Additional File 1: The World Health Organization (WHO) Trial Registration Data Set for the ReMInDAR trial

1. Primary Registry and Trial Identifying Number
   Australian New Zealand Clinical Trials Registry: ACTRN12618000766213

2. Date of Registration in Primary Registry
   7/05/2018

3. Secondary Identifying Numbers
   Universal Trial Number (UTN): U1111-1213-2859

4. Source(s) of Monetary or Material Support
   Australian Government, as part of the Sixth Community Pharmacy Agreement Pharmacy Trial Program

5. Primary Sponsor
   Australian Government

6. Secondary Sponsor(s)
   N/A

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9. **Public Title**  
Pharmacist service to reduce side effects of medicines in older people in aged care

10. **Scientific Title**  
Pharmacist-led service to reduce medicine-induced deterioration and adverse reactions in older people living in residential aged care facilities

11. **Countries of Recruitment**  
Australia

12. **Health Condition(s) or Problem(s) Studied**  
Medicine-induced deterioration, frailty, cognitive function, 24-hour movement behaviour, grip strength, adverse events

13. **Intervention(s)**  
The intervention is a 12-month pharmacist-led assessment of signs and symptoms of medicine-induced deterioration and adverse medicine events. The intervention group will receive a sessional pharmacist-led assessment which occurs every 8 weeks.

The service includes assessment for adverse medicine events and medicine-induced deterioration including assessment of cognition (using the Montreal Cognitive Assessment (MoCA)), 24-hour movement behaviour including sleep (Activinsights Bands, Activinsights Ltd, Cambridgeshire, UK fitted for one year), and hand grip strength (dynamometer, Jamar, Illinois, USA).

During the visit, the pharmacists will review participant care records to identify any new illnesses or conditions present since the last assessment. The pharmacists will review the care record to identify any adverse events (e.g. falls, delirium events, bowel or urinary changes, weight loss) or any signs or symptoms noted in the care record that could be indicative of adverse events (e.g. changes in nutritional status, pain). The pharmacists will also access the medication chart to identify any medication changes that have occurred since the last visit.

The pharmacist service also involves discussions with the participants and care staff to identify any concerns. The pharmacists will compare the results for the 24 hour movement behaviour, MoCA test, grip strength and weight with the most recent previous assessment and with baseline data to identify immediate and cumulative changes in each category.

Where medicine-induced deterioration is detected in the intervention-group participants and considered clinically significant, the pharmacists will contact the participants’ GPs to discuss the participants’ condition, fill out a report to the GP including recommended actions and follow-up with the GP and facility staff. The pharmacists will reassess the participant at the next sessional visit to determine if medicine-induced deterioration or adverse events have resolved.

The comparator cohort will receive usual care provided under the existing pharmacist service. Usual care refers to the annual or biennial Residential Medication Management Reviews (RMMR) provided to residents in approved Australian Government funded aged
care facilities. These services will still be available to the intervention and control group during this time.

14. Key Inclusion and Exclusion Criteria

Inclusion criteria
1) Receive services from an eligible aged-care facility;
2) Use four or more medicines at the time of recruitment or on more than one medicine one of which has anticholinergic or sedative properties.

Exclusion criteria
1) Persons with significant existing frailty burden, defined as a score of 0.40 or above using the Frailty Index;
2) Persons with moderate or severe dementia;
3) Persons receiving palliative care;
4) Persons receiving respite care;
5) Persons participating in another research project.

15. Study type

Study type: Interventional
Method of allocation: Randomized
Masking: Open
Assignment: Parallel

16. Date of First Enrollment

8/8/2018

17. Sample Size

354

18. Recruitment Status

Recruiting

19. Primary Outcome(s)

Outcome: Frailty
Metric/method of measurement: Assessed using the frailty index
Timepoint: Baseline, 6-months post-baseline, 12 months post-baseline

20. Key Secondary Outcomes

Outcome: Cognitive function
Metric/method of measurement: Montreal Cognitive Assessment (MoCA)
Timepoint: Baseline, 6-months post-baseline, 12 months post-baseline

Outcome: 24-hour movement behaviour including sleep time, total activity time, and light, moderate and vigorous intensity activity
Metric/method of measurement: Assessed using the GENEActiv activity tracker
Timepoint: Baseline, 6-months post-baseline, 12 months post-baseline

Outcome: Grip strength
Metric/method of measurement: Assessed using a dynamometer
Timepoint: Baseline, 6-months post-baseline, 12 months post-baseline
Outcome: Weight
Metric/method of measurement: Assessed using a digital scale
Timepoint: Baseline, 6-months post-baseline, 12 months post-baseline

Outcome: Percentage of robust, pre-frail and frail individuals
Metric/method of measurement: Assessed using the frailty phenotype
Timepoint: Baseline, 6-months post-baseline, 12 months post-baseline

Outcome: Rate of adverse events (such as falls, fractures, delirium, faecal impaction)
Metric/method of measurement: Review of the resident care assessment record
Timepoint: Baseline, 6-months post-baseline, 12 months post-baseline

Outcome: Quality of life
Metric/method of measurement: Assessed using the EQ-5D
Timepoint: Baseline, 6-months post-baseline, 12 months post-baseline

Outcome: Health resource use
Metric/method of measurement: Review of the resident care assessment record
Timepoint: Baseline, 6-months post-baseline, 12 months post-baseline

21. Ethics Review
   Status: Approved
   Date of approval: 15/05/2017
   Name and contact details of Ethics committee: University of South Australia Human Research Ethics Committee, GPO Box 2471, Adelaide, South Australia 5001
   Date of approval: 15/02/2018
   Name and contact details of Ethics committee: Tasmania Health and Medical Human Research Ethics Committee, Office of Research Services, University of Tasmania, Private Bag 1, Hobart, TAS, 7001

22. Completion date
   N/A

23. Summary Results
   N/A

24. IPD sharing statement
   Plan to share IPD: The IPD for this trial will not be made available.
   Plan description: Study protocol