# Feasibility study of medication review by a specialist pharmacist and guided by a prognostic indicator for older people entering Aged Residential Care

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## Abstract

**Introduction:** Older people in Aged Residential Care (ARC) usually have multiple complex, physical, mental and social needs. Most are on multiple medications (polypharmacy). This is associated with adverse outcomes including falls, fractures, cognitive decline, incontinence and hospital admissions. This study will examine the intervention of a pharmacist-led medication review, guided by a routinely collected prognostic scale, and a frailty score.

**Methods and analysis:** This is a feasibility study.*Study population:* Participants will be new admissions to long-term residential care in Christchurch. There will be 8 intervention facilities and 4 control facilities. Participants will be approached in the first month after they enter ARC. *Intervention:* A specialist pharmacist will review medications, guided by patient’s treatment priorities, a prognostic scale (InterRAI CHESS scale) and a frailty index (Reported Edmonton Frailty Score, REFS). Recommendations will be made to GPs, who will make final decisions on any medication changes. *Primary outcomes:* Number of older people and GPs accepting a medication review. Number of pharmacist recommendation adopted by GPs (measured by number and classes of medications) after three and six months. *Secondary outcomes:* quality of life at baseline, three and six months. Hospital admissions after 3 and 6 months. Increased level of care after three and six months.

**Ethics and dissemination:** Ethics approval has been granted by the Human Disability and Ethics Committee. Ethical approval number (TBC)

**Trial registration:** Australian New Zealand Clinical Trial registry (TBC).

**Funding:** This work is funded by a Health Research Council (HRC) emerging researcher grant. No other funding was requested or received for this study. The principal investigator is employed by the University of Otago.

## Keywords

Frailty, polypharmacy, appropriate prescribing, medication review, feasibility study

## Background

Polypharmacy, or the prescription of multiple medications, is increasingly common in frail older people, and is a focus of national and international research interest([1](#_ENREF_1)). This is driven by older people having multiple comorbidities for which treatment is available, and the increasing use of guidelines, for example for cardiovascular disease, which recommend multiple medicines([2](#_ENREF_2)). Many of these medicines are prescribed to reduce risk of future events rather than to treat symptoms. Polypharmacy increases the risk of adverse outcomes including adverse drug effects, drug-drug or drug-disease interactions, hospitalizations, falls and fractures, decreased mobility, delirium, weight loss and malnutrition ([3](#_ENREF_3), [4](#_ENREF_4)). In people with short life-expectancy the potential benefits are reduced and in frail people the potential harms are increased. Most drug trials are completed in younger, fitter community-dwelling populations. Frail elderly, Aged Residential care (ARC) residents are usually excluded from clinical trials and are a group for whom the potential harms of polypharmacy are high and the potential benefits uncertain.

ARC residents are a particularly frail group, with a short life expectancy. One-third to one half of those admitted to higher level care die within one year([5](#_ENREF_5), [6](#_ENREF_6)). ARC residents have polypharmacy with the mean numbers of medicines 7 to 8 per person, and over a third on 9 or more medications([5](#_ENREF_5), [7](#_ENREF_7)). In a recent New Zealand study(8) in those who died within 12 months 70% were on psychotropics, 60% were on antihypertensives, 50% on anti-platelet agents, and 25% on statins.

Notable findings from recent studies include:

* Lower blood pressure and treatment with **anti-hypertensives** in nursing home residents was associated with higher mortality and no reduction in major cardiovascular events ([9,10](#_ENREF_9)).
* In those with prognosis of less than 1 year stopping **statins** was not associated with any adverse outcomes, reduces drug burden and improves quality of life ([1](#_ENREF_10)1).
* Studies of **aspirin** treatment for the primary prevention of cardiovascular events have been performed in younger populations (mean age 57 years)(1[2](#_ENREF_11)). Even in this younger group, they found a number needed to treat (NNT) of 120 for 6 years to prevent one adverse cardiovascular outcome and a number needed to harm (NNH) of 73. In those in ARC with limited prognosis it is unlikely they will survive to benefit, and will be at high risk of complications.
* While anticoagulation with **warfarin** has been shown to reduce the rate of thromboembolic stroke in those with atrial fibrillation, haemorrhagic complications are common and have been found at a rate of up to 25% in the frail and nursing home residents(13,14).
* Studies of glycaemic control in those treated for **Type 2 Diabetes** have shown a U-shaped curve, with lower HbA1c (tighter control) actually being associated with poorer outcomes in frail elderly(15). Another recent study found high rates of hypoglycaemia in ARC residents (up to 60%)(16). Guidelines call for the prevention of hypoglycaemia, rather than strict glycaemic control, to be one of the main priorities in the treatment of diabetes in ARC([1](#_ENREF_16)7).
* Deprescribing **psychotropics** has been shown to reduce falls and improve cognitive function([1](#_ENREF_1)).

General Practitioners are the main prescribers in ARC, but there are a number of barriers to stopping medications. These include uncertainty about prognosis, not wanting to discuss poor prognosis with patients, the sense of having “given up” by withdrawing medications, not wanting to cause harm, and wanting to adhere to guidelines([1](#_ENREF_17)8,19). In an ongoing New Zealand study of GPs working in residential care issues raised have included the need for evidence to inform practice, and the challenges of identifying poor prognosis and discussing this with patients and families (Ailabouni, 2015, Dunedin, personal communication). In a recent Australasian study of geriatricians, issues included limited life expectancy, cognitive impairment and pill burden as influencing the decision to stop medications(20).

The International Residential Assessment Instrument (InterRAI) is a data-set developed by a multidisciplinary network of academics and clinicians. It includes 236 standardized questions and is designed to be a comprehensive assessment for older people. It is now widely used internationally and has been mandated by the NZ Government for use in older people requiring long-term care, and an assessment is required in those entering ARC. The InterRAI CHESS (changes in health, end-stage disease and signs and symptoms) scale is a 6 point scale which is extracted routinely from InterRAI data, and is therefore available for all those entering ARC. It has been shown to be predictive of 6 and 12 month mortality in those in ARC([2](#_ENREF_20)1), and those with neurological conditions including dementia and stroke([2](#_ENREF_21)2).

Polypharmacy and appropriate prescribing in ARC are currently a focus of considerable interest worldwide, in both research and clinical practice. This study aims to investigate these issues in the context of New Zealand society and healthcare system. There is a background of local Canterbury interest in, and support for a medication review intervention, and an existing primary care education programme, on which this study aims to build. The proposed use of the InterRAI tool which is now mandated by the New Zealand government when older people enter ARC will allow us to target the intervention appropriately. It is the first time the InterRAI tool has been used to guide such an intervention, and if trials are successful will be an important clinical use of the tool. The InterRAI tool is now widely used internationally, so this study has the potential to influence research and clinical practice worldwide. The long term goal is to provide a stepping stone on the way to a large multicentre clinical trial of a medication review intervention in ARC, utilising data from InterRAI assessment.

## Aims

### To evaluate the feasibility and acceptability of a pharmacist-led Medicines Therapy Assessment (MTA) to older people at the time of entry to Aged Residential Care (ARC).

### To evaluate the acceptability of a pharmacist-led MTA to General Practitioners (GPs) providing care for older people in ARC.

1. To evaluate the uptake of recommendations from the MTA by older people and their General Practitioners.
2. To assess whether there is any change in Quality-of-Life (QOL) following a medication review intervention.

## Methods

### Study setting

* Aged Residential Care facilities in Canterbury District Health Board region
* 8 intervention facilities
* 4 control facilities

### Participants

**Inclusion criteria**

* Aged over 65 years (>55y for Maori)
* Admitted for the first time to long-term Aged Residential Care within the Canterbury District Health Board region
* InterRAI Long Term Care Facility (LTCF) assessment available (consent given for data to be used for planning and research)
* On 3 or more medications

**Exclusion criteria**

* Respite or short-term entry to ARC facility
* Palliative or terminal care
* No consent given for data to be used for planning and research
* Less than 3 medications
* Non-English speaking

### Recruitment, consent and intervention

**Participants**: Older people entering long-term ARC in participating facilities for the first time.

* InterRAI assessment (performed as standard for all people entering ARC). The routinely collected scores of Changes in Health, End-stage Symptoms and Signs (CHESS) prognostic indicator, Activities of Daily Living (ADL) scale, and Cognitive Performance scale (CPS) will be extracted.
* Potential participants allocated to intervention and control groups by facility.
* Older people entering ARC are identified by manager or Registered Nurse (RN).
* RN approaches them to take part in study.
* RN makes a brief global assessment of cognition, based on observed day-to-day functioning, and aided by InterRAI CPS. From there are 2 pathways.

***Intervention Facilities (Flow chart one)***

**Pathway one: Person has capacity to understand and consent**

* Those who agree to meet research team identified by RN.
* Research assistant (RA) goes to ARC facility and meets older person. They explain study, provide information, answer questions and obtain consent.
* RA completes the validated and widely used EuroQOL quality-of-life and Reported Edmonton Frailty Score (REFS).
* RA identifies if the person wishes to have time to consult with family/ whanau members or gain other advice. They will encourage the involvement of family/ whanau.
* RA identifies if any family/ whanau should be involved in study. They then telephone these people and explain study. Information sheet is sent by post or email.

*If after time to consider and discuss, the older person is willing to take part in study:*

* Research pharmacist visits and conducts MTA.
* Based on findings of MTA, REFS and CHESS scores pharmacist makes recommendations about medication changes, together with advice about how these changes should be actioned (for example gradual weaning off sleeping tablets or benzodiazepines), to GP.
* GP considers these recommendations and discusses with the older person, and (where appropriate) family/ whanau members.
* GP decides on any medication changes and actions these.
* RA records medications at baseline; 3 and 6 months after the initial consultation.
* RA repeats EuroQOL and REFS measures at 3 and 6 months.
* Repeat InterRAI assessment conducted routinely at 6 months- CHESS, CPS and ADL scores extracted.

**Pathway two: Person may not have full capacity to understand and consent**

* RN contacts older person’s Enduring Power of Attorney (EPOA - welfare) or significant other (where no EPOA for welfare) and asks if willing for research team to contact them.
* RN informs research team.
* RA speaks to EPOA/significant other (ideally in person), explains study risks and benefits, and answers questions. Information sheet will be provided in person, by email or post, or at a visit to the facility.
* If EPOA considers that the study is in the person’s best interest to participate in this review to encourage appropriate prescribing and has potential benefit for the older person they will inform RA, and complete a declaration form supporting person’s participation.
* Independent consultant geriatrician will then consider the case and if he/she considers the study has potential benefits for the older person, he will give proxy consent to include the person in the study (This step would only proceed if EPOA or significant other supports participation in the study).
* Research pharmacist will arrange a time to visit with the EPOA available.
* Pharmacist will conduct MTA, and based on their findings and the CHESS score, make recommendations to GP.
* GP considers these recommendations, reviews older person and discusses with EPOA.
* GP decides on any medication changes and actions these.
* RA records medications at baseline; 3 and 6 months after the initial consultation.
* Repeat InterRAI assessment conducted routinely at 6 months- CHESS, CPS and ADL scores extracted.

***Control Facilities (Flow chart two)***

**Pathway one: Person has capacity to understand and consent**

* Those who agree to meet the research team identified by RN.
* RA goes to ARC facility and explains study (ie We are trialling a new medication review process, they are in the control/ comparison group, so there won’t be any changes for them, their GP will continue to provide best standard current care. We are simply asking to access their health data, particularly their medications at different time points, and complete two simple scales.)

*If they consent*

* RA completes the EuroQOL quality-of-life score and Reported Edmonton Frailty Score (REFS).
* GPs continue standard care, which may include a medication review if they feel this is appropriate.
* RA records medications at baseline; 3 and 6 months after the initial consultation.
* RA repeats EuroQOL and REFS measures at 3 and 6 months.
* Repeat InterRAI assessment conducted routinely at 6 months- CHESS, CPS and ADL scores extracted.

**Pathway two: Person may not have full capacity to understand and consent**

* RN contacts older person’s Enduring Power of Attorney (EPOA - welfare) or significant other (where no EPOA for welfare) and asks if willing for research team to contact them.
* RN informs research team.
* RA contacts EPOA/ significant other and explains study (ie that a new medication review process is being trialled, that the person is in a control facility and best standard care from GP will continue as normal) and asks for permission to access their health records.

*If EPOA/ significant other agrees to team accessing records*

* GPs continue standard care, which may include a medication review (by either GP or pharmacy services) if they feel this is appropriate.
* RA records medications at baseline; 3 and 6 months after the initial consultation.
* Repeat InterRAI assessment conducted routinely at 6 months- CHESS, CPS and ADL scores extracted.

## Outcomes

1. Number of older people (able to consent) or EPOAs (unable to give consent) accepting the offer of a medication review.
2. Number of GPs accepting the offer of a medication review.
3. Uptake of pharmacist MTA recommendations by older people, EPOAs and GPs.
4. Number and types of medications before and after intervention (as a marker of uptake of recommendations).
5. Changes in EuroQOL scale from baseline to 3 and 6 months post-intervention.
6. Changes in InterRAI CPS and ADL scores from baseline to 3 and 6 months post-intervention.

## Analysis

For the statistical analysisparticipant characteristics (demographics, medication use, and clinical characteristics) will be summarised by group using simple descriptive statistics, numbers and percentages for categorical data and means and standard deviations or medians and interquartile ranges for descriptive statistics.

Feasibility outcomes will be summarised descriptively. Specifically the number and percentage of those approached of older people/ caregivers who consent to take part in the study and the number of GPs who consent to take part in the study, and the level of missingness in the data collected.

Participant outcomes (medication use at the different time points, clinical events and QoL) will be summarised descriptively by group. In particular the type of medications prescribed (ie preventative versus symptomatic treatments) will be described. Differences for those receiving the intervention and those who received usual care will be explored using regression models.

## Summary

Polypharmacy is common in frail older people in ARC, and is known to be associated with a number of serious adverse outcomes. While many medications were prescribed earlier in life to prevent disease, these medications may no longer be appropriate in this group of people. This feasibility study aims to trial a pharmacist-led medication review intervention. A specialist pharmacist will visit older people newly admitted to ARC. She will discuss their treatment priorities with them and conduct a Medicines Therapy Assessment (MTA). Recommendations will be made to GPs along with a prognostic indicator (the InterRAI CHESS score). GPs will make the final decisions on medication changes.

Outcomes will be the acceptability of this intervention to older people, EPOAs/ family/ whanau and GPs; the number of pharmacist recommendations taken up by GPs and a quality of life measure.

## Abbreviations

**ARC** Aged Residential Care; **InterRAI** International Resident Assessment Instrument; **LTCF** Long-term care facilities; **CHESS** Changes in Health, End stage disease and Symptoms and Signs; **REFS** Reported Edmonton Frail Scale; **QOL** Quality of Life; **ADL** Activities of Daily Living; **MTA**  Medicines Therapy Assessment; **EPOA** Enduring Power of Attorney (welfare); **GP** General Practitioner; **RN** Registered nurse; **NNT** Number needed to treat; **NNH** Number needed to harm.

## Trial Status

We aim to begin recruitment on 16/4/2018 and continue until the final date for data collection which is to be 30/11/2019.

## Funding statement

This study is being funded by a Human Research Committee emerging researcher grant.

## Competing interests

The author declares that they have no competing interests and are responsible for the content of this report.

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### Flow-chart one:

### Intervention facilities

Older Person enters ARC

InterRAI LTCF completed

GP declines

RA contacts GP

No

No

No

Independent clinician consent

GP declines

RA contacts GP

Pharmacist MTA

CHESS, EFS scores and recommendations to GP

Cognition OK

No

Cognition impaired

RA meets participant

Contacts EPOA/ family/ whanau if appropriate

Informed consent process, EFS, QOL scale

No

Yes

Manager/ RN asks their permission to meet research team

ARC manager/ RN identifies new admission

CHESS score, CPS, ADL score

Brief assessment of cognition

Manager/ RN contacts EPOA

Asks their permission for research team to contact them

Yes

RA speaks to EPOA

Declaration form completed

Yes

Yes

Yes

3 months: RA records medications, repeat EFS, QOL scores

6 months: RA records medications, repeat EFS, QOL scores

GP reviews patient (EPOA/ significant other)

Discuss medications

### Flow chart two:

### Control facilities

Older Person enters ARC

InterRAI LTCF completed

No

No

Cognition OK

No

Cognition impaired

ARC manager/ RN identifies new admission

CHESS score, CPS, ADL score

Brief assessment of cognition

RA meets participant

Contacts EPOA/ family/ whanau if appropriate

Consent to access clinical records

REFS, QOL scales

No

Yes

Manager/ RN asks their permission to meet research team

Manager/ RN contacts EPOA

Asks their permission to speak for research team to contact them

Yes

RA speaks to EPOA

Declaration form completed, agreement to access clinical records

Yes

Independent clinician consent

No

Yes

Yes

GP continues best standard care to participant

(EPOA/ family/ whanau)

Discuss medications as normal

3 months: RA records medications, repeat EFS, QOL scores

6 months: RA records medications, repeat EFS, QOL scores