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A pharmacist-led medicines review intervention in community-dwelling Māori older adults– a feasibility study protocol

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Title: A pharmacist-led medicines review intervention in community-dwelling Māori older adults– a feasibility study protocol

Background

Medicines are the most commonly used healthcare intervention in Aotearoa New Zealand (NZ). They are prescribed with the intent of providing therapeutic benefit i.e. to prevent, treat, or cure acute and chronic conditions. Medicines can, however, also cause harm, the risk of which increases with the number of medicines prescribed.¹ Internationally, and in NZ, the number of medicines prescribed to an individual increases as people age.² This occurs for a number of reasons including the increasing number of comorbidities with increasing age, and prescribing according to best practice guidelines for single disease states.³ As the number of medicines increases, so does the complexity of medicines regimens and potential for harm from medicines use in older adults.¹ Adverse drug events (ADEs) are the cause of between 10 and 30% of older adult hospitalisations⁴, with an ADE prevalence rate of up to 35% in community-dwelling older adults.⁵ In older adults, potentially inappropriate prescribing (PIP) can result from the prescription of medicines with the known potential to cause more harm in older adults, and from failure to initiate medicines with the potential to treat or prevent medical conditions⁶ and are a major cause of ADEs (including morbidity, hospitalisation and mortality).^{7,8} There are a number of tools that can be used to measure PIP prevalence.^{9,10}

Pharmacists have a role to play in improving medicine use and reducing medicine-related harm. Pharmacist-led medicines reviews have been shown to reduce ADEs and PIP in older adults.^{5,11} The term ‘medicines review’ is used widely, and can incorporate a number of activities (such as medicines education, adherence support and development of medicines management plans). For the purposes of this protocol, the term is used to describe an 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

Abbreviations: ADE = Adverse drug event; PIP=Potentially inappropriate prescribing; GP=general practitioner; QoL=quality of life;

DHB=District Health Board; WDHB=Waiitematā District Health Board; MUR=Medicines Use Review; MTA=Medicines Therapy Assessment;

CMM=Comprehensive Medicines Management; SF-36=Short Form (36) Health Survey

63 improve the quality, safety and appropriate use of medicines.¹² Medicines reviews are
64 particularly beneficial when the intervention is delivered by a pharmacist working as part of
65 a collaborative, multi-disciplinary team, and, in the case of older adults, when the
66 pharmacist has expertise in geriatric medicine.¹³ A recent Cochrane review showed that
67 pharmacists based in the community (including community pharmacy, general practitioner
68 (GP) practices and other primary care settings) may improve patient outcomes relating to
69 measures which impact on the control of long-term conditions such as cardiovascular
70 disease and diabetes.¹⁴

71 In NZ, inequities in health outcomes exist between Māori (Indigenous people of NZ) and
72 non-Māori resulting from the unfair, differential allocation and distribution of resources and
73 power related to the determinants of health.¹⁵ Māori experience worse health outcomes,
74 including increased morbidity, increased avoidable mortality,¹⁶ and lower life expectancy,¹⁷
75 than non-Māori. These inequities occur across the spectrum of health services^{16,18–21} and
76 include access to medicines and medicine-related services.^{21–24} Māori older adults are more
77 likely to be prescribed ‘high risk’ medicines (those associated with an increased likelihood of
78 harm) than non-Māori²⁵ and are more likely to experience an adverse outcome resulting
79 from the omission of an appropriate medicine, than the prescription of an inappropriate
80 medicine.²⁶ These inequities exist despite guarantees made under the Treaty of Waitangi,
81 one of NZ’s founding documents, which asserts the right of Māori to receive services and
82 resources that reflect their needs as Māori, and which result in equitable outcomes. There is
83 ever-growing evidence that the systems governing, legislating, administering and funding
84 primary healthcare services fail to meet the needs of Māori. This has been formally
85 recognised by the recent Waitangi Tribunal Hauora Report,²⁷ as a breach of the Treaty of
86 Waitangi. Service models which improve medicines use for Māori, including the access to
87 medicines, and quality of prescribing are needed to support the attainment of health
88 equity.²⁸

89 *Study aim and objectives*

The aim of the current study is to test the feasibility of a pharmacist-led medicines review intervention, informed by Indigenous methodologies, for (and with) community-dwelling Māori older adults.

The study objectives are:

1. To test the acceptability of the medication review intervention.
2. To test the ability to recruit Māori older adults into the feasibility study.
3. To assess medicines knowledge, quality of life (QoL) and PIP scores in study population at baseline and post-intervention.
4. To report number of changes made to the medicines regimen as a result of the intervention.
5. To test the feasibility of the tools chosen to assess medicines knowledge, QoL and PIP, including administration time required.
6. To test the intervention practicality in relation to time required to deliver the intervention.
7. To assess whether modification to recruitment methods, intervention content or delivery, and methods of assessing outcomes is required prior to wider implementation and testing.

Methods

This research project will use a mixed methods approach to test the feasibility of a pharmacist-led medicines review intervention for community-dwelling Māori older adults. This study will be guided by kaupapa Māori research theory.^{29,30} 'Kaupapa Māori' is translated as a 'Māori way' or 'Māori ideology'³¹ and has developed as a research methodology over the last 4 decades. It aims to normalise Māori worldviews and ways of knowing,²⁹ and take back space and power for Māori in the research process,³² which includes authentic Māori participation at all stages. Kaupapa Māori research affirms the right of Māori to actively participate in research. In the context of health this includes the right to partner with health providers to develop and receive relevant, appropriate and safe health services, and experience equitable health outcomes. It aims to have positive impact for Māori and comes from a place of dreaming of infinite possibilities for Māori.³³ Kaupapa Māori methodology allows the incorporation of methods developed within different theoretical approaches, as long as they have relevance and can be utilised in a way that

upholds the principles of kaupapa Māori theory and practice. In health service research this means that tools developed within a biomedical framework may have relevance, and be able to be applied, within a kaupapa Māori methodological approach.

Medicines review services, which include multiple practitioners as well as patients and family, are complex interventions as there are multiple interacting components.³⁴ This can make the development, implementation and evaluation of an intervention more difficult, hence the development of the United Kingdom Medical Research Council's guidance document on the development of complex interventions.³⁴ This document supports kaupapa Māori approaches of authentically engaging with those receiving and delivering interventions, and has been utilised to support the development of the proposed research. The intervention to be tested in the current study has been informed through previous research by the current authors (Phase 1a, 1b and 2a – see Figure 1). In Phase 1a, in addition to a systematic review,²³ Māori older adults (n=10) and health practitioners and commissioners of services (n=11) were interviewed to inform the development of the intervention and outcomes measures (Figure 1). The proposed intervention and outcome measures were reported back to the interviewees with wider dissemination to community groups. The intervention was found to be acceptable within these groups.

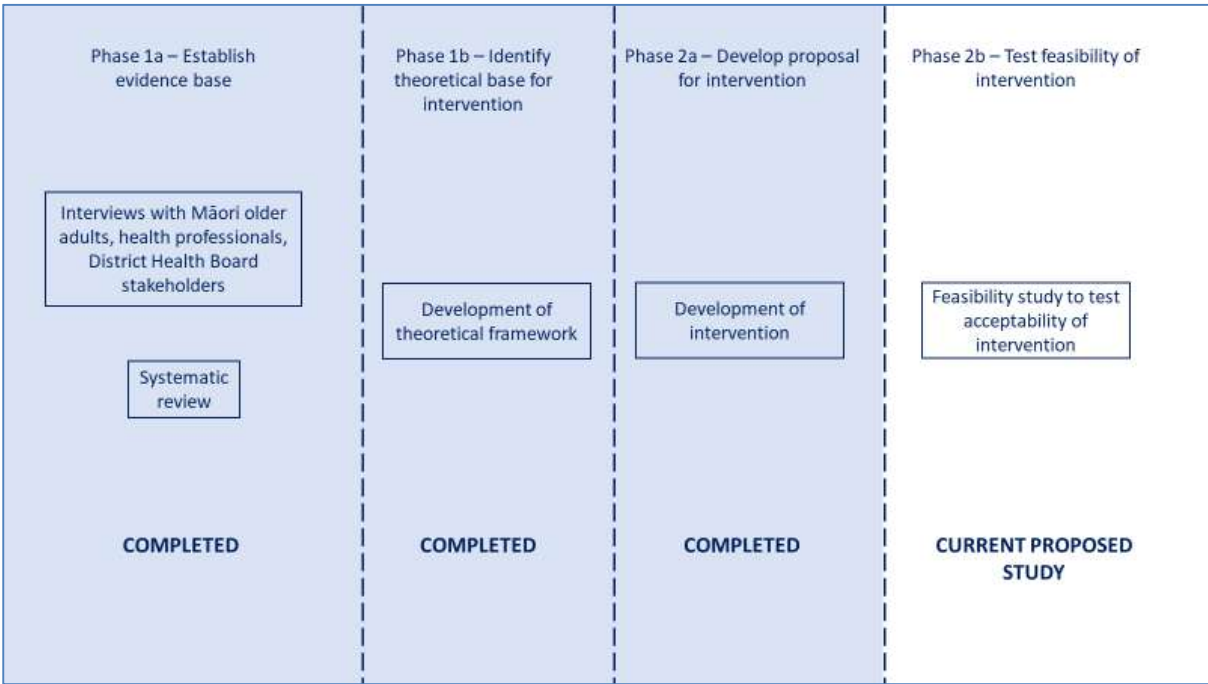


Figure 1. Phases in intervention development and evaluation

140 *Trial Design*

141 The intervention will be tested in a single-arm feasibility study with baseline and post-
142 intervention measurement of predefined outcomes. The study will be reported in
143 accordance with the CONSIDER statement³⁵ aimed to strengthen the reporting of health
144 research which involves Indigenous peoples to ultimately “advance Indigenous health
145 outcomes”,³⁵ and the CONSORT 2010 statement: extension to randomised pilot and
146 feasibility trials,³⁶ as relevant to the non-randomised nature of the currently described
147 study.

148

149 *Project oversight*

150 An advisory team including Māori older adults, health professionals (including a Māori
151 public health physician and health researcher) and the lead investigator (JH) will provide
152 project oversight.

153

154 *Study population*

155 NZ is geographically divided into 20 District Health Boards (DHBs) which are responsible for
156 the provision and funding of health services. Participants will be drawn from Waitematā
157 District Health Board (WDHB), Auckland, NZ.

158 **Inclusion criteria for patients**

159 Enrolled in a general practice (GP practice) within WDHB AND
160 Māori ethnicity (self-identified) AND
161 Community dwelling (not resident in rest home, private hospital or hospice) AND
162 Taking 4 or more regular medicines for at least three months AND
163 55 years of age or older (55 years is often used as entry age for service funding and
164 provision for Māori ‘older adults’ due to earlier onset of chronic disease and lower
165 life expectancy)

166 **Exclusion Criteria**

167 Unable to give informed consent

168

169 *Recruitment of participants*

A number of recruitment strategies will be employed to meet the needs of Māori older adults, as informed by interviews with health professionals and Māori older adults in Phase 1a. Potential participants will be given a Participant Information Sheet and Brief Study Outline via: GP practices (mail-out to all enrolled patients that meet eligibility criteria; during consultations; in waiting areas), community pharmacies, and during investigator (JH) presentations to Māori older adult groups. In addition, the Māori older adults involved in Phase 1a of this research, will be contacted directly and invited to participate (Māori older adult participants from Phase 1a wanted to have the option of being involved in service delivery developed as a result of the initial phases of this research. In kaupapa Māori methodology the research relationship continues past distinct research projects and requires long-term commitment and the ability for Māori to participate in ongoing translational work. Therefore, participants from Phase 1a will be given the option to participate in the subsequent phase investigated in this study). The information provided will outline the steps involved in the intervention, including baseline and post-intervention assessments. It will ask potential participants to contact the lead investigator to discuss participation. Those that find out about the project through ‘word-of-mouth’, and meet the inclusion criteria, will also be eligible to participate.

Setting and location of collection of eligibility information and consent

Participants will be assessed for eligibility and consented by the lead investigator in a face-to-face meeting. The location of this meeting will be determined by the potential participant but may include GP practice, community centre or participant’s home. At point of written informed consent, baseline demographic data will be collected. This will also include recording the recruitment method for the particular individual.

Recruitment of general practices

Where GP practices are used to support recruitment, convenience sampling will be used to recruit practices. Practices will be eligible if they are within WDHB. JH will approach GP practices, discuss the project and gain written consent from a staff member at the GP practice (for example clinical director, practice manager, GP, practice owner) with authority to give consent.

Intervention

Intervention Content and Delivery

Participant flow through the intervention and related outcome assessments is shown in Figure 2.

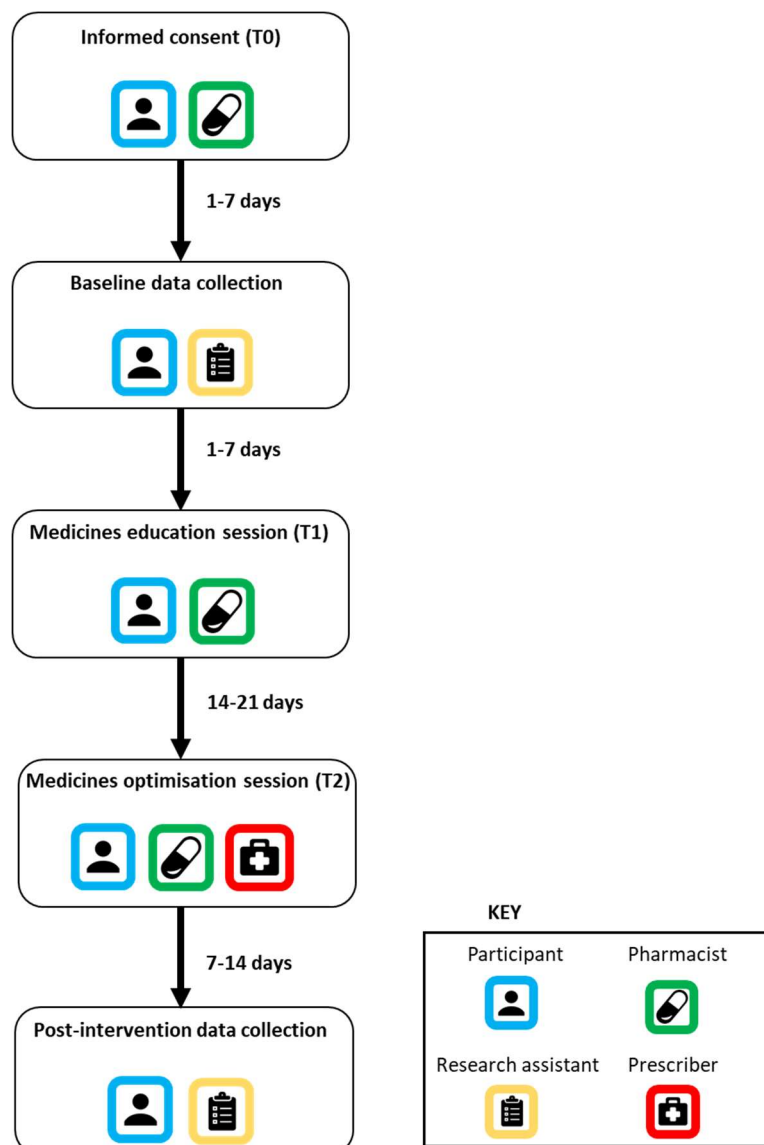


Figure 2. Process flow for participant for data collection and intervention

The intervention will be delivered by JH, a Māori clinical pharmacist with experience in older adult medicines reviews and who is leading all the phases of the service development.

The intervention will consist of 2 parts:

1. Medicines education session (participant and pharmacist)

The session will centre on allowing time and space to talk about medicines and to improve the participants' understanding of what the medicines are used for,

potential side effects and likely length of treatment, as well as improving the pharmacist's understanding of what is important to the participant. Participants will be asked to bring their medicines along to the education session to guide discussions. Discussions will be guided by what the participant identifies as priority areas and will exert the participant's right for self-determination and control in their health journey. This component will include tasks to the level of Medicines Use Review (MUR) and Medicines Therapy Assessment (MTA) in the Pharmaceutical Society of NZ National Pharmacist Services Framework.³⁷ These tasks include medicines reconciliation (including access to the electronic dispensed medicine repository Testsafe™ by pharmacist prior to education session), discussion of medicines-related needs and goals of wellbeing, provision of relevant information resources, medicines effectiveness or ADEs, and discussion of medicines in the context of participant-identified goals of therapy.

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

Prior to meeting with the participant and prescriber, the pharmacist will review clinical records via the WDHB electronic clinical portal (contains hospital discharge summaries, clinic letters, laboratory investigations, hospital inpatient observations, history of dispensed medicines). Following review, the prescriber, pharmacist and participant will meet and develop a medicines management plan. This session will align services described under MTA and Comprehensive Medicines Management (CMM) in the PSNZ Pharmacist Services Framework³⁷ and the guidance set out in the Royal Pharmaceutical Society of Great Britain's Medicines Optimisation good practice guidance.³⁸ The medicines optimisation session is optional with consent requested at point of initial consent. This session will occur 14-21 days after the medicines education session.

After each session, discussions will be summarised and sent to the participant's primary prescriber and community pharmacy either via post or secure electronic mail. This aspect of the intervention allows for connected communication between those involved in provision of health care to the participant. Participants will also be able to invite family and/or support people to be present at these sessions.

Intervention Location

The medicines education component will take place in a location of the participant's choosing and may include their own home, GP practice or community centre. The medicines optimisation session will occur at the GP practice.

Study Outcomes

The primary outcome investigated in this feasibility study is the acceptability or otherwise of the intervention to participants, family members/support people and healthcare providers. The inclusion of these 3 groups has occurred in kaupapa Māori assessment previously³⁹ and acknowledges that services can be evaluated from different view-points and experiences. Secondary outcomes: ability to recruit; medicines knowledge, PIP and QoL scores; number of medicine changes; resource required to deliver intervention and administer assessment tools (Table 1).

Data Collection

The assessment tools, methods of data collection and time points for data collection are detailed in Table 1. Participants will be assigned a random 4-digit study number to be used during data collection. Acceptability questionnaires have been developed specifically for this research project and are based on the theoretical framework developed in Phase 1b, in addition to review of other Indigenous outcomes measures and frameworks.⁴⁰ Acceptability questions will ask participants to respond on a 5-point Likert scale with 'strongly agree' to 'strongly disagree' statements. Questions will focus on aspects relating to participant control and medicines knowledge, relevance and usefulness of the medicines review service, appropriateness of the pharmacist to deliver intervention, likelihood to use this type of service and refer others, and whether the care was culturally appropriate and delivered in a respectful and collaborative manner. In addition, there will be some open-ended questions relating to perceived value of the intervention and areas for improvement. All assessment tools which require correspondence with the participant for completion (acceptability questionnaire, medicines knowledge and QoL) will be administered by a research assistant to reduce potential bias due to participants having a therapeutic relationship with the lead investigator. These will be administered via the telephone, with data collected using QualtricsTM as the survey tool.

275 **Table 1. Study outcomes and tools, methods and time points for data collection.**

	Outcomes	Assessment tool	Method of data collection	Time point of data collection
Primary outcome	Acceptability	Participant acceptability questionnaire	Telephone administration by research assistant; data collection in Qualtrics™	4 weeks post-intervention
		Family member/support person acceptability questionnaire	Online survey using Qualtrics™	
		Prescriber acceptability questionnaire	Online survey using Qualtrics™	Post-intervention for all subjects
Secondary outcomes	Recruitment	Recruitment methods detailed including time taken, cost (e.g. postage). Approaches for participation by those not eligible will also be noted and with the potential to suggest changes to eligibility criteria for future studies.	Log book	Throughout study
	Medicines knowledge	Medicines knowledge will be assessed using a tool developed for this study	Telephone administration by research assistant; data collection in Qualtrics™	Baseline and 4 weeks post intervention
	Potentially inappropriate prescribing (PIP)	PIP will be assessed using the STOPP/START criteria. ⁹ Participants' medicines lists will be assessed for two different time points in time – medicines reconciliation at point of 'medicines education' component and medicines list immediately after medicines optimisation component (this list will take into account changes agreed as part of the medicines optimisation meeting).	Lead investigator will assign appropriateness using the 114 criteria in the STOPP/START guidelines ⁹	Baseline and post-intervention (all assignment of medicines appropriateness completed post-intervention)

	Participant QoL	Short Form (36) Health Survey (SF-36) ⁴¹	Telephone administration by research assistant; data collection in Qualtrics™	Baseline and 4 weeks post-intervention
	Medicine regimen changes	Number of changes in medicines regimen resulting from medicines optimisation intervention (including medicine, dose, frequency)	Data collected by lead investigator in Qualtrics™	Post-intervention
	Time required to deliver intervention	Time taken to deliver intervention will be recorded. This will be further categorised by non-contact and participant-contact time.	Log book by lead investigator/pharmacist delivering intervention.	Each time any aspect relating to the intervention is undertaken.
		Prescribers will be requested to estimate their time input in relation to the intervention as part of the Prescriber acceptability questionnaire.	Online survey using Qualtrics™	Post-intervention for all patient participants
	Assessment tool feasibility	<p>The feasibility of applying assessment tools relating to medicines knowledge, QoL and medicines appropriateness in this population will be assessed, including their use in informing further service/intervention development. The medicines knowledge tool has been developed for this study whilst the SF-36 and STOPP/START criteria have been widely validated although not in this population setting and intervention type.</p> <p>Time taken for the independent research assistant to perform the various assessments will also be noted to inform future studies.</p>	Research assistant and lead investigator who are administering the tools will keep record of questions asked, clarification required throughout assessment process	Each time assessment tool is administered

277 *Sample size*

278 Although sample size justification is important, sample size calculations may not be
279 appropriate in feasibility studies. A variety of methods for justification of sample size have
280 been utilised in feasibility studies.⁴² Most of these are ‘rule of thumb’ methods which are
281 regarded as ‘flat’ methods as they do not account for the potential size of the main trial.⁴⁶
282 Using the ‘rule of thumb’ methods, recommended sample sizes range from 12-70.⁴⁶ A recent
283 paper suggests that if rule of thumb methods are to be used, they should at least vary
284 according to standardised difference in outcome measures; smaller standardised
285 differences require a larger sample size and vice versa. In this study, the SF-36⁴¹ serves as a
286 basis for sample size justification as the SF-36 has been widely validated across a range of
287 clinical contexts including pharmaceutical care services.⁴³ A meta-analysis of the effect of
288 pharmaceutical care interventions on SF-36⁴³ showed a standardised mean difference of
289 0.39 for general health. Theoretical modelling of sample size calculation has been
290 performed for pilot randomised trials.⁴⁴ Based on the standardised mean difference of 0.39,
291 if a randomised pilot were to be undertaken using this approach, each treatment arm for a
292 90% powered trial should have 21 or 33 participants for a 80% or 95% upper confidence
293 level respectively.⁴⁴ Although this feasibility study is not randomised or controlled, these
294 figures can be used as an estimation in our work. We aim to recruit and deliver the
295 intervention to 30 participants. Results from this feasibility study will be used to guide
296 sample size calculations in future studies.⁴⁵

297

298 *Analytical Methods*

299 Data analysis will consist of quantitative and qualitative methods. Simple descriptive statistics
300 will be used to summarise the data relating to acceptability questionnaire agree-disagree
301 statements, recruitment methods, medicines knowledge, QoL, PIP and time resource
302 required to deliver intervention and apply assessment tools. Qualitative data analysis using a
303 general inductive approach within a critical kaupapa Māori theoretical framework will be used
304 to assess open-ended questions in acceptability questionnaires, to describe appropriateness
305 of assessment tools and report on changes to the intervention and/or research processes that
306 should be revised or changes prior to wider testing/implementation. Due to the small sample
307 size, subgroup analysis will not be performed. Quantitative data analysis will be conducted
308 using IBM SPSS Statistics for Windows, v25.0 (IBM Corp., Armonk, N.Y., USA).

Discussion

Although internationally, pharmacist-led medicines review services have been shown to reduce inappropriate prescribing and adverse drug events in the older adult population,^{5,11} their ability to respond to the needs of Māori older adults, and the contribution they may make to achieving health equity in NZ, remains unknown.²³ Māori older adults report that medicines are a key factor contributing to their wellness⁴⁶ and there is a need to develop culturally congruent medicines-related services to support this for Māori.²⁸ The intervention to be tested in this study includes pharmacist-led medicines education and optimisation components, was designed using kaupapa Māori informed methods and could shape further health service development in this space.

The intervention to be tested was informed by Māori older adults' desire to be more in control of their medicines management journey. Therefore, the medicines optimisation component was optional to allow participants choice over whether the research pharmacist had full access to their clinical notes and whether they were present in a meeting with their prescriber. The intervention also includes participant, pharmacist and prescriber at the point where decisions are made about medicines management.

Limitations

A small sample size and a short follow-up period will be used which is appropriate for a feasibility study⁴⁷ to reduce the risk of committing extensive resource when intervention content and delivery, and outcomes evaluation, may need modification. Clinical outcomes, such as mortality and hospitalisation, are unlikely to be significantly impacted during the study period given the type of intervention and small sample size. Given the potential for diversity of co-morbidity and medicines utilisation in this study (which is not focused on a single disease state or medicine) it is unlikely that there will be a significant impact on particular participant clinical observations (such as blood pressure). Therefore, this study does not seek to report on these or use them as outcome measures. The approach of focusing on participant and prescriber acceptability was supported by health practitioner and DHB stakeholder interviews undertaken in Phase 1b.

Generalisability

Due to the small participant numbers, intervention implementation and results are unlikely to be generalisable, especially in populations outside Waitematā DHB. The study will be conducted in participants who either reside or access primary healthcare services in Waitematā DHB, the largest DHB in NZ, with a predominately urban population and with the highest life expectancy.

A complex intervention is being studied in this research.³⁴ Multiple practitioners and processes are involved, and thus being able to replicate the results of this study using different practitioners, in different settings, is unlikely. However, it is intended that this study will generate insights into which elements of the intervention were important (or not) and the ability to administer evaluation tools. The intervention and assessment tools can then be adapted, as needed, prior to the intervention being tested in a larger study. This pragmatic approach is reflective of real-life interventions and learnings from this may be relevant to other research settings, including other feasibility studies relating to health service development.

This study serves as an example of health service design, delivery and evaluation, informed by Indigenous knowledge and methodology, developed explicitly to address inequities in health outcomes for, and with, Māori.

Ethics and dissemination

Ethical approval was granted by the Northern B Health and Disability Committee (19/NTB/106). The study has been registered with the Australia and New Zealand Clinical Trials Registry (ACTRN12619001070123) and the full trial protocol is publicly available on this site.

A dissemination plan will be developed by the research team in collaboration with the project advisory group. Results, 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, GP practices, and pharmacy and primary care sector groups. Results will be reported as research articles in international peer-reviewed journals, at international and national conferences and in the lead author's doctoral thesis.

Declaration of Interest

None

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