with your substitute medical decision-maker.

We will calculate a measure of your independence with daily activities with the staff looking after you.

We will follow up your hospital use for 12 months.

The research will be monitored at 3-monthly intervals. All issues between these times will be communicated from the facility/or participant/ or substitute medical-decision maker directly by phone or email to Dr. Ruth Martin.

The commitment required by you or your substitute medical decision maker is to provide consent to take part in a memory test, to fill the Goals of Patient Care form if in an intervention facility, and to allow Dr Martin and her team access to your facility and local healthcare records for 12 months before and after the study commences.

This type of project is called a cluster randomised controlled research project. Sometimes we do not know which treatment is best for patients. To find out we need to compare different treatments.

We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each facility is put into a group by chance (random). The chance of receiving the investigational form is 1 in 2.

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

There are no additional costs associated with participating in this research project, nor will you or the participant be paid. All tests and medical care required as part of the research project will be provided to the participant free of charge.

If you decide to take part in this research project, the study doctor will inform your local doctor.

4 What do I have to do?

You will have to:

1. Take part in a brief memory test and depression screen
2. Take part in a discussion about your health and what is important to you regarding your health, so that Dr Ruth Martin can complete a Goals of Patient Care form with you. It would be good if your substitute medical decision maker is able to be part of the discussion
3. Allow Dr Martin and her team access to your facility and local hospital records for 12 months before and after the study commences.
4. Complete a brief follow-up survey
5. Allow staff to take part in a focus group during which the participant's personal information may be discussed in order to understand better the use of the Goals of

Patient Care form better – outside of the group this information will then be made anonymous so the participant cannot be identified.

5 Other relevant information about the research project

Overall we will be conducting the study in 6 residential aged care facilities in Northern Health. Three facilities will use the form and three will not use the form. There are five researchers involved in the project, all working within the departments of Aged Care and Advance Care Planning.

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

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether you take part or not take part, or take part and then be withdrawn, will not affect your routine treatment, your relationship with those treating them, or the your relationship with Northern Health.

7 What are the alternatives to participation?

You do not have to take part in this research project to have your healthcare preferences known. Other options are available; these include advance care planning which can be helpful in guiding healthcare decisions. Your study doctor will discuss these options with you before you decide whether or not you can take part in this research project. You can also discuss the options with your local doctor.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits include your healthcare decisions being more in keeping with your wishes and more appropriate for your care.

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

The main risk that we foresee is that the form may not reflect your wishes fully and healthcare decisions made about you may not be in keeping with your preferences.

There may be problems that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any such problems.

If this research uncovers a medical condition of which you were unaware we will inform you and your GP. This should not affect your participation in the research project.

10 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team and your information will be excluded and destroyed.

11 What happens when the research project ends?

When the research project ends the results will be analysed to see the effect the Goals of Patient Care form has had on participants using it. If it is found to be successful it will be offered for continuation in the facilities it is in and GPs in the other facilities will be given education

about its use and access to it for all residents. If it is not deemed beneficial, it will be withdrawn and facilities will continue with Advance Care Planning already in place or can be referred to the Advance Care Planning department in Northern Health for advance care planning advice.

The results from the study will be made available to every facility following completion of the project, by October 2016. Residents and substitute medical-decision makers will have access to these results from their facility. A copy of all publications from the study will be made available to each facility also.

Part 2 How is the research project being conducted?

12 What will happen to information about the participant?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. It will be kept on

computer file with a password to access it until the study is over. It will then be grouped and stored in an anonymous format. Paper documentation will be kept in a locked cabinet within an office in Northern Health, which is locked when unattended. Only the five team members will be able to access the information at any time. The data will be stored in this format for the duration of the study and for 7 years post. At this stage it will be securely destroyed.

Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to participation in this research project. The original copy of your Goals of Patient Care form will be placed in your health record at the facility so that it can be used in your medical care. Your GP will also be informed of its presence for their review.

It is anticipated that the results of this research project will be published in medical journals and presented at conferences. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. The information will be grouped and not individualised for this process.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the study team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify the participant will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

13 Complaints

If you have any problems as a result of this research project, you should contact the study team or your GP as soon as possible and you will be assisted.

14 Who is organising and funding the research?

This research project is being organised by Dr Ruth Martin on behalf of Northern Health

15 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the Human Research Ethics Committee, Northern Health Ph: (03) 8405 2918 or ethics@nh.org.au.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

16 Further information and who to contact in case of adverse events

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project, you can contact the principal study doctor on (03) 8405 2463 or ruth.martin@nh.org.au. In the case of any serious adverse events you can contact Dr Penelope Harvey an external advisor on the project at Penelope.Harvey@nh.org.au or 0407535629. If you have any concerns or complaints regarding the way the research is or has been conducted, you can contact the Ethics Officer, Human Research Ethics Committee, Northern Health Ph: (03) 8405 2918 or ethics@nh.org.au.

Consent Form - Adult providing own consent

Title	Implementation of "Goals of Patient Care" medical treatment orders in residential aged care facilities.
Protocol Number	[Protocol Number]
Project Sponsor	Northern Health Small Research Grant
Coordinating Principal Investigator	Dr Ruth Martin
Associate Investigator(s)	Professor Kwang Lim, Professor Anastasia Hutchinson and Dr Barbara Hayes
Location	Northern Health

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, and local hospitals to release information to Northern Health concerning my medical records for the purposes of this project. I understand that such information will remain confidential.

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

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

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

Name of Participant (please print)	_____
Signature _____	Date _____

Name of Witness* to Participant's Signature (please print)	_____
Signature _____	Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher[†]

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

Name of Study Doctor/ Senior Researcher [†] (please print) _____	
Signature _____	Date _____

[†] A senior member of the research team must provide the explanation of, and information concerning, the research project.

Form for Withdrawal of Participation - Adult providing own consent

Title	Implementation of "Goals of Patient Care" medical treatment orders in residential aged care facilities.
Protocol Number	[Protocol Number]
Project Sponsor	Northern Health Small Research Grant
Coordinating Principal Investigator	Dr Ruth Martin
Associate Investigator(s)	Professor Kwang Lim, Professor Anastasia Hutchinson and Dr Barbara Hayes
Location	Northern Health

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Northern Health

Name of Participant (please print) _____	
Signature _____	Date _____

Description of Circumstances

Declaration by Study Doctor/Senior Researcher[†]

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/ Senior Researcher [†] (please print) _____	
Signature _____	Date _____

[†] A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature

Appendix 11 PICF Substitute Decision Maker

PARTICIPANT INFORMATION & CONSENT FORM (PICF)

Project Name: Implementation of “Goals of Patient Care” medical treatment orders in residential aged care facilities

NH HREC No:

Principal Investigator: Dr Ruth Martin, Advanced Trainee in Aged Care Medicine

Participant’s Involvement in project –

Start Date: 01/05/2015

Finish Date: 01/10/2016

Participant Information:

The residential aged care facility “Goals of Patient Care” form is a medical treatment order incorporating prior Advance Care Planning and wishes. It is based on a medical assessment of each individual. The form serves as a communication tool about the individual's healthcare decisions for staff in the aged care facility, visiting doctors (regular or locum GPs), ambulance staff and Emergency Department staff. The form helps guide these decisions

Part 1 What does participation involve?

1 Introduction : Substitute Medical Decision-Maker / Person Responsible

The resident is invited to take part in this research project as they are a resident in an aged care facility electing to take part. The research project is testing a new medical treatment order form called a “Goals of Patient Care” form.

This Participant Information Sheet and Consent Form tell you about the research project. It explains the intervention involved. Knowing what is involved will help you decide if you want the resident to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not the resident can take part, you might want to talk about it with a relative, friend or the resident's local doctor.

Participation in this research is voluntary. If you don't wish the resident to take part, they don't have to. They will receive the best possible care whether or not they take part.

If you decide you want the resident to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read

- Consent to the resident taking part in the research project
- Consent to the resident having the tests and treatment orders that are described
- Consent to the use of the resident's personal and health information as described.

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

2 What is the purpose of this research?

Our project is looking at the effect of the Goals of Patient Care medical treatment order on the hospital use of residents from aged care facilities. We feel that the introduction of this form, which indicates the treatment preferences of residents, will lead to healthcare decisions being more in line with the wants and needs of residents. As a result of this we feel that the number of unhelpful transfer of residents' to hospitals will decrease.

Currently there are no medical treatment orders in use in Victorian residential aged care facilities and we feel by investigating the effect of this type of form we will contribute to the care provided in aged care facilities. These types of forms have been thoroughly researched and are in place in other countries and have been well received.

We hope to bring this form to Northern Health and make it available to other facilities to help guide healthcare decisions made on behalf of residents in our catchment. The results of this research will be used by the study doctor, Dr Ruth Martin, to complete a research doctorate (MD) degree.

A research grant has been applied for from the Northern Health small research grant fund

3 What does participation in this research involve?

Consent forms will be signed prior to any study assessments being performed. All residents that can sign the consent form will sign for themselves. When a resident lacks the ability to provide consent we will invite the substitute medical decision-maker (Person Responsible) to consent for them to participate.

For each pair of facilities, the participants in one facility will have the Goals of Patient Care form completed while participants in the paired facility will not fill the form. We will examine the effect the form has on participants' use of hospital care. We will compare this with participants in the paired residential aged care facilities where the form is not in use.

We will gather information about all participants' characteristics including age, sex, English speaking status, medical problems, medications, prior 12 month hospital attendance, presence of Advance Care Plan, use of palliative care.

We will conduct a short memory test and depression screen with all participants.

If in the intervention facility (using the form), we will complete the Goals of Patient Care form with the participant and their substitute medical decision-maker, if in a control facility (not using the form) we will not complete the form.

We will calculate a measure of participants' independence with daily activities with the staff looking after them.

We will follow up the participants' hospital usage for 12 months.

The research will be monitored at 3-monthly intervals. All issues between these times will be communicated from the facility/or resident/ or substitute medical decision-maker directly by phone or email to Dr Ruth Martin.

The commitment required by the participant and substitute medical decision-maker is to provide consent for residents to partake in a memory screen, to fill the Goals of Patient Care form, depending on facility, and to allow Dr Martin and her team access to their facility and local healthcare records for 12 months before and after the study commences.

This type of project is called a cluster randomised controlled research project. Sometimes we do not know which treatment is best for patients. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each facility is put into a group by chance (random). The chance of receiving the investigational form is 1 in 2.

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

There are no additional costs associated with participating in this research project, nor will you or the participant be paid. All tests and medical care required as part of the research project will be provided to the participant free of charge.

If you decide that the resident can take part in this research project, the study doctor will inform their local doctor.

4 What does the participant have to do?

The participant will have to

1. Take part in a brief memory test and depression screen
2. If in an intervention facility: With their substitute medical decision-maker, take part in a discussion about the participant's health and what is important to them regarding their health, so that Dr Ruth Martin can complete a Goals of Patient Care form
3. Allow Dr Martin and her team access to their facility and local healthcare records for 12 months before and after the study commences.
4. If in an intervention facility the substitute medical decision-maker will be asked to complete a brief survey on behalf of the participant
5. Allow staff to take part in a focus group during which the participant's personal information may be discussed in order to understand better the use of the Goals of Patient Care form better – outside of the group this information will then be made anonymous so the participant cannot be identified.

5 Other relevant information about the research project

Overall we will be conducting the study in 6 residential aged care facilities in Northern Health. Three facilities will use the form and three will not use the form. There are five researchers involved in the project, all working within the departments of Aged Care and Advance Care Planning.

6 Does the participant have to take part in this research project?

Participation in any research project is voluntary. If you do not wish the resident to take part, the resident does not have to. If you decide that the resident can take part and later change your mind, you are free to withdraw the resident from the project at any stage.

If you do decide that the resident can take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether the resident can take part or not take part, or take part and then be withdrawn, will not affect the participant's routine treatment, your or the resident's relationship with those treating them, or the resident's relationship with Northern Health

7 What are the alternatives to participation?

The resident does not have to take part in this research project to have their healthcare preferences known. Other options are available; these include advance care planning which can be helpful in guiding healthcare decisions. The resident's study doctor will discuss these options with you before you decide whether or not the resident can take part in this research project. You can also discuss the options with the resident's local doctor.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that the resident will receive any benefits from this research; however, possible benefits include their healthcare decisions being more in keeping with their wishes and more appropriate for their care.

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

The main risk that we foresee is that the form may not reflect the residents' wishes fully and healthcare decisions made about them may not be in keeping with their preferences. There may be problems that the researchers do not expect or do not know about. Tell the resident's study doctor immediately about any such problems.

If this research uncovers a medical condition of which the residents or the substitute medical-decision makers were unaware we will inform them and their GP. This should not affect their participation in the research project

10 What if I withdraw the resident from this research project?

If you decide to withdraw the resident from the project, please notify a member of the research team and their information will be excluded and destroyed

11 What happens when the research project ends?

When the research project ends the results will be analysed to see the effect the Goals of Patient Care form has had on participants using it. If it is found to be successful it will be offered for continuation in the facilities it is in and GPs in the other facilities will be given education about its use and access to it for all residents. If it is not deemed beneficial, it will be withdrawn and facilities will continue with Advance Care Planning already in place or can be referred to the Advance Care Planning department in Northern Health for ACP advice.

The results from the study will be made available to every facility following completion of the project, by October 2016. Residents and substitute medical-decision makers will have access to these results from their facility. A copy of all publications from the study will be made available to each facility also.

Part 2 How is the research project being conducted?

12 What will happen to information about the participant?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about the participant for the research project. Any information obtained in connection with this research project that can identify the participant will remain confidential. Paper documentation will be kept in a locked cabinet in an office in Northern Health which is locked when unoccupied. Computer files will be kept under password locking until the study is complete at 12 months. Only the team members will be able to access the information at any time.

The data will be stored in this format for the duration of the study at which time it will be made anonymous and it will then be stored for 7 years post. At this stage it will be destroyed

The participant's information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about the participant may be obtained from their health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing the participant's health records if they are relevant to participation in this research project.

The original copy of your Goals of Patient Care form will be placed in their health record at the facility so that it can be used in your medical care. Their GP will also be informed of its presence for their review.

It is anticipated that the results of this research project will be published in medical journals and presented at conferences. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. The information will be grouped and not individualised for this process.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to the participant's information collected and stored by the study team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access the participant's information.

Any information obtained for the purpose of this research project that can identify the participant will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

13 Complaints

If the participant suffers any problems or complications as a result of this research project, you should contact the study team or your GP as soon as possible and you will be assisted.

14 Who is organising and funding the research?

This research project is being organised by Dr Ruth Martin on behalf of Northern Health

15 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the Human Research Ethics Committee, Northern Health Ph: (03) 8405 2918 or ethics@nh.org.au.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

16 Further information and who to contact in case of adverse events

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project, you can contact the principal study doctor on (03) 8405 2463 or ruth.martin@nh.org.au. In the case of any serious adverse events you can contact Dr Penelope Harvey an external advisor on the project at Penelope.Harvey@nh.org.au or 0407535629. If you have any concerns or complaints regarding the way the research is or has been conducted, you can contact the Ethics Officer, Human Research Ethics Committee, Northern Health Ph: (03) 8405 2918 or ethics@nh.org.au.

Consent Form – Person Responsible/SMDM

Title	Implementation of “Goals of Patient Care” medical treatment orders in residential aged care facilities.
Protocol Number	[Protocol Number]
Project Sponsor	Northern Health Small Research Grant
Coordinating Principal Investigator/ Principal Investigator	Dr Ruth Martin
Associate Investigator(s)	Professor Kwang Lim, Professor Anastasia Hutchinson, Dr Paul Yates and Dr Barbara Hayes
Location	Northern Health

Declaration by Person Responsible/Substitute Medical Decision-Maker

I am the Person Responsible/ Substitute Medical Decision-Maker for
..... (the Participant).

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

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

I believe that the participation of the participant in this study is not contrary to their best interests.

I freely agree to the participant participating in this research project as described and understand that I am free to withdraw the participant at any time during the research project without affecting their future health care.

I am aware of my responsibilities as the Person Responsible/ Substitute Medical Decision-Maker for the participant and I understand that I will be assisting the participant in meeting their responsibilities whilst they are participating in this study.

I understand that I will be given a signed copy of this document to keep on behalf of the participant.

I give permission for the participant’s doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Dr Ruth Martin concerning the participant’s medical history for the purposes of this research project. I understand that such information will remain confidential.

Name of Participant (please print) _____
Name of Person Responsible/SMDM (please print) _____
Relationship of Person Responsible to Participant _____
Signature of Person Responsible _____ Date _____

In case of telephone consent

Name of Witness* to Substitute Medical Decision-Maker/ Person Responsible Assent to inclusion (please print) _____
Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher[†]

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

Name of Study Doctor/ Senior Researcher [†] (please print) _____
Signature _____ Date _____

[†] A senior member of the research team must provide the explanation of, and information concerning, the research project.

Form for Withdrawal of Participation – Person Responsible/SMDM

Title	Implementation of “Goals of Patient Care” medical treatment orders in residential aged care facilities.
Protocol Number	[Protocol Number]
Project Sponsor	Northern Health Small Research Grant
Coordinating Principal Investigator/ Principal Investigator	Dr Ruth Martin
Associate Investigator(s)	Professor Kwang Lim, Professor Anastasia Hutchinson, Dr Paul Yates and Dr Barbara Hayes
Location	Northern Health

Declaration by Person Responsible

I wish to withdraw the participant from taking part in the above research project and understand that such withdrawal will not affect the participant's routine treatment, relationship with those treating them or their relationship with Northern Health

Name of Participant (please print)	
Name of Person Responsible (please print)	
Relationship of Person Responsible to Participant	
Signature of Person Responsible	Date

Name of Study Doctor/ Researcher (please print)	
Signature	Date

Description of Circumstances

Appendix 12 Baseline assessments (1)



Goals of Patient Care Study

MINI-MENTAL STATE EXAMINATION

1. Orientation (Maximum score 10) Ask, "What is today's date?" Then specifically for parts omitted; eg. "Can you also tell me what season it is?" Ask, "Can you tell me the name of this hospital/residential aged care facility?" "What suburb are we in?" "What city are we in?" "What state are we in?"	Date (eg. Jan 21) Day (eg. Monday) Month Year Season Place of residence Ward / Street name Suburb City State
2. Registration (Maximum score 3) Ask, the subject if you may test his/her memory. Then say "ball", "flag", "tree", clearly and slowly about one second for each. After you have said all 3 words, ask the subject to repeat them. This first repetition determines the score (0-3) but keep saying them (up to 6 trials) until the subject can repeat all 3 words, if (s)he does not eventually learn all three, recall cannot be meaningfully tested.	"ball" "flag" "tree" record number of trials
3. Attention and calculation (maximum score 5) Ask the subject to begin at 100 and count backward by 7. Stop after 5 subtractions (93, 86, 72, 65). Score one point for each correct number. If the subject cannot or will not perform this task, ask him/her to spell "world" backwards (D,L,R,O,W). The score is one point for each correctly place letter, eg. DLROW = 5. DLORW = 3. Record how the subject spelled "world" backwards: _____ DLROW	"93" "86" "79" "72" "65" Number of correctly placed letters
4. Recall (Maximum score 9) Ask the subject to recall the three words you previously asked him/her to remember (learned Registration)	"ball" "flag" "tree"
1. Language (Maximum score 9) Naming: show the subject a wristwatch and ask, "what is this?" Repeat for pencil. Score one point for each item named correctly. Repetition: Ask the subject to repeat "No ifs and or buts". Score one point for correct repetition. 3-state command: give the subject a piece of blank paper and say, "Take the paper in your right hand, fold it in half and put it on the floor". Score one point for each action performed correctly. Reading: On a blank piece of paper, print the sentence "close your eyes" in letters large enough for the subject to see clearly. Ask subject to read it and do what it says. Score correct only if (s)he actually closes his/her eyes. Writing: Give the subject a piece of paper, ask him/her to write a sentence. It is to be written spontaneously. It must contain a subject and verb and make sense. Correct grammar and punctuation are not necessary. Copying: On a clean piece of paper, draw intersecting pentagon's each side 1 inch and ask subject to copy it exactly as it is. All 10 angles must be present and two must intersect to score 1 point. Tremor and rotation are	Watch Pencil Repetition Take in right hand Folds in half Puts on floor Closes eyes Writes sentence

ignored.

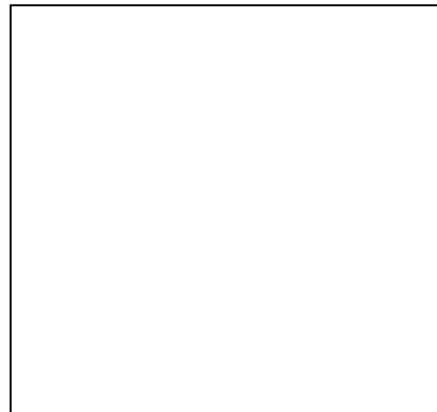
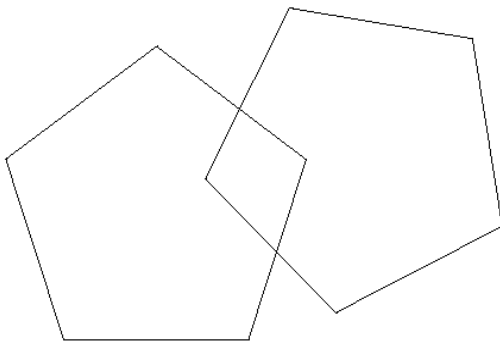
Draws pentagons

Score: Add number of correct responses (Maximum score 30) **Total Score** _____

Close your eyes

Write a sentence here:

Copy this drawing:



Appendix 12 Baseline assessments (2)

 Goals of Patient Care	AFFIX PATIENT IDENTIFICATION LABEL HERE U.R. NUMBER:
---	---

Goals of Patient

Care

Geriatric Depression Scale – Short Form

Choose the best answer for how you have felt over the past week:

1. Are you basically satisfied with your life? YES / **NO**
2. Have you dropped many of your activities and interests? **YES** / NO
3. Do you feel that your life is empty? **YES** / NO
4. Do you often get bored? **YES** / NO
5. Are you in good spirits most of the time? YES / **NO**
6. Are you afraid that something bad is going to happen to you? **YES** / NO
7. Do you feel happy most of the time? YES / **NO**
8. Do you often feel helpless? **YES** / NO
9. Do you prefer to stay at home, rather than going out and doing new things? **YES** / NO
10. Do you feel you have more problems with memory than most? **YES** / NO
11. Do you think it is wonderful to be alive now? YES / **NO**
12. Do you feel pretty worthless the way you are now? **YES** / NO
13. Do you feel full of energy? YES / **NO**
14. Do you feel that your situation is hopeless? **YES** / NO

15. Do you think that most people are better off than you are? **YES** / NO

Answers in bold indicate depression. Score 1 point for each bolded answer.

A score > 5 points is suggestive of depression.

A score $\geq$ 10 points is almost always indicative of depression.

Source: <http://www.stanford.edu/~yesavage/GDS.html>

This scale is in the public domain.

Appendix 12 Baseline assessments (3)

Goals of Patient Care Study

Barthel Index of Activities of Daily Living

Instructions: Choose the scoring point for the statement that most closely corresponds to the patient's current level of ability for each of the following 10 items. Record actual, not potential, functioning. Information can be obtained from the patient's self-report, from a separate party who is familiar with the patient's abilities (such as a relative), or from observation.

The Barthel Index

Bowels

0 = incontinent (or needs to be given enemata)

1 = occasional accident (once/week)

2 = continent

Patient's Score:

Bladder

0 = incontinent, or catheterized and unable to manage

1 = occasional accident (max. once per 24 hours)

2 = continent (for over 7 days)

Patient's Score:

Grooming

0 = needs help with personal care

1 = independent face/hair/teeth/shaving (implements provided)

Patient's Score:

Toilet use

0 = dependent

1 = needs some help, but can do something alone

2 = independent (on and off, dressing, wiping)

Patient's Score:

Feeding

0 = unable

1 = needs help cutting, spreading butter, etc.

2 = independent (food provided within reach)

Patient's Score:

Transfer

0 = unable – no sitting balance

1 = major help (one or two people, physical), can sit

2 = minor help (verbal or physical)

3 = independent

Patient's Score:

Mobility

0 = immobile

1 = wheelchair independent, including corners, etc.

2 = walks with help of one person (verbal or physical)

3 = independent (but may use any aid, e.g., stick)

Patient's Score:

Dressing

0 = dependent

1 = needs help, but can do about half unaided

2 = independent (including buttons, zips, laces, etc.)

Patient's Score:

Stairs

0 = unable

1 = needs help (verbal, physical, carrying aid)

2 = independent up and down

Patient's Score:

Bathing

0 = dependent

1 = independent (or in shower)

Patient's Score:

Total Score:

(Collin et al., 1988)

Scoring:

Sum the patient's scores for each item. Total possible scores range from 0 – 20, with lower scores indicating increased disability. If used to measure improvement after rehabilitation, changes of more than two points in the total score reflect a probable genuine change, and change on one item from fully dependent to independent is also likely to be reliable.

Sources:

- Collin C, Wade DT, Davies S, Horne V. The Barthel ADL Index: a reliability study. *Int Disabil Stud.* 1988;10(2):61-63.
- Mahoney FI, Barthel DW. Functional evaluation: the Barthel Index. *Md State Med J.* 1965;14:61-65.
- Wade DT, Collin C. The Barthel ADL Index: a standard measure of physical disability? *Int Disabil Stud.* 1988;10(2):64-67.

Appendix 12 Baseline assessments (4)

Clinical Frailty Scale*



1 Very Fit – People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.



2 Well – People who have **no active disease symptoms** but are less fit than category 1. Often, they exercise or are very **active occasionally**, e.g. seasonally.



3 Managing Well – People whose **medical problems are well controlled**, but are **not regularly active** beyond routine walking.



4 Vulnerable – While **not dependent** on others for daily help, often **symptoms limit activities**. A common complaint is being “slowed up”, and/or being tired during the day.



5 Mildly Frail – These people often have **more evident slowing**, and need help in **high order IADLs** (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.



6 Moderately Frail – People need help with **all outside activities** and with **keeping house**. Inside, they often have problems with stairs and need **help with bathing** and might need minimal assistance (cuing, standby) with dressing.



7 Severely Frail – **Completely dependent for personal care**, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).



8 Very Severely Frail – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.



9. Terminally Ill - Approaching the end of life. This category applies to people with a **life expectancy <6 months**, who are **not otherwise evidently frail**.

Scoring frailty in people with dementia

The degree of frailty corresponds to the degree of dementia. Common **symptoms in mild dementia** include forgetting the details of a recent event, though still remembering the event itself, repeating the same question/story and social withdrawal.

In **moderate dementia**, recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with prompting.

In **severe dementia**, they cannot do personal care without help.

* 1. Canadian Study on Health & Aging, Revised 2008.

2. K. Rockwood et al. A global clinical measure of fitness and frailty in elderly people. CMAJ 2005;173:489-495.

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Appendix 13 PICF Healthcare professional

PARTICIPANT INFORMATION & CONSENT FORM (PICF)

Project Name: Implementation of “Goals of Patient Care” medical treatment orders in residential aged care facilities

NH HREC No:

Principal Investigator: Dr Ruth Martin, Advanced Trainee in Aged Care Medicine

Participant’s Involvement in project –

Start Date: 01/05/2015

Finish Date: 01/10/2015

Participant Information:

The residential aged care facility “Goals of Patient Care” form is a medical treatment order incorporating prior Advance Care Planning and wishes. It is based on a medical assessment of each individual. The form serves as a communication tool about the individual's healthcare decisions for staff in the aged care facility, visiting doctors (regular or locum GPs), ambulance staff and Emergency Department staff. The form helps guide these decisions made on behalf of the resident in both planned and emergency situations. The form is filled in by a doctor in discussion with the resident, or substitute medical decision maker. We are trialling the form in pairs of aged care facilities, with one facility using the form and its pair not using it. This way we can examine its effect.

Part 1 What does my participation involve?

1 Introduction: Healthcare Worker

You are invited to take part in this research project. This is because you are a healthcare worker involved in the care of residents in an aged care facility taking part in testing a new medical treatment order form. This is called a "Goals of Patient Care" form.

This Participant Information Sheet and Consent Form tell you about the research project. It explains the intervention involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to taking part in the research project
- Consent to having the tests that are described
- Consent to the use of your personal information as described.

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

2 What is the purpose of this research?

Our project is looking at the effect of the Goals of Patient Care medical treatment orders on the hospital usage of residents in aged care facilities. We feel that the introduction of this form, which indicates the treatment preferences of residents, will lead to healthcare decisions being more in line with the wants and needs of residents. As a result of this we feel that it will be easier to make healthcare decisions about the residents.

Currently there are no medical treatment orders in use in Victorian residential aged care facilities and we feel by investigating the effect of this type of form we will contribute to improving the care provided in aged care facilities. These types of forms have been thoroughly researched and are in place in other countries and have been well received.

We hope to bring this form to Northern Health and make it available to other facilities to help guide healthcare decisions made on behalf of residents in our catchment. The results of this research will be used by the study doctor, Dr Ruth Martin, to complete a research doctorate (MD) degree.

This research team have applied for a small research grant from Northern Health.

3 What does participation in this research involve?

Consent forms will be signed prior to any study assessments being performed. The commitment required by healthcare workers involved will be to sign consent to be involved in 1-2 surveys and a focus group or brief interview 12 months after the study commences.

The type of project the residents are involved in is called a cluster randomised controlled research project. Sometimes we do not know which treatment is best for participants. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each facility is put into a group by chance (random). The chance of receiving the investigational form is 1 in 2.

We are involving you to investigate the effect the trialling of the Goals of Patient Care had in your facility or a facility you visit.

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

4 What do I have to do?

The participant will have to:

1. Complete written informed consent
2. Take part in 1-2 surveys
3. (i) Take part in a focus group (6-8 people) discussing Advance Care Planning and your experiences with the Goals of Patient Care form. This will be audiotaped for accuracy.

Or

(ii) Take part in a short confidential one-to-one interview discussing Advance Care Planning and your experiences with the Goals of Patient Care form. This will be audiotaped for accuracy.

5 Other relevant information about the research project

Overall we will be conducting the study in six residential aged care facilities in Northern Health. Three facilities will use the form and three will not use the form. There are five researchers involved in the project, all working within the departments of Aged Care and Advance Care Planning.

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

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether you take part or not take part, or take part and then be withdrawn, will not affect your relationship with Northern Health.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that participant will receive any benefits from this research; however, possible benefits include the introduction of medical treatment orders which help facilitate healthcare decision making for residents especially in times of acute deterioration. We also hypothesise that it will help guide healthcare decisions when the resident is being reviewed by a healthcare worker who doesn't know them well.

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

There are no risks or disadvantages to taking part, except giving some time to complete the surveys, focus groups or interviews. For the surveys 5-10 minutes, the interview 10-15 minutes, and the focus group 20-30 minutes

10 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team and your information will be excluded and destroyed

11 What happens when the research project ends?

When the research project ends the results will be analysed to see the effect the Goals of Patient Care form has had on residents and healthcare workers. If it is found to be successful it will be offered for continuation in the facilities it is in and GPs in the other facilities will be given education about its use and access to it for residents. If it is not deemed beneficial, it will be withdrawn and facilities will continue with Advance Care Planning already in place or can be referred to the Advance Care Planning department in Northern Health for further ACP advice.

The results from the study will be made available to every facility involved following completion of the project, by October 2016. Healthcare workers, residents and substitute medical-decision makers will have access to these results from their facility. A copy of all publications from the study will be made available to each facility also.

Part 2 How is the research project being conducted?

12 What will happen to information about the participant?

By signing the consent form you consent to the being involved in the study as described. The information recorded will be grouped according to profession and kept anonymous (non-identifiable). Your name and facility name will not be identified. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. Paper documentation will be kept in a locked cabinet within an office in Northern Health that is locked when unattended. Computer documentation will be kept under password locking. Only the team members will have access to it. The data will be kept for 7 years and then securely destroyed.

It is anticipated that the results of this research project will be published in academic journals and presented at conferences and medical meetings. In any publication and/or presentation, information will be provided in such a way that neither the facility nor the participant can be identified, without their permission. The information will be grouped and not individualised for this process.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the team up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the study team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify the participant will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

13 Complaints

If you suffer any problems or complications as a result of this research project, you should contact the study team or your GP as soon as possible and you will be assisted.

14 Who is organising and funding the research?

This research project is being organised by Dr Ruth Martin on behalf of Northern Health.

15 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the Human Research Ethics Committee, Northern Health Ph: (03) 8405 2918 or ethics@nh.org.au.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

16 Further information and who to contact in case of adverse events

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project, you can contact the principal study doctor on (03) 8405 2463 or ruth.martin@nh.org.au. In the case of any serious adverse events you can contact Dr Penelope Harvey an external advisor on the project at Penelope.Harvey@nh.org.au or 0407535629. If you have any concerns or complaints regarding the way the research is or has been conducted, you can contact the Ethics Officer, Human Research Ethics Committee, Northern Health Ph: (03) 8405 2918 or ethics@nh.org.au.

Consent Form – Healthcare Worker providing own consent

Title	Implementation of “Goals of Patient Care” medical treatment orders in residential aged care facilities.
Protocol Number	[Protocol Number]
Project Sponsor	Northern Health Small Research Grant
Coordinating Principal Investigator	Dr Ruth Martin
Associate Investigator(s)	Professor Kwang Lim, Professor Anastasia Hutchinson, Dr Paul Yates and Dr Barbara Hayes
Location	Northern Health

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

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

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study.

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

Name of Participant (please print)	_____
Signature	_____
Date	_____

Name of Witness* to Participant's Signature (please print)	_____
Signature	_____
Date	_____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher[†]

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

Name of Study Doctor/ Senior Researcher [†] (please print) _____	
Signature _____	Date _____

[†] A senior member of the research team must provide the explanation of, and information concerning, the research project

Form for Withdrawal of Participation – *Healthcare Worker providing own consent*

Title	Implementation of “Goals of Patient Care” medical treatment orders in residential aged care facilities.
Protocol Number	[Protocol Number]
Project Sponsor	Northern Health Small Research Grant
Coordinating Principal Investigator	Dr Ruth Martin
Associate Investigator(s)	Professor Kwang Lim, Professor Anastasia Hutchinson, Dr Paul Yates and Dr Barbara Hayes
Location	Northern Health

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Northern Health

Name of Participant (please print) _____
Signature _____ Date _____

Description of Circumstances

--

Declaration by Study Doctor/Senior Researcher[†]

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/ Senior Researcher [†] (please print) _____
Signature _____ Date _____

[†] A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature

Appendix 14 Question Guide for focus groups

1. What is your position here in the aged care facility?
2. How long have you worked in aged care?
3. How long have you worked here?
4. What do you understand by advance care planning?
5. Have you noticed changes in advance care plans over recent years?
6. Have you ever been involved in completing advance care plans with residents and their families?
7. Do you find advance care plans help with decision making when residents are unwell?
8. Do you look at the advance care plans when making decisions about what to do when residents become sick?
9. Do you find the doctors you call review the advance care plans when making decisions about what to do when residents become sick?
10. Do you find any differences between your regular and Locum GPs with regards to this?
11. Are you familiar with the Goals of Patient Care form that we completed with residents 12 months ago?
12. Did you have cause to refer to a GOPC form with residents, families or doctors?
13. In what way did you use it/ refer to it?
14. Did it affect the decisions made? In what way?

Appendix 15 Question guide for Medical Practitioner interviews

1. How long have you worked in aged care facilities?
2. Do you have patients in more than one facility?
3. What has been your experience of advance care planning?
4. Over the time you've been working have you noticed changes in advance care planning?
5. Have you ever been involved in completing advance care plans with residents and their families? What was your role?
6. How helpful are advance care plans with decision making when residents are unwell?
7. Is it something you routinely look for when reviewing unwell residents?
8. Are you familiar with the Goals of Patient Care form that we completed with residents 12 months ago?
9. Did you have cause to refer to a GOPC form with residents, families or facility staff?
10. In what way did you use it/ refer to it?
11. Did it affect the decisions made?
12. From our focus groups a recurrent theme was that locum GPs don't tend to follow the advance care plan- is that your experience?
13. Do you think that changes when you have made the treatment plan? Is that just in cases of palliation or in other cases also?

Appendix 16 Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
<i>Personal Characteristics</i>		
1. Inter viewer/facilitator	Which author/s conducted the interview or focus group?	Methods 3.4.8 p42-43
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	Methods 3.4.8 p42-43
3. Occupation	What was their occupation at the time of the study?	Methods 3.4.8 p42-43
4. Gender	Was the researcher male or female?	N/A
5. Experience and training	What experience or training did the researcher have?	Methods 3.4.8 p42-32
<i>Relationship with participants</i>		
6. Relationship established	Was a relationship established prior to study commencement?	Methods 3.4.12 p46
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Methods 3.4.8 p42-43
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Methods 3.4.8 p42-43
Domain 2: study design		
<i>Theoretical framework</i>		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Methods 3.4.10 p43
<i>Participant selection</i>		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Methods 3.4.8 p42-43
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Methods 3.4.8 p42-43
12. Sample size	How many participants were in the study?	Results 5.1.1 p 60
13. Non-participation	How many people refused to participate or dropped out? Reasons?	Nil
<i>Setting</i>		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Methods 3.4.8 p42
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	Results 5.1.1 p60
16. Description of sample	What are the important characteristics of	Results 5.1.1 p60

No. Item	Guide questions/description	Reported on Page #
	the sample? e.g. demographic data, date	
<i>Data collection</i>		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Appendix 14 and 15 p169-170
18. Repeat interviews	Were repeat inter views carried out? If yes, how many?	N/A
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Methods 3.4.8 p42
20. Field notes	Were field notes made during and/or after the inter view or focus group?	Methods 3.4.9 p43
21. Duration	What was the duration of the inter views or focus group?	Methods 3.2.5 p29
22. Data saturation	Was data saturation discussed?	Results 5.1.1 p60
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	Results 5.1.1 p60
Domain 3: analysis and findings		
<i>Data analysis</i>		
24. Number of data coders	How many data coders coded the data?	Methods 3.4.10 p43
25. Description of the coding tree	Did authors provide a description of the coding tree?	N/A
26. Derivation of themes	Were themes identified in advance or derived from the data?	Methods 3.4.10 p43
27. Software	What software, if applicable, was used to manage the data?	NVivo
28. Participant checking	Did participants provide feedback on the findings?	6.6.2 p80
<i>Reporting</i>		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Results Chapter 5 p60-78
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Discussion 6.3 p89, 6.4 p92
31. Clarity of major themes	Were major themes clearly presented in the findings?	Results Chapter 5 p60-78
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Results Chapter 5 p60-78

Appendix 17 presents a summary table on ‘Completing an Advance Care Plan’, describing the numbers of quotes and sources on the 6 subthemes outlined.

Theme	Subthemes	Number of quotes	Number of sources
Completing an Advance Care Plan	Views about Advance Care Plan completion	30	3 FG, 3 Interviews
	Timing of Advance Care Plan completion	9	3 FG
	Roles in Advance Care Plan completion	19	3 FG, 3 interviews
	Cultural differences in Advance Care Plan completion	7	1 FG, 2 interviews
	Effect of Health Literacy on Advance Care Plan completion	5	3 FG
	Changes in Advance Care Plan completion over time	13	3 FG, 3 interviews

Appendix 18 presents a summary table on ‘Activating an Advance Care Plan’, describing the main numbers of quotes and sources on the 4 subthemes outlined

Theme	Subthemes	Number of quotes	Number of sources
Following (activating) an advance care plan	Advance Care Plan as a guide	7	2 FG, 1 GP
	Family issues	21	3 FG, 2 GP
	Mistrust	6	1 FG, 1 GP
	Best Interests of Resident	3	2 FG, 1 GP

Appendix 19 presents a summary table on 'End-of-life', describing the main numbers of quotes and sources on the 4 subthemes.

Theme	Subthemes	Number of quotes	Number of sources
End-of-life	Difficulty predicting death	6	2 FG, 2 GP
	Palliative Care provision	15	3 FG, 3 GP
	Family issues	12	3 FG, 2 GP
	Residential-In-Reach support	13	3 FG, 3 GP

Appendix 20 presents a summary table on ‘Goals of Patient Care’, describing the main numbers of quotes and sources on the 2 subthemes.

Main Theme	Subthemes	Number of quotes	Number of sources
Goals of Patient Care	Attitudes to GOPC	9	3 FG, 3GP
	Confusion about GOPC and ACP	5	3 FG, 2 GP

Appendix 21 JAMDA publication



JAMDA

journal homepage: www.jamda.com

Review Article

The Effects of Advance Care Planning Interventions on Nursing Home Residents: A Systematic Review



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ABSTRACT

Keywords:

Advance Care Planning
advance directive
nursing home
aged care facility

Background: Advance care planning (ACP) encompasses a process by which people may express and record their values and preferences for care and treatment should they lose the capacity to communicate them in the future. We believe the effects that ACP can have on the nursing home population is distinct from others and sought to gain insight into the outcomes of relevant studies on the topic.

Aim: To identify the effects of ACP interventions on nursing home residents.

Design: Systematic review.

Methods: A comprehensive literature search was conducted using the following 4 electronic databases, Embase, Medline, PsychINFO, and CINAHL, with no limits on year or language. Gray literature search of relevant journals was also performed as was reviewing of the reference lists of all included articles. Inclusion criteria were randomized controlled trials, controlled trials, pre/post study design trials and prospective studies examining the effects of ACP on nursing home residents. A detailed narrative synthesis was compiled as the heterogeneous nature of the interventions and results precluded meta-analysis.

Results: The initial search yielded 4654 articles. Thirteen studies fitted inclusion criteria for analysis. The ACP interventions included (1) 5 studies evaluating educational programs; (2) 5 studies introducing or evaluating a new ACP form; (3) 2 studies introducing an ACP program with a palliative care initiative; and (4) 1 study observing the effect of do not resuscitate orders on medical treatments for respiratory infections. A range of effects of ACP was demonstrated in the study populations. Hospitalization was the most frequent outcome measure used across the included studies. Analysis found that in the nursing home population, ACP decreased hospitalization rates by 9%–26%. Of note, in the 2 studies that included mortality, the decrease in hospitalization was not associated with increased mortality. Place of death is another important effect of ACP. Analysis found significant increases in the number of residents dying in their nursing home by 29%–40%. Medical treatments being consistent with ones' wishes were increased with ACP although not to 100% compliance. Two studies showed a decrease in overall health costs. One study found an increase in community palliative care use but not in-patient hospice referrals.

Conclusions: ACP has beneficial effects in the nursing home population. The types of ACP interventions vary, and it is difficult to identify superiority in effectiveness of one intervention over another. Outcome measures also vary considerably between studies although hospitalization, place of death, and actions being consistent with resident's wishes are by far the most common. Very few studies with high quality methodology have been undertaken in the area with a significant lack of randomized controlled trials. More robust studies, especially randomized controlled trials, are required to support the findings.

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The authors declare no conflicts of interest.

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<http://dx.doi.org/10.1016/j.jamda.2015.12.017>

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The proportion of people reaching older age is increasing globally because of significant advances in medicine and technology. In 2013, the proportion of older persons over 80 years of age, “the oldest old,” was 14%, and this is projected to reach 19% by 2050.¹ Unfortunately, not all are maintaining their functional independence to live in the

community, leading to larger numbers requiring care in nursing homes.² The population in nursing homes is increasingly frail with multiple comorbidities. This is reflected by the high incidence of acute healthcare utilization³ with hospital admission incidence reported to be 0.62 admissions per person-year among the nursing home residents and 0.26 among the community dwellers.⁴ A systematic review by Arendts et al⁵ has shown the range of emergency department (ED) transfers to be 0.2–1.5 transfers per nursing home bed per year with large variations existing not just between but within geographic areas.

The nursing home population has the unique characteristic of 24-hour access to nursing or support staff care. Despite the increasingly large ratio of residents to staff, this still enables care delivery in the facility that would be difficult to give in the community. Knowing how detrimental unnecessary hospital admissions can be to residents^{6,7} and that research has shown both residents and families have a preference for treatment in the facility,⁸ interventions to reduce hospital transfer from nursing homes are common.

Advance care planning (ACP) has been one of these targeted interventions with legislation or policy supporting it since the 1990s in the United States of America (USA) (Patient Self Determination Act), 2005 in the United Kingdom (Mental Capacity Act), and 2011 in Australia (Australian National Framework for Advance Care Directives).⁹ There are many different types of ACPs used in nursing homes, some of which are specific to the facility or group of facilities. ACP may also be included within medical treatment orders such as do-not-resuscitate (DNR) orders, do-not-hospitalize (DNH) orders, and the newer physician orders for life-sustaining treatments (POLST). However, if these medical treatment orders are unilateral decisions made by physicians, they would not be in keeping with the ethos of ACP, which is regarded as recording the “voice of the patient.”¹⁰

In the last 2 years, there have been 10 studies looking specifically at the effects of ACP in nursing homes, 7 of which are of retrospective design and, therefore, not included in this review.^{11–17} A systematic review by Sharp et al¹⁸ has shown that the majority of older people welcome the chance to discuss end-of-life care, with most perceiving the risk of leaving it too late.

ACP allows people to have a voice in their healthcare decisions should they lose the capacity to be involved in these conversations in the future. Loss of capacity may be transient, at times of acute illness or delirium, or permanent and progressive because of dementia. Dementia is estimated to affect between 50% and 80% of nursing home residents,^{7,19,20} impairing their decision-making capacity, which highlights the relevance and importance of ACP for this group. Some large studies have failed to show a significant impact on care with ACP in the ambulatory population²¹ because of shortcomings including difficulty with ACP interpretation^{21–25} and the orders not being in a format that ambulance staff can follow.²⁶ However, some studies have shown positive outcomes with ACP for patients and families,²⁷ specifically in our nursing home populations,^{28,29} thus, supporting their ongoing prioritization for healthcare services.³⁰

Heterogeneity of studies, for both the ACP interventions and their outcome measures, leads to some difficulty in their interpretation and application. In the United States, the ACP focus from the late 1990s has been on POLST. These medical treatment orders and their permutations are said to be now in use, or in development, in 41 American states.³¹ With POLST, research has shown that nursing home residents are less likely to receive unwanted interventions including hospitalization^{32–34} and intravenous fluids.³² These medical treatment orders are completed by physicians, in consultation with residents or their substitute medical decision-makers, taking into account residents' preferences for care as well as their current health status. They were developed to deal with the shortcomings of original ACP. In countries outside the USA, the types of ACP and the terminology referring to the different directives are very varied.³⁵

Although there have been systematic reviews in the area of ACP, no reviews have focused on the nursing home population. We believed it was important to do a systematic investigation to collate the findings of the effects of ACP on this unique population as the effects found in other populations may not be generalizable to ours.

Methods

Design

This systematic review has been prospectively registered with PROSPERO.³⁶

Search Strategy

In April 2015, a comprehensive literature search was conducted using the following 4 electronic databases, Embase, Medline, PsychINFO, and CINAHL, with no limits on year or language. The search strategy is available for review in Figure 1. The search yielded 4654 titles. There were no restrictions by study design at this time so as to allow identification of all studies related to the question. Hand-searching of citations in these articles, to identify additional relevant studies, was performed as well as searching of gray literature.

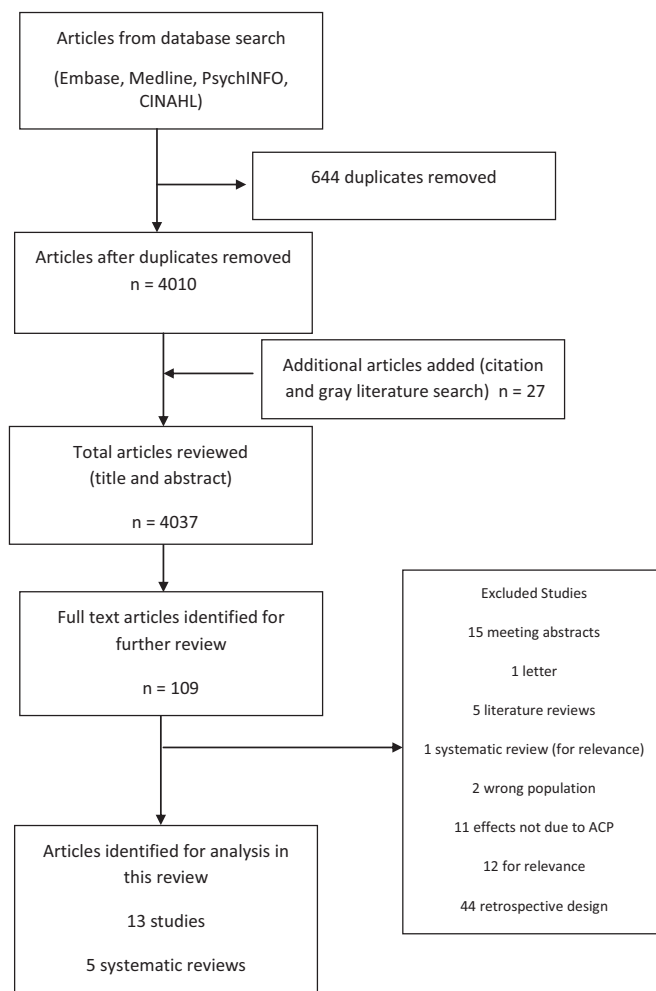


Fig. 1. Strategy used to identify published studies on ACP suitable for our analysis.

Selection Criteria

Inclusion criteria were studies examining an effect of advance care planning on nursing home residents. Nursing homes were defined for this review as residential aged care facilities, long-term care units, and skilled nursing facilities or care homes. ACP was defined as any advance discussions or directives, including medical treatment orders, with effect on nursing home residents. Having reviewed all the articles for relevance, articles pertaining to randomized controlled trials, controlled trials, pre/poststudy design trials, and prospective trials were assessed, with 13 studies fitting all the inclusion criteria (Figure 1). None of these studies involved appointment of a medical substitute decision-maker as the sole element of ACP. A further 5 systematic reviews were also identified as partially relevant and will be discussed separately.

Data Extraction

Data was extracted using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system. As with other systems for data extraction, it is based on the rigor of the study design. The systematic approach suggested by the GRADE working group was followed^{37,38} and categorization of the studies into 4 groups according to a judgement on their evidence was performed; high, moderate, low, and very low. As per the GRADE protocol, randomized controlled trials start as high quality evidence and observational studies start as low evidence. They then moved up or down categories depending on the robustness of their study design according to GRADE criteria, as seen in Tables 1 and 2.³⁸ Two reviewers appraised each study with high levels of agreement. Disagreements were resolved through discussion with a third reviewer.

Data Synthesis

It was not possible to perform a meta-analysis on the pooled results because of the heterogeneous nature of the both the

interventions and results. For this reason, a detailed narrative synthesis has been compiled.

Results

Study Characteristics

Seven of the studies took place in the USA, 1 took place in Australia, 1 in Hong Kong, 1 in Canada, 1 in the United Kingdom, 1 in Singapore, and in The Netherlands. The intervention in 5 studies was an educational program. For 2 of these, the ACP education was provided just to healthcare staff,^{39,40} whereas in the other 3, education was provided to healthcare staff, residents, and families.^{28,29,41} Five studies involved introduction or evaluation of a new ACP form in the facility.^{32,42–45} Two studies involved an ACP program with a palliative care initiative^{46,47} and 1 study involved observation of the effect of DNR orders on the medical treatments of residents with lower respiratory infections.⁴⁸

Quality of the Studies

The overall quality of the study methodologies was low as can be seen in Table 3. Only 1 study was of high quality and 2 of moderate quality, using GRADE criteria. The majority, 8 of the studies, were of low quality, with 2 being of very low quality.

Hospitalization and Costs

Hospital utilization is a frequent measure used across the included studies.^{28,29,43,44,46–48} In the nursing home population, ACP has been shown to decrease hospitalization rates between 9% and 26%. Mott et al⁴⁴ in their intergroup comparison found a decrease in admissions of 77% between their group 1 (opting for full medical management) and group 4 (opting for comfort measures only).⁴⁴ Associated healthcare costs is less frequently studied in these included articles but Molloy et al²⁸ found a significant decrease in both the hospital costs, intervention home \$1772 vs control home \$3869 per patient

Table 1
Evaluation of studies according to GRADE criteria

Studies	Design	Limitations	Indirectness	Inconsistency	Imprecision	Publication Bias	Quality
Caplan 2006	Controlled trial	Minor	Little or no	Little or no	Little or no	No	Moderate ⊕⊕⊕○
Hickman 2010	Controlled trial	Minor	Little or no	Little or no	Little or no	No	Moderate ⊕⊕⊕○
Levy 2008	Pre- postintervention	Minor	Little or no	Little or no	Little or no	No	Low ⊕⊕○○
Molloy 2000	Randomized controlled trial	Serious	Little or no	Little or no	Little or no	No	High ⊕⊕⊕⊕
Morrison 2005	Controlled trial	Serious	Little or no	Little or no	Little or no	No	Low ⊕⊕○○
Danis 1991	Prospective cohort	Serious	Little or no	Little or no	Little or no	No	Low ⊕⊕○○
Zweig 2004	Prospective cohort	Serious	Little or no	Little or no	Little or no	No	Low ⊕⊕○○
Tolle 1998	Prospective cohort	Very Serious	Little or no	Little or no	Little or no	No	Very Low ⊕○○○
Mott 1988	Prospective cohort	Very serious	Little or no	Little or no	Little or no	No	Very Low ⊕○○○
Livingston 2013	Pre-postintervention	Serious	Little or no	Little or no	Little or no	No	Low ⊕⊕○○
Van Soest-Poortvliet 2015	Prospective cohort	Serious	Little or no	Little or no	Little or no	No	Low ⊕⊕○○
Chan 2010	Controlled trial	Serious	Little or no	Little or no	Little or no	No	Low ⊕⊕○○
Kelvin 2014	Controlled trial	Serious	Little or no	Little or no	Little or no	No	Low ⊕⊕○○

Table 2
A Summary of the GRADE Approach to Grading the Quality of Evidence for Each outcome

Source of Body of Evidence	Initial Rating of Quality of a Body of Evidence	Factors that may Decrease the Quality	Factors that may Increase the Quality	Final Quality of a Body of Evidence
Randomized trials	High	1. Risk of bias	1. Large effect	High (⊕⊕⊕⊕)
Observational studies	Low	2. Inconsistency	2. Dose-response	Moderate (⊕⊕⊕○)
		3. Indirectness	3. All plausible residual confounding would reduce the demonstrated effect or would suggest a spurious effect if no effect was observed	Low (⊕⊕○○)
		4. Imprecision		Very Low (⊕○○○)
		5. Publication Bias		

($P = .003$), and total healthcare costs, intervention home \$3400 vs control home \$5239 per patient ($P = .01$).

In Singapore, Teo et al⁴⁷ showed significant reduction in total health costs in both the last 3 months and last month of life associated with decreased hospitalization in the ACP group vs control. They found per-resident cost savings of SGD7129 over the last 3 months of life (US \$1–SGD1.3) and per-resident cost savings SGD3703 over the last 1 month of life.⁴⁷ Caplan et al²⁹ showed a decrease in hospital bed use by 26% in the intervention vs control facilities from which one can safely deduce a decrease in hospital costs but cannot presume a decrease on overall healthcare costs. Similarly, Mott et al⁴⁴ showed a decrease of 79% in hospital bed days from their group for active intervention compared with their group for comfort measures only, with an associated decrease in hospital costs but not necessarily a reduction in overall healthcare costs. Levy et al⁴⁶ found no significant change in length of stay in those hospitalized 5.17 vs 3.33 days.

Place of Death

Place of death is another important studied effect of ACP. The studies found significant increases in the number of residents dying in their nursing home^{29,40,44,46} by 29%–40% compared with control. Some studies compare this effect between groups according to stated wishes in their ACP; for example Mott et al⁴⁴ found that there was an increase from 55% to 85% of residents dying in their facility between group 1 (opting for full medical management) to group 4 (opting for comfort measures only). This difference reflects an effective ACP. It also reflects the influence the type and specificity of the ACP can have on the approach to the resident's care. Caplan et al²⁹ found that of the 32 residents in the ACP intervention group who died 100% of them died in their preferred place as specified.

Consistency With Resident's Wishes

Actions being consistent with residents' wishes are outcome measures in many of the studies.^{39,40,42,43} The range of increase in effect is 13%–29% in the intervention compared with controls across these studies. However, when the ACP is broken down into different components, it becomes apparent that some directives are easier to follow than others and some ACP outcomes are easier to measure. For example, studies show ACP with regard to cardiopulmonary resuscitation can be up to 100% effective.^{32,43} In contrast, the guidance of ACP with regard to the administration of antibiotics was found to be ineffective.³² Danis et al⁴² investigated variables associated with consistency and found that when treated in hospital rather than treated in the nursing home the ACP was more consistent with their expressed wishes 87% vs 46% ($P = .00003$), as most inconsistencies tended toward under treatment and they felt the approach to medical care was less aggressive in the nursing home.⁴²

Use of Life-Sustaining Treatments

Use of life-sustaining treatments is another outcome measure of ACP studies, which overlaps with the outcome measure of a resident's care being consistent with their ACP wishes. It is addressed in 2 of the included studies.^{32,44} Hickman et al³² found that those opting for "comfort measures only" were significantly less likely to receive life-sustaining medical treatment than those with ACP for full active management, those with DNR orders and those with for resuscitation orders. In a sample of residents who were only for hospitalization in the event of unmanageable symptoms, 4 of 24 hospitalizations were for the use of life-sustaining treatments⁴³ showing it is possible for even the most specific ACP to be ignored.

Quality of Life and Satisfaction

Perceived improvements in quality of life of the resident and satisfaction of family, although difficult to measure, are studied in 2 of the included articles.^{41,45} Van Soest-Poortvliet et al⁴⁵ found that establishing baseline comfort goals for residents was associated with more satisfaction with end-of-life care ($P = .03$). The effect, however, was significant only when residents were living in the nursing home for less than 6 months before they died. Chan et al⁴¹ found with introduction of ACP, there were statistically significant improvements in overall quality of life (QOL) ($P = .034$), physical discomfort ($P = .017$), and existential distress ($P = .038$) for residents.

Mortality

Mortality associated with ACP has been measured in 2 of the included studies.^{28,29} Both studies showed that ACP was not associated with increased mortality. In fact Caplan et al²⁹ found no significant change in mortality except for the third year of their study when the mortality rate rose in the control nursing homes by 10% rather than the intervention homes, 30.4 vs 41.6 per 100 beds ($P = .0425$). Similarly Molloy et al²⁸ found no significant difference in death rate between the intervention and control groups 24% vs 20% ($P = .2$) despite lower hospitalization in the intervention group.

In-Patient Hospice and Community Palliative Care

Although many ACP studies look at in-patient hospice and community palliative care referral in association with ACP, most are of a retrospective observational nature and so are not included in this analysis. Only 1 of the studies investigated these effects, and they found no change in in-patient hospice referrals pre- and post-implementation of their intervention but community palliative care referrals increased by 23.7% ($P = .02$).⁴⁶ Mean length of stay in hospice did not differ significantly either with 24.3 days pre- vs 32.7 post-ACP intervention. The mean number of days, however, in the community palliative care programs did increase, from 1 day to 13.8 ± 25.9 days, but did not reach significance ($P = .09$).⁴⁶ No difference was found in

Table 3
Characteristics of included studies

Study Year	Population (NH Residents)	Design	Country	Intervention	Outcomes	GRADE
Caplan et al 2006	45 residents for personal intervention Facility Intervention I: 1344 residents C: 523 residents	Controlled trial	Australia	Educational program for residents, families, staff, and GPs Let me decide ACP and HITH in facilities surrounding 2 hospitals in a geographic area	Hospitalization and costs 1. Decrease in hospitalization from the NHs year 1, 22.7% decrease in admissions 2. Increase in hospitalization in control NH year 1 by 4.2% (decrease not just due to HITH as reviews increased from just 31–37 in the year) 3. Rate of admissions higher year 1 at intervention hospitals 1.341 vs 1.044 RR 1.07; 95% CI 1.03–1.11; $P = .0005$, by year 3 the rate was lower at 0.865 vs 1.254 RR 0.89; 95% CI 0.85–0.93; $P < .0001$ 4. Hospital bed use per NH bed similar in both areas at commencement 9.441 vs 9.042; RR = 1.01; 95% CI 0.98–1.04; $P = .442$ whereas after 3 years rate was more than double in the control area 5.743 vs 12.755 RR 0.74 CI 0.72–0.77; $P < .0001$ 5. Emergency calls to ambulance services-intervention vs control –1% vs +21%; $P = .0019$ Place of death 1. Place of death 32 (71%) died, 100% in their preferred place specified Mortality 1. No significant change in mortality except for the third year when the rate rose in the control NHs 30.4 vs 41.6 per 100 beds; $P = .0425$	Moderate ⊕⊕⊕○
Molloy et al 2000	I: 444 C: 374	Randomized Controlled trial	Canada	Educational ACP program, Let Me Decide, included educating staff in local hospitals and NHs, residents and families about advance directives Offering competent residents or next-of-kin an advance directive which offered choices for life-threatening illness, cardiac arrest and nutrition	Hospitalization and costs 1. Lower risk of hospitalization in intervention homes 0.27 vs 0.48 mean per patient, $P = .001$ 2. Lower mean no of hospital days in intervention group 2.61 vs 5.86, $P = .01$ 3. Mean hospital cost for intervention homes was \$1772 vs \$3869, $P = .003$ 4. Total healthcare cost for intervention group was \$3400 vs \$5239, $P = .01$ Mortality 1. Death rate similar between both groups 24% vs 20%, $P = .2$ despite lower hospitalization in the intervention group QOL/satisfaction 1. Statistically significant improvements in overall QOL, $P = .034$, physical discomfort $P = .017$, and existential distress $P = .038$	High ⊕⊕⊕⊕
Chan et al 2010	I: 59 C: 62	Controlled trial	Hong Kong	Educational ACP program, Let Me Talk, 4 themes life stories, illness narratives, life views and end-of-life care, 4 sessions 1 hour/session	QOL/satisfaction 1. Statistically significant improvements in overall QOL, $P = .034$, physical discomfort $P = .017$, and existential distress $P = .038$	Low ⊕⊕○○
Morrison et al 2005	I: 49 C: 96	Controlled trial	USA	Educational ACP program for NH social workers randomized to intervention or control. Structured approach to completion and review of ACP with residents and other healthcare staff.	Actions consistent with wishes 1. 2/49 (5%) of intervention residents received a treatment in conflict with their prior stated wishes vs 17/96 (18%) controls, $P = .04$	Low ⊕⊕○○

Livingston et al 2013	Pre: 63 Post: 49	Pre-postintervention	United Kingdom	Educational program on ACP and end-of-life care: 10 sessions for residential and senior care workers and general nurses	2. OR 5.06 retreatments being consistent with wishes 95% CI 1.12–22.87 (Houben 2014) Place of death 1. Significant increase in residents with dementia dying in the care home from 47% to 76%, χ^2 test = 5.3, $P = .02$ Actions consistent with wishes 1. Where recorded (n = 20) end-of-life care was consistent residents with dementias wishes 71% to 100%, $P = .04$	Low ⊕⊕○○
Van Soest-Poortvliet et al 2015	I: 148	Prospective cohort	The Netherlands	New ACP completion: Establishing “goal of care” with residents within 8 weeks after admission. Measuring outcome with End-Of-Life in Dementia—Satisfaction With Care scale (EOLD-SWC)	QOL/satisfaction 1. Significant interaction between LOS and baseline comfort goal for family satisfaction with care and quality of dying, $P = .03$ 2. Only significant for families where residents were in NH < 6 months	Low ⊕⊕○○
Danis et al 1991	I: 175	Prospective cohort	USA	New ACP completion: Prospective interview of residents with documentation of their preferences with respect to hospitalization, intensive care, cardiopulmonary resuscitation, artificial ventilation, surgery and tube feeding in event of critical illness, terminal illness or permanent unconsciousness	Actions consistent with wishes 1. In 96 events- medical treatment was consistent with the directive in 75% of cases 2. 24/96 (25%) events were inconsistent with stated wishes 3. Consistency with patients wishes occurred less often when the AD was in the chart, $P = .045$ 4. Consistency with patients wishes more often when the patient remained competent, $P = .014$ 5. Consistency with patients wishes more likely when even occurred in hospital rather than the NH 59/68 vs 13/28, $P = .00003$	Low ⊕⊕○○
Mott et al 1988	I: 110	Prospective cohort	USA	New ACP completion: Medical treatment orders form filled by practice physicians looking after the facility, 4 levels of care: maximum care (all), intermediate care (hospitalization but to avoid surgery or intensive care if possible), Intermediate, less active care (avoid hospital but using antibiotics when indicated), comfort care only (avoid hospitalization, antibiotics and IV fluids except for comfort)	Use of life-sustaining treatments 1. Those in the less aggressive treatment groups group 1 58 admissions per 1000 person months compared with 13 admissions per 1000 person months in group 4, $P < .001$ 2. 774 hospital bed days vs 162 hospital bed days; $P < .001$ (G1 vs G4) Place of death 1. Deaths occurring in NH, group 1 55% vs group 4 85%; $P < .0001$	Very Low ⊕○○○
Tolle et al 1998	I: 180	Prospective cohort	USA	New ACP evaluation: Effect of POLST form	Hospitalization 1. Low rates of hospitalization 13% (n = 24), 2/24 died in hospital 2. 15% of hospitalizations were to extend life contrary to POLST (n = 4), 85% for comfort 3. Of 24 hospitalized 85% had DNR order, no one received CPR nor ICU Actions consistent with wishes 1. LOS hospitalization rates, 85% of hospitalization for symptom control as POLST advised	Very low ⊕○○○

(continued on next page)

Table 3 (continued)

Study Year	Population (NH Residents)	Design	Country	Intervention	Outcomes	GRADE
Hickman et al 2010	I: 817 C: 894	Controlled trial	USA	New ACP evaluation; Effect of POLST form	Use of life-sustaining treatments 1. CPR usage only 1 in POLST and 4 in non-POLST, too small to comment, tube feeding was similar-too little usage to analyze 25 POLST (3.4%), 62 non-POLST (6.9%) 2. No difference in use of medical interventions b/n residents with DNR orders and traditional full code orders OR 1.4, 95% CI 0.91–2.14, $P = .12$ 3. POLST had no effect on use of antibiotics regardless of whether choices specifies 4. POLST forms for comfort measures only were significantly less likely to receive life-sustaining medical treatment than those with POLST full tx, DNR and For resuscitation orders Palliative care and hospice 1. No difference in symptom assessment or management on logistic regression for those with and without POLST forms	Moderate ⊕⊕⊕○
Levy et al 2008	I: 45 C: 27	Pre-Post intervention	USA	Making ACP a Priority- a program designed to (1) identify residents at high risk of death, (2) inform the attending physician of the resident's mortality risk, (3) obtain palliative care or hospice consultation, (4) improve ACP documentation	Hospitalization 1. No change in LOS in those hospitalized 5.17 vs 3.33 post, $P = .42$ Place of death 1. Fewer residents died in hospital post intervention 48.2% pre and 8.9% post, $P < .0001$ 2. Significance persists when covariates taken into consideration in regression Palliative care/hospice 1. Mean no of days in palliative care programs in the pre-implementation was 1 day, this increased to 13.8 ± 25.9 days, $P = .09$ 2. No change in percentage of residents referred to hospice but pall care referral increased by 23.7%, $P = .02$ 3. Mean LOS in hospice did not differ significantly 24.3 vs 32.7 days postimplementation	Low ⊕⊕○○○
Zweig et al	I: 1031 residents C: 3000 residents (approx)	Prospective cohort	USA	Observational study to determine the effect of DNR orders on the treatment of NH residents with lower respiratory infection	Hospitalization 1. Less likely to be hospitalized with DNR order 23% vs 32% without, $P < .003$ 2. Even with other characteristics which make you more likely to be hospitalized	Low ⊕⊕○○○

AD, advance directive; CPR, cardiopulmonary resuscitation; CI, confidence interval; GP, general practitioner; HITH, hospital in the home; ICU, intensive care unit; LOS, length of stay; NH, nursing home; OR, odds ratio; RR, relative risk; Tx, treatment.

end-of-life symptom assessment or management between those with and those without ACPs in the 1 study in which it was examined.³²

DNR Orders and Interventions

One study showed no difference in medical interventions including hospitalization for residents with full code and residents with DNR orders,³² whereas a large study investigating the effect of DNR orders on hospitalization of residents with lower respiratory infection found 23% of those with DNR orders, and 32% of those without DNR orders, were hospitalized.⁴⁸

The Systematic Reviews

The literature search yielded 5 systematic reviews of partial relevance to this review. One had performed a meta-analysis while the others had a narrative synthesis. Houben et al⁴⁹ conducted a meta-analysis on concordance between patient preferences for end-of-life care and end-of-life care delivery. They included 3 studies on effect of the ACP intervention vs control, and found in favor of intervention. Of note, 1 of the included studies involved nursing home residents. Brinkman et al⁵⁰ systematically examined the effect of ACP on end-of-life care. Of the 113 studies included, they found 95% of them were observational, many retrospective in design, and 32% included nursing home populations. They found ACP was associated with decreased use of life-sustaining treatments, decreased hospitalizations, and increased use of in-patient hospice and community palliative care. Kirolos et al⁵¹ examined interventions to improve in-patient hospice and community palliative care referral, and 5 of the 6 studies included demonstrated an increase in in-patient hospice referral. Only 1 of their studies included an ACP intervention and, thus, was included in our analysis. This study did not show an increase in in-patient hospice referrals but did show an increase in community palliative care referrals.⁴⁶

Robinson et al⁵² studied the effectiveness of ACP interventions for people with pre-existing cognitive impairment and dementia. They found 2 studies that showed decrease in hospitalization and 1 study that showed increase in in-patient hospice use. Their conclusion was that the nursing home is too late for ACP conversations with only 36% of residents having capacity. Arendts et al⁵³ examined the interface between a residential aged care facility and the emergency department and found a complex interplay of factors influencing hospitalization from facilities including the type of facility, the functional and clinical status of residents, and individual facility transfer policies. They did find that ACP is helpful and compliance with it is generally good.

Discussion

Interventions

Findings from this review show beneficial effects for ACP interventions in the nursing home population, but the evidence supporting the findings is of generally low quality. The variability in the interventions was considerable, but over 75% could be classified broadly into 2 categories: (1) educational programs; or (2) introduction and evaluation of a new ACP in the facilities. Five of the 13 studies took either an educational approach for staff or an educational approach for staff, families, and residents; the most multifaceted of which included education of staff outside facilities including general practitioners and emergency department staff.^{28,29,39–41} Five of the 13 introduced or evaluated a new ACP in the facility, all of which were in the format of medical treatment orders.^{32,42–45} Two of these involved POLST^{32,43} and 3 were individual to the facility.^{42,44,45} These 2 categories of ACP interventions along with a third, the examination of other medical treatment orders including DNR and DNH, are the

most common interventions included in the area of ACP study. Comparing the types of interventions in this review is difficult as the grading of the studies was more focused on the study design than their proven outcome effects. The studies using educational programs were more robust generally in their design, but there is insufficient evidence to conclude that educational programs are better than introduction of new ACPs in facilities.

Outcomes; Hospitalization and Mortality

This review found that ACP reduces hospitalization of nursing home residents. These decreases were in the range of 9%–26%^{28,29,43–48} and could lead to considerable hospital savings. It is difficult to say whether this always translates to overall healthcare savings but Molloy et al²⁸ and Teo et al⁴⁷ did demonstrate this outcome. Interestingly, where studied, mortality was not decreased by hospitalization^{28,29}; an outcome that further supports treatment of nursing home residents in the facility and avoiding hospitalization where possible.

Outcomes; Consistency With Resident's Wishes

The studies showed that actions are highly consistent with resident's wishes when their ACP is completed^{39,40,42,43} and lead to decreased usage of unwanted life-sustaining treatments.^{32,44} This is not at a level of 100% compliance, as unwanted admissions and life-sustaining treatments are still recorded, but at much lower levels.⁴³ In some areas, such as antibiotics, ACP is less helpful³²; perhaps because antibiotics can also be given as part of "comfort measures" to alleviate discomfort, secretions, and delirium, 3 of the prevalent symptoms of infection that may occur at the end of life.

Outcomes; Place of Death, Palliative Care, and Hospice

The evidence shows that residents with ACP have a high incidence of dying in their preferred place of death, which was more often, in the nursing home.^{29,40,44,46} Increased need for knowledge and experience of nursing home staff in palliation at end of life is required to facilitate good dying. ACP was found to lead to increased and earlier community palliative care referrals,⁴⁶ which may indicate earlier recognition of the end-of-life phase and provision of care. However, another study found no difference in symptom assessment or management with ACP vs controls.³² Referral to in-patient hospice was not affected by ACP in the 1 study that looked at this outcome measure,⁴⁶ but prior systematic reviews have shown an increase in in-patient hospice referrals with ACP.^{50,51} In the USA, cost neutrality or savings was a policy goal of the Medicare hospice benefit at its onset.⁵⁴ A recent publication now shows that provision of in-patient hospice care did not reduce overall health costs.⁵⁴ This is worrying, as its provision, which is proven to improve quality of care,⁵⁵ should not be a money-saving exercise but a health initiative to provide good end-of-life care for nursing home residents and one would hope that it will not lead to withdrawal of this funding support.

Outcomes; QOL

QOL and satisfaction with the dying process were rarely measured in the studies reviewed but, when they were, ACP was found to improve both, in certain circumstances.^{41,45} In residents residing in the nursing home for less than 6 months, establishing goals of care was found to improve family satisfaction with the death but was not significant in those present for longer periods making it less generalizable to the entire nursing home population.⁴⁵ The 1 study looking at QOL found improvements with ACP and this extended to improvements in existential distress also.⁴¹ Again, given this is the

result from 1 small study, it would require further research to support its findings.

Outcomes; DNR Orders

The effect of DNR orders on medical treatment was addressed in 2 studies with conflicting results.^{32,48} One found no difference in the medical treatments provided to residents with full code vs DNR orders.³² The second found those with DNR orders were less likely to be hospitalized than those without.⁴⁸ The latter is more in keeping with both general consensus and systematic review of the area.⁵⁰ A DNR and DNH order is often taken as a proxy for a path toward less aggressive care, whether that was the original intention of the directive or not. Given the conflicting results from our review, we can draw no conclusions from this area.

Conclusions

The data on ACP interventions shows beneficial effects in nursing home populations; the most important of which include actions being consistent with the person's wishes and avoidance of unwanted hospitalization and life-sustaining treatments. The available evidence is generally not of high quality. Most studies in the area are of retrospective designs and, as a consequence, 44 such studies were excluded from this review.

ACP is important for frail older people where the possibility of developing cognitive impairment and losing decision-making capacity is high. With such high rates of dementia and decreased capacity in nursing home populations,⁵² it does feel like the opportunity for true ACP here has been lost. Most often the ACP is completed with substitute medical decision-makers who we know do not always make the same decisions that the resident would have.⁵⁶ This highlights the need for earlier commencement of the ACP process.

This review found that ACP can have important effects in the nursing home population, but the effect measurements are being derived from very few studies. Further high quality studies, especially randomized controlled trials, are required to support the reported outcomes and to help identify the types of ACP interventions that are most effective and beneficial for a nursing home population.

Key Points

- The nursing home population has unique characteristics for ACP.
- ACP has beneficial effects for the nursing home population.
- ACP leads to actions being more consistent with resident's wishes.
- ACP decreases unwanted hospitalization and use of life-sustaining treatments, and increases probability of dying in the nursing home.
- ACP is important for decreasing unwanted medical interventions at end-of-life
- ACP can decrease healthcare costs.
- The effects found are mainly from pooled low quality studies because of lack of high quality experimental studies in the area.

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Appendix 22 BMJ Open publication

BMJ Open Implementation of 'Goals of Patient Care' medical treatment orders in residential aged care facilities: protocol for a randomised controlled trial

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To cite: Martin RS, Hayes BJ, Hutchinson A, *et al.* Implementation of 'Goals of Patient Care' medical treatment orders in residential aged care facilities: protocol for a randomised controlled trial. *BMJ Open* 2017;**7**:e013909. doi:10.1136/bmjopen-2016-013909

► Prepublication history and additional material is available. To view please visit the journal (<http://dx.doi.org/10.1136/bmjopen-2016-013909>).

Received 17 August 2016
Revised 12 December 2016
Accepted 2 February 2017



CrossMark

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ABSTRACT

Introduction: Systematic reviews demonstrate that advance care planning (ACP) has many positive effects for residents of aged care facilities, including decreased hospitalisation. The proposed Residential Aged Care Facility (RACF) 'Goals of Patient Care' (GOPC) form incorporates a resident's prior advance care plan into medical treatment orders. Where none exists, it captures residents' preferences. This documentation helps guide healthcare decisions made at times of acute clinical deterioration.

Methods and analysis: This is a mixed methods study. An unblinded cluster randomised controlled trial is proposed in three pairs of RACFs. In the intervention arm, GOPC forms will be completed by a doctor incorporating advance care plans or wishes. In the control arm, residents will have usual care which may include an advance care plan. The primary hypothesis is that the GOPC form is superior to standard ACP alone and will lead to decreased hospitalisation due to clearer documentation of residents' medical treatment plans. The primary outcome will be an analysis of the effect of the GOPC medical treatment orders on emergency department attendances and hospital admissions at 6 months. Secondary outcome measurements will include change in hospitalisation rates at 3 and 12 months, length of stay and external mortality rates among others. Qualitative interviews, 12 months post GOPC implementation, will be used for process evaluation of the GOPC and to evaluate staff perceptions of the form's usefulness for improving communication and medical decision-making at a time of deterioration.

Dissemination: The results will be disseminated in peer review journals and research conferences. This robust randomised controlled trial will provide high-quality data about the influence of medical treatment orders that incorporate ACP or preferences adding to the current gap in knowledge and evidence in this area.

Trial registration number: ACTRN12615000298516, Results.

INTRODUCTION

Goals of Patient Care (GOPC) form

The trial Residential Aged Care Facility (RACF) GOPC form (see online

Strengths limitations of this study

- New medical treatment order, specifically for aged care facility residents.
- First randomised controlled trial examining the effects of the Goals of Patient Care (GOPC) process in Residential Aged Care Facilities.
- Quantitative and qualitative methods for thorough examination of the GOPC medical treatment orders' effects.
- Small number of residential aged care facilities involved.
- The GOPC is not evaluated in this study for its effect on improving compliance of medical treatment with the residents' treatment preferences.

supplementary appendix 1) is a document used to record medical treatment plans for residents in the event of clinical deterioration. It takes into account the current medical condition as well as residents' wishes and any prior advance care planning (ACP). As it is specifically for residents in RACFs, it identifies whether residents are open to hospital transfer for treatment escalation. The form is completed by a physician with the resident or their substitute medical decision-maker (SDM), or both.

The GOPC form originated in Tasmania, Australia, where it was developed for their inpatient and RACF populations.¹ This approach identifies: (1) the overall goals of care; and (2) specific treatment escalation and limitations proportionate to that goal. The aim is to avoid focusing only on interventions in isolation, such as cardiopulmonary resuscitation (CPR), intubation or intravenous antibiotics. In 2013, this approach was adapted by one of the authors (BH) to replace the hospital 'limitation of medical treatment' form in use by Northern Health, Victoria.² From this, BH developed the trial version of the GOPC specifically for RACF residents addressing limitations to

treatment and place of care. The form was developed in consultation with geriatricians working with the RACF inreach service. This is the first study examining its effects on RACF residents. The form has been made available to other health services in the state of Victoria and there are plans for its wider use.

There are three overall goals with six potential goal options, see [figure 1](#):

- Goal A and B apply to residents for whom the plan is to treat reversible illness, even if the burdens of that treatment might be considerable; hospital transfer would be appropriate. Goal A identifies residents for no treatment limitation and for whom attempted CPR would apply. Goal B identifies residents for whom some treatment limitations apply, including not for attempted CPR or intubation.
- Goal C applies to residents for whom investigations or treatment should only be undertaken if non-burdensome. Goal C1 identifies residents for trial of treatment at facility and for hospital transfer if required. Goal C2 identifies residents for trial of treatment at the facility but not for hospital transfer in the event of deterioration. Goal C3 identifies residents who are not for further treatments of new illnesses, and who are opting for symptom management only.

- Goal D identifies residents who are in the terminal stage of illness (last hours and days of life), and for whom all interventions should be for comfort only.

The GOPC form is different from, but related to, an advance care plan. An advance care plan is usually regarded as a communicate between residents or their SDM and staff, and is completed by the resident/SDM. The GOPC, however, is a communicate between staff and is completed by a doctor. Using a shared decision-making discussion with the resident and/or SDM, information about the resident's illness trajectory, potential for deterioration and medical management options is provided. Within this context, prior ACP is translated into clinical language to guide healthcare professionals in their treatment decisions for that resident. In the absence of formal prior ACP, medical treatment planning can still take place by exploring, and taking into account, the resident's values and what matters most to them. This can be done with a resident who retains capacity or with the SDM of a resident lacking capacity to participate. Availability of a GOPC form can be particularly helpful when a resident is being reviewed by a doctor or nurse who is unfamiliar with that person, their values or their treatment plans. Availability of a

GOAL A: FOR TREATMENT OF ALL REVERSIBLE ILLNESSES	
☐ FOR CPR and appropriate life-sustaining treatments	→ FOR TRANSFER TO HOSPITAL (if required treatment cannot be provided in the facility)
GOAL B: FOR TREATMENT OF REVERSIBLE ILLNESS WITH FOLLOWING LIMITATIONS	
☐ NOT FOR CPR or INTUBATION - but is for other appropriate life-sustaining treatments	→ FOR TRANSFER TO HOSPITAL (if required treatment cannot be provided in the facility)
GOAL C: FOR TREATMENT OF REVERSIBLE ILLNESS ABLE TO BE MANAGED WITH SIMPLE, NON-BURDENSOME TREATMENT. GOOD SYMPTOM MANAGEMENT	
NOT FOR CPR or INTUBATION	
☐ - is for treatment of illness if this can be done without causing excessive distress. For hospital treatment if required.	→ Aim to provide care in the facility but TRANSFER TO HOSPITAL if necessary
OR	
☐ - is for trial of treatment at the facility, if this can be done without causing excessive distress. If deteriorates, is for comfort measures only.	→ NOT FOR TRANSFER TO HOSPITAL if condition deteriorates - unless symptoms cannot be managed in facility eg fracture
OR	
☐ - NOT for life-prolonging treatment of new illness / deterioration. All treatment is aimed at comfort and relieving symptoms.	→ NOT FOR TRANSFER TO HOSPITAL unless symptoms cannot be managed in the facility eg fracture
GOAL D: COMFORT DURING DYING – TERMINAL CARE (prognosis is assessed to be hours or days)	
☐ All treatment is aimed at relieving symptoms and supporting the resident / patient and their family / important others	→ Commence End-of-life Plan → NOT FOR TRANSFER TO HOSPITAL unless symptoms cannot be managed in the facility eg fracture pain

Figure 1 The options on the Goals of Patient Care medical treatment orders as seen on the complete Goals of Patient Care Residential Aged Care Facility form are shown here.

completed GOPC form is not intended to replace a discussion with the SDM at the time of deterioration. It does provide a starting point for that discussion by a clinician who does not know the resident and can be particularly helpful when the SDM is unable to be contacted in a timely way. Additionally, the language is unambiguous and directive in nature.

Background

Systematic review identifies ACP as a beneficial intervention for aged care facility residents.³ Studies in the USA have shown improvements in treatment decisions for residents with the introduction of medical treatment forms such as the Physician Orders for Life-Sustaining Treatment (POLST) and others adapted from it.⁴ Such studies have not been conducted in Australia and the intention of this study is to show that such innovations are translatable to our target population. We hypothesise that the introduction of this medical treatment order will lead to decreased acute healthcare usage, when compared with usual care, by improving communication of the residents' wishes to all healthcare staff leading to more appropriate healthcare decisions.

The POLST was first introduced to address shortcomings found with advance care plans, including difficulty with their interpretation^{5–9} and not being in a form that ambulance paramedics could follow.¹⁰ A systematic review of the literature has shown that extensive ACP interventions have resulted in increased compliance with patient wishes and satisfaction with care, but needs to include more than just a written document.¹¹ The POLST intervention, like the GOPC form, was developed to help ensure the wishes of individuals with advanced illness or frailty were honoured by documenting their preferences as medical treatment orders.¹² Studies have shown that patients with such orders were less likely to receive unwanted interventions including hospitalisation,^{13–15} and intravenous fluids,¹⁶ than those with traditional ACPs alone.¹³

The incidence of transfers from RACFs to the emergency department (ED) has been measured at <30 transfers per 100 bed days,¹⁷ but varies depending on facility and location. Hospitalisation can be burdensome for nursing home residents,^{5 18} and many, when asked, would prefer to be treated in their RACF where possible.¹⁹ Given their frailty, high incidence of dementia and multimorbidity RACF residents have an increased incidence of acute illness compared with the ambulatory population. This is reflected by a high incidence of acute healthcare usage.⁶ Up to 48% of these hospital transfers are thought to be avoidable.^{7 20} Interventions targeting these admissions, according to a recent systematic review,²⁰ include, improving palliative care provision,^{21–23} improving ACP interventions,^{24 25} improving treatment of pneumonia and chronic obstructive pulmonary disease within facilities^{26–28} and providing ambulatory geriatric care through geriatrician review of residents within RACFs.^{19 29 30}

Dementia, estimated to affect over 50% of RACF residents,^{18 31 32} hinders the decision-making capacity of the resident, especially at times of acute illness. The prevalence of dementia also means that at the time of admission to the RACF, many residents will no longer be able to undertake their own ACP. Local RACF practice for this situation is to invite the SDM to complete an ACP on behalf of the resident, a document that cannot have the same authority as a resident-completed advance care plan. The introduction of the RACF 'GOPC' medical treatment orders will make the wishes of frail residents clearer, but within the parameters of treatment that might be effective for their condition. We hypothesise that the GOPC implementation will result in medical decisions being more congruent with residents' wishes, and more appropriate for residents' medical conditions.

Study objectives

The primary objective is to show that the introduction of the 'GOPC' medical treatment orders will lead to decreased ED attendances and admissions for RACF residents at 6 months post implementation as compared with usual care, by improving communication of the residents wishes leading to more appropriate usage of acute hospital care.

The secondary objectives are to demonstrate that between intervention and control facilities the intervention will result in:

- ▶ a change in the rate of ED attendances, inpatient admissions and acute length of stay at 3 and 12 months;
- ▶ a change in acute healthcare usage;
- ▶ a change in healthcare costs;
- ▶ a change in external mortality rate;
- ▶ a change in facilitation of healthcare decision-making for all staff;
- ▶ a change in conflict between RACF staff, visiting healthcare professionals, residents and families when there is a need for acute healthcare decisions.

METHODS

Baseline characteristics and assessments will be documented for all participants. These will include age, sex, English-speaking status, comorbidities, presence of a life-limiting illness (excluding dementia) and medications. A cognitive screen will be undertaken using the Mini Mental State Examination (MMSE)³³ and also correlated with a diagnosis of dementia and use of medical treatments for dementia. A functional assessment screen will use the Barthel Index,³⁴ depression will be screened for using the Geriatric Depression Scale,³⁵ frailty will be assessed with Clinical Frailty Scale³⁶ and a geriatrician will do a brief capacity assessment. The presence of a prior instructional advance care plan and/or appointment of a SDM (medical enduring power of attorney) will be recorded, if available in the facility notes.

Hospital usage for each facility will be evaluated by accessing local hospital records to calculate a baseline event rate for this, 3, 6 and 12 months prior to initiation of the study.

The following data will be collected at 3, 6 and 12 months for included participants: acute healthcare usage including ED attendances, emergency admissions, outpatient department (OPD) attendances, residential inreach reviews (ambulatory geriatricians), length of hospital stay (LOS) and the associated costs. Death rates and place of death will also be recorded. 12 months after the implementation of the GOPC, the qualitative evaluation will take place with staff from the intervention facilities. The qualitative aspect of the study will complement the quantitative study and provide evidence that implementation of the GOPC intervention in RACFs is feasible and acceptable to clinicians caring for RACF residents.

Data triangulation between the quantitative and qualitative data will be undertaken to ascertain that the intervention is beneficial from a clinical and a healthcare administration perspective.^{37 38}

Focus group interviews will be used for exploring experiences of ACP and the GOPC implementation with RACF staff (excluding doctors). The views of general practitioners (GPs) who visit the intervention facilities will be explored using one-to-one semistructured interviews.

Focus groups and individual interviews will be audio recorded and a question guide will be used to explore with participants: their understanding of ACP; experiences of undertaking and implementing ACP within the RACF; understanding of the purpose and use of the GOPC; experiences of using the GOPC form at a time of resident deterioration and views about the relative usefulness of ACP and GOPC. Qualitative research is iterative and unanticipated themes from earlier interviews will be explored in the later interviews.^{38 39} The focus groups will be facilitated by the principal researcher and an associate researcher trained in qualitative methodology. Individual interviews will be undertaken by the principal researcher.

The recorded interviews will be transcribed and key themes emerging from the interviews will be identified by the principal researcher and a coresearcher on an ongoing basis. Qualitative research is iterative and unanticipated themes from earlier interviews will be explored in the later interviews.^{38 39} The RACF staff focus groups will be repeated until saturation of themes has been reached, it is anticipated that saturation will be achieved with three focus groups, however, if required additional focus groups will be conducted.

A table indicating a schedule table of enrolment, interventions and assessments as is used in Standard Protocol Items; Recommendations for Interventional Trials (SPIRIT) is attached (see online supplementary appendix 2).⁴⁰

Table 1 Baseline characteristics and assessments

Baseline characteristics	Baseline assessments
Sex	Mini Mental State Examination
Age	Barthel Index of function
Comorbidities	Clinical Frailty Scale
Presence of life-limiting illness	Geriatric Depression Scale
Diagnosis of dementia	Capacity
Dementia treatment	
Regular medications	
PRN medications	
English as first language	
Advance care plan	
Medical power of attorney	
Evidence medical power of attorney	

Baseline characteristics and assessments

Baseline characteristics of participants were gathered and baseline assessments performed as outlined in table 1.

Study design

The study design, see figure 2, is an unblinded prospective cluster randomised controlled trial evaluating the effects of the implementation of the GOPC medical treatment orders for RACF residents. The clusters are defined as the individual RACFs. The RACFs are organised into cluster pairs and then randomised at a facility level.

Participants

The study population is all residents within the six participating RACFs for whom written informed consent can be obtained. A total of 45 facilities in the area were invited to partake by email contact followed up with a phone call to the facility manager. For those agreeable, a meeting took place to explain the study and confirm willingness to participate. Written informed consent form the facility manager was then obtained so as to access the RACFs prior 12-month hospital usage rates from local health services as well as basic demographic information. Of the 45 facilities, eight agreed to participate. Two withdrew consent due higher management of the aged care group not wanting to partake. The six remaining facilities were matched on key characteristics and randomised. Individual recruitment of residents then took place in each participating facility.

Healthcare staff will be invited to take part in focus groups and individual interviews by personal invitation. Staff across a range of positions within the facilities will be included.

Inclusion criteria

All residents in the age care facilities participating in the study, together with their SDM, will be invited to participate.

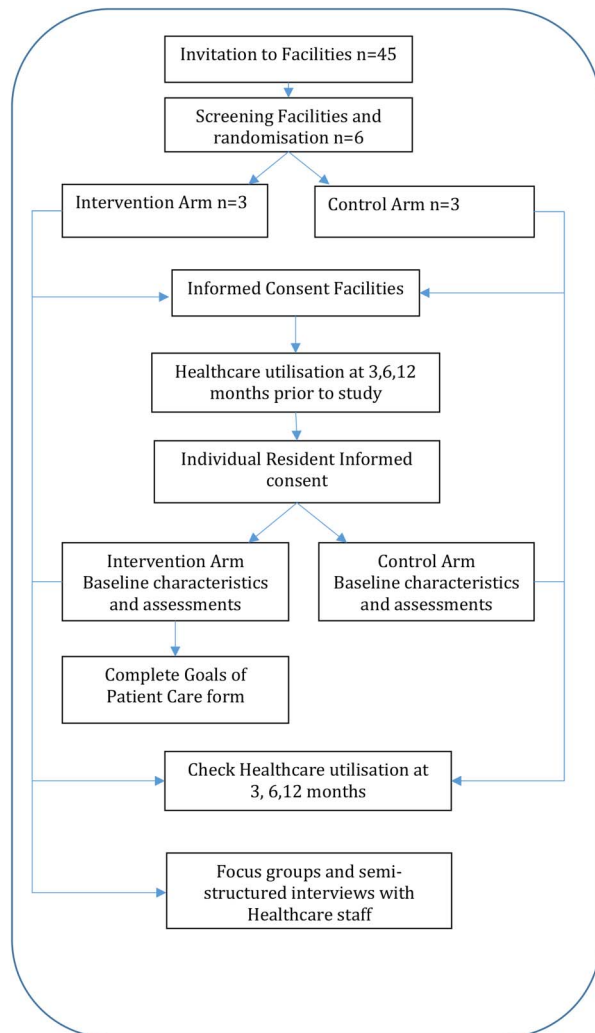


Figure 2 The study design is outlined from point of recruitment through to implementation and quantitative and qualitative data collection.

Exclusion criteria

Residents who lack capacity to provide written informed consent will be excluded from participating in our study, unless they have a SDM who is able to participate in the study in conjunction with or on behalf of a resident lacking medical decision-making capacity.

Consent

Participation in the study by individual residents, SDMs and staff is voluntary. Written informed consent will be obtained from the management of the RACFs involved. Written informed consent will be obtained from all participants in the intervention and control group. In event of decreased or a definite lack of capacity, cosigning/ substitute signing of the consent form by the SDM will be obtained. Telephone consent will be obtained from those SDMs that cannot attend in person (anticipating frailty issues with partners of residents) but wish to be involved. Telephone consent will be witnessed by a second person. A participant information sheet and consent form and a sample copy of the GOPC form will

be mailed to those persons from whom telephone consent will be sought.

For the healthcare professionals who participate in the study, written informed consent will be obtained prior to participation in focus group or individual interviews.

Intervention

The interventions to be compared are that of the new GOPC medical treatment order form and discussion, and usual care. It is important to note that immediately prior to this study there has been an extensive ACP and palliative care education initiative for local RACF staff using standardised content. This was an Australian Government and Advance Care Planning Australia initiative known as 'Decision Assist'.⁴¹

The GOPC form, as described in the introduction, is a medical treatment order completed by a doctor in collaboration with the resident or their SDM. This will occur in addition to any ACP already being undertaken by the RACF staff in the intervention sites. The GOPC indicates the preferred course of action in the event of clinical deterioration. It will be placed in the residents notes in their section on ACP. It will be available to all healthcare professionals reviewing the resident and a copy will be transferred with them to the ED with their RACF documentation. In case of computerised medical notes, the document will be scanned on to the system to the ACP section.

Usual care

'Usual care' will include the current processes in use within the individual RACFs. For many residents, this will include an advance care plan, which should be present in their paper or computerised notes. These advance care plans are sometimes completed by the resident and/or their SDM alone, without input from health professionals. In some facilities the RACF staff is involved in the ACP discussion and form completion. In others, the GPs are either required to be involved in the discussion or simply to sign the completed form. In no facilities will medical treatment orders be in use, as they are not currently used anywhere in local health services. Not all residents will be expected to have an advance care plan but it is expected that all will have been invited to complete an advance care plan at some stage since admission to the RACF.

Outcome measures

The primary outcome measure is that providing residents with a 'GOPC' medical treatment order will result in a 40% decrease in emergency attendance and emergency hospital admission at 6 months compared between intervention and control facilities.

- ▶ Secondary outcome measures will include:
- ▶ acute healthcare usage at 3, 6 and 12 months (ED attendances, acute care admissions, acute care length of stay, total inpatient bed days and number of ambulatory care attendances);

- ▶ direct costs of acute healthcare usage;
- ▶ the rate of uptake of the GOPC by residents in intervention RACFs
- ▶ the number of changes made to GOPC over 12 months;
- ▶ the presence of a diagnosis of Dementia with associated MMSE score and medical treatments on recruitment;
- ▶ 12-month mortality rate and place of death.

Qualitative outcomes

- ▶ The staff/resident/SDM opinion on improved communication of residents' healthcare wishes;
- ▶ the staff opinion on effect of GOPC on healthcare decision-making;
- ▶ staff/resident/SDM opinion on decreased conflict between RACF staff, visiting healthcare professionals, residents and families at times of acute healthcare decision-making.

Sample size

On calculation for individual randomisation for this study, $n=157$ persons per period for each arm were given a significance of 0.05 and 80% power. On calculation for cluster randomisation given an anticipated event rate of 0.5 (emergency reviews or admissions/6 months/facility bed) in control and 0.3 in intervention facilities and assumed intracluster correlation (ρ) which is a combination of within cluster variance, of 0.01 the estimated number of clusters required per intervention and control strata is 3.5. On testing feasibility of three clusters, it was found to be feasible if the number of clusters (k) was $>n(157) \times \rho(0.011)$. The anticipated event rates were based on a prior randomised controlled trial where the level of reduction in hospitalisation was in this range.²⁴

Randomisation

Randomisation will use the add-in random allocation program 'ralloc' available in Stata V.12.1 (StataCorp LP, Texas, USA). The randomisation will occur at facility level to minimise contamination between residents within the same facility. Facilities will be organised into cluster pairs based on their prior 12-month event rate for hospital attendances and admissions. Facilities will be blinded to the random allocation prior to agreeing to participate. On randomisation, no further blinding will be undertaken.

STATISTICAL METHODS

Quantitative data analysis

Descriptive statistics will be used to compare healthcare usage rates, and other secondary outcomes, between the intervention and the control arms at 3, 6 and 12 months. Multilevel Poisson regression models will be established to account for the intraclass correlation within each RACF when assessing the primary outcome of healthcare usage rates. Appropriate parametric and

non-parametric continuous data statistical tests and χ^2 tests will be used to evaluate the effectiveness of the intervention for the secondary outcomes. Descriptive statistics will also be reported at baseline to demonstrate the consistency of healthcare usage between the intervention and control arms prior to the study intervention. A table of statistical methods used for each outcome has been made (see online supplementary appendix 3).

Qualitative data analysis

The transcribed focus group and individual interviews will be transcribed verbatim. Transcribed data will be analysed thematically, using open and axial coding.³⁸ The coding will be undertaken by two researchers independently. Findings from the qualitative data will be analysed using qualitative description.⁴² Triangulation of findings from the qualitative analysis will be applied to the quantitative analysis to better understand, and interpret, the quantitative findings.

DISCUSSION

This study protocol is the first randomised controlled trial examining the effect of a GOPC medical treatment order in RACFs. Clinical studies have previously shown positive effects of ACP, particularly when translated into medical treatment orders,^{12 13 43} in the RACF population. Owing to lack of high quality studies in the area, the evidence is mainly taken from pooled low-quality publications.³

This study will perform a cluster randomised controlled trial in the area to provide the required data on medical treatment order effects in the RACF population. This trial design will allow for clustering of sites with similar key baseline characteristics thus limiting the intracluster variance and allowing for better comparison. By clustering residents by site, contamination of effect between residents in the same facility will be minimised. By using a control arm, it will be possible to examine and compare the effect of the intervention versus that of usual care. By minimising exclusion criteria, it is expected that a representative sample of all nursing home residents will be recruited for the study.

Hospitalisation has been chosen as the primary outcome measure for this study as it is well described as a positive effect of other types of ACP.^{12 24 25 43 44} Open communication regarding residents' wishes can lead to a decrease in unwanted acute hospitalisation.⁶ Given the frailty of this population, a 6-month period for the primary outcome was judged as most appropriate, with additional assessments at 3 and 12 months to provide a clearer picture of event rates over time. The GOPC form clearly states whether residents are open to a trial of treatment in the facility and if they wish for hospital transfer for treatment escalation if not improving. The clear language should avoid ambiguity and should help staff more easily decide on a treatment plan according to the prior choices made on the form.

Death rates and place of death are being examined to identify whether the form leads to a greater number of residents dying within the facility, which is the preference of the majority of residents and their SDMs.⁴⁵ Prior studies have shown that ACP can increase the rates of residents dying in their home by 29–40%.^{25 43 45 46} This study will examine whether similar rates are achieved through introduction of the GOPC form.

Evaluation of the situations in which the forms were used by staff will occur through the focus groups and semistructured interviews. Additionally, the effect the GOPC form had on the decisions made for residents when they became unwell will be explored, together with whether the decisions made were consistent with the medical treatment plan documented on the form. It is expected that the GOPC form, with clearly stated intentions for treatment, will help decision-making at a time of clinical deterioration and decrease conflict between healthcare staff. There is rich information about use of the form that can only be identified through this qualitative analysis. It is expected that the reported experiences of nursing staff, management staff and GPs with ACP, and with the GOPC form, will provide valuable insights about the use of medical treatment orders in RACFs.

Limitations in the study include a small number of included RACFs; it would provide further confidence in the results to repeat it with an increased sample size. The primary outcome is hospitalisation rather than congruency with wishes, which is a secondary outcome; however, due to an inability to accurately identify all the times in which actions would be congruent with wishes as well as not, it was felt hospitalisation would be a more accurate observation. The reasons for any identified hospitalisations against proposed wishes will then be reviewed.

CONCLUSION

The GOPC medical treatment orders are an innovation in the field of ACP. It is anticipated that this robust examination, using quantitative and qualitative methodologies, will demonstrate their implementation to have beneficial effects for residents, RACFs and health services.

Acknowledgements The authors acknowledge Northern Health Foundation for a small research grant for the study, and Northern Health Aged Care Research Department and The University of Melbourne for research scholarships for the principal researcher.

Contributors All authors, RSM, BJH, AH, PY and WKL were involved in the conception of the study. RSM and WKL were responsible for recruitment. BJH developed the GOPC form. AH was involved in the statistical planning. PY was involved in the ethics applications. RSM, BJH, AH, PY and WKL were involved in drafting the work. RSM, BJH, AH, PY and WKL have approved the final version for print. RSM, BJH, AH, PY and WKL agree to be accountable for all aspects of the work.

Funding Northern Health Foundation.

Competing interests None declared.

Ethics approval The trial has ethical approval from the Northern Health Human Research Ethics Committee (HREC/15/NH/6). For retrieval of baseline hospital usage rates two further ethics approvals were sought. Approval was given from the Austin Health Human Research Ethics Committee; LNR 15/Austin/169. Approval was also given from the Melbourne Health Quality Assurance section of the Ethics Committee; QA2016047.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement Sharing of data from the project will be carried out through research publications and presentations at local, national and international meetings.

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BMJ Open 2017 7:

doi: 10.1136/bmjopen-2016-013909

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