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Implementation of "Goals of Patient Care" Medical Treatment Orders in Residential Aged Care Facilities: protocol for a randomised controlled trial.

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Keywords: Advance Care Planning, Medical Treatment Orders, Residential Aged Care Facilities, End-Of-Life

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Abstract

Introduction

Systematic reviews demonstrate that advance care planning has many positive effects for residents of aged care facilities, including decreased hospitalisation,[1]. The Residential Aged Care Facility (RACF) “Goals of Patient Care” (GOPC) form presented here,[appendix 1] incorporates residents’ advance care plans or wishes into medical treatment orders. They help guide healthcare decisions made in planned and emergency situations.

Methods and analysis

A study is proposed to evaluate the GOPC form using a cluster randomised controlled trial in three pairs of RACFs. Baseline characteristics will be recorded from all participants. The comparator will be usual care. Acute healthcare utilisation in all facilities will be measured and compared. At 12 months, qualitative analysis, using focus groups and semi-structured interviews, will further explore use of the form. The primary outcome will analyse the effect of the GOPC medical treatment orders on Emergency Department attendances and hospital admissions at 6 months. Secondary outcomes will include; 1. change in hospitalisation rates at 3 and 12 months; 2.out-patient appointments; 3. Residential InReach reviews; 4. length-of-stay; 5. healthcare costs; 6. uptake of GOPC in the RACFs; 7. resident’s cognitive function, MMSE score diagnosis of dementia; and 8. death rates and place of death. Qualitative analysis will be used to do a process evaluation of the form and also to evaluate staff perceptions on whether its use improves communication and facilitation of medical-decision making, twelve months post implementation.

Ethics and dissemination

The trial is approved by the Northern Health Human Research Ethics Committee;HREC/15/NH/6. The results will be disseminated in peer review journals, national and international research conferences and local meetings. This robust randomised controlled trial will provide high quality data about the influence of medical treatment orders, that incorporate advance care planning or preferences. It will add to the current gap in knowledge and evidence in this area.

Trial Registration

The trial is registered with the Australia and New Zealand Clinical Trial Registry; Trial ID: ACTRN12615000298516.

Keywords: Advance Care Planning, Medical Treatment Orders, Residential Aged Care Facilities, End-Of-Life

Strengths of the study

- New medical treatment order, specifically for aged care facility residents
- Robust study design
- First randomised controlled trial examining any effects of an ACP in RACFs since the 1990s
- Both quantitative and qualitative methods for thorough examination of the GOPC medical treatment orders’ effects

Limitations of the study

- Small number of residential aged care facilities involved

Introduction

Goals of Patient Care form

The Goals of Patient Care form,[appendix 1], is a document used to record medical treatment plans for residents in event of clinical deterioration. It takes into account the current medical condition as well as residents' wishes and any prior advance care planning. 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.

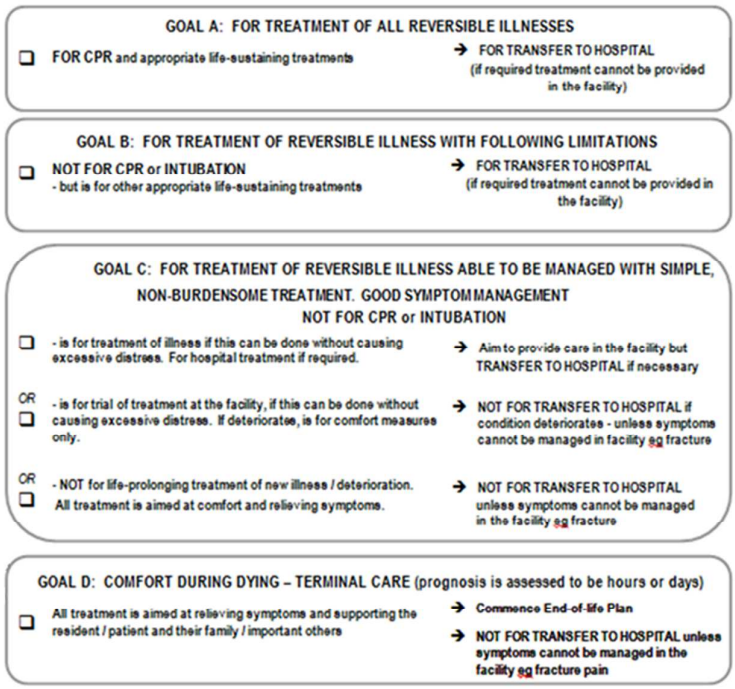

Figure 1. GOPC Options

There are six Goal options. 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 CPR 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 GOPC form relates to advance care planning. An ACP is usually regarded as a communique between residents or their SDM and staff, and is completed by the resident/SDM. The GOPC, however, is a communique between staff and is completed by a doctor. It translates ACP into clinical language and guides healthcare professionals in their treatment choices for that resident. It is 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. Additionally, the language is unambiguous and directive in nature.

Background

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,[2]. 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 the this medical treatment order will lead to decreased acute healthcare utilisation, 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 ACPs, including difficulty with their interpretation,[3-7] and not being in a form that ambulance paramedics could follow,[8]. A systematic review of the literature has shown that extensive advance care planning interventions have resulted in increased compliance with patient wishes and satisfaction with care, but needs to include more than just a written document,[9]. 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,[10]. Studies have shown that patients with such orders were less likely to receive unwanted interventions including hospitalisation,[11-13], and intravenous fluids,[14], than those with traditional ACPs alone,[11].

The incidence of transfers from RACFs to the emergency department (ED) has been measured at greater than 30 transfers per 100 bed days,[15], but varies depending on facility and location. Hospitalisation can be burdensome for nursing home residents,[3,16], and many, when asked, would prefer to be treated in their RACF where possible,[17]. Given their frailty, high incidence of dementia and multi-morbidity RACF residents have an increased incidence of acute illness compared with the ambulatory population. This is reflected by a high incidence of acute healthcare utilisation,[18]. Up to 48% of these hospital transfers are thought to be avoidable,[5,19]. Interventions targeting these admissions, according to a recent systematic review,[19], include, improving palliative care provision,[20-22], improving ACP interventions,[23,24], improving treatment of pneumonia and COPD within facilities,[25-27], and providing ambulatory geriatric care through Geriatrician review of residents within RACFs,[17,28,29].

Dementia, estimated to affect over 50% of RACF residents,[30-32], hinders the decision making capacity of the resident, especially at times of acute illness. The introduction of the RACF “Goals of Patient Care” 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 care.

Study design

The study is a prospective cluster randomised controlled trial evaluating the effects of the implementation of the GOPC medical treatment orders for RACF residents. Randomisation will use the add-in random allocation program ‘ralloc’ available in Stata version 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 baseline characteristics. Facilities will be blinded to the random allocation prior to agreeing to participate. Upon randomisation no further blinding will be undertaken.

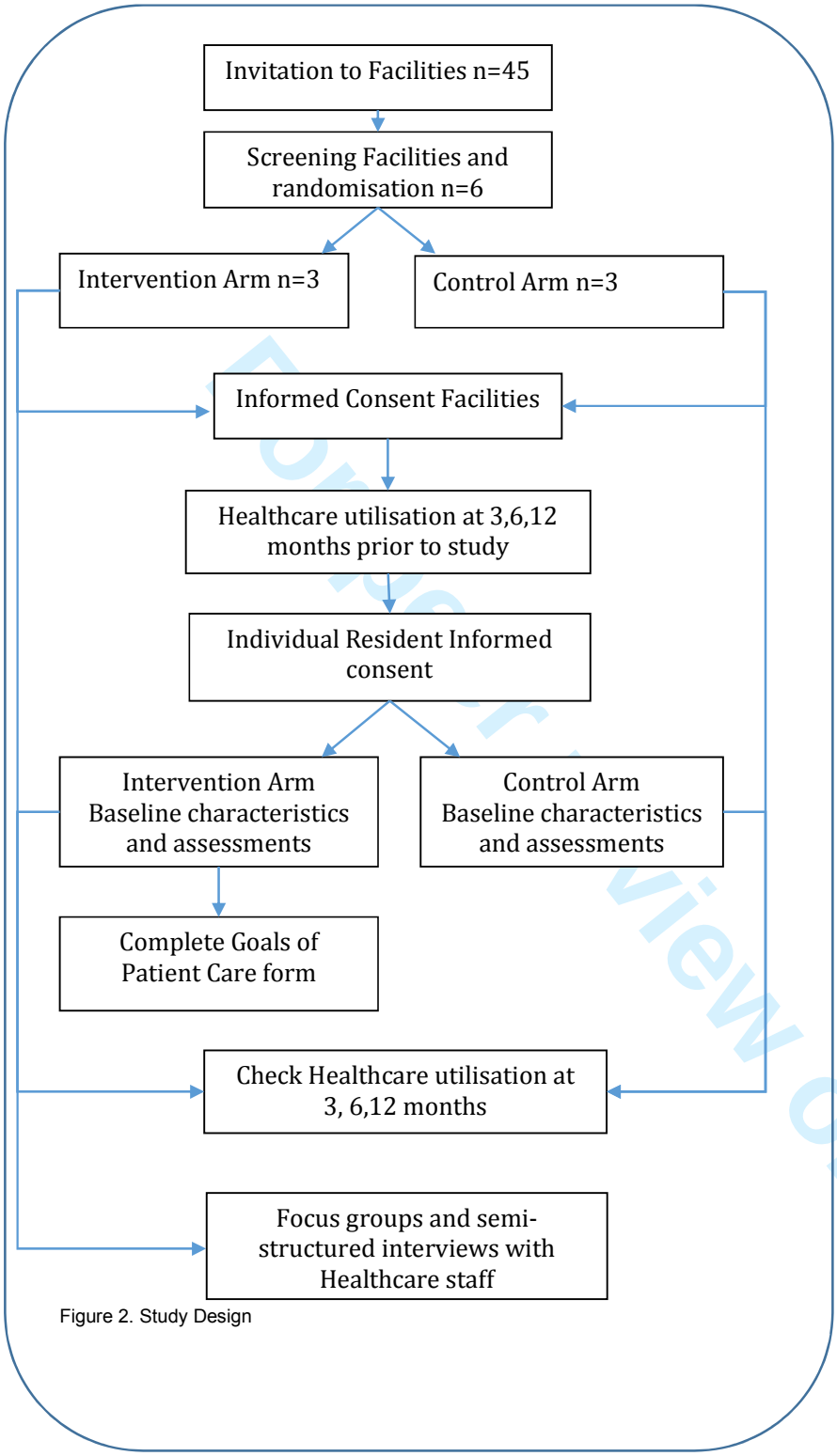

Figure 2. Study Design

Study registration and ethics

The trial has ethical approval from 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 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. It is also registered with the Australia and New Zealand Clinical Trial Registry (Trial ID: ACTRN12615000298516).

Study Objectives

The primary objective is to show that the introduction of the "Goals of Patient Care" medical treatment orders will lead to decreased emergency department attendances and admissions for residential aged care facility residents at six 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 that the intervention will result in:

- A change in the rate of emergency department attendances and admissions at 3 and 12 months
- A change in acute health care utilisation
- A change in health care costs
- A change in external mortality rate
- A change in communication of the residents wishes
- 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

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.

The secondary outcome measures will include:

- The change in the rate of emergency department attendance and admission at 3 and 12 months
- The change in acute healthcare utilisation and costs at 6 and 12 months
- The rate of uptake of the GOPC in intervention RACFs
- The rate of changes made to GOPC
- The number of residents with active palliation
- The presence of a diagnosis of Dementia with associated MMSE score and medical treatments
- The change in death rate and place of death
- The staff/resident/substitute medical-decision maker opinion on improved communication of residents' healthcare wishes
- The staff opinion on effect of GOPC on healthcare decision making
- Staff/resident/substitute medical-decision maker opinion on decreased conflict between RACF staff, visiting healthcare professionals, residents and families at times of acute healthcare decision making

Study population

The study population will be all residents within the six participating RACFs for whom written informed consent can be obtained. Forty-five facilities in the area will be invited to partake, three pairs of RACFs will then be selected, matched on key characteristics and randomised. Individual recruitment will then take 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 substitute decision-maker, will be invited to participate.

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 co-signing/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 usual care. 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. It indicates the preferred course of action in case of clinical deterioration. It will be placed in the residents notes in their section on Advance Care Planning. It will be available to all healthcare professionals reviewing the resident and a copy will transfer with them to the emergency department with their RACF documentation. In case of computerised medical notes the document will be scanned on to the system to the Advance Care Planning 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 ACPs are sometimes completed by the resident and/or their SDM alone, without input from health professionals. In some facilities the RACF staff are 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 ACP but it is expected that all will have been invited to complete an ACP at some stage since admission to the RACF.

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	Capacity
Dementia Treatment	
Regular Medications	
PRN Medications	
English As first Language	
Advance Care Plan	
Medical Power Of Attorney	
Evidence Medical Power Of Attorney	

Table 1. Baseline Characteristics and Assessments

Investigational Plan

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 Exam (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 Scale,[36]. A Geriatrician will do a brief capacity assessment. The presence of a prior instructional ACP and/or appointment of a SDM (medical enduring power of attorney) will be recorded, if available in the facility notes.

Hospital utilisation 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 commencement of the study.

The following data will be collected at 3, 6 and 12 months for included participants: acute healthcare utilisation including ED attendances, emergency admissions, outpatient department (OPD) attendances, residential in-reach reviews (ambulatory geriatricians) , length of hospital stay (LOS), and the associated costs. Death rates and place of death will also be recorded.

At 12 months the qualitative analysis will take place with focus groups and semi-structured interviews in Intervention facilities.

Statistical methods

Sample Size

On calculation for individual randomisation for this study, n = 157 persons per period for each arm 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/6months/facility bed) in control and 0.3 in intervention facilities and assumed intra-cluster correlation (p) 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 3 clusters, it was found to be feasible if the number of clusters (k) was greater than n (157) x p (0.011).

Qualitative data analysis

An interview question guide will be used for focus groups and individual interviews. 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. Focus groups and semi-structured interviews will be audio recorded and transcribed verbatim. Focus groups will be repeated until saturation of themes has been reached, it is anticipated that saturation will be achieved with three focus groups. The transcribed focus group and individual interviews will be analysed thematically, using open and axial coding.

Quantitative data analysis

Descriptive statistics will be used to compare healthcare utilisation rates, and other secondary outcomes, between the intervention and the control arms at 3, 6 and 12 months. Multi-level Poisson regression models will be established to account for the intra-class correlation within each RACF when assessing the primary outcome of health care utilisation rates. Chi-square and appropriate parametric and non-parametric continuous data statistical 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 health care utilisation between the intervention and control arms prior to the study intervention.

Discussion

This study protocol is the first randomised controlled trial examining the effect of advance care planning in RACFs since the 1990s,[23]. Clinical studies have previously shown positive effects of advance care planning, particularly when translated into medical treatment orders,[10,11,39], in the RACF population. Due to lack of high quality studies in the area, the evidence is mainly taken from pooled low quality publications,[1].

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 intra-cluster 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 advance care planning,[10,23,24,39,40]. Open communication regarding residents' wishes can lead to a decrease in unwanted acute hospitalisation,[18]. 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,[37]. Prior studies have shown that ACP can increase the rates of residents dying in their home by 29-40%,[24,37-39].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 semi-structured 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 general practitioners with both ACP, and with the GOPC form, will provide valuable insights about the use of medical treatment orders in RACFs.

Conclusion

The Goals of Patient Care 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.

Acknowledgement

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Contributorship Statement

All authors, RM, BH, AH, PY and KL were involved in the conception of the study. RM and KL were responsible for recruitment. BH developed the GOPC form. AH was involved in the

statistical planning. PY was involved in the ethics applications. RM, BH, AH, PY AND KL were involved in drafting the work. RM, BH, AH, PY and KL have approved the final version for print. RM, BH, AH, PY AND KL agree to be accountable for all aspects of the work.

Competing Interests

There are no significant competing financial, professional or personal interests that might have influenced the work described in this manuscript.

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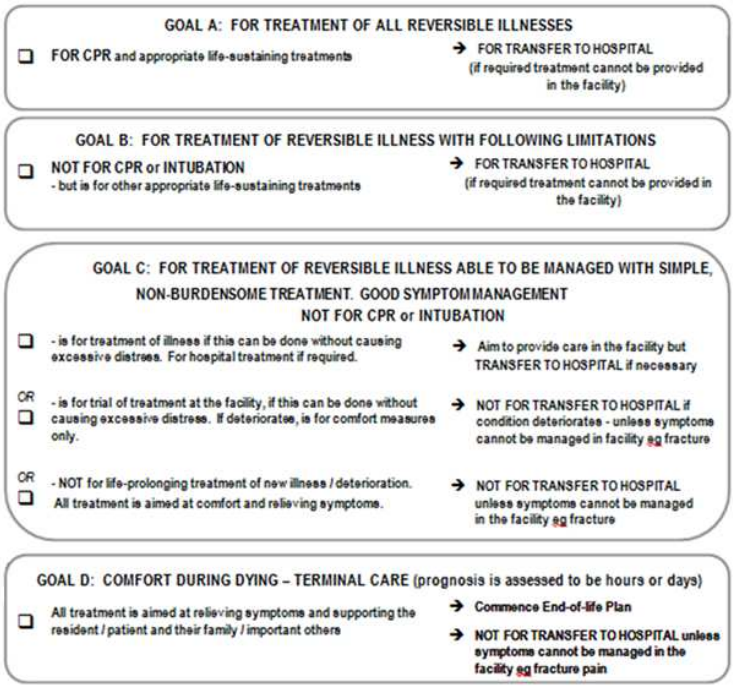

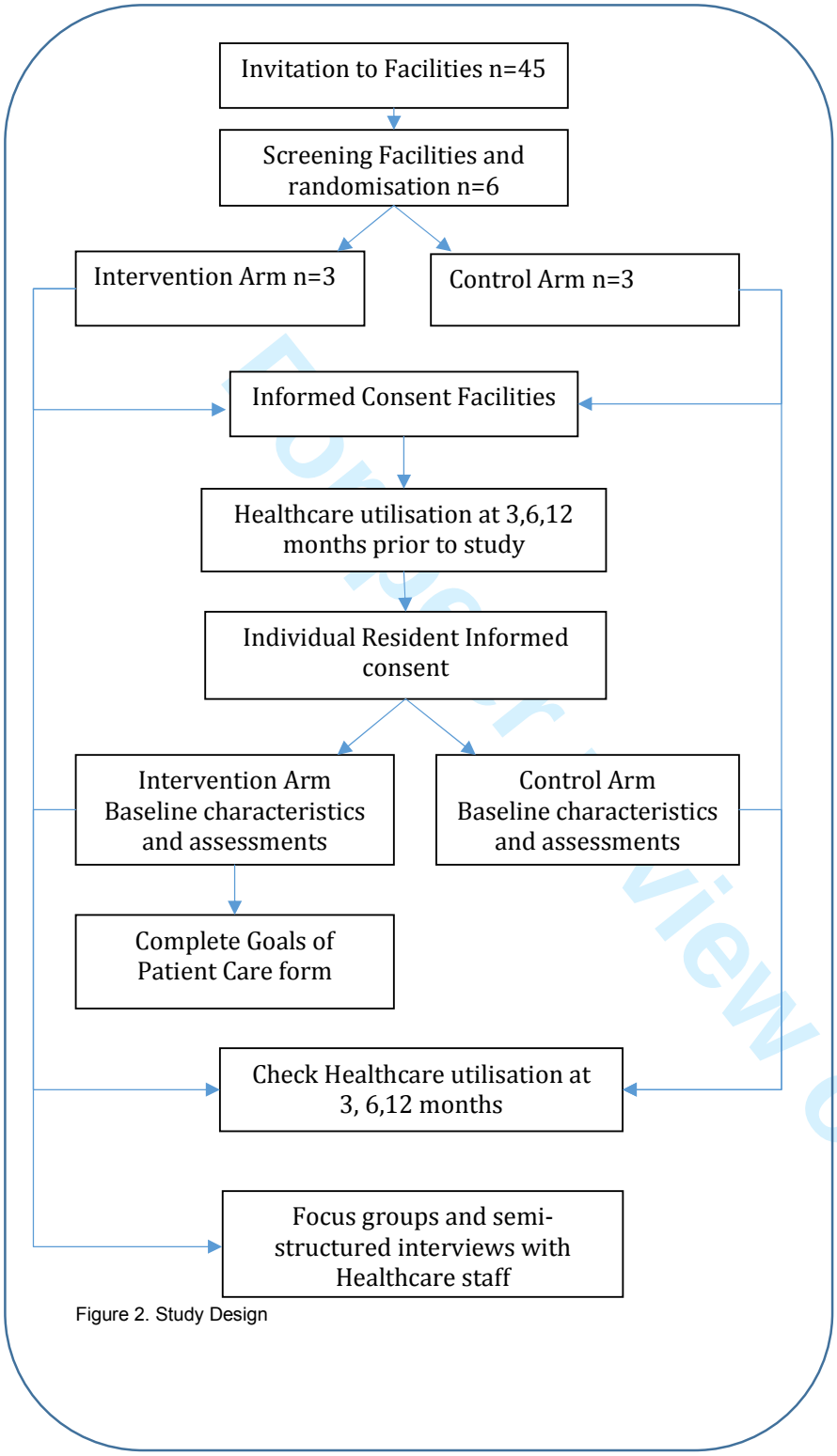

Figure 2. Study Design

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	Capacity
Dementia Treatment	
Regular Medications	
PRN Medications	
English As first Language	
Advance Care Plan	
Medical Power Of Attorney	
Evidence Medical Power Of Attorney	

Table 1. Baseline Characteristics and Assessments

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: _____

Northern Health

Last updated Dec 2014

CPR = Cardiopulmonary Resuscitation ACP = Advance Care Plan / Directive

Adapted from the Southern Tasmania Goals of Care Plan and Northern Health Goals of Patient Care Summary

Used with permission of Northern Health – not to be modified

RESIDENTIAL AGED CARE --- GOALS OF PATIENT CARE (MEDICAL) - *TRIAL FORM*

SURNAME: _____ GIVEN NAME: _____ D.O.B. _____

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

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.)

Table 1: CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)[1,2]	See table 2	1
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	3
	2b	Specific objectives or hypotheses	Whether objectives pertain to the the cluster level, the individual participant level or both	6
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		**7**
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	7
	4b	Settings and locations where the data were collected		**7**
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	7,8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and	Whether outcome measures pertain to the cluster level, the individual participant level or both	9

		when they were assessed		
	6b	Any changes to trial outcomes after the trial commenced, with reasons		**9**
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines		
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		**4**
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	4
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	4
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	4
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	4
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete	4

			enumeration, random sampling)	
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		**N/A**
	11b	If relevant, description of the similarity of interventions		
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		**N/A**
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	Not applicable yet
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	Not applicable yet
Recruitment	14a	Dates defining the periods of recruitment and follow-up		Not applicable yet
	14b	Why the trial ended or was stopped		Not applicable yet
Baseline data	15	A table showing baseline demographic and clinical	Baseline characteristics for the individual and cluster levels as	8

		characteristics for each group	applicable for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	Not applicable yet
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	Not applicable yet
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		Not applicable yet
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		Not applicable yet
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[3])		Not applicable yet
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		**2**
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	9
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		Not applicable yet
Other information				
Registration	23	Registration number and		**1**

		name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	**This is the protocol**
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	**10**

** Note: page numbers optional depending on journal requirements*

Table 2: Extension of CONSORT for abstracts[1,2] to reports of cluster randomised trials

Item	Standard Checklist item	Extension for cluster trials
Title	Identification of study as randomised	**Identification of study as cluster randomised**
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected	**Eligibility criteria for clusters**
Interventions	Interventions intended for each group	
Objective	Specific objective or hypothesis	**Whether objective or hypothesis pertains to the cluster level, the individual participant level or both**
Outcome	Clearly defined primary outcome for this report	**Whether the primary outcome pertains to the cluster level, the individual participant level or both**
Randomization	How participants were allocated to interventions	**How clusters were allocated to interventions**
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	
Results		
Numbers randomized	Number of participants randomized to each group	**Number of clusters randomized to each group**
Recruitment	Trial status[1]	
Numbers analysed	Number of participants analysed in each group	**Number of clusters analysed in each group**
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	**Results at the cluster or individual participant level as applicable for each primary outcome**
Harms	Important adverse events or side effects	
Conclusions	General interpretation of the results	
Trial registration	Registration number and name of trial register	
Funding	Source of funding	

[1] Relevant to Conference Abstracts

REFERENCES

1 Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, et al. CONSORT for reporting randomised trials in journal and conference abstracts. *Lancet* 2008, 371:281-283

2 Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG at al (2008) CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. *PLoS Med* 5(1): e20

3 Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D. Better reporting of harms in randomized trials: an extension of the CONSORT statement. *Ann Intern Med* 2004; 141(10):781-788.

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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Complete List of Authors:	Martin, Ruth; Northern Health, Aged Care; University of Melbourne, Faculty of Medicine, Dentistry, and Health Sciences Hayes, Barbara; Northern Health, Advance Care Planning Hutchinson, Anastasia; Northern Health, Northern Health Research Centre Yates, Paul; University of Melbourne, Faculty of Medicine, Dentistry, and Health Sciences; University of Melbourne, Faculty of Medicine, Dentistry, and Health Sciences Lim, Wen; Northern Health, Aged Care; University of Melbourne, Department of Medicine
Primary Subject Heading:	Geriatric medicine
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Keywords:	Advance Care Planning, Medical Treatment Orders, Residential Aged Care Facilities, End-Of-Life

Implementation of "Goals of Patient Care" Medical Treatment Orders in Residential Aged Care Facilities: protocol for a randomised controlled trial.

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Keywords: Advance Care Planning, Medical Treatment Orders, Residential Aged Care Facilities, End-Of-Life

Word count: 4074

Abstract

Introduction

Systematic reviews demonstrate that advance care planning 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 advance care planning (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 amongst 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.

Ethics and dissemination

The trial is approved by the Northern Health Human Research Ethics Committee;HREC/15/NH/6. 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 advance care planning or preferences adding to the current gap in knowledge and evidence in this area.

Trial Registration

The trial is registered with the Australia and New Zealand Clinical Trial Registry; Trial ID: ACTRN12615000298516.

Keywords: Advance Care Planning, Medical Treatment Orders, Residential Aged Care Facilities, End-Of-Life

Strengths of the study

- New medical treatment order, specifically for aged care facility residents
- Robust study design
- First randomised controlled trial examining the effects of the Goals of Patient Care process in RACFs
- Both quantitative and qualitative methods for thorough examination of the GOPC medical treatment orders’ effects

Limitations of the study

- 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.

Introduction

Goals of Patient Care form

The trial RACF Goals of Patient Care form [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. 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 Goals of Patient Care form originated in Tasmania, Australia, where it was developed for their inpatient and RACF populations [1]. This approach identifies: (i) the overall goals of care; and (ii) specific treatment escalation and limitations proportionate to that goal. The aim is to avoid focusing only on interventions in isolation, such as 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 not just limitations to treatment but also place of care. The form was developed in consultation with Geriatricians working with the RACF in-reach 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 cardiopulmonary resuscitation (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 communique between residents or their SDM and staff, and is completed by the resident/SDM. The GOPC, however, is a communique 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 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 the this medical treatment order will lead to decreased acute healthcare utilisation, 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 advance care planning 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 greater than 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 multi-morbidity RACF residents have an increased incidence of acute illness compared with the ambulatory population. This is reflected by a high incidence of acute healthcare utilisation [20]. Up to 48% of these hospital transfers are thought to be avoidable [7,21]. Interventions targeting these admissions, according to a recent systematic review [21], include, improving palliative care provision [22-24], improving ACP interventions [25,26], improving treatment of pneumonia and COPD within facilities [27-29], and providing ambulatory geriatric care through Geriatrician review of residents within RACFs [19,30,31].

Dementia, estimated to affect over 50% of RACF residents [32-34], 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 may 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 “Goals of Patient Care” 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 "Goals of Patient Care" medical treatment orders will lead to decreased emergency department attendances and admissions for residential aged care facility residents at six 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 emergency department attendances, inpatient admissions and acute length of stay at 3 and 12 months
- A change in acute health care utilisation
- A change in health care 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 Exam (MMSE) [35] and also correlated with a diagnosis of dementia and use of medical treatments for dementia. A functional assessment screen will use the Barthel Index [36]. Depression will be screened for using the Geriatric Depression Scale [37]. Frailty will be assessed with Clinical Frailty Scale [38]. 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 utilisation 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 commencement of the study.

The following data will be collected at 3, 6 and 12 months for included participants: acute healthcare utilisation including ED attendances, emergency admissions, outpatient department (OPD) attendances, residential in-reach reviews (ambulatory geriatricians), length of hospital stay (LOS), and the associated costs. Death rates and place of death will also be recorded. A table for

Twelve 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 to complement the quantitative study and provide evidence that implementation of the GOPC intervention in RACFs is both feasible and acceptable to clinicians caring for RACF residents

Data triangulation between the quantitative and qualitative data will be undertaken to ascertain that the interventional is beneficial both from a clinical and a healthcare administration perspective [39,40].

Focus group interviews will be used for exploring experiences of ACP and the GOPC implementation with RACF staff (excluding doctors). The views of General Practioners who visit the intervention facilities will be explored using one-to-one semi-structured interviews.

Both focus groups and individual interviews will be audio-recorded and use a question guide 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 both ACP and GOPC. Qualitative research is iterative and unanticipated themes from earlier interviews will be explored in the later interviews [40,41]. 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 co-researcher on an ongoing basis. Qualitative research is iterative and unanticipated themes from earlier interviews will be explored in the later interviews [40,41]. 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 SPIRIT is attached [appendix 2] [42].

Baseline Characteristics and Assessments

Baseline characteristics of participants were gathered and baseline assessments performed as outlined in table 1.

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	Capacity
Dementia Treatment	
Regular Medications	
PRN Medications	
English As first Language	
Advance Care Plan	
Medical Power Of Attorney	
Evidence Medical Power Of Attorney	

Table 1. Baseline Characteristics and Assessments

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. Forty-five 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 substitute decision-maker, will be invited to participate.

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 co-signing/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' [43].

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 Advance Care Planning. It will be available to all healthcare professionals reviewing the resident and a copy will transfer with them to the emergency department with their RACF documentation. In case of computerised medical notes the document will be scanned on to the system to the Advance Care Planning 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 are 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 utilisation at 3, 6 and 12 months (emergency department attendances, acute care admissions, acute care length of stay, total inpatient bed-days and number of ambulatory care attendances).
- Direct costs of acute healthcare utilisation
- 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/substitute medical-decision maker opinion on improved communication of residents' healthcare wishes
- The staff opinion on effect of GOPC on healthcare decision making

- Staff/resident/substitute medical-decision maker 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 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/6months/facility bed) in control and 0.3 in intervention facilities and assumed intra-cluster correlation (p) 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 3 clusters, it was found to be feasible if the number of clusters (k) was greater than n (157) x p (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 [25].

Randomisation

Randomisation will use the add-in random allocation program 'ralloc' available in Stata version 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. Upon randomisation no further blinding will be undertaken.

Statistical methods

Quantitative data analysis

Descriptive statistics will be used to compare healthcare utilisation rates, and other secondary outcomes, between the intervention and the control arms at 3, 6 and 12 months. Multi-level Poisson regression models will be established to account for the intra-class correlation within each RACF when assessing the primary outcome of health care utilisation rates. Chi-square and appropriate parametric and non-parametric continuous data statistical 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 health care utilisation between the intervention and control arms prior to the study intervention. A table of statistical methods used for each outcome has been made [Appendix 3].

Qualitative data analysis

The transcribed focus group and individual interviews will transcribed verbatim. Transcribed data will be analysed thematically, using open and axial coding [40]. The coding will be undertaken by two researchers independently. Findings from the qualitative data will be analysed using qualitative description [44]. 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 advance care planning, particularly when translated into medical treatment orders [12,13,45], in the RACF population. Due 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 intra-cluster 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 advance care planning [12,25,26,45,46]. Open communication regarding residents' wishes can lead to a decrease in unwanted acute hospitalization [20]. 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 [47]. Prior studies have shown that ACP can increase the rates of residents dying in their home by 29-40% [26,45,47,48].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 semi-structured 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 general practitioners with both 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 Goals of Patient Care 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.

Study Registration

It is registered with the Australia and New Zealand Clinical Trial Registry (Trial ID: ACTRN12615000298516).

Study ethics

The trial has ethical approval from 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 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.

Acknowledgement

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.

Contributorship Statement

All authors, RM, BH, AH, PY and KL were involved in the conception of the study. RM and KL were responsible for recruitment. BH developed the GOPC form. AH was involved in the statistical planning. PY was involved in the ethics applications. RM, BH, AH, PY AND KL were involved in drafting the work. RM, BH, AH, PY and KL have approved the final version for print. RM, BH, AH, PY AND KL agree to be accountable for all aspects of the work.

Competing Interests

There are no significant competing financial, professional or personal interests that might have influenced the work described in this manuscript.

Figure Legends

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.

Figure 2. The study design is outlined from point of recruitment through to implementation and quantitative and qualitative data collection.

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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	Capacity
Dementia Treatment	
Regular Medications	
PRN Medications	
English As first Language	
Advance Care Plan	
Medical Power Of Attorney	
Evidence Medical Power Of Attorney	

Table 1. Baseline Characteristics and Assessments

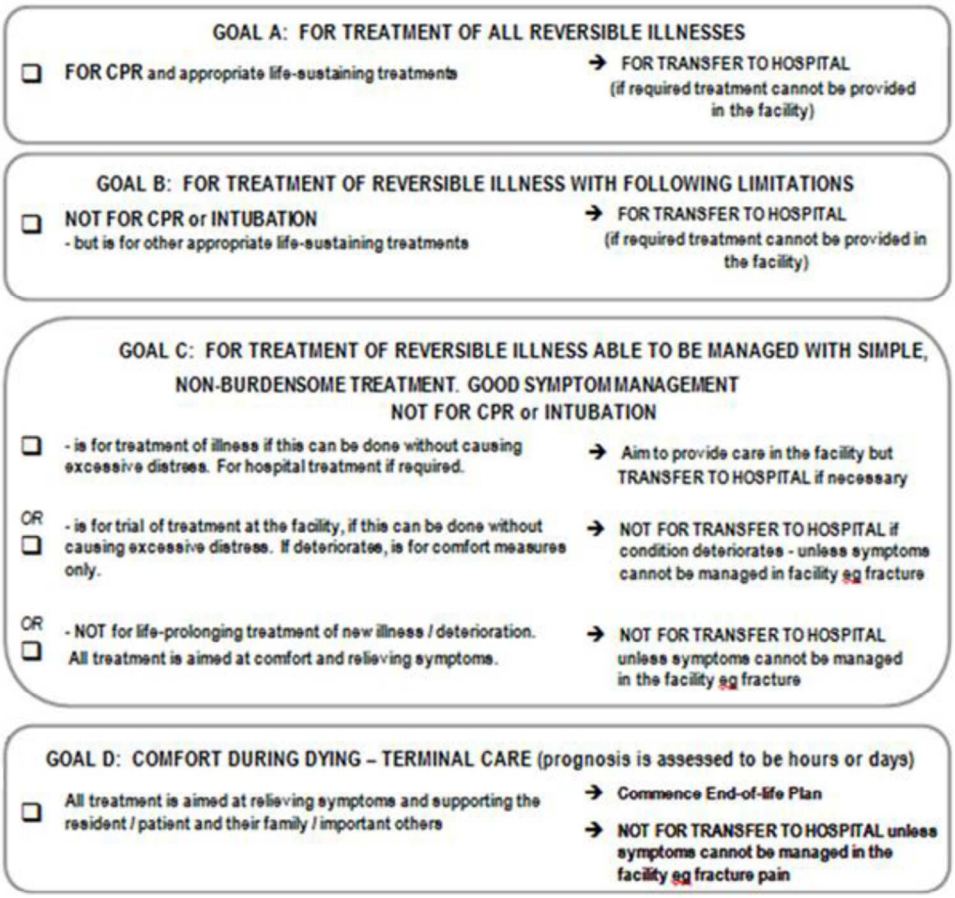

Figure 1. The options on the Goals of Patient Care medical treatment orders as seen on the complete Goals of Patient Care Residential Aged Care Facility form are shown here.

107x106mm (300 x 300 DPI)

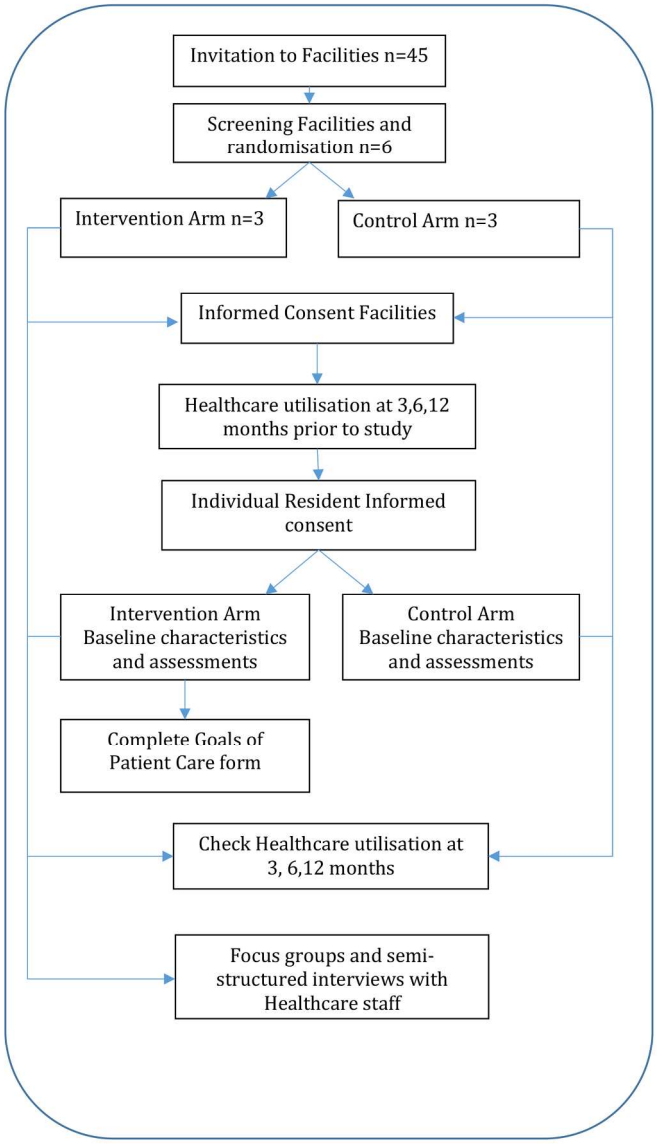

Figure 2. The study design is outlined from point of recruitment through to implementation and quantitative and qualitative data collection.

128x229mm (300 x 300 DPI)

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

Adapted from the Southern Tasmania Goals of Care Plan and Northern Health Goals of Patient Care Summary

Used with permission of Northern Health – not to be modified

Last updated Dec 2014

RESIDENTIAL AGED CARE --- GOALS OF PATIENT CARE (MEDICAL) - *TRIAL FORM*

SURNAME: _____ GIVEN NAME: _____ D.O.B. _____

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

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.)

Schedule of enrolment, interventions, and assessments.

	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			Close-out
TIMEPOINT	$-t_{1}$ (1 week)	0	t_{1} (3 months)	t_{2} (6 months)	t_{3} (12 months)	t_{x} (14 months)
ENROLMENT:						
Eligibility screen	x					
Facility Informed consent	x					
Individual Informed Consent	X					
Allocation		X				
INTERVENTIONS:						
[Treatment Arm]			X	X		
[Control Arm]			X	X		
ASSESSMENTS:						
Baseline Variables						
Demographics		X	X	X		
Past medical history		X	X	X		
Number of medications		X	X	X		
Presence of Dementia Diagnosis		X	X	X		
Presence of Advance Care Plan		X	X	X		
Documented Medical Power of Attorney		X	X	X		
Presence of Medical Power of Attorney	X	X	X	X		
Barthel Index of Function		X	X	X		
Clinical Frailty Scale		X	X	X		

Mini- mental state exam		X	X	X		
Geriatric Depression Scale		X	X	X		
Capacity assessment		X	X	X		
OUTCOME VARIABLES:						
Completion of GOPC process			X	X		
ED attendances and admissions			X	X		
Length of stay			X	X		
Outpatient visits			X	X		
Residential Inreach visits			X	X		
Date of death			X	X		
Place of death			X	X		
Date of transfer			X	X		

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Outcome	Hypothesis	Outcome Measure	Method of Analysis
ED attendances /admissions	Decrease in hospitalisation in intervention group	Ed attendances and admissions per facility resident per time period	zero-inflated poisson regression model
Length of Stay (LOS)	Decrease in LOS in intervention group	Hospital bed-days per facility resident per time period	zero-inflated negative binomial model
External mortality rate	Decrease in external mortality rate in intervention group	Proportion of deaths outside of RACF	t-test or chi-squared test
Acute healthcare utilisation	Decrease in acute healthcare utilisation in intervention group	Acute hospital visits outside of Emergency Department and emergency admissions	t-test or chi-squared test
Healthcare costs	Decrease in healthcare costs in intervention group	Comparison of costs of hospitalisation and or admission	t-test or chi-squared test
Facilitation of healthcare decision making	Improvement on the ease with which healthcare decisions are made by staff	Direct questioning on whether the GOPC facilitated healthcare decision making	Qualitative exploration using focus groups and semi-structured interviews
A change in level of conflict at times of crisis	A decreased in conflict about decisions between staff, residents and families	Direct questioning on whether the GOPC heled decrease conflict between stakeholders	Qualitative exploration using focus groups and semi-structured interviews

Table 1: CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)[1,2]	See table 2	1
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	5
	2b	Specific objectives or hypotheses	Whether objectives pertain to the the cluster level, the individual participant level or both	6
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	8
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		**8**
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	8
	4b	Settings and locations where the data were collected		**9**
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	9

Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Whether outcome measures pertain to the cluster level, the individual participant level or both	9
	6b	Any changes to trial outcomes after the trial commenced, with reasons		**9**
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty	10
	7b	When applicable, explanation of any interim analyses and stopping guidelines		
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		**10**
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	10
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	10
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	10
	10a		Who generated the random allocation sequence, who	10

			enrolled clusters, and who assigned clusters to interventions	
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	10
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		**N/A**
	11b	If relevant, description of the similarity of interventions		
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		**N/A**
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	Not applicable yet

	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	Not applicable yet
Recruitment	14a	Dates defining the periods of recruitment and follow-up		Not applicable yet
	14b	Why the trial ended or was stopped		Not applicable yet
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Baseline characteristics for the individual and cluster levels as applicable for each group	7
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	Not applicable yet
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	Not applicable yet
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		Not applicable yet
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		Not applicable yet
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[3])		Not applicable yet
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias,		**2**

		imprecision, and, if relevant, multiplicity of analyses		
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	11
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		Not applicable yet
Other information				
Registration	23	Registration number and name of trial registry		**12**
Protocol	24	Where the full trial protocol can be accessed, if available		**This is the protocol**
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders		**12**

** Note: page numbers optional depending on journal requirements*

Table 2: Extension of CONSORT for abstracts[1,2] to reports of cluster randomised trials

Item	Standard Checklist item	Extension for cluster trials
Title	Identification of study as randomised	**Identification of study as cluster randomised**
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected	**Eligibility criteria for clusters**
Interventions	Interventions intended for each group	
Objective	Specific objective or hypothesis	**Whether objective or hypothesis pertains to the cluster level, the individual participant level or both**
Outcome	Clearly defined primary outcome for this report	**Whether the primary outcome pertains to the cluster level, the individual participant level or both**
Randomization	How participants were allocated to interventions	**How clusters were allocated to interventions**
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	
Results		
Numbers randomized	Number of participants randomized to each group	**Number of clusters randomized to each group**
Recruitment	Trial status[1]	
Numbers analysed	Number of participants analysed in each group	**Number of clusters analysed in each group**
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	**Results at the cluster or individual participant level as applicable for each primary outcome**
Harms	Important adverse events or side effects	
Conclusions	General interpretation of the results	
Trial registration	Registration number and name of trial register	
Funding	Source of funding	

[1] Relevant to Conference Abstracts

REFERENCES

1 Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, et al. CONSORT for reporting randomised trials in journal and conference abstracts. *Lancet* 2008, 371:281-283

2 Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG at al (2008) CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. *PLoS Med* 5(1): e20

3 Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D. Better reporting of harms in randomized trials: an extension of the CONSORT statement. *Ann Intern Med* 2004; 141(10):781-788.