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Clinical expertise, advocacy and enhanced autonomy – Acceptability of a pharmacist-facilitated medicines review intervention for community-dwelling Māori older adults



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ABSTRACT

Background: Pharmacist-facilitated medicines reviews are effective at identifying medicines-related problems and can improve the appropriate use of medicines in older adults. Current services in Aotearoa New Zealand (NZ) are not developed specifically for Māori (Indigenous people of NZ) and may increase health disparities between Māori and non-Māori. We developed a medicines review intervention for and with Māori older adults, and tested it in a feasibility study.

Objective: To assess patient acceptability of a pharmacist-facilitated medicines review intervention for Māori older adults.

Methods: The intervention consisted of a medicines education session (pharmacist and participant) and an optional medicines optimisation session (pharmacist, participant, and prescriber). Participant acceptability was assessed post-intervention using a structured telephone interview developed specifically for this study. Participants responded to statements using a five-point Likert scale (strongly agree-strongly disagree; numerical analysis/reporting) which focused on the topics of power/control, support mechanisms, intervention content and delivery, and perceived usefulness. Open-ended questions relating to the intervention value and suggestions for improvement were analysed using general inductive analysis.

Results: Seventeen participants took part in the feasibility study from December 2019–March 2020 and all completed the acceptability interview. Participants perceived the intervention content and mode of delivery to be appropriate, and that their power and control over their medicines and health improved and as did their confidence in self-management. Five themes were generated: medicines knowledge from a trusted professional, increased advocacy, 'by Māori, for Māori', increased confidence and control, and financial and resource implications.

Conclusion: A pharmacist-facilitated medicines review intervention for Māori older adults developed by Māori, for Māori, was acceptable to patient participants. Participants valued the clinical expertise and advocacy provided by the pharmacist, and the increase in medicines knowledge, control and autonomy. Participants wanted the service to continue on an ongoing basis.

Background

Pharmacist-facilitated medicines reviews have the potential to improve the appropriate use of medicines in older adults. Services which are currently available in Aotearoa New Zealand (NZ) are effective in identifying medicine-related problems, ^{2,3} and improving medicines adherence. In NZ it is recognised that Māori (the Indigenous people of NZ comprising

16% of the population) have the right to culturally appropriate healthcare services. ^{5,6} This has been postulated as an effective step in reducing inequities in medicines-related care that exist between Māori and non-Māori. ^{7,8} Current medicine review services do not incorporate culturally-specific design or adaption, and may increase disparities in health outcomes between Māori and non-Māori. ⁹ Interventions which do include culturally-specific considerations, such as family support during interventions,

Abbreviations: WDHB, Waitematā District Health Board

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accessing kaumātua (Māori older adults who provide cultural support), and critical reflection of racist power dynamics which exist in health service provision, have been shown to have positive outcomes for Māori. ¹⁰

A number of steps are recommended in the development of complex health interventions such as medicine reviews. These include reviewing the available literature, engaging with key stakeholders (including potential patients) and testing the feasibility of the proposed models. 11 Evaluating health interventions through the use of feasibility studies allows issues in the research approach and intervention model to be addressed, and redeveloped, prior to widespread implementation and resource investment. 11,12 For any health intervention to have maximum benefit, it has to be 'acceptable' to those using it. Acceptability is socially and culturally constructed, and subjective. 13 Acceptability influences all stages of engagement with an intervention from the willingness to take part, to the experience during the intervention, and the participant-perceived evaluation of outcomes. Measures of acceptability are varied and, to measure this, research studies may employ acceptability frameworks which incorporate a variety of factors such as perceived effectiveness, intervention burden and participant control. 13

Our research group aimed to develop a medicines review intervention model for community-dwelling Māori older adults that improves health outcomes. A systematic review, and interviews with stakeholders, including Māori older adults, 4,15 were undertaken. The intervention and research approaches were structured around the Treaty of Waitangi (one of NZ's founding documents which guarantees Māori the right to equitable health outcomes⁵), and details the considerations included to ensure culturally appropriate design and adaption. This work has been published elsewhere. Outcomes from the study relating to medicines, pharmacist recommendations, quality of life and methodological feasibility are reported elsewhere. The aim of the current paper is to report patient acceptability of a pharmacist-facilitated medicines review intervention for community-dwelling Māori older adults.

Method

Ethics and Trial registration

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

Study design and location

The protocol for this single-arm prospective interventional feasibility study has been previously published. ¹⁸ The study took place in Waitematā District Health Board (WDHB), the largest of the 20 DHBs in NZ which are charged with commissioning and providing health services for those in their discrete geographical boundaries.

Theoretical basis of acceptability and structured interview schedule development

Kaupapa Māori theory was used as the theoretical framework to examine acceptability. Principles of kaupapa Māori theory, and kaupapa Māori models of healthcare, include giving power and control to participants, affirming the right of Māori to participate in and inform research processes, acknowledging Māori knowledge and ways of doing, and aiming for positive, real-world solutions for Māori communities that are involved in the research. ^{19,20} An extensive search of the literature did not identify any theoretical frameworks of acceptability which adequately examined acceptability in the context of kaupapa Māori principles. Our previous research included exploring stakeholder service expectations around how a pharmacist-facilitated medicines review intervention for older Māori should be designed and delivered ^{14,15} and the development of the intervention model using a Treaty of Waitangi rights-based approach. ¹⁶ Using this

previous research, the principles of kaupapa Māori theory discussed above, and with review of Sekhon et al.'s Framework of Acceptability, 13 domains of acceptability were identified in collaboration between JH, RJ and NM. The four domains were:

Power and control – Did the intervention allow participants retain power and control over their health and wellbeing and in what ways was this demonstrated? Did the intervention fit with participants value systems?

Support mechanisms – Did participants have the opportunity to have relevant external people support them during the intervention?

Intervention content and mode of delivery – Was the intervention delivered by appropriate people, in an appropriate location, over an adequate length of time? Did communication occur between other healthcare interventions and providers?

Perceived usefulness – Was the intervention beneficial to the individual? To investigate these domains, questions were developed by JH, RJ and NM. Content and face validity were undertaken by the Māori advisory group that supported the larger body of work for refinement through a wānanga process (group discussion and deliberation where consensus was sought). The advisory group had five members and included Māori health professionals, traditional healers and Māori older adults. The questions were then piloted with older adults with no further refinements needed.

Study population

To be eligible to participate in the intervention study, participants had to meet all of the following criteria: Māori ethnicity, prescribed or taking four or more regular medicines for at least 3 months, 55 years or older (due to earlier onset of chronic morbidity in Māori), community-dwelling, and enrolled in a general practice in WDHB). Those unable to provide informed consent were excluded.

Participant recruitment and consent

There were several recruitment methods: presentation at Māori older adult community groups, invitation through general practice mailout or during a consultation, direct entry option for those who took part in the earlier research, ¹⁴ and word-of-mouth. With each of these methods, information was provided to potential participants regarding the research pharmacist's (JH's) Māori genealogical connections, commitment to healthcare provision in the local region, and clinical experience in geriatric medicine. Participants provided written, informed consent to participate in both the multiple-component intervention and acceptability interviews during a face-to-face meeting with JH.

Intervention

The intervention, including culturally-specific considerations, is published in full elsewhere. 18 In brief, the study intervention comprised two components:

- 1. Medicines education session: attended by the pharmacist and participant in a location of the participant's choosing (including own home, general practice, place of work). Family/support people could be invited to attend. The pharmacist had access to the secondary care clinical notes and primary care dispensing records as an employee of the health service where these records were held, and reviewed these prior to the session. The focus of this session was to discuss and identify medicine and health concerns, wellbeing goals, and to provide medicines education. Written communication in the form of a letter was posted to the participant, the participant's primary prescriber (as identified by the participant), and community pharmacy after this session to summarise the discussions, points of action, and recommendations for prescriber follow up. The same letter was sent to all
- 2. Medicines optimisation session: This was held 14–21 days postmedicines education session and attended by the prescriber, participant and pharmacist at the general practice with all discussions undertaken

together as a group. Family/support people could be invited to attend. The written communication from the previous session was discussed, which included pharmacist recommendations, and a health and wellbeing plan was developed and recorded by the prescriber in the clinical notes. This session was optional and consent could be given in the initial consent meeting, or at any later stage.

The one research pharmacist (JH) who delivered the intervention was Māori and had over a decade of experience in older adult medicines optimisation in primary and secondary care, including delivery as part of a multidisciplinary team. They were not the participants'community pharmacist or a member of their usual healthcare team. Although this was a 'medicines review' intervention, the context in which it was applied required it to be "approached in a holistic manner addressing the domains of wellbeing (physical and mental health, and social connectedness)". ¹⁶

Study outcomes

The primary outcome was participant (patient) acceptability. In accordance with our pre-defined criteria, ¹⁸ if this feasibility study was acceptable to participants, it would justify further testing and service expansion.

Data collection

Structured interviews were conducted over the telephone by a research assistant (HA) 7–14 days post-intervention. The first part of the interview required participants to respond to 29 statements based on a on a 5-point Likert scale with possible responses ranging from 'strongly agree' to 'strongly disagree'. Two open-ended questions asked "what did you find most valuable about the service?" and "what could be done to improve the service?". The research assistant could follow up on these responses to probe further, similar to approaches undertaken in semi-structured interviews. Data were collected in Qualtrics™ experience management software, entered by the research assistant at the time of interview.

Data analysis

For acceptability questions that utilised Likert scale scoring, responses were aggregated (i.e. 'strongly agree' and 'agree' were combined, as were 'disagree' and 'strongly disagree') and analysed in terms of numbers agreed/disagreed. For the open-ended questions, data were analysed using a general inductive approach, ²¹ whereby JH read through interview answers, coded the data and sorted the codes into groups of shared meaning. Data and grouped codes were reviewed with RJ and NM to ensure the grouped codes were related and captured connected meaning. The grouped codes were then used to name and define the themes. Data (quotes) were then reviewed again to ensure they supported the themes that had been generated. Quotes were included verbatim with the use of parentheses '[]' to change words in order to clarify the meaning or context. Participants are reported as [Px] where x is the order in which participant acceptability interviews were completed.

Sample size

Sample size calculations were based on change in Quality of Life (QoL) scores from previous pharmaceutical care interventions, ²² with a 90% power to detect difference, and guidance for appropriate sample sizes for feasibility studies. ¹⁸ We aimed to recruit, and deliver the intervention to 30 participants.

Results

Seventeen consented participants (patients) took part in the feasibility study from December 2019 to March 2020. Recruitment closed before the planned sample number of 30 participants due to the COVID-19 pandemic. The majority of participants were recruited through GP mailout (n=12 from 227 letters which were sent). ¹⁷ All 17 participants completed the

acceptability interview. The mean age of participants was 69.3 years (range 58–92); 12 participants identified as female and participants took a mean 7.7 (2–15) regular medicines at baseline. Three participants had a family support person present during at least one component of the intervention. Common medical conditions of participants included: hypertension (n=12), diabetes (n=7), history of myocardial infarction or stroke (n=6), atrial fibrillation (n=5), congestive heart failure (n=5), asthma and/or chronic obstructive respiratory disorder (n=4), and gastro-oesophageal reflux disorder (n=4). All participants consented to both the medicines education and medicines optimisation components. After the education session, six participants chose not to take part in the optimisation session as there were no urgent issues and they were happy to discuss any potential interventions with their prescriber independently. No prescribers declined to be involved in the medicines optimisation component.

Participant acceptability

Participants were generally supportive of this intervention. Table 1 shows the responses to statements relating to the intervention. Participants' power and control over their medicines and health improved and as did their confidence in their abilities to self-manage. Family and support people were included to the extent desired by participants; the majority did not want to have the involvement of kaumātua (Māori older adult/s who provide cultural support) during the intervention. Participants perceived the intervention content and mode of delivery, the location and length of intervention to be appropriate. They felt that a pharmacist was the right person to deliver the intervention, an appropriate relationship was developed, that the face-to-face meeting was important and that health professionals communicated well as a team. Participants perceived the service to be useful and would use it again, recommend it to family and friends, and felt their medicines knowledge improved. Views on which pharmacist should deliver the intervention were mixed, with 4 participants preferring their regular community pharmacist to deliver the service, and the majority either ambivalent (n = 5) or preferring that the research pharmacist (the Māori pharmacist with experience in older adult medicine) deliver the intervention (n

As part of the acceptability interview, participants were asked how much they would pay for the service. All said they would pay \$20 or less, with some commenting specifically that they thought this was a beneficial service that should be publicly funded and offered free of charge to them. Participants felt they would use the service at least annually (n = 3), with the majority wanting to utilise the service more frequently (3-monthly (n = 8); 6-monthly (n = 6)).

Five themes were generated from the participant responses to the openended questions: medicines knowledge from a trusted professional; increased advocacy; 'by Māori, for Māori'; increased confidence and control; financial and resource implications.

1. Medicines knowledge from a trusted professional.

Participants reported that improving their medicines knowledge was one of the most important aspects of the intervention and that having information delivered by a trusted professional aided this. Two participants wished they had used the opportunity to ask more questions and would have liked to have access to the pharmacist on an ongoing basis.

"[It was valuable to have] someone that knew what they were talking about. I was able to ask the things I wanted and felt comfortable asking her."

[[P13]]

2. Increased advocacy.

The intervention provided more than just medicines information and support. It also had an advocacy role which supported participants' ability to communicate with other health professionals, and also access to services.

"The follow ups were the most beneficial for me. [The pharmacist] came along and followed it up and within a month I got an appointment.

Table 1Participant (patient) acceptability – level of agreement with statements.

Statements	Strongly agree/agree n	Neither agree or disagree	Disagree/strongly disagree n
I feel more confident to manage my medicines in a way that suits me	17	0	0
I was given the opportunity to raise concerns about my medicines	17	0	0
I felt listened to	17	0	0
This service allowed me to feel like I could participate in my healthcare	16	1	0
I feel confident about making decisions about my medicines	16	0	1
This service respected my worldviews and things that were important to me	14	3	0
This service has helped me to improve my confidence in talking to my GP/prescriber about my medicines	14	2	1
I have more control over my medicine-related wellbeing	14	2	1
This service enhanced my mana ^a	13	4	0
This service has helped me to improve my confidence in talking to my community pharmacist about my medicines	14	3	0
Support mechanisms			
I was able to have my whānau/friends to be involved to the extent that I wanted them involved	14	2	1
I would have liked a kaumātua ^b to attend the sessions with me	1	8	8
Intervention content and mode of delivery			
The pharmacist is the right person to deliver this service	17	0	0
The location of the service suited my needs and made me feel safe to share information	17	0	0
There was enough time provided for me to say and hear what I wanted to	17	0	0
The pharmacist developed an effective relationship with me	17	0	0
I felt comfortable discussing my health and medicines with the pharmacist	17	0	0
Having a face-to-face meeting with the pharmacist was important to me	17	0	0
The health professionals worked as a team to communicate	16	1	0
I would prefer my community pharmacist to deliver this service rather than a separate pharmacist	4	5	8
It would be better if a different health professional delivered his service	0	1	16
Perceived usefulness			
I would use this service again if it was available	17	0	0
I would recommend this service to my family and friends	17	0	0
This service is worth the government or district health board investing money in	17	0	0
The advice from the pharmacist was useful	17	0	0
I know more about my medicines	16	0	1
My medicines treatment improved because of this service	14	3	0
It was a negative experience for me to be involved in this service	2	0	15
My health got worse as a result of this service	0	1	16

^a Mana = prestige, authority, standing.

Someone else besides my wife advocating for me was the world of difference in my health care." [P6] Note: in this context when the participant referred to 'follow-ups' they were indicating that the pharmacist followed through with recommendations to ensure they were put into action. "I would like them to be there at any opportunity to help me voice my needs in a way that the other health professionals can understand."

[[P5]]

3. Increased confidence and control.

Participants reported that the intervention improved their confidence in their self-management abilities and that they had more control of their medicines as a result of the intervention.

"[The pharmacist] gave me permission, and [I was] motivated by her, to take hold of my health care."

[[P17]]

"[The intervention] gave me more confidence and let me have more control over my medicines."

[[P3]]

4. 'By Māori, for Māori'.

Participants commented on the importance of the pharmacist being Māori, and that this contributed to service value.

"Māori helping Māori - that makes the world of difference."

[[P2]]

"[The pharmacist is] Māori; she can communicate in a way that enhances my mana (prestige, standing, authority)."

[[P8]]

5. Financial and resource implications.

Participants expressed that they felt the service should be funded and that they would have limited ability to pay for the service themselves, despite seeing the value of it.

"The service should be provided free of charge. I wouldn't pay for it - I believe in this service being free, especially for the pensioner"

[[P13]]

"[The service] just needs more people, more funding and more support."

[[P6]]

Participants had comments regarding the sustainability of the service: that further pharmacist resource was needed to support the high needs of the community, that current participants could be used as 'spokespeople' to promote the service to others, and that ongoing support for the intervention was needed from funders and providers of health services.

b Kaumātua = Māori older adult/s who provide cultural support.

Discussion

Our feasibility study showed that the medicines review intervention was acceptable to participants. Participants viewed the service positively, their medicines knowledge and ability to participate in their healthcare improved, they would engage with it in the future if it was available, and they believed that the intervention should be funded. This small study allowed us to identify aspects that were important to participant acceptability and will help inform future research and wider implementation.

Māori older adults have the "ability, desire and right to control their medicines journey". 14 Despite this, numerous health services in NZ deny Māori the ability to have control.⁵ An important aspect of this intervention was that participants felt in control. This may have been enabled through the sharing of power between the participant and pharmacist, an aspect shown as important in previous research, 14,15 and a right guaranteed in NZ legislation.⁵ Although providers of health services and interventions may be very aware of the different roles, responsibilities, and duties of particular professions, to consumers they are an access point into the health system in general; an insider, with privilege and power. The holistic approach, which extended beyond medicines and into advocacy and increased healthcare access, increased participants' perceived value of the service. Participants reported they had increased confidence talking to healthcare providers and managing their medicines/healthcare which suggests there may be intervention benefits which extend beyond the discrete education and optimisation components.

Participants' perceived usefulness of the studied intervention contributed to its acceptability. Participants perceived that their medicines knowledge improved and reported a willingness to continue to engage with this type of intervention in the future, a factor used in other frameworks which measure acceptability. ¹³ In our study, the perceived usefulness of the intervention was reflected in the value placed on it by the fact participants wanted the service to continue, would recommend it to others, would engage with it if it were available again in the future, and felt the DHB should invest in the service.

There was limited visible whānau (family) involvement during this intervention with only three participants having a family member or support person attend any component. The limited whanau involvement in the intervention may have occurred for a number of reasons including that participants were comfortable making decisions without wider support, whānau may not have lived locally or been available, the ability for participants to invite whānau was not sufficiently highlighted, and/or whānau participation may have occurred at different points (e.g. the participant may have discussed the intervention with whanau when they saw them during everyday life). Of note, our results also showed that participants felt able to include family/support people to the extent they wanted, suggesting it was participant choice which influenced the degree of whānau involvement. Although whānau is an important component of Māori wellbeing, ²³ it may be that whānau involvement is realised in ways other than being present during specific health interventions. There is also the potential that participants did not want to appear vulnerable in the eyes of their whānau, which was expressed by older Māori in previous research our group has undertaken, 14 and, therefore, chose not to involve them in these discussions. The level of whānau input may change through people's lives, and the extent to which participants want whanau inclusion will vary, reflecting the diversity in this population. Reasons for low whanau participation during the intervention could be explored further in future studies. Prescribers are a key stakeholder in this type of intervention and their inclusion in the planning and evaluation is vital to deliver and improve the intervention. Prescriber acceptability has been investigated and will be reported elsewhere.

Participants reported in the open-ended question portion of the interview that the delivery of the intervention by a Māori pharmacist, who had expert knowledge of medicines and communicated well, was important to them. The participant-pharmacist relationship started at the first point of contact with the study (either at the recruitment meeting or in the mailout from the general practice), where information relating to the lead

researcher's Māori genealogical connections, clinical experience and connections to the local area was presented to potential participants. Racism and lack of cultural concordance between health practitioners and patients is associated with poorer Māori health outcomes, 26,27 and increasing the Māori health workforce is one of the methods recommended to improve health inequities which exist in NZ. 28 Increasing the Māori workforce is of particular importance in the pharmacy sector, with less than 2% of this workforce in NZ currently identifying as Māori. 29 The low numbers of Māori pharmacists make it difficult to provide widespread services of a similar nature to those in this intervention, particularly taking into account that previous research shows these interventions are most effective when the pharmacist has experience in geriatric medicine. 30 Increasing the Māori pharmacist workforce capacity and capabilities is, therefore, important to be able to meet participants' expectations to see the intervention offered more widely, by Māori pharmacists, and in an ongoing manner. To address this, action is required by pharmacy educational institutions and professional organisations now, although the outcomes of these actions will not have immediate impact. Findings from this research, which have application to the ability of the non-Māori pharmacist and pharmacy workforce to provide culturally appropriate care, have also been shared and incorporated into undergraduate, pre-registrant and professional educational resources.

Visible Māori research leadership was also a vital component of the study design. The Māori older adult groups we engaged were keen to contribute to upskilling the Māori research workforce and this helped with engagement and acceptance of the project. These were all seen as an important part of the research, helping to establish connections between the participants and researchers, and also ensuring that the research team had the appropriate skills to undertake the work. Relationship development between the pharmacist-participant was also an important part of the intervention itself potentially allowing for easier sharing of information and the development of treatment recommendations better suited to the individual. Our findings suggest that although the provision of medicines information was an important part of the intervention, other aspects, such as advocacy and supporting increased participant control of health all within a culturally congruent and safe model for Māori, were also important.

Strengths and limitations

We developed our own tool to assess acceptability specifically for this intervention, informed by interviews with multiple, diverse stakeholders, centred on a kaupapa Māori theory approach. 14,15,18 Kaupapa Māori theory is based on Māori ways of knowing and knowledge systems, and aims to give power and control to Māori in the research process by challenging normative power structures.²⁰ The deficiencies of using Western approaches to evaluate kaupapa Māori services has previously been noted, 10,15 and can impact on the ability to attract funding and continue the provision of these services, despite the benefits seen from these services that 'align with the holistic and collective nature of the Māori health worldview'. 10 Although this tool has not been previously validated or applied in other research, there is the potential that the interview schedule we developed could be used and modified to support evaluation of acceptability in other kaupapa Māori, and other Indigenous, health interventions. The reason that participants chose to be involved in this interventional research was not explored in the interviews which is a weakness of the study as it may have provided further information regarding the perceived benefits of these interventions and this aspect should be included in future acceptability tools and explored in future studies.

The acceptability interview was very structured and was conducted over the telephone which may have limited feedback from participants. This method was chosen to reduce research burden on participants as the acceptability interview was just one component of the post-intervention follow up (participants were also required to undertake medicines knowledge questionnaires and quality of life assessments). It is likely that that, although more resource-intensive, face-to-face semi-structured interviews would have elicited richer data. In assessing the feasibility of this

acceptability interview schedule it was noted that participants often made comments to the research assistant that were not captured in the interview. To Going forwards, participants could be invited to be part of future planning and development work, enabling solutions-focused, active participation in health service design.

A strength of the study is that all intervention participants took part in the acceptability interview, allowing feedback from all participants involved. However, the number of participants was still small and the results are not generalisable. Recruitment closed early due to the impacts of the COVID-19 pandemic in NZ, particularly noting that eligible participants were one of the groups most at risk of adverse outcomes relating to COVID-19. 31,32 Further, acceptability in a group of clients who have been interested enough to volunteer to participate in a research study may not accurately reflect acceptability to the general population of interest, and thus acceptability would need to be reassessed in this latter group if this service were to be widely implemented. There was, however, a high level of agreement in our participant group, which gives us further confidence that this intervention is worth developing and investigating further. An obvious limitation is that few family members/support people and no prescribers participated and therefore the ability to report on our predetermined outcomes of family and prescriber acceptability was limited.

Conclusion

A pharmacist-facilitated medicines review intervention for Māori older adults developed by Māori, for Māori, was acceptable to participants. Participants valued the clinical expertise and advocacy provided by the pharmacist during the intervention, and the perceived increase in medicines knowledge, control and autonomy. Participants wanted the service to continue on an ongoing basis and recognised the need for health providers and commissioners to support the initiative.

Declaration of interest

There is the potential for perceived conflict of interest given that 1. the intervention was acceptable and participants saw value in continuing it with appropriate resourcing and 2. the lead author, as a Māori pharmacist with experience in older adult medicine, is well positioned to deliver this type of intervention. There are no further conflicts of interests to declare.

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Study protocol

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.

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