# Title and abstract

## (1a) Title

1a A study protocol for evaluating the feasibility and acceptability of *MedsCheck Plus* within community pharmacy: a non-randomised pilot study

## (1b) Abstract:

Introduction: To date, Australian community pharmacists have had a limited role in supporting people living with dementia and those who care for them at home, and reducing this risk of medication-related harm. This protocol outlines a study to determine the feasibility of *MedsCheck Plus*, in-pharmacy medication reviews that aim to identify and address medication supply and adherence issues for people living with dementia in the community.

### Methods and analysis

The primary objective is to evaluate the feasibility and acceptability of *MedsCheck Plus* in a pilot study. In this pragmatic, uncontrolled study, five pharmacists working in community pharmacies will complete a bespoke training course, then each will provide and initiate *MedsCheck Plus* for at least four people living with dementia, with planned follow-ups over the subsequent four months. Participating pharmacists will recruit appropriate consumer participants based on specific criteria .

***Ethics and dissemination***

Curtin University Human Research Ethics Committee (HREC) has approved this study (HREC number HRE2021-0763). Research findings will be disseminated in 2023 through conferences and in journal articles.

# Introduction

## Background and objectives

The use of medication is ubiquitous amongst people living with dementia, for both symptomatic treatment of the dementia itself, in addition to managing various comorbidities experienced by these people. Whilst medications are used to improve health outcomes, there is a considerable risk of harm with their inappropriate use. To date, community pharmacists have had a limited role in supporting people living with dementia and those who care for them at home, and reducing this risk of medication-related harm.

The task of managing medications has additional negative implications for people living with dementia and their informal caregivers. Informal carers have reported that medication management can be stressful, complex and difficult[[1]](#endnote-1), and a significant source of burden within their caregiver role.[[2]](#endnote-2)[[3]](#endnote-3) However, there are few programs in Australia that specifically addresses medication management for people living with dementia and their informal caregivers. One of the few resources available is the website *Managing Medicines for People with Dementia1*. Whilst this resource is perceived by caregivers to be valuable, a recent evaluation of it identified that additional information and support is required1.

A potential means to improve medication management for people living with dementia in the community is to expand the involvement of community pharmacists within their care. Literature supports the concept of trust-based relationships in healthcare, whereby care is best provided, and more likely accepted, if the care is provided by a health professional they trust.[[4]](#endnote-4) Community pharmacists are highly trusted health professionals. Internationally, people living with dementia, their carers and healthcare team have been shown to be receptive to the potential for community pharmacists to be more involved in this area[[5]](#endnote-5). A systematic review of pharmacist-led interventions aimed at improving medication management amongst people living with dementia and their carers reported that these interventions were associated with a number of benefits, including improved adherence and understanding, and reduced medication burden.[[6]](#endnote-6) More recently, a collaborative dementia care program that involved pharmacists improved quality of life and reduced emergency department visits for the people living with dementia, whilst decreasing depression and carer burden amongst their primary care givers.[[7]](#endnote-7)

Australian pharmacists currently have a limited yet developing formal role in dementia care. A number of community pharmacies have embarked on programs that aim to improve their ability to meet the need of people living with dementia and their informal carers, with several now recognised as being dementia-friendly.[[8]](#endnote-8) Furthermore, pharmacist involvement in residential care has been found to have a number of positive outcomes in reducing medication-related problems.[[9]](#endnote-9) However, limited research has been undertaken into pharmacist-led interventions to improve medicine safety for people living with dementia in the community.

Programs such as Home Medicines Reviews (HMRs) and *MedsCheck* are currently provided by pharmacists in the community, in collaboration with general practitioners (GPs), to identify medication-related issues amongst community-dwelling people, although neither service is specific for people living with dementia.[[10]](#endnote-10)[[11]](#endnote-11) *MedsChecks* may be particularly beneficial for people living with dementia. A *MedsCheck* is an in-pharmacy review of a person’s medicines that focusses on providing education and improving their medicine management. *MedsChecks* aim to identify and resolve issues with medicines, whilst helping people to learn more about their medicines and how to best use and store them. The service is currently available only for people who fulfil certain risk criteria, and disease-specific *MedsChecks* are provided to people with diabetes or chronic pain. Examples of criteria that may identify potential *MedsCheck* service recipients are shown in Table 1.

Table 1 - Examples of criteria used to identify people who may benefit from MedsChecks[[12]](#endnote-12). The high prevalence of many of these amongst people living with dementia is noteworthy

|  |  |
| --- | --- |
| * Patients experiencing difficulties with their medicines * Patients with complex medication regimens * Patients with recent changes to their medication regimens * Patients with poor health literacy * Patients accessing multiple prescribers * Patients with chronic illnesses * Patients with co-morbidities * Patients who are non-adherent | * Patients with literacy/language barriers * Patients with dexterity, vision or hearing problems * Patients living alone or without access to social support * Patients recently diagnosed with type 2 diabetes * Patients with poor blood glucose control * Patients unable to gain timely access to existing diabetes education/health services in their community |

In view of the need for improved medication management amongst people living with dementia, it is feasible that a form of *MedsCheck* tailored to people living with dementia would improve outcomes for them.

As part of the set up of this project, a Project Management Group (PMG) was convened at the commencement of the project to provide oversight and governance throughout the project. The PMG consists of the project investigators and representatives from: (1) consumers (2) the Pharmaceutical Society of Australia (PSA) and (3) Royal Australian College of General Practitioners (RACGP). The representatives were recruited through existing contacts with the investigator team.

An initial literature review of national and international trials of similar interventions, relevant guidelines and existing frameworks (such as the generic MedsChecks service guide)) were utilised to identify the key elements of successful interventions which informed the draft MedsCheck Plus framework.

To follow this initial review, 5 x heterogenous focus group discussions made up of pharmacists, people living with dementia and carers as small groups were conducted.

As a result, the focus group discussions have identified 6 key themes:

1) Complexity of dementia

2) Integrated multidisciplinary approach to dementia

3) Communication and engagement

4) Role of carers and support person

5) Facilitators to dementia care in pharmacy

6) Barriers to dementia care in pharmacy

The feedback gathered from the focus group discussions has then been incorporated into the development of an implementation framework which forms the basis of the intervention to be trialled in this study. The framework consists of the following processes: (further information of each step within [*Interventions*](#_Interventions))

* Identify the need for *MedsCheck Plus*
* Obtain consent
* Reconcile medication
* Counselling and communication
* Documentation
* Monitoring and follow-up
* Quality assurance and evaluation.

# Methods

## Trial design

3a This is a pilot study that is being undertaken to assess the acceptability and feasibility of *MedsCheck Plus*. It is a pragmatic, uncontrolled, non-randomised study whereby all participating patients will receive the intervention. This study will be conducted in Western Australia.

## Participants

4a Five pharmacists working in community pharmacies will complete the training materials developed, then each will provide and initiate *MedsCheck Plus* for at least four people living with dementia, with planned follow-ups over the subsequent four months. For the purpose of this pilot study, participating pharmacists and consumers will be located in the Perth metropolitan region. All pharmacists will be currently registered to practise with the Australian Health Practitioner Regulation Agency. Participating consumers will be required to meet the following criteria for recipients of *MedsCheck Plus*: Medicare and/or Department of Veterans’ Affairs (DVA) cardholder, identified or suspected dementia or mild cognitive impairment and living at home in a community setting.

All eligible participants recruited by the pharmacist will have the capacity to provide written consent and will not rely on their carer to make their medical decision. Completion of consent is through the supplementary written form.

## Interventions

5 A summary of the trial process which encompasses a 4-month period (see *Timeline*) is as follows:

The first step of the intervention is the recruitment of the pharmacists. Industry contacts were utilised to gather expressions of interest. From this pool, the pharmacists were then recruited to participate in the pilot trial.

The second step of the intervention involves the pilot pharmacists completing 3-hour Dementia Friendly Pharmacy Course, followed by a 2-hour case study scenario assessment. Pharmacists will be given one month to complete the provided training material This will ensure that only pharmacists who have completed the required training will be eligible to participate in this study. Training and assessment records will be recorded in Pharmaceutical Society of Australia’s (PSA) Learning Management System (LMS). Pharmacists are also encouraged to record completion of training in their personal training record.

The third step of the intervention will involve the trained pharmacist providing the initial face-to-face *MedsCheck Plus* to the participant. The steps in the patient journey are as follows:

* Identifying the need for *MedsCheck Plus* by initiating a MedsCheck service
* Determining eligibility and obtaining consent for a *MedsCheck Plus*(see [*Participants*](#_Participants))
* Reconciliation of patient medication including all prescription, non-prescription and complementary and alternative medication. The family carer may be required to assist with completing this part of the process in collaboration with the patient. The medication profile should be confirmed with the patient’s prescriber/s, and a copy of the completed medication profile will be provided to the patient’s prescriber. The patient and +/- carer should also be provided with the medication profile.
* Medication counselling involving a two-way discussion with the patient and +/- carer to ensure that medications are used appropriately and safely. The pharmacist, patient and +/- carer will also agree to any follow up actions and who is responsible. This should be documented in action plan, with dates agreed upon for a follow-up discussion to review the patient’s progress. The patient, caregiver (if present), prescribers and, if relevant, support services, health and/or community care professionals will be provided with copies of the documentation.

The final step of the intervention will involve the pharmacist providing a follow-up *MedsCheck Plus* consultation. At this time, the pharmacist will monitor the progress of actions identified and agreed upon in the action plan. The timeframe for the follow-up consultation will be at the discretion of the reviewing pharmacist, based on their perception of clinical need and individual patient circumstances. Given the targeted nature of follow-up consultations, it is expected that the normal duration of the consultation would be considerably less than the initial *MedsCheck Plus*, depending on the complexity and number of issues being followed up.

## Outcomes

6a The primary outcome of the pilot will be to determine the feasibility and acceptability of *MedsCheck Plus* as an in-pharmacy review service. The primary outcomes will be assessed using both quantitative and qualitative approaches.

Quantitative data will be collected from patients and pharmacists participating in the pilot through a written survey. The pharmacist survey will focus on the (1) the outcome of the training (2) benefit and eligibility of the patients (3) attendance of sessions (4) characteristics of patients attending the session (5) confidence providing information (6) referral services and (7) future provision of the service. The patient survey will focus on (1) medication management prior to the service (2) support of a carer (3) the knowledge and information provided by the pharmacist (4) the benefit from the service (5) medication management following the service and (6) referral services offered.

Qualitative data will be generated from the 5 participating pharmacists through a focus group undertaken after the intervention. The approach taken will be used to evaluate (1) the training, (2) the value of service and (3) provision of service. Consent will be obtained from the pharmacists prior to the focus group session commencing. The focus group discussion guide will be undertaken by three members of the research team. The session will be audiotaped, transcribed, analysed and stored using the qualitative data management program NVivoTM.

6b It is not anticipated that changes to the outcome measuring tools will be required

## Sample size

7a The sample size has been selected based upon previous pilot studies of community pharmacy interventions

7b N/A – This trial is not reliant on interim analysis

## Randomisation:

### Statistical methods

12 Qualitative data will be analysed following a thematic, inductive approach. The qualitative data management program, NVivo™ (QSR International, Melbourne), will be used to organise focus group discussion narration and facilitate a two-phase coding process. Two researchers will independently code the data, then they will agree on the themes and subthemes.

Quantitative data will be analysed using IBM SPSS Statistics (IBM, Armonk). Data will be presented as mean and standard deviation, median and interquartile range, or percentages, as appropriate.

# Other information

## Registration

23. This trial registration registered 383662 (Developing and piloting *MedsCheck Plus*). Universal Trial Number (UTN) U1111-1275-0863

## Funding

25. This study was funded through the University of New South Wales (UNSW).

26. Curtin University Human Research Ethics Committee (HREC) has approved this study (HREC number HRE2021-0763) 30th November 2021

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