Exploratory Research in Clinical and Social Pharmacy 2 (2021) 100018

Contents lists available at ScienceDirect

Exploratory Research in Clinical and Social Pharmacy

journal homepage: www.elsevier.com/locate/rcsop

# Feasibility of a pharmacist-facilitated medicines review intervention for community-dwelling Māori older adults

Joanna Hikaka [a,b,*], Carmel Hughes [c], Rhys Jones [d], Hunter Amende [b], Martin J. Connolly [b,e], Nataly Martini [a]

[a] School of Pharmacy, University of Auckland, New Zealand
[b] Waitematā District Health Board, Auckland, New Zealand
[c] School of Pharmacy, Queen's University, Belfast, UK
[d] Te Kupenga Hauora Māori, University of Auckland, New Zealand
[e] Department of Geriatric Medicine, University of Auckland, New Zealand

ARTICLE INFO

*Article history:*
Received 17 December 2020
Received in revised form 29 April 2021
Accepted 29 April 2021

ABSTRACT

*Background:* Pharmacist-facilitated medicines review services have been postulated as a way to address current inequities in health outcomes between Māori and non-Māori. These interventions have been shown internationally to improve the appropriate use of medicines but remain underutilised in Aotearoa New Zealand (NZ). By reviewing the literature and engaging with key stakeholders, we developed an intervention, which included collaborative goal-setting, education and medicines optimisation, for testing in a feasibility study.
*Objective:* To determine the feasibility (recruitment, intervention delivery, and data collection methods) of a pharmacist-facilitated medicines review intervention for Māori older adults, and proposed intervention outcomes.
*Methods:* This study was reported in accordance with the CONSORT 2010 statement: extension to randomised controlled pilot and feasibility trials and the Consolidated criteria for strengthening reporting of health research involving indigenous peoples: the CONSIDER statement. Participant eligibility criteria were: Māori; aged 55-plus; community-dwelling; enrolled in a general practice in Waitematā District Health Board (Auckland, NZ). Consented participants engaged in a medicines education component (participant and pharmacist) and an optional medicines optimisation component (participant, pharmacist and prescriber). Outcomes measures included: the feasibility of data collection tools and methods, time taken to conduct the intervention and research processes; medicines knowledge, medicines appropriateness and quality of life (QoL); pharmacist recommendations and prescriber acceptance rate.
*Results:* Seventeen consented participants took part in the intervention from December 2019–March 2020 with the majority ($n = 12$) recruited through general practice mail-outs. Data collection was feasible using the predetermined outcome measure tools and was complete for all patient participants. Pharmacist intervention delivery was feasible. A mean of 9.5 recommendations were made per participant with a prescriber acceptance rate of 95%. These included non-medicine-related recommendations.
*Conclusion:* The feasibility testing of pharmacist-facilitated medicines review intervention developed for (and with) community-dwelling Māori older adults allows for intervention refinement and can be utilised for further studies relating to pharmacist services in primary care.

## 1. Background

Pharmacist-facilitated medicines review services improve the quality use of medicines and reduce adverse outcomes in older adults.[1] Medicines reviews can be defined as 'intentional, structured and critical review of medicines, carried out by health professionals, in discussion with the patient, and with the aim of agreeing on optimal medicines use to improve the quality, safety and appropriate use of medicines.'[2,3] There are many different applications of the term 'medicines review', which have not been standardised internationally.[4] Subsequently, there is no standardisation of medicines review interventions, or the activities which fall under this type of intervention, which include medicines reconciliation, medicines adherence, therapeutic drug monitoring, management of adverse drugs outcomes, goal-setting and medication changes in the context of complex

*Abbreviations:* ADEs, Adverse Drug Events; DS, descriptive statistics; MRC, Medical Research Council; MTA, Medicines Therapy Assessment; MUR, Medicines Use Review; PIM, potentially inappropriate medicines; PIP, potentially inappropriate prescribing; PPO, potential prescribing omissions; QoL, Quality of Life; RA, research assistant; RP, research pharmacist; WDHB, Waitematā District Health Board.

* Corresponding author at: School of Pharmacy, University of Auckland, Private Bag 92019, Auckland 1142, New Zealand.
*E-mail address:* j.hikaka@auckland.ac.nz (J. Hikaka).

http://dx.doi.org/10.1016/j.rcsop.2021.100018
2667-2766/© 2021 The Author(s). Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

multi-morbidity.[3–5] Medicines reviews may be carried out between the patient and pharmacist, or may include other members of the healthcare team, such as primary prescribers, case workers and nurses, and may involve the patient's family members or support people.

In Aotearoa New Zealand (NZ), the Pharmaceutical Society of New Zealand has defined different types of medicines reviews, in the Pharmacist Services Framework.[5] The spectrum of formal medicines review services range from an adherence focus [Long Term Care Service and Medicines Use Reviews (MUR)], to optimising medicines effectiveness [Medicines Use Reviews (MUR)] and comprehensive medicines optimisation (Comprehensive Medicines Management) which may or may not include a pharmacist working as a prescriber.[5] The training requirements and settings vary between review types and funding, contracting arrangements, and availability vary across the regions.[6] Medicines reviews in older adult populations can improve the quality of medicines prescribing and medicines adherence and reduce medicines-related adverse effects and healthcare costs.[7–10] National policies and reports in NZ call for increased utilisation of pharmacists' clinical skills to deliver these services and to improve health outcomes for older adults.[11,12]

In NZ, Māori (the Indigenous people; 16% of the population) experience poorer access to and quality of health care, including medicines[13] and related services, compared to non-Māori.[6] Despite the call for Māori health equity to be centred in the health system and services,[14] disparities in health outcomes continue, with Māori experiencing earlier onset of chronic morbidity and lower life expectancy than non-Māori.[15,16] Pharmacist-facilitated medicines review services which currently exist in NZ, have low rates of Māori recruitment, and are based on international models with little adaption to the NZ context, particularly in relation to the development of pro-equity models of care.[6] They may increase disparities in outcome from Māori, who are less likely to benefit from improved adherence or medicines knowledge than non-Māori.[6] The development of culturally safe[17] medicines review services has been postulated as a method to support the attainment of health equity for Māori.[18]

Medicines review interventions are regarded as complex interventions due to the number of intersecting components involved.[19] In the United Kingdom's Medical Research Council (MRC) guidance on developing a complex health intervention,[19] one of the key steps is to undertake a feasibility study. Outcomes investigated in a feasibility study can include methodological aspects, for example recruitment methods and evaluation tools, as well as testing of proposed primary and secondary outcomes measures, prior to undertaking a larger randomised controlled trial (RCT) (or an alternative study design when an RCT is not possible). In the case of medicines review interventions, outcome measures may include change in medicines knowledge and quality of life (QoL) scores.[20] The testing of interventions in a smaller scale study, prior to larger (and more expensive) service implementation and evaluation, is recommended to ensure efficient and effective resource utilisation, feasibility of recruitment methods, intervention delivery and data collection methods, patient and practitioner acceptability, to identify implementation barriers and enablers, and to reduce the risk of harm.[19,21–23]

The research group undertook a systematic review[6] and interviews with key stakeholders[24,25] to inform the development of a pharmacist-facilitated medicines review intervention for community-dwelling Māori older adults, for testing in a feasibility study.[2] The Treaty of Waitangi, one of NZ's founding documents, were used to structure the intervention model.[26] The Treaty of Waitangi guarantees Māori the right to partnership in healthcare, options of both culturally safe mainstream services and Māori-centered services, and equitable health outcomes.[14] As part of the feasibility study, patient acceptability was assessed and is reported elsewhere.[27] In brief, the intervention was acceptable to the older Māori participants who perceived an increase in their autonomy, control and medicines knowledge. They highlighted the importance to them of a 'by Māori, for Māori' approach and valued the clinical expertise and advocacy provided by the pharmacist.

The aims of this paper are to report the feasibility of the:

- recruitment, assessment tools, and time resources required for research and intervention components.
- proposed intervention outcomes relating to pharmacist recommendations, and prescriber acceptance rates, appropriateness of medicines and QoL.

## 2. Methods

### 2.1. Ethics and Trial registration

Ethical approval was granted by theNorthern B Health and Disability Committee (19/NTB/106) and Te Whānau o Waipareira Ethics Committee (Hikaka/2019). The study is registered with the Australia and New Zealand Clinical Trials Registry (ACTRN12619001070123); Universal Trial Number (UTN): U1111-1234-2170.

### 2.2. Study design

The protocol for this single-arm feasibility study has been published previously.[2] This study was guided by kaupapa Māori theory which gives power to Māori in the research process, is informed by Māori knowledge systems, and affirms the right of Māori to participate in the research process.[28,29] This study was reported in accordance with the CONSORT 2010 statement: extension to randomised controlled pilot and feasibility trials[30] (as relevant to the current, non-randomised study) and the CONSIDER statement, used to strengthen the reporting of health services research which involves Indigenous peoples.[31]

### 2.3. Study population

#### 2.3.1. Inclusion criteria

Māori ethnicity (self-identified) AND.

Prescribed or taking four* or more medicines for at least three months AND.

55 years or older (Māori are generally eligible in NZ for 'older adult' health services at age 55 due to earlier onset of chronic co-morbidity and lower life expectancy) AND.

Community-dweller enrolled in a general practice in Waitematā District Health Board (WDHB - NZ is geographically divided into 20 District Health Boards charged with the funding and provision of health services).

#### 2.3.2. Exclusion criteria

Not able to give informed consent.

* It was originally proposed that five or more medicine would be the cut-off for eligibility as this is often an arbitrary number used to define polypharmacy,[1] however, feedback from the research advisory group and stakeholder engagement was that four medicines should be the cut-off due to complexity that can occur even with that number of medicines.

### 2.4. Recruitment of participants

Proposed recruitment methods comprised:

a) Mail-out by general practices to eligible participants;
b) Presentation at Māori older adult community groups with invitation to participate;
c) Study information provided to potential participants by prescribers during consultation or in waiting areas in general practices/community pharmacies;
d) Word-of-mouth;
e) Contacting participants involved in an earlier study[24] to invite participation (in keeping with earlier commitments to research participants).

The mail-out method above (a) involved recruiting WDHB general practices to support participant recruitment (no other recruitment methods required general practice recruitment). Convenience sampling was used to identify and approach practices. Written consent was obtained by the research pharmacist in a face-to-face meeting with a staff member with the authority to provide consent (e.g. a practice manager). For recruitment methods a-d, potential participants were required to contact the research pharmacist i.e. the researchers were not provided with contact details for eligible participants; this approach was chosen to give potential participants more control in the research process. For all methods, a written participant information sheet was provided. Written informed consent was obtained by the research pharmacist in a face-to-face meeting in a location of the potential participants' choosing. Access to both general practices and Māori older adult community groups was facilitated through researcher relationships, established over time working in WDHB and over the course of the research project.

### 2.5. Intervention

#### 2.5.1. Intervention location, content and delivery

Participants, researchers and health professionals involved in the intervention, and communication pathways through the intervention components, are shown in Fig. 1.

The research pharmacist, who was Māori and had experience in older adult medicines optimisation and postgraduate qualifications in Clinical Pharmacy, delivered the intervention. The intervention consisted of two parts, which both incorporated various activities consistent with medicines review interventions:

1. Medicines education session (participant and pharmacist)

This session took place in a location of the participant's choosing. The participant could invite family/support people to attend. Prior to this session the pharmacist had accessed the participant's secondary care health

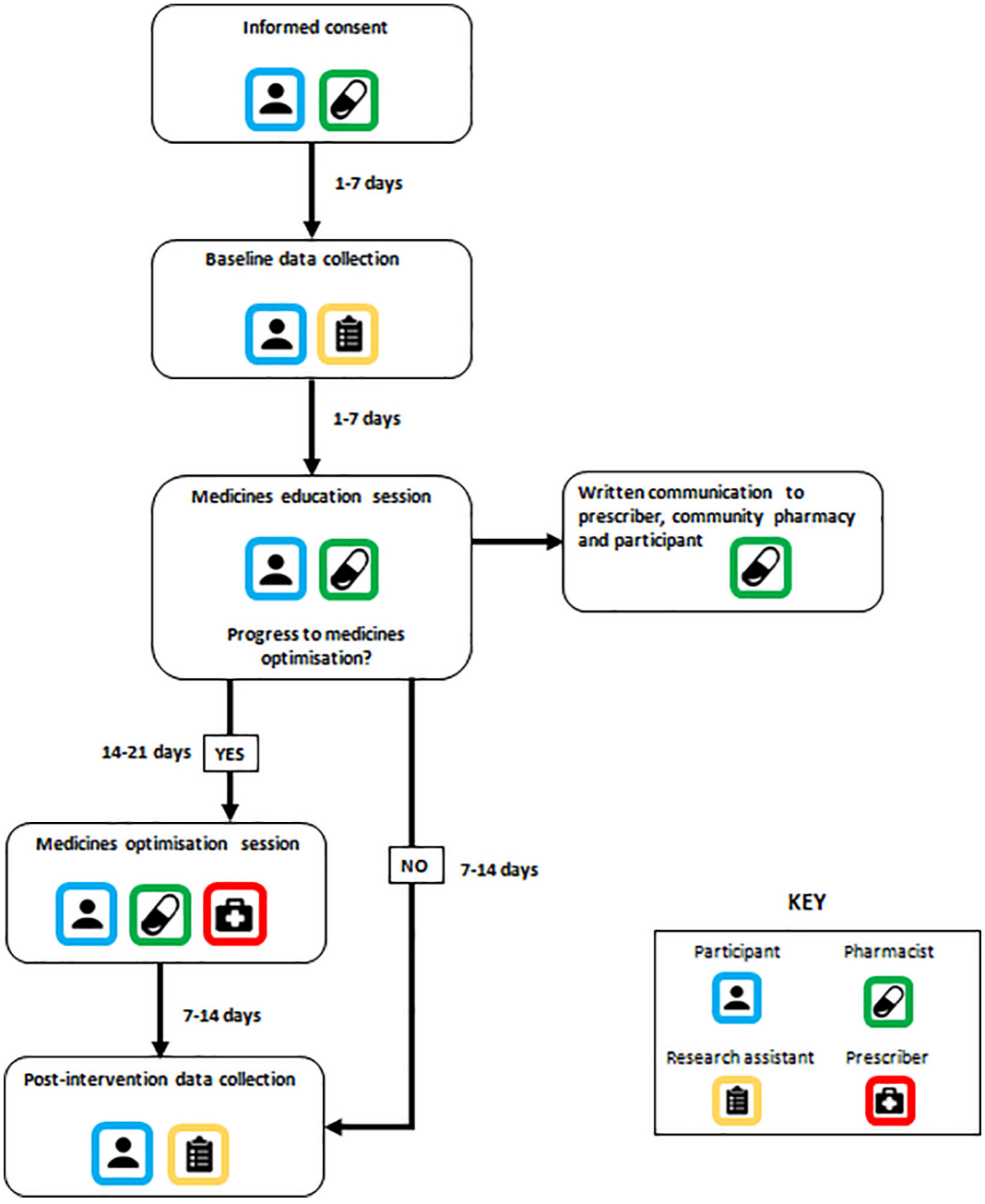


**Fig. 1.** Process flow for data collection and intervention.

records (including outpatient clinic letters, referrals, hospital discharge summaries, inpatient notes, laboratory investigations). This part of the intervention included tasks at the level of MUR (adherence focus with very little access to clinical records) and MTA (medicines optimisation with review of clinical appropriateness and access to clinical records including laboratory investigations) in the National Pharmacist Services Framework.[5] This component included activities such as medicines reconciliation, medicines education, goal planning, medicines and laboratory monitoring, assessing for effectiveness and adverse drug effects (ADEs), and the provision of medicines resources. A written summary of the discussion, action points and recommendations to the prescriber, was provided to the participant, community pharmacy and general practice. This was compiled and posted by the research pharmacist after completion of the medicines education session. The participant was aware of the information that would be included.

2. Medicines optimisation session (participant, pharmacist and primary prescriber)

This session was optional to support participants to have more control over who was included at various stages of their care. Consent for the medicines optimisation session could be given during the initial consent process or during the medicines education session. If the participant consented to a medicines optimisation session, a discussion with the pharmacist at the end of the medicines education session was used to confirm their willingness to participate further. The participant decision was recorded.

The medicines optimisation session took place at the participant's general practice to avoid the need for prescribers to travel. The prescriber was the participant's normal primary care prescriber. The participant could invite family/support people to attend. Pharmacist recommendations (based on the medicines education session) were discussed and a medicines management plan was developed and recorded by the prescriber as part of the participant's clinical records. It was proposed that this session would be 15–30 min long. The patient payment (to the practice) for this visit was paid from the research budget.

### 2.6. Study outcomes

Feasibility evaluation focused on two aspects:

1. Research and intervention processes (recruitment, intervention delivery, and data collection methods).
2. Intervention outcomes (pharmacist recommendations, and prescriber acceptance rates, appropriateness of medicines and QoL).

Appropriate prescribing was measured using the STOPP/START criteria which allow identification of potentially inappropriate medicines (PIM; potential harm outweighs therapeutic benefit) and potential prescribing omissions (PPOs; an indicated medicine has not been prescribed) in older adults.[32] The research assistant (HA) completed this assessment using baseline and post-intervention medicines lists (blinded), medical conditions and relevant laboratory test results provided by the research pharmacist. The research pharmacist had collected these data as part of the intervention delivery. All STOPP/START criteria were applied except A1 ('any drug prescribed without an evidence-based clinical indication') and A2 ('any drug prescribed beyond the recommended duration, where treatment duration is well defined') which were excluded as the research assistant did not have access to enough information to apply these two criteria. A full list of outcomes

**Table 1**
Outcome measures with method for data collection and analysis.

| | Outcome measure | Data collection method (collector) | Assessment Tool | Time point for data collection | Analytical method |
|---|---|---|---|---|---|
| Recruitment, assessment tools, time resource evaluation | Recruitment rates | Recorded in Excel™ intervention recruitment rates/method; associated time; approaches by non-eligible people (RP) | N/A | Throughout study. RP collected start and finish times for each recruitment and consent meeting. | Descriptive statistics |
| | Assessment tool feasibility | Recorded time taken to administer assessment tools in Excel™ (RA) | N/A | Baseline and 7–14 days post-intervention completion when tools were administered. For STOPP/START criteria assessment, the total time taken was recorded by the RA. | Descriptive statistics |
| | | Reflection on difficulties with administration in reflective journal (RA) | N/A | Baseline and 7–14 days post-intervention completion when tools were administered. | General inductive analysis |
| | Time resources required to deliver intervention | Recorded time taken to deliver intervention in Excel™ (RP) | N/A | Immediately post-intervention delivery. RP collected start and finish times for each aspect of the intervention (including non-contact aspects such as pharmacist review of clinical information). | Descriptive statistics |
| Proposed intervention outcome evaluation | Number of medicines | Recorded in Excel™ | N/A | Baseline and immediately post-intervention | Descriptive statistics |
| | Medicines knowledge | Over the telephone, recorded in Qualtrics™(RA) | Questionnaire[a] | Baseline and 7–14 days post-intervention completion. | Descriptive statistics |
| | Potentially inappropriate medicine (PIM) and potential prescribing omission (PPO) | Medicines appropriateness assigned by RA in Excel™ | STOPP/START criteria[32] | Baseline and post-intervention (all assignment of medicines appropriateness completed post-intervention by RA) | Descriptive statistics |
| | Participant QoL | Over the telephone, recorded in Qualtrics™(RA) | SF-36[35] | Baseline and 7–14 days post-intervention completion | Descriptive statistics |
| | Medicine-related pharmacist recommendations | Record number in Excel™ (RP) | N/A | Medicines education session recommendations recorded from communication letter; Medicines optimisation changes/recommendations recorded during and immediately post session | Descriptive statistics |
| | Recommendation acceptance rate by prescriber | Record number and prescriber acceptance in Excel™ rate (RP) | N/A | Prescriber acceptance of recommendations was recorded during the medicines optimisation session, based on recommendations made in the written communication. | Descriptive statistics |
| | Non-pharmacological pharmacist recommendations | Record number and prescriber acceptance rate in Excel™ (RP) | N/A | Acceptance rates were not documented for those who did not attend the medicines optimisation session as it could not be recorded. | |

Abbreviations: PIP (Potentially inappropriate prescribing); QoL (Quality of Life); RA (research assistant); RP (research pharmacist); SF-36 (Short Form (36) Health Survey).
[a] Questionnaire developed specifically for this feasibility study.[2] Questionnaire and scoring are provided as supplementary material.

**Table 2**
Changes in methods between study protocol and current study.

| Component | Study protocol | Current study | Reason for change |
|---|---|---|---|
| Eligibility criteria | Taking four or more medicines | *Prescribed* or taking four or more medicines | Allowed for identification of those who were prescribed, but not taking, medicines. |
| Recruitment | Record related costs | Costs not recorded | Economic analysis of feasibility was outside scope. |
| Time point for pharmacist to access clinical notes | Prior to medicines optimisation component | Prior to medicines education component | Participants' expectation was that pharmacists would access their notes prior to first meeting. |
| Post intervention follow-up | 4 weeks | 1–2 weeks | Research project timeframes were affected by COVID-19 restrictions. |
| STOPP/START criteria analysed | All criteria | Criteria A1 and A2 were excluded | The data required to apply these criteria could not be collected. |

reported in this paper, including measurement tools, is shown in Table 1. Reasons for inclusion of particular outcomes and the selected measurement tools are further detailed in our previously published study protocol.[2]

The medicines knowledge questionnaire was developed specifically for this study and was based on a patient information sheet relating to '5 questions to ask about your medications',[33] which has also been adopted by the NZ Health Quality and Safety Commission as guidance for the key information all patients should know about their medicines.[34] Construct, content and face validity were undertaken by the research team and the questionnaire was also reviewed by the research advisory group (Section 2.10 of this paper).

#### 2.6.1. Criteria for deciding on future testing of the intervention

Progression criteria were not predefined, however, if the intervention was acceptable to participants, there was agreement that further study would be undertaken.

#### 2.6.2. Deviations from initial study protocol

Differences between the proposed methods, and the methods that were employed in this study are shown in Table 2.

### 2.7. Data collection

Baseline characteristics were self-reported and gathered in a pre-prepared form in the consent meeting, after consent was gained. Data were collected by the research pharmacist and an independent research assistant (a Māori intern pharmacist) at baseline, pre-intervention, during each intervention component, and post-intervention. At the time of consent, participants were given a written profile about the research assistant. This was done so the participant could learn more about the person they would be talking to by telephone, in an attempt to increase participant ease and comfort. The profile included a photo, whakapapa (genealogical connections), professional experience and that he lived and worked in WDHB. Table 1 details collection methods, and proposed time points. The decision to re-assess QoL 7–14 days post-intervention was driven by research timelines and the fact we were evaluating tool and data collection method feasibility as opposed to measuring changes in QoL, which is unlikely to change in this short time period with this type of intervention.

### 2.8. Sample size

The intention was to recruit and deliver the intervention to 30 participants. This was based on change in QoL scores (standardised mean difference of 0.39) from previous pharmaceutical care interventions, with a 90% power to detect difference and guidance for appropriate sample sizes for feasibility studies.[2]

### 2.9. Analytical methods

Methods used for data analysis are reported in Table 1. Quantitative analyses were conducted using IBM SPSS Statistics for Windows, v25.0 (IBM Corp., Armonk, N.Y., USA) and results presented as simple descriptive statistics. Further statistical analysis was not performed due to the small sample size. Kaupapa Māori theory was used as basis for interpreting findings in the wider context of health and wellbeing, taking into account Māori older adults' cultural and social contexts, including current health inequities.

### 2.10. Researcher positionality and research oversight

The research team consisted of health professionals and researchers, three of whom were Māori. Together the team had experience in research and provision of healthcare relating to health service development, older adult medicines optimisation, public health, pharmacy practice, Māori health and health equity. The research was overseen by a Māori advisory group which supported the intervention and study design, presentation of results and dissemination plan. The terms of reference for this group, including mutual expectations and level of input, were collaboratively developed and agreed on by members and they were provided a koha (gift vouchers) for their involvement which reflected their level of knowledge and expertise.

### 2.11. Indigenous research capacity

Steps were included to increase Māori research capability and capacity. The Māori research pharmacist, led this project with the supervision of those more experienced in research, increasing her skills. She also undertook formal postgraduate education in kaupapa Māori theory and research. The employment of a Māori research assistant enabled the research pharmacist to gain experience in research supervision, as well as supporting the capacity building of younger Māori researchers. The research assistant was chosen because of his pharmacy training, Māori whakapapa, and links to WDHB.

## 3. Results

### 3.1. Recruitment

A total of 2 general practices and 18 participants were recruited from November 2019 to February 2020 (Fig. 2). Two additional general practices were approached, one of which verbally agreed to participate but was not formally consented prior to study end date. The other practice declined to participate as practice management felt they did not have any prescribers who would effectively support the intervention, despite being a practice with high Māori enrolment. Recruited practices chose to recruit patients through mailout to potential participants, rather than supplying written information during their consultations or at their practice (alternatively proposed recruitment method). Eligible participants were identified by practice staff through the use of reports generated in their patient management systems. Practice staff then sent the letters out by post. One general practice sent out 92 letters from which ten participants were recruited; the other practice sent 135 letters and two participants were recruited. Letters sent by the latter practice were sent at a time when COVID-19 cases were first being identified in the community in NZ. Other methods of recruitment used were presentation at Māori older adult community groups ($n = 4$) and from contacting those involved in previous related research ($n = 2$). Three participants who had been involved in earlier research and indicated they would like to be approached for participation in the

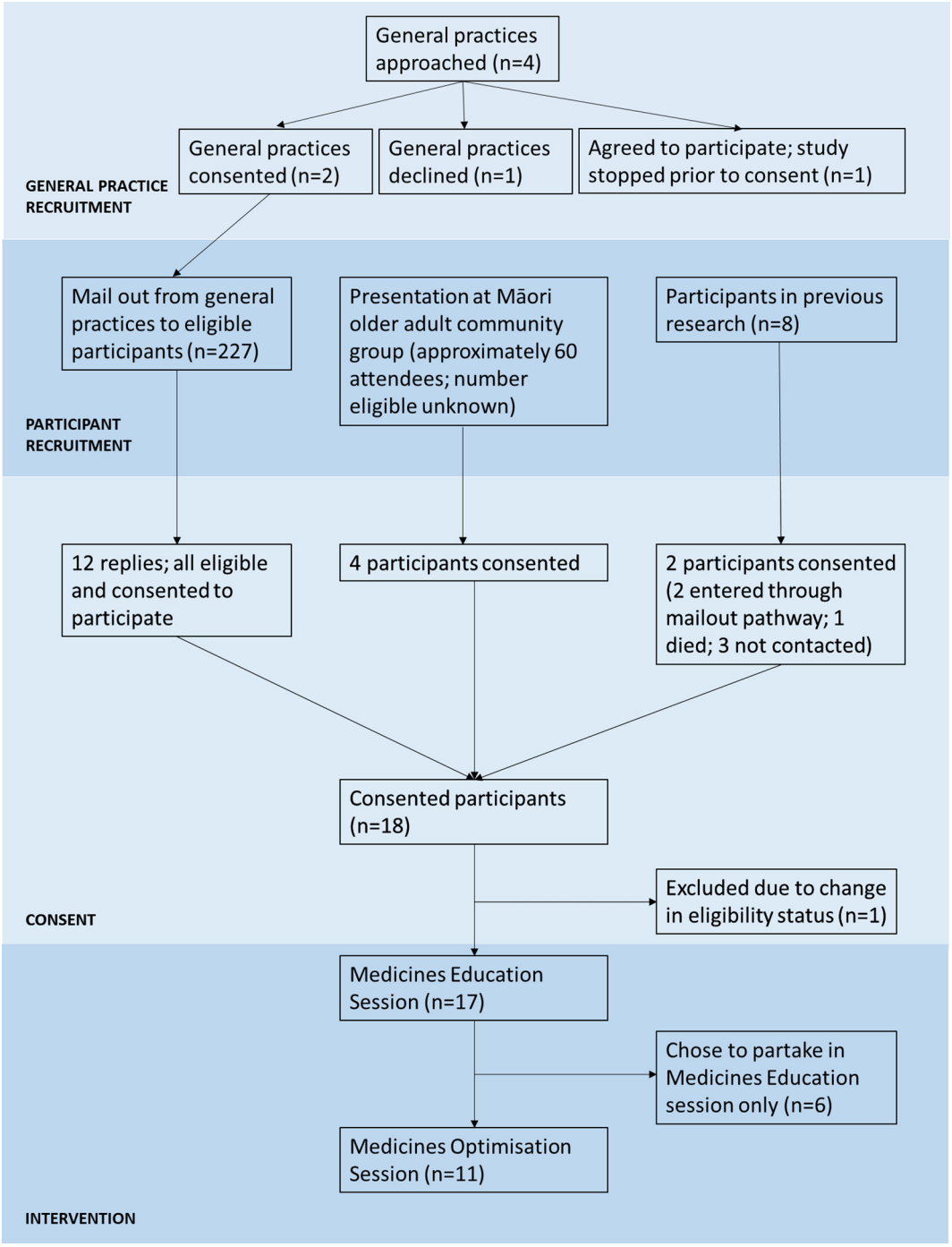


**Fig. 2.** Recruitment methods and participant flow.

current study were not approached (Fig. 2) as the study prematurely ended (COVID-19-related) prior to this occurring. No participants were recruited through word-of-mouth; therefore, this has not been included in Fig. 2. One consented participant was removed prior to the intervention delivery as they no longer met the eligibility criteria (their medicines had been stopped recently and she was prescribed and taking only one medicine). Reason for non-participation from eligible people receiving mail-out invitations could not be captured. There were no requests for entry to the study by ineligible people. Recruitment was paused in March 2020 due to the COVID-19 pandemic and NZ 'lockdown',[36] and the decision was made to stop recruitment completely in April 2020. All participants consented to be involved in both intervention components (education and optimisation).

*3.1.1. Recruited participants*

The intervention was completed in 17 consented participants from December 2019 to March 2020. (Fig. 2). The medicines education session took place in participants' homes ($n$ = 16) or place of work (n = 1). Data collection was complete for all participants, and for all outcome measures. At baseline, participants' mean age was 69.3 years, the majority were female ($n$ = 12) and they took a mean of 7.7 regular medicines (Table 3). Almost all participants ($n$ = 15) managed their medicines on their own, with just two participants having the support of a spouse or formal carer to administer medicines daily. The majority of participants ($n$ = 12) used either compliance packing (i.e. where all regular, oral solid dose medicines to be taken at a particular time of day are packaged together) or a dosette box to

support their daily medicine administration. The majority of participants (n = 12) obtained their medicines from pharmacies that did not charge them the government co-payment for medicines. This charge was $5 per item when the study was undertaken, collected from the patient and then on-paid to the government by the pharmacy. Where the patients are not charged, the cost is covered by the pharmacy instead.

Eleven participants took part in the medicines optimisation session component, with 5 different prescribers (general practitioner (n = 4); nurse practitioner (n = 1)). Six participants chose not to take part in the medicines optimisation session with the prescriber as they were happy to discuss any potential changes with their prescriber at their next visit. Participant flow is shown in Fig. 2. Only three participants had family/support people attend any part of the intervention, although a number of participants had family or friends in the house at the same time that the medicines education session was taking place.

### 3.2. Feasibility of tools and data collection methods used to measure outcomes

Participants found the QoL tool (SF-36) repetitive and it was perceived by the research assistant that they felt uncomfortable answering questions relating to mental health. One question which asked if they felt "full of pep", confused participants as to its meaning. In the medicines knowledge questionnaire, participants were asked to name each medicine they were taking, and then asked a number of questions about each medicine. The research assistant reported that the questionnaire was generally well understood except for a question relating to whether participants knew 'how long the medicines were to be taken for'; this question was often misunderstood as being how long *had* they been taking it for. In some instances, participants instructed the research assistant to record the "same as last time". For example, if, when asked "what side effects does this medicine have", and they responded "I don't know, the doctor hasn't told me", then this was the recorded response to that question for all the medicines that the participant was taking. Participants understood all questions in the acceptability survey which was developed specifically for this study. It was easy for the research assistant to complete, although it did not allow the capture of other relevant comments that participants made throughout the course of completing the survey. Acceptability results are reported elsewhere.[27]

**Table 3**
Baseline characteristics of participants.

| Characteristics | *N* (%) |
|---|---|
| *N* (%) | 17 (100%) |
| Mean age | 69.3 years (range 58–92) |
| Gender | |
| Female | 12 (71%) |
| Male | 5 (29%) |
| Ethnicity | |
| Māori | 15 (88%) |
| Māori/ NZ European | 2 (12%) |
| Mean number of medicines taken | |
| Regular | 7.7 (range 2–15) |
| As required | 1.5 (range 0–5) |
| Medicine administration | |
| Self | 15 (88%) |
| Supported by carer/spouse | 2 (12%) |
| Medicine adherence aid | |
| Compliance packaging | 7 (41%) |
| Self-filled dosette box | 5 (29%) |
| None | 5 (29%) |
| Medicine collection method | |
| Pick up from pharmacy | 14 (82%) |
| Delivered by pharmacy | 3 (18%) |
| Dispensing frequency of regular medicines | |
| Weekly | 1 (6%) |
| Monthly | 5 (29%) |
| Every 3 months | 11 (65%) |
| Regular pharmacy waives co-payment | |
| Yes | 12 (71%) |
| No | 5 (29%) |

The STOPP/START criteria[32] used to assess medicines appropriateness was found to be relatively simple to administer. This was completed by the research assistant (with no specialised training in geriatric medicine) for all participants in five hours total. This process was supported by the research pharmacist who had collated a list of medical conditions and relevant laboratory results from secondary care sources as a part of the routine pre-work (prior to the medicines education component).

The assessments were administered over the telephone at a time convenient to the research assistant and participant (including weekends and evenings). There was one participant with some hearing loss, which made telephone administration more difficult for both parties, however, all the data were still able to be collected.

The assessment tools were administered by a research assistant with a Bachelor of Pharmacy degree which was valuable for interpreting medicine names (in cases where pronunciation was different to that used by health professionals) and clarifying participant responses. The research assistant perceived that there was an expectation from participants that the person administering the tools would be able to answer questions about medicines.

The time it took to administer the assessment tools (Table 4) and difficulties with administration were noted by the research assistant. Consent, and the baseline and post-intervention questionnaires, took a mean of 103.7 (70–165) minutes per participant in total. A similar amount of time (approximately 38 min mean average; up to 55 mins) was required to administer both baseline and post-intervention assessments, noting that the post-intervention assessment contained the participant acceptability questionnaire in addition to the other assessments completed at baseline.

For those involved in the education session alone, the mean pharmacist time taken to deliver the intervention (including non-participant contact activities) was 96 min (Table 4). For those who participated in the optimisation session, mean pharmacist time was 166 min, with an additional mean of 18 min for the prescriber appointment (excluding appointment wait time). Of the 17 participants, 11 were in contact with the pharmacist post-intervention for a number of reasons including: clarification of information; reporting new potential adverse drug events; requesting advice regarding annual influenza vaccinations; updating the pharmacist on outcomes from intervention; and asking for next steps in the treatment plan.

### 3.3. Timeline for research and intervention activities

The timeframes, in which each part of the intervention and associated research processes would be carried out, were included as part of the study protocol,[2] and are shown in Fig. 1. The actual point in time at which the various components were completed often fell outside the proposed timeframes (Table 5), suggesting protocol timeframes required further consideration to allow for real-world application. The variation was largely due researchers and participants finding a mutually agreeable time to undertake the intervention and/or assessments. This was influenced by annual leave, sickness, hospitalisations, holidays and unplanned/extenuating circumstances. On occasion, intervention components were delivered outside proposed timeframes to better align with other planned healthcare. For example, the medicines optimisation session for one

**Table 4**
Time resource for data collection and intervention (results).

| Activity | Mean time in minutes (range) |
|---|---|
| Research activity ($n$ = 17) | |
| Consent | 26.7 (5–90) |
| Baseline questionnaires | 38.2 (25–55) |
| Post-intervention questionnaires | 38.8 (20–55) |
| Intervention activity | |
| Review of clinical records by pharmacist ($n$ = 17) | 36.8 (15–70) |
| Medicines education session ($n$ = 17) | 52.6 (15–105) |
| Preparation of written communication ($n$ = 17) | 38.4 (14–90) |
| Medicines optimisation ($n$ = 11) | |
| Appointment with prescriber | 18.2 (11–35) |
| Wait time for appointment | 17.7 (0–90) |

participant was delayed until after they had had a secondary care specialist appointment as this would directly impact on future medicines and health management. The availability of a prescriber appointment to undertake the medicines optimisation component was never cause for changes in intervention timeframes.

### 3.4. Intervention outcomes

The mean number of medicines did not change post-intervention vs baseline (Table 6). Medicines knowledge scores could be calculated from the pre-defined scoring criteria (Supplementary material_1). Mean medicines knowledge scores changed from 62% at baseline to 80% after the intervention although the small sample size did not allow for statistical significance to be calculated to understand whether this change was due to the intervention or chance. There was a low rate of prescribing of potentially inappropriate medicines (PIMs) and potentially inappropriate omissions (PPOs) both pre- and post-intervention.

Pharmacist recommendations were made at multiple points in the intervention (Table 7). A total of 162 recommendations were made for the 17 participants across the course of the study (mean of 9.5/participant). Recommendations relating to medicine changes contributed 25.9% ($n$ = 42) of recommendations. The majority of recommendations occurred during the medicines education session ($n$ = 93; 57%). Recommendations made in the written communication to the prescriber (which related to issues identified during the medicines education sessions) were accepted by the prescriber in 95% of cases (42/45 recommendations accepted). Prescriber acceptance rates for 'recommendations' made in the medicines optimisation sessions were not reported as this involved communication between everyone in the session, hence, it was not necessarily one person's recommendation. Numbers of recommendations made during the optimisation session have, however, been reported as the prescriber appointment was made for the specific purpose of this study, and changes would not have occurred otherwise (e.g. during the medicines optimisation session it may have been identified that there was a skin infection present which needed treatment with oral antibiotics). The number of pharmacist recommendations made to the prescriber in the written communication was higher in those who chose to participate in the medicines optimisation session (3.36 recommendations per participant; range 2–5) compared to those who chose not to (1.33 recommendations per participant; range 0–3). There were a number of non-medicine-related recommendations such as referral to other primary and secondary care services, non-pharmacological management of chronic conditions, exercise and nutrition advice, and advice about medical conditions. For those who attended the medicines optimisation session ($n$ = 11), there were a total of 24 'recommendations'/changes to treatment plans made during the session which were initiated for reasons such as changes in acute presentations, observations that required action (e.g. low blood pressure) or issues raised by the participant that had not previously been disclosed.

## 4. Discussion

This study is the first to describe a pharmacist-facilitated medicines review service designed specifically for, and with, Indigenous older adults. Review of the research and intervention processes identified areas which could be changed and improved prior to future, larger studies.

**Table 5**
Proposed versus actual timeline for research activities (results).

| Activity | Proposed days[a] | Actual days[a] Mean ± SD |
|---|---|---|
| Consent ($n$ = 17) | Day 0 | |
| Baseline data collection ($n$ = 17) | 1–7 | 9.5 ± 9.4 |
| Medicines Education Session ($n$ = 17) | 1–7 | 14.1 ± 17.7 |
| Medicines Optimisation Session ($n$ = 11) | 14–21 | 24.4 ± 11.0 |
| Post-intervention data collection ($n$ = 17) | 7–14 | 15.4 ± 16.0 |

SD = Standard deviation
[a] The number of days after the previous research or intervention component.

**Table 6**
Medicines-related outcomes and quality of life.

| Outcome measure | Baseline | Post-intervention |
|---|---|---|
| Medicines-related outcomes | Number (range) | |
| Mean number of prescribed medicines | | |
| Regular | 7.71 (2–15) | 7.64 (4–14) |
| As required | 1.53 (0–5) | 1.47 (0–3) |
| Medicines knowledge score (0 − 100) | Mean +/− SD | |
| | 62% ± 3.8 | 80% ± 3.5 |
| Number of potentially inappropriate medicines (PIM) per person | 0.29 ± 0.14 | 0.06 ± 0.06 |
| Number of potential prescribing omissions (PPO) per person | 0.29 ± 0.14 | 0.06 ± 0.06 |
| Quality of life – SF-36[35] | | |
| Eight domains | Mean ± SE | |
| Physical functioning | 47.94 ± 5.25 | 49.71 ± 5.52 |
| Role limitations due to physical health | 44.12 ± 5.04 | 44.12 ± 9.71 |
| Role limitations due to emotional problems | 86.27 ± 5.00 | 84.31 ± 8.14 |
| Energy/fatigue | 47.94 ± 4.29 | 44.71 ± 4.74 |
| Emotional well-being | 80.47 ± 2.83 | 78.12 ± 3.84 |
| Social functioning | 63.97 ± 5.76 | 69.85 ± 5.03 |
| Pain | 65.53 ± 6.52 | 72.79 ± 5.87 |
| General health | 50.59 ± 4.33 | 51.76 ± 5.28 |

SD = standard deviation; SE = standard error.

Baseline characteristics of participants were not compared to the rest of the eligible population at recruited practices as we did not have ethics approval to undertake this comparison. The proportion of male recruits is lower than would be anticipated in the population and the number of medicines participants prescribed is higher than the general Māori population of a similar age,[37] although this would be expected given that participants were only eligible if they were prescribed or taking four or more medicines.

The recruitment rate through mail-out gave a low yield, however, was likely affected by the impacts of COVID-19. This method could have been improved if the letters were individualised, detailing potential benefits to a particular person in the letter. Recruitment may have been improved through in-person prescriber referral of potential participants or using 'advertising' in general practices/community pharmacies (another method proposed in the study protocol). General practices chose the mail-out method, which allowed administrative staff to manage this, and was less resource intensive for practitioners. GP referral is the method used in similar medicines review intervention research in NZ,[38] and in the federally funded Australian Home Medicines Reviews (HMRs)[39] for community-dwelling older adults programme, which has many of the same components as the intervention in the current study. If GP referral is used for recruitment in the future, this will have cost and resource implications which will need to be included in the research budget. The HMR service also allows for GPs to be remunerated reviewing pharmacist recommendations,[39] something which was not allowed for in this study. Using GP referral recruitment methods may have increased participants' confidence in the service as their health professional would have been seen to be directly supporting it, and could be employed in future research.

Recruitment was closed early with just over half the intended participant numbers due to COVID -19. This decision was made as the participant population included people at most risk of COVID-19 infection and related adverse outcomes[40]; it was unclear how long social restrictions would be in place; interim review indicated that findings (even from the smaller study population) supported further development and action.

QoL is included in a Core Outcome Set that has been recently developed for trials aimed at improving polypharmacy appropriateness in older adults in primary care, however, there is no current consensus on the best way to

**Table 7**
Recommendations made during the different intervention components.

| Recommendation type | Intervention component | | |
|---|---|---|---|
| | Pharmacist education session ($n$ = 17) | Written communication to prescriber ($n$ = 17) | Medicines Optimisation Session ($n$ = 11) |
| | Number of recommendations | Number of recommendations | Number of recommendations |
| Medicine changes | | | |
| Stop medicine (e.g. amlodipine stopped because of low blood pressure) | 1 | 10 | 2 |
| Start medicine (e.g. start Ovestin cream to prevent recurrent urinary tract infections) | 6 | 4 | 4 |
| Reduce dose (e.g. reduce glipizide dose because of low HbA1c) | | 5 | |
| Increase dose (e.g. increase dose of insulin because of high HbA1c) | | | 1 |
| Rationalisation (e.g. Change simvastatin to atorvastatin to allow for once daily administration to medicines in the morning) | 1 | 2 | 1 |
| Timing change (e.g. change night time frusemide to midday to reduce nocturesis) | 3 | 2 | |
| Pharmacist education | | | |
| Medication card[a] provided | 16 | | |
| Medication card[a] updated | 1 | | |
| Correct device technique | 6 | | 2 |
| Provide dosette box | 4 | | |
| New blood glucose machine | 1 | | |
| Vaccination advice | 4 | | |
| Medicines education | 17 | | 5 |
| Well-being support | | | |
| Information about medical conditions | 17 | | |
| Additional education resources | 2 | | |
| Advice about fixing a medical device | 1 | | |
| Dietary advice | 2 | | |
| Non-pharmacological management of chronic conditions | 3 | | |
| Strengthening exercise advice | 2 | | |
| Fluid balance advice | 2 | | |
| Medicines supply or funding issue | | | |
| Organise supply of repeat medicines or new prescription for medicines | 4 | | 6 |
| Monitoring | | | |
| Laboratory investigation | | 5 | 1 |
| Lying and standing blood pressures | | 7 | |
| Referral to another health service | | | |
| Specialist services | | 4 | 1 |
| Orthotics referral | | 2 | |
| Community physiotherapist | | 1 | |
| Mental health services | | 2 | |
| Pharmacist liaison with secondary care | | 1 | |
| Home phlebotomist | | | 1 |
| Total number per intervention component | 93 | 45 | 24 |
| Total number | 162 | | |

[a] Medication card = A card listing participant's medicines with dose/frequency instructions, indication, potential adverse effects.

measure this.[20] We used the SF-36 (comprising 36 questions) to measure QoL as it had been previously employed in pharmacy services research,[38] and validated in older adults and over the telephone.[41,42] Our participants found the questions repetitive, and some questions caused discomfort (mental health questions) and confusion, which may affect results. There is the potential to change the QoL tool to the SF-12,[43] a shortened version that takes approximately 20% of the time to answer and is well-validated against SF-36 scores in older adults.[44] The EQ-5D QoL tool[45] could be considered as an alternative, although recent research investigating a similar medicines review intervention as in our current study showed QoL scores improved when measured using SF-36 but not when using EQ-5D.[46]

The medicines knowledge tool, developed specifically for this study, was relatively easy to administer and analyse, and may be of use to other investigators seeking to use medicines knowledge as an outcome measure. Use in larger studies would allow for further validation of this tool. The STOPP/START criteria are widely used to assess medicines appropriateness in older adults and in this study, we found these criteria were relatively easy to apply. Previous studies have reported difficulties with applying these criteria.[47] These difficulties are reduced when those applying the criteria have access to full clinical information and a clinician-led individual review is included,[47] as was the case in our study. Previous research has shown that Māori older adults have lower rates of potentially inappropriate prescribing than non-Māori,[48,49] but that inappropriate prescribing may be more strongly associated with adverse outcomes for Māori.[50,51] Given that the criteria used to measure medicines appropriateness still require validation in Māori older adults, the lack of current evidence in this area, and the relative ease with which they were administered in this study, it would be beneficial to include medicines appropriateness as an outcome measure in future research in this area. The limitation of the acceptability survey was that it was reasonably structured and only allowed for limited participant 'commentary' to be recorded.

For participants with hearing impairment, telephone assessments were able to be completed, however, it was perceived by the research assistant that there were further difficulties. In future research, methods could be actively employed to overcome this (e.g. simplified questions, modification of speech rate and tone).[52] Additional methods of data collection could also be considered including in-person completion with a research assistant or web-based questionnaire tools. Online tools could increase the speed and ease of completion, reducing research costs and improving participant experience.[53]

Communicating medicines information to patients is one of a pharmacist's core roles.[5] The intervention appears to have the potential to improve medicines knowledge, which may be associated with reduced healthcare service dependency and costs.[54] The majority of pharmacist recommendations were made and actioned in the education session, suggesting that there is value in continuing to separate the medicines education and optimisation components, better utilising clinician resources. Recommendations that required prescriber action were accepted in the vast majority of cases

in our study. Although no controls were put in place to determine whether changes were made because of pharmacist recommendations, as opposed to independent decisions by the prescriber, in most cases pharmacist recommendations related to long-standing issues which had not been actioned in previous appointments. The prescriber acceptance rate of 95% is higher than those found in similar studies (72–90%).[55] It is known that recommendation rates appear to be higher in interventions where pharmacists have access to clinical information, as in the current study.[55] Another possible explanation for this higher acceptance is that the education component focused on a two-way exchange of information between the pharmacist and participant. Patient-practitioner partnership with Māori is seen as a right, as well as essential for health equity.[14,24] Recommendations that are developed in partnership may be more appropriate as they take into account patient-led health goals, and hence may be more likely to be actioned by prescribers. This partnership may also increase participant engagement and undertaking of recommendations as they have been involved in the planning, and potential benefits of action have been explored together.[56] Given the high recommendation acceptance rate by prescribers, it may be appropriate for some recommendations (such as referral to community physiotherapy), which currently require prescriber input in NZ, to be actioned directly by appropriately trained pharmacists, and may support more efficient access pathways. Further work in this area should be considered.

The medicines optimisation session was optional. The intention of this was to increase participant control in the research. In reality, for those who did not undertake the medicines optimisation, it was thought unnecessary as the participants felt comfortable discussing any issues identified with the prescriber themselves. The number of pharmacist recommendations made to the prescriber in the written communication were lower for those who did not participate in the medicines optimisation session. Also, less pharmacist contact time was required in the medicines education session for those that did not attend the optimisation session compared to those who did. This suggests that when the pharmacist spends more time with a person, trust is developed, with increased willingness to share information and more issues are identified. Partnership between the participant and pharmacist was key to this intervention.[26] Developing deeper connections through getting to know each other (whakawhanaungatanga) supports the development of partnership, and has been identified in both Māori and Indigenous health development,[57–60] as something that requires more time to be spent with people, increases the sharing of health issues, and is crucial to the success of interventions and services. Relationship development is supported in HMR model,[39] through the use of community pharmacists to deliver the intervention. However, these pharmacists do not have specialist knowledge of geriatric medicine, a factor that has been shown to be important to improving outcomes in the past.[61] Those who chose not to attend the optimisation session may have had less need for the intervention or pharmacist support in prescriber discussions and potentially, less complex health needs, although this phenomenon has largely been unstudied in the literature due to difficulties with defining 'complexity'.[62]

When both the education and optimisation components were undertaken, just under three hours of pharmacist time was required, on average, for each participant. This is similar to the time taken in HMRs[62] which have many of the same components as the intervention in the current study, and which are federally funded.[39] This study also showed that pharmacists who were more experienced, performed more medicines reviews than those less experienced, and that those who performed more reviews required less time to complete a review.[62] Some studies report shorter pharmacist time inputs; however, these interventions have had a narrow focus, e.g. reviewing one type of medicine only,[63] or are not reflective of our comprehensive, holistic approach which includes the patient in all the discussions.[64] Reporting the pharmacist time input for the intervention delivery is important for future service development, which includes the need to access appropriate resources and remunerate for pharmacist services. This is particularly relevant in the NZ context where there is policy to support wider use of this type of service.[11,12]

Designing the intervention with a *mandatory* optimisation session may have risked reduced uptake and less perceived benefit relative to the time input by all concerned. The need for a flexible approach was also clear in the variation of length of time both between aspects in the intervention and research process, and in the length of time spent on each activity. Each participant had different needs and a variety of other commitments. This reflects real-world healthcare interactions and is likely to be reflective of the nature of this population and intervention, requiring changes to the study protocol rather than the intervention itself. In a larger study, with increased researcher resource, the researcher may have more flexibility to undertake the baseline and post-intervention follow-up, compared to this study where the researcher was working around other full-time work. The flexible approach allowed tailoring to these individual requirements, as well as alignment with other aspects of health service delivery to best utilise health resources. These findings highlight the need to have a pragmatic approach to research design that reflects real-life service delivery.

### 4.1. Strengths and limitations

A strength of this study is the in-depth analysis of both the intervention and research processes, allowing for our group, and other researchers in this area, to build and improve on the intervention. Low participant numbers have, however, very likely affected the ability to demonstrate the statistical significance of results (though acknowledging that this is not the function of a feasibility study). As this was a feasibility study which aimed for a low number of participants (a target of 30 participants in the study protocol) we did not attempt to recruit a study sample representative of community-dwelling older Māori, nor have claims been made that the study findings can be generalised to this entire population.

Medicines knowledge was only tested once (and at a relatively early time-point) post-intervention and we cannot say whether any effect would have persisted. Medicines review studies often report the identification of drug-related problems as an outcome, and classify according to problem type.[65,66] This was not done in the current study due to low recommendation numbers, however, it may be beneficial to add this in future, larger studies. The pharmacist delivering the intervention was also involved in some analysis, such as categorising the pharmacist recommendations and identifying which recommendations were accepted, which could have introduced researcher bias. This approach was taken because of the limited availability of both pharmacists and researchers with relevant expertise in this area of study. This approach also (intentionally) supported some research processes (e.g. increasing familiarity of potential participants with the pharmacist delivering the intervention; reduced 'research burden' on prescribers whom otherwise would have had to complete documentation relating to acceptance rates). The independent research assistant was employed to undertake tasks to reduce the risk of potential research pharmacist bias as much as possible.

### 4.2. Dissemination and future direction

The findings from this study, including suggested refinements to intervention and study design, will be disseminated to various groups and stakeholders within WDHB and nationally including Māori communities, Māori older adult groups, health practitioners, DHB funders and planners, general practices, and pharmacy and primary care sector groups. The intention is to undertake a larger study, likely a pragmatic, randomised controlled trial,[67] once an assessment undertaken to assess the 'readiness' of progressing to this next step.[68]

## 5. Conclusion

The pharmacist-facilitated medicines review intervention developed for (and with) community-dwelling Māori older adults, which included participant-led discussions relating to goals of care, led to the identification of medicine and non-medicine related recommendations. The comprehensive reporting of research and intervention processes allows for

intervention refinement and can be utilised for further studies relating to pharmacist services in primary care.


## Funding sources

The lead author is funded by a Health Research Council of New Zealand Clinical Research Training Fellowship [HRC Ref: 17/134] and received a Ngā Pae o Te Māramatanga PhD Doctoral Support Grant [Ref: 21DSG09]. This study was funded in part by a Waitematā District Health Board Contestable Grant. Funders had no role or influence over study design; the collection, analysis and interpretation of data; in the writing of the report; or the decision to submit the article for publication.


## Study protocol

Ethical approval was granted by theNorthern B Health and Disability Committee (19/NTB/106) and Te Whānau o Waipareira Ethics Committee (Hikaka/2019). The study is registered with the Australia and New Zealand Clinical Trials Registry (ACTRN12619001070123); Universal Trial Number (UTN): U1111-1234-2170

## Declaration of Competing Interest

None.


## Acknowledgments

We would like to thank all the participants, prescribers and whānau who took part in this project, the kaumātua groups, and the National Hauora Coalition for supporting recruitment, Te Puna Hauora for their support of the research, and the project advisory group who supported throughout the feasibility study.


## Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.rcsop.2021.100018.

## References


1. Cooper JA, Cadogan CA, Patterson SM, et al. Interventions to improve the appropriate use of polypharmacy in older people: a Cochrane systematic review. BMJ Open 2015;5 (12), e009235.
2. Hikaka J, Hughes C, Jones R, Connolly MJ, Martini N. A systematic review of pharmacist-led medicines review services in New Zealand–is there equity for Māori older adults? Res Soc Adm Pharm 2019 Dec;115(12):1383–1394.
3. Blenkinsopp A, Bond C, Raynor DK. Medication reviews. Br J Clin Pharmacol 2012;74 (4):573–580.
4. Rose O, Cheong V-L, Dhaliwall S, et al. Standards in medication review: an international perspective. Can Pharm J (Ott) 2020 Jul 14;153(4):215–223.
5. Pharmaceutical Society of New Zealand. *New Zealand National Pharmacist Services Framework 2014. Wellington, NZ.* 2014.
6. Hikaka J, Hughes C, Jones R, Connolly MJ, Martini N. A systematic review of pharmacist-led medicines review services in New Zealand–is there equity for Māori older adults? Res Soc Adm Pharm 2019 Dec;115(12):1383–1394.
7. Chan D-C, Chen J-H, Wen C-J, Chiu L-S, Wu S-C. Effectiveness of the medication safety review clinics for older adults prescribed multiple medications. J Formosan Med Assoc 2014;113(2):106–113.
8. Milosavljevic A, Aspden T, Harrison J. The impact of a New Zealand community pharmacy service on patients' medication adherence and ambulatory sensitive hospitalizations. Res Soc Adm Pharm 2020;16(7):904–913.
9. Gray SL, Hart LA, Perera S, Semla TP, Schmader KE, Hanlon JT. Meta-analysis of interventions to reduce adverse drug reactions in older adults. J Am Geriatr Soc 2018;66 (2):282–288.
10. Dalton K, Byrne S. Role of the pharmacist in reducing healthcare costs: current insights. Integr Pharm Res Pract 2017;6:37–46.
11. Health and Disability System Review. *Health and Disability System Review: Interim report. Wellington, NZ. Hauora manaaki ki Aotearoa whānui - Pūrongo mō tēnei wā.* Wellington: HDSR. 2019.
12. Ministry of Health. *Pharmacy Action Plan 2016 to 2020. [Internet].* Wellington, N.Z.: Ministry of Health. 2016. Available from:. , https://www.health.govt.nz/system/files/documents/publications/pharmacy-action-plan-2016-to-2020.pdf.
13. Metcalfe S, Beyene K, Urlich J, et al. Te Wero tonu—the challenge continues: Māori access to medicines 2006/07–2012/13 update. N Z Med J 2018;131:1485.
14. Waitangi Tribunal. *Hauora -Report on Stage One of the Health Services and Outcomes Kaupapa Inquiry. Wai 2575.* Waitangi Tribunal: Wellington. 2019.
15. Robson B, Harris R. Eru Pōmare Maori Health Research Centre. Hauora: Māori standards of health IV: a study of the years 2000-2005 [Internet]. Wellington: Te Rōpū Rangahau Hauora a Eru Pōmare. [cited 2020 Apr 30]. Available from:. , http://www.hauora.maori.nz 2007.
16. Ministry of Health. *Tatau Kahakura: Māori Health Chart Book 2015. 3rd ed.* Wellington: Ministry of Health. 2015.
17. Curtis E, Jones R, Tipene-Leach D, et al. Why cultural safety rather than cultural competency is required to achieve health equity: a literature review and recommended definition. Int J Equity Health 2019;18(1):174.
18. Te Karu L, Bryant L, Harwood M, Arroll B. Achieving health equity in Aotearoa New Zealand: the contribution of medicines optimisation. J Prim Health Care 2018;10(1): 11–15.
19. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ 2008;337:a1655.
20. Rankin A, Cadogan CA, Ryan C, Clyne B, Smith SM, Hughes CM. Core outcome set for trials aimed at improving the appropriateness of polypharmacy in older people in primary care. J Am Geriatr Soc 2018;66(6):1206–1212.
21. Levati S, Campbell P, Frost R, et al. Optimisation of complex health interventions prior to a randomised controlled trial: a scoping review of strategies used. Pilot Feas Stud 2016;2 (1):17.
22. Bowen DJ, Kreuter M, Spring B, et al. How we design feasibility studies. Am J Prev Med 2009;36(5):452–457.
23. Eldridge SM, Lancaster GA, Campbell MJ, et al. Defining feasibility and pilot studies in preparation for randomised controlled trials: Development of a conceptual framework. PLoS One 2016;11(3):1-22.
24. Hikaka J, Jones R, Hughes C, Martini N. It is through shared conversation, that I understand"—Māori older adults' experiences of medicines and related services in Aotearoa New Zealand. N Z Med J 2020 Jun;12133(1516):33–46.
25. Hikaka J, Jones R, Hughes C, Connolly MJ, Martini N. Developing pharmacist-facilitated medicines review services for community-dwelling Māori older adults in New Zealand–A qualitative study exploring stakeholder views. Health Soc Care Comm 2021 Mar;29(2): 564–573.
26. Hikaka J., Jones R., Hughes C., Connolly M.J., Martini N. Utilising Te Tiriti o Waitangi to approach health intervention development and research: Pharmacist-facilitated medicines review interventions for Māori older adults. 2021. J Prim Health Care. Accepted for publication
27. Hikaka J, Jones R, Hughes C, Amende H, Connolly MJ, Martini N. Clinical expertise, advocacy and enhanced autonomy–Acceptability of a pharmacist-facilitated medicines review intervention for community-dwelling Māori older adults. Exp Res Clin Soc Pharm 2021 Apr;18:100010.
28. Smith LT. *Decolonising Methodologies: Research and Indigenous Peoples. 2nd ed.* London: Zed Books. 2012.
29. Pihama L. Kaupapa Māori theory: transforming theory in Aotearoa. He Pukenga Korero 2010;9(2):5-14.
30. Eldridge SM, Chan CL, Campbell MJ, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. Pilot Feas Stud 2016;2(1):64.
31. Huria T, Palmer S, Pitama S, et al. Consolidated criteria for strengthening reporting of health research involving indigenous peoples: the CONSIDER statement. BMC Med Res Methodol 2019;19(1):173.
32. O'Mahony D, O'Sullivan D, Byrne S, O'Connor MN, Ryan C, Gallagher P. STOPP/START criteria for potentially inappropriate prescribing in older people: version 2. Age Ageing 2015;44(2):213–218.
33. Watt A, Murray M, Herold D, Hyland S, Hoffman C, Cass M. Empowering patients: 5 questions to ask about your medications. Healthcare Q 2020;22:58–71. (SP).
34. 5 Questions to ask About Your Medications – consumer Safety Poster [Internet]. Health Quality & Safety Commission. 2021. [cited 2021 Mar 4]. Available from:. , https://www.hqsc.govt.nz/our-programmes/medication-safety/publications-and-resources/.
35. Hays R, Sherbourne C, Mazel R. The RAND 36-item health survey 1.0. Econ Evaluat 1993;2:217–227.
36. Cousins S. New Zealand eliminates COVID-19. Lancet 2020;395:1474.
37. Health Quality and Safety Committee. Polypharmacy in people aged 65 and over [Internet]. [cited 2019 Mar 15]. Available from:. , https://www.hqsc.govt.nz/our-programmes/health-quality-evaluation/projects/atlas-of-healthcare-variation/polypharmacy/ 2019.
38. Bryant LJM, Coster G, Gamble GD, McCormick RN. The general practitioner–pharmacist collaboration (GPPC) study: a randomised controlled trial of clinical medication reviews in community pharmacy. Int J Pharm Pract 2011;19(2):94-105.
39. Australian Government Department of Health. *Home Medicines Review [Internet].* Pharmacy Programs Administrator. 2021. [cited 2021 Mar 6]. Available from:. , https://www.ppaonline.com.au/programs/medication-management-programs/home-medicines-review.
40. Steyn N, Binny RN, Hannah K, et al. Estimated inequities in COVID-19 infection fatality rates by ethnicity for Aotearoa New Zealand. N Z Med J 2020;133(1520):28–39.
41. Hayes V, Morris J, Wolfe C, Morgan M. The SF-36 health survey questionnaire: is it suitable for use with older adults? Age Ageing 1995;24(2):120–125.
42. García M, Rohlfs I, Vila J, et al. Comparison between telephone and self-administration of Short Form Health Survey Questionnaire (SF-36). Gac Sanit 2005 Dec;19(6):433–439.
43. Ware J, Kosinski M, Keller SD. A 12-item short-form health survey: construction of scales and preliminary tests of reliability and validity. Med Care 1996;34(3):220–233.
44. Der-Martirosian C, Kritz-Silverstein D, Barrett-Connor E. Five-year stability in associations of health-related quality of life measures in community-dwelling older adults: the rancho Bernardo study. Qual Life Res 2010;19(9):1333–1341.

45. Brooks R. EuroQol: the current state of play. Health Policy 1996;37(1):53–72.
46. Bosch-Lenders D, Jansen J, HEJHJ Stoffers, et al. The Effect of a Comprehensive, Interdisciplinary Medication Review on Quality of Life and Medication Use in Community Dwelling Older People with Polypharmacy. J Clin Med 2021;10:4.
47. Hill-Taylor B, Sketris I, Hayden J, Byrne S, O'Sullivan D, Christie R. Application of the STOPP/START criteria: a systematic review of the prevalence of potentially inappropriate prescribing in older adults, and evidence of clinical, humanistic and economic impact. J Clin Pharm Therapeu 2013;38(5):360–372.
48. Bala SS, Jamieson HA, Nishtala PS. Factors associated with inappropriate prescribing among older adults with complex care needs who have undergone the interRAI assessment. Curr Med Res Opin 2019;35(5):917–923.
49. Narayan SW, Nishtala PS. Prevalence of potentially inappropriate medicine use in older New Zealanders: a population-level study using the updated 2012 Beers criteria. J Eval Clin Pract 2015;21(4):633–641.
50. Nishtala PS, Narayan SW, Wang T, Hilmer SN. Associations of drug burden index with falls, general practitioner visits, and mortality in older people. Pharmacoepi Drug Safety 2014;23(7):753–758.
51. Hikaka J, Jones R, Hughes C, Connolly MJ, Martini N. Ethnic Variations in the Quality Use of Medicines in Older Adults: Māori and Non-Māori in Aotearoa New Zealand. Drugs & Aging 2021;38:205–217.
52. Musselwhite K, Cuff L, McGregor L, King KM. The telephone interview is an effective method of data collection in clinical nursing research: a discussion paper. Int J Nurs Stud 2007;44(6):1064–1070.
53. Weber BA, Yarandi H, Rowe MA, Weber JP. A comparison study: paper-based versus web-based data collection and management. Appl Nurs Res 2005;18(3):182–185.
54. Costa E, Giardini A, Savin M, et al. Interventional tools to improve medication adherence: review of literature. Patient Prefer Adherence 2015;9:1303–1314.
55. Desborough J, Twigg M. Pharmacist-led medication reviews in primary care. Rev Clin Gerontol 2014;24:1–9.
56. Parsons J, Rouse P, Robinson EM, Sheridan N, Connolly MJ. Goal setting as a feature of homecare services for older people: does it make a difference? Age Ageing 2012;41(1):24–29.
57. Levack WM, Jones B, Grainger R, Boland P, Brown M, Ingham TR. Whakawhanaungatanga: the importance of culturally meaningful connections to improve uptake of pulmonary rehabilitation by Maori with COPD – A qualitative study. Int J Chron Obstruct Pulmon Dis 2016;11(101273481):489–501.
58. Wihongi H. The process of whakawhanaungatanga in kaupapa Māori research. 2004, , https://sites.uws.edu.au/schools/ashs/anztsr/02conf/anztsrpapers/wihongi,%20Helen.pdf 2004.
59. Slater T, Matheson A, Davies C, et al. "It's whanaungatanga and all that kind of stuff": Maori cancer patients' experiences of health services. J Prim Health Care 2013;5(4):308–314.
60. Wilson AM, Kelly J, Jones M, et al. Working together in Aboriginal health: a framework to guide health professional practice. BMC Health Serv Res 2020;20(1):1-11.2020 Jul 1 [cited 2021 Mar 6];20. Available from:. , https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7329497/.
61. Spinewine A, Fialová D, Byrne S. The role of the pharmacist in optimizing pharmacotherapy in older people. Drugs Aging 2012;29(6):495–510.
62. Czarniak P, Hattingh L, Sim TF, Parsons R, Wright B, Sunderland B. Home medicines reviews and residential medication management reviews in Western Australia. Int J Clin Pharm 2020;42(2):567–578.
63. van der Meer HG, Wouters H, Teichert M, et al. Feasibility, acceptability and potential effectiveness of an information technology-based, pharmacist-led intervention to prevent an increase in anticholinergic and sedative load among older community-dwelling individuals. Therap Adv Drug Saf 2019:10. 2042098618805881.
64. Verdoorn S, Kwint H-F, Blom JW, Gussekloo J, Bouvy ML. Effects of a clinical medication review focused on personal goals, quality of life, and health problems in older persons with polypharmacy: a randomised controlled trial (DREAMeR-study). PLoS Med 2019;16(5), e1002798.
65. Huiskes VJB, Burger DM, van den Ende CHM, van den Bemt BJF. Effectiveness of medication review: a systematic review and meta-analysis of randomized controlled trials. BMC Fam Pract 2017;18(1):5.
66. Sorensen L, Stokes JA, Purdie DM, Woodward M, Elliott R, Roberts MS. Medication reviews in the community: results of a randomized, controlled effectiveness trial. Br J Clin Pharmacol 2004;58(6):648–664.
67. Patsopoulos NA. A pragmatic view on pragmatic trials. Dialogues Clin Neurosci 2011 Jun;13(2):217–224.
68. Baier RR, Jutkowitz E, Mitchell SL, McCreedy E, Mor V. Readiness assessment for pragmatic trials (RAPT): a model to assess the readiness of an intervention for testing in a pragmatic trial. BMC Med Res Methodol 2019 Dec;19(1):1–8.