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Effect of a health literacy intervention trial on knowledge about cardiovascular disease medications among Indigenous peoples in Australia, Canada and New Zealand

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ABSTRACT

Objectives To assess the effect of a customised, structured cardiovascular disease (CVD) medication health literacy programme on medication knowledge among Indigenous people with, or at high risk of, CVD.

Design Intervention trial with premeasures and postmeasures at multiple time points.

Setting Indigenous primary care services in Australia, Canada and New Zealand.

Participants 171 Indigenous people aged ≥20 years of age who had at least one clinical diagnosis of a CVD event, or in Canada and Australia had a 5-year CVD risk ≥15%, and were prescribed at least two of the following CVD medication classes: statin, aspirin, ACE inhibitors and beta blockers.

Intervention An education session delivered on three occasions over 1 month by registered nurses or health educators who had received training in health literacy and principles of adult education. An interactive tablet application was used during each session and an information booklet and pill card provided to participants.

Primary outcome measures Knowledge about the CVD medications assessed before and after each session.

Results Knowledge at baseline (presession 1) was low, with the mean per cent correct answers highest for statins (34.0% correct answers), 29.4% for aspirin, 26.0% for beta blockers and 22.7% for ACE inhibitors. Adjusted analyses showed highly significant (P<0.001) increases in knowledge scores between preassessments and postassessments at all three time points for all medication classes. For the four medications, the absolute increases in adjusted per cent correct items from presession 1 to postsession 3 assessments were 60.1% for statins, 76.8% for aspirin, 71.4% for ACE inhibitor and 69.5% for beta blocker.

Conclusions The intervention was highly effective in contextually diverse Indigenous primary healthcare services in Australia, Canada and New Zealand. The findings from this study have important implications for health services working with populations with low health literacy more generally.

Trial registration number ACTRN12612001309875.

Strengths and limitations of this study

- This is a well-designed, cross-country, multisite pre–post intervention trial.
- Cross-country, multisite intervention trials with Indigenous communities that successfully incorporate Indigenous research principles, processes and practices are rare.
- This study has high retention rates.
- A control group has not been used because of sample size considerations and due to the risk of contamination in small communities.
- This study does not assess the effect of the intervention on clinical outcomes/medication adherence.

INTRODUCTION

Although Māori (New Zealand; NZ), Aboriginal (Australia) and First Nations (Canada) peoples are distinct Indigenous populations, their shared history of colonisation, historically and in its contemporary expressions, has resulted in similar patterns of inequity in health and social outcomes, relative to the non-Indigenous populations in each country.[1 2] In recent decades, cardiovascular disease (CVD) mortality and morbidity inequities experienced by Indigenous populations have received increasing attention.[3–5] The prevalence of CVD risk factors and mortality and hospitalisation rates have been well-documented for Aboriginal and Torres Strait Islander populations in Australia,[6] First Nations, Inuit and Metis populations in Canada,[7] and Māori populations in NZ.[8 9] Prevention and management of CVD for Indigenous populations are of central importance given the described burden of CVD and inequities experienced by these populations. Evidence-based guidelines for

primary and secondary prevention of CVD are widely available and emphasise 'lifestyle' and medications management.[10–12] However, CVDs are long-term conditions, and self-management by patients and their families is essential for good outcomes.[13 14] Capacity to effectively self-manage long-term conditions is influenced by an array of factors, including, in the case of CVD, knowledge about risk factors and medications.[15] Available literature describing patient CVD knowledge primarily focuses on risk factors and risk assessment, with a lack of equivalent emphasis on medication knowledge.[16–21] Further investigation with regard to knowledge about medications is needed, as inadequate medication knowledge is associated with intermittent and non-adherence to medications.[22] Intermittent and non-adherence has been reported for Indigenous populations[23 24] and is associated with poorer health outcomes, including increased hospitalisations, morbidity and mortality, and inadequate control of risk factors for disease.[25 26] Inadequate knowledge about a broader group of medications has been found among an Indigenous prison population; however, at present limited data exist to describe knowledge for CVD medications specifically.[27]

Health literacy is defined as the 'the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.[28] Health literacy is integral to patient knowledge and self-management. Low levels of health literacy are associated with a range of adverse health outcomes.[28–34] More recently it has been recognised that the health system, healthcare organisations and health professionals are critical to reducing health literacy demands and developing the heath literacy of patients.[35]

In NZ a higher proportion of the Māori population has low levels of health literacy than the non-Māori population.[36] While rigorous population-based data for Indigenous populations in Australia and Canada are lacking, the needs of these populations are likely to be similar to those in NZ, given the similar inequities in health and education observed between Indigenous and non-Indigenous people in all these countries.

A customised, structured CVD medication health literacy intervention was developed during a development phase that included in-depth interviews with community members who were taking CVD prevention medications. Interview participants described their knowledge about their medications, what they would like to know about these medications and how they would like to be provided with this information. Participants' responses in relation to these topics were similar in all three countries. While content was the same across all three countries, all resources were customised for use with the three different Indigenous groups. This included graphics, images and Indigenous words and phrases used throughout the resources.

The objective of this study was to assess the effect of a customised, structured CVD medication health literacy programme on medication knowledge among Indigenous people with, or at high risk of, CVD.

METHODS

A detailed trial protocol has been published elsewhere.[37] In brief, the trial used a multisite pre–post design with multiple measurement points. The study was registered with the Australian and New Zealand Clinical Trials Register on 18 December 2012 (ACTRN12612001309875). Community engagement and research processes were consistent with guidelines for research with Indigenous communities.[38–41]

The intervention was implemented in Indigenous primary healthcare services in Australia (one urban service), Canada (one service with two urban sites) and NZ (one urban and one rural service). Primary outcomes were patients' knowledge about CVD medications (statins, beta blockers, ACE inhibitors and aspirin). Secondary outcomes examined changes in health literacy skills and practices. This paper reports the results of a combined (three-country) analysis of the primary outcomes (medication knowledge).

In NZ and Canada potential participants were identified from the health services' medical records. In Australia eligible participants were referred by their general practitioner, Aboriginal health worker or pharmacist. Eligibility criteria were that participants were Indigenous people aged ≥20 years of age; had at least one clinical diagnosis of a CVD event (angina, myocardial infarction, ischaemic stroke or transient ischaemic attack), or for Canada and Australia had a 5-year CVD risk ≥15%; were prescribed at least two of the following CVD medication classes: statin, aspirin, ACE inhibitors and beta blockers; and could provide informed consent to participate.

The intervention consisted of an education session delivered by registered nurses or health educators who had received training in health literacy and adult education principles to support the development of health literacy knowledge and skills. An interactive tablet application was used during each session. The application also produced a customised pill card for each participant. At the first session a booklet containing information about CVD, medication use, the four CVD medication classes, and treatment targets for lipid and blood pressure was given to all participants. Information in the tablet and booklet was standardised across all three countries; however, background graphic design features, images and Indigenous language words and phrases were country-specific. The use of the application ensured that the nurse/educator covered all the CVD medication information in a structured way and, in the context of a trial, standardised the provision of information across all five sites. The education session was delivered three times over 4 weeks (table 1). The programme was customised for each participant so they only received information about the medication classes they were taking.

Table 1 Summary of trial contacts and data collection

Activity	Time point	Measurement
Enrolment visit	T0	Consent and enrolment in study In Canada baseline demographic and clinical information was also collected at this visit.
Session 1	T1—Presession 1	Baseline demographic and clinical information (New Zealand, Australia) Medication knowledge and health literacy practices
	T2—Postsession 1	Medication knowledge and health literacy practices
Session 2 Seven days after session 1	T3—Presession 2	Medication knowledge and health literacy practices
	T4—Postsession 2	Medication knowledge and health literacy practices
Session 3 28 days after session 1	T5—Presession 3	Medication knowledge and health literacy practices
	T6—Postsession 3	Medication knowledge and health literacy practices

Data collection

Table 1 summarises data collection at each time point.

Baseline data were collected from participants and from the health services' medical records.

Outcome measures for statins, ACE inhibitors, aspirin and beta blockers assessed knowledge of the scientific and brand names of the medications, what the medication does, how to take it, important side effects, and lipid and blood pressure treatment targets. The number of items in the outcome questionnaire varied for each medication class. There were 9 items for statins, 11 for beta blockers, 12 for ACE inhibitors and 13 for aspirin (table 2).

Patient knowledge was assessed by first inviting the patient to tell the nurse/health educator about that medicine. When the participant had volunteered as much information as they could, the nurse/educator would then provide a prompt about information the participant had not mentioned, for example, 'can you tell me about the serious side effects of…'.

Participants were recruited between 18 February 2013 and 29 November 2013.

Statistical analysis

Continuous variables are reported using means and SD. Categorical data are expressed as percentages and 95% CI. All categorical data analyses have been calculated using a binomial distribution. Histograms were used to determine whether continuous data were normally distributed. Medication knowledge scores were calculated as the percentage of questions answered correctly in each assessment. In descriptive analyses estimates were determined to vary significantly from each other if the 95% CI did not overlap.

Generalised estimating equations were used to investigate change in the proportion of questions answered correctly across the preassessments and postassessments for each session. The analysis was based on a linear scale response. It controlled for site and diabetes comorbidity. All analyses were performed using SPSS V.22.

RESULTS

In total 171 participants were recruited and completed session 1. Session 2 was completed by 166 participants (97.1%), and 160 participants (93.6%) completed session 3. Of the 11 participants who did not complete the intervention, one patient did not complete as they were admitted to an aged care residential facility; the remaining 10 participants were lost to follow-up.

Table 3 provides site-specific and aggregated baseline data. Baseline characteristics did not vary significantly by site with regard to age, sex, time with CVD, prevalence of gout, study medications at baseline, number of medication classes taken at baseline, medication allergy/side effects, blood pressure or lipids. There were significant site differences with regard to type of CVD, number of CVD diagnoses, the prevalence of diabetes, congestive heart failure (CHF) and chronic obstructive pulmonary disease (COPD), as well as the number of comorbidities (table 3). Myocardial infarction (MI) was more common in the NZ urban site. Prevalence of stroke was significantly higher in the NZ rural site than in Canada site B and Canada site A. All NZ participants had at least one CVD diagnosis, while participants with high risk only were included in the other sites. Diabetes was a common comorbidity at all sites; however, the prevalence was significantly lower at one NZ site than the other sites. The prevalence of CHF was significantly higher at the two NZ sites than in the Australian site. The prevalence of COPD was significantly lower in the NZ rural site than in the four other sites. The proportion of participants who did not have a comorbidity was significantly higher at the NZ rural site than in Australia and Canada site B, while the proportion who had two comorbidities was significantly lower at the NZ rural site than at the Australian site.

Health literacy knowledge scores

Presession 1 knowledge of all four medications was low, with mean per cent correct highest for statins (34.0% correct answers), 29.4% for aspirin, 26.0% for beta blockers and 22.7% for ACE inhibitors. For all four medications, the knowledge scores increased significantly in

Table 2 Items in outcome measures

	ACE inhibitors	Beta blockers	Statin	Aspirin
Name of medication (scientific or brand)	Eg of scientific name: perindopril Eg of brand name: *Coversyl*	Eg of scientific name: atenolol Eg of brand name: *Noten*	Eg of scientific name: atorvastatin Eg of brand name: *Lipitor*	Eg of scientific name: aspirin Eg of brand name: *Cartia*
Pronounced correctly	Yes/No	Yes/No	Yes/No	Yes/No
Name of medication (class)	ACE inhibitor	Beta blocker	Statin	Aspirin
Pronounced correctly	Yes/No	Yes/No	Yes/No	Yes/No
Function/s	Lowers blood pressure Protects heart and kidneys	Lowers blood pressure Protects heart	Lowers cholesterol	Stops you having blood clots
Instruction/s	Start on low dose and increase Blood tests every 6 months Avoid food with too much potassium	Take at the same time every day Do not suddenly stop taking	Take with evening meal Avoid grapefruit juice	Take indigestion medication 2 hours after taking aspirin Take with food or after eating
Serious side effects	Tongue, lips or face swell up Dizzy or faint	Dizzy or faint Breathing problems or asthma	Muscle pain, tenderness or weakness	Tongue, lips or face swell up Dizzy or faint Itchy rash Bad stomach pain Black or bloody poos Vomiting brown liquid
Treatment targets	If no kidney disease SBP <130 and DBP <80 mm Hg If kidney disease SBP <125 and DBP <75 mm Hg	If no kidney disease SBP <130 and DBP <80 mm Hg If kidney disease SBP <125 and DBP <75 mm Hg	LDL <3.4 mmol/L	

DBP, diastolic blood pressure; LDL, low-density lipoprotein; SBP, systolic blood pressure.

postsession 1 assessments. Knowledge scores fell slightly in the interval between postsession 1 and presession 2 assessments and rose in postsession 2 assessment. A similar pattern was observed in the assessments associated with session 3 (table 4).

Adjusted analyses showed highly significant (P<0.001) increases in knowledge scores between presession and postsession assessments at all three time points for all medication classes (table 5). For the four medications, the absolute increases in items answered correctly from presession 1 to postsession 3 assessments were 60.1% for statins, 76.8% for aspirin, 71.4% for ACE inhibitor and 69.5% for beta blocker (table 5).

DISCUSSION

According to the Ottawa Charter, enabling people to have increased control over their health leads to improved health.[42] Health literacy was initially viewed as a patient factor that could be used as a risk factor or a marker for poor outcomes. In recent years discussions regarding health literacy have broadened to include the role that health systems, services and health professionals play in determining the level of health literacy required to successfully navigate health services, and supporting patients to build their health literacy skills and capabilities so they are better equipped to meet their health needs.[34 43 44] The intervention used in this trial systematically incorporated several approaches to achieve this, including health professional training and interactive resources (electronic tablet application, pill card and booklet). Furthermore, the session was repeated to reinforce and further develop participants' knowledge and skill acquisition. This intervention sought to build health literacy skills, such as knowledge and the ability to both

Table 3 Baseline characteristics of participants by site and total

	Australia	NZ rural	NZ urban	Canada A	Canada B	Total
Number of participants						
Session 1, n (%)	29 (100.0)	55 (100)	40 (100)	26 (100)	21 (100)	171 (100)
Session 2, n (%)	24 (82.8)	55(100)	40 (100)	26 (100)	21 (100)	166 (97.1)
Session 3, n (%)	23 (79.3)	54 (98.2)	36 (90.0)	26 (100)	21 (100)	160 (93.6)
Age, years mean (SD)	59 (11)	68 (11)	6 (19)	59 (10)	58 (7)	62 (11)
Male sex, n (% male, 95% CI)	18 (62.1, 44.4 to 79.7)	21 (38.2, 25.3 to 51.0)	17 (42.5, 27.2 to 57.8)	11 (42.3, 23.3 to 61.3)	11 (52.4, 31.0 to 73.7)	78 (45.6, 38.1 to 53.1)
CVD diagnoses, n (%, 95% CI)						
Angina	11 (37.9, 20.3 to 55.6)	30 (54.5, 41.4 to 67.7)	27 (67.5, 53.0 to 82.0)	10 (38.5, 19.8 to 57.2)	10 (47.6, 26.3 to 69.0)	88 (51.5, 44.0 to 59.0)
MI	14 (48.3, 30.1 to 66.5)	17 (30.9, 18.7 to 43.1)	33 (82.5, 70.7 to 94.3)	8 (30.8, 13.0 to 48.5)	7 (33.3, 13.2 to 53.5)	79 (46.2, 38.7 to 53.7)
Stroke	6 (20.7, 5.9 to 35.4)	17 (30.9, 18.7 to43.1)	7 (17.5, 5.7 to 29.3)	1 (3.8, 0.0 to 11.2)	1 (4.8, 0.0 to 13.9)	32 (18.7, 12.9 to 24.6)
TIA	2 (6.9, 0.0 to 16.1)	6 (10.9, 2.7 to 19.1)	4 (10.0, 0.7 to 19.3)	4 (15.4, 1.5 to 29.3)	4 (19.0, 2.3 to 35.8)	20 (11.7, 6.9 to 16.5)
CVD risk or number of CVD diagnosis, n (%, 95% CI)						
High CVD risk only	8 (27.6, 11.3 to 43.9)	0	0	8 (30.8, 13.0 to 48.5)	6 (28.6, 9.2 to 47.9)	22 (12.9, 7.8 to 17.9)
One	13 (44.8, 26.7 to 62.9)	40 (72.7, 61.0 to 84.5)	14 (35.0, 20.2 to 49.8)	14 (53.8, 34.7 to 73.0)	9 (42.9, 21.7 to 64.0)	90 (52.6, 45.1 to 60.1)
Two	5 (17.2, 3.5 to 31.0)	15 (27.3, 15.5 to 39.0)	22 (55.0, 39.6 to 70.4)	3 (11.5, 0.0 to 23.8)	5 (23.8, 5.6 to 42.0)	50 (29.2, 22.4 to 36.1)
Three or more	3 (10.3, 0.0 to 21.4)	0	4 (7.5, 0.0 to 15.7)	1 (3.8, 0.0 to 11.2)	1 (4.8, 0.0 to 13.9)	7 (4.1, 1.1 to 7.1)
Time with CVD, years, mean (95% CI)	7.2 (4.4 to 9.9)	7.5 (5.6 to 9.4)	7.7 (2.6 to 12.8)	10.4 (7.3 to 13.5)	7.9 (5.3 to 10.6)	7.9 (6.6 to 9.2)
Comorbidity, n (%, 95% CI)						
Diabetes	18 (62.1, 44.4 to 79.7)	13 (23.6, 12.4 to 34.9)	22 (55.0, 39.6 to 70.4)	18 (69.2, 51.5 to 87.0)	18 (85.7, 70.7 to 100)	89 (52.0, 44.6 to 59.5)
CHF	0 (0)	11 (20, 9.4 to 30.6)	8 (20.0, 7.6 to 32.4)	1 (3.8, 0.0 to 11.2)	2 (9.5, 0.0 to 22.1)	22 (12.9, 7.8 to 17.9)
COPD	14 (48.3, 30.1 to 66.5)	5 (9.1, 1.5 to 16.7)	16 (40.0, 24.8 to 55.2)	14 (53.8, 34.7 to 73.0)	8 (38.1, 17.2 to 58.9)	57 (33.3, 26.3 to 40.4)
Gout	6 (20.7, 5.9 to 35.4)	14 (25.5, 13.9 to 37.0)	14 (35.0, 20.2 to 49.8)	2 (7.7, 0.0 to 17.9]	4 (19.0, 2.3 to 35.8)	40 (23.4, 17.0 to 29.7)
Peptic ulcer	4 (13.8, 1.2 to 26.3)	0 (0)	3 (7.5, 0.0 to 15.7)	4 (15.4, 1.5 to 29.3)	3 (14.3, 0.0 to 29.3)	14 (8.2, 4.1 to 12.3)

Continued

Table 3 Continued

	Australia	NZ rural	NZ urban	Canada A	Canada B	Total
Number of comorbidities, n (%, 95% CI)						
None	3 (10.3, 0.0 to 21.4)	25 (45.5, 32.3 to 58.6)	8 (20.0, 7.6 to 32.4)	5 (19.2, 4.1 to 34.4)	2 (11.1, 0.0 to 25.6)	43 (25.6, 18.6 to 31.6)
One	11 (37.9, 20.3 to 55.6)	20 (36.4, 23.7 to 49.1)	10 (25.0, 11.6 to 38.4)	8 (30.8, 13.0 to 48.5)	7 (38.9, 16.4 to 61.4)	56 (33.3, 26.2 to 40.5)
Two	14 (48.3, 30.1 to 66.5)	7 (12.7, 3.9 to 21.5)	13 (32.5, 18.0 to 47.0)	10 (38.5, 19.8 to 57.2)	6 (33.3, 11.6 to 55.1)	50 (29.8, 22.8 to 36.7)
Three	1 (3.4, 0.0 to 10.1)	3 (5.5, 0.0 to 11.5)	9 (22.5, 9.6 to 35.4)	1 (3.8, 0.0 to 11.2)	2 (11.1, 0.0 to 25.6)	16 (9.5, 5.1 to 14.0)
Four	0 (0)	0 (0)	0 (0)	2 (7.7, 0.0 to 17.9)	1 (5.6, 0.0 to 16.1)	3 (1.8, 0.0 to 3.8)
CVD medications at baseline, n (%, 95% CI)						
Statin	29 (100)	51 (92.7, 85.9 to 99.6)	37 (92.5, 84.3 to 100)	24 (92.3, 82.1 to 100)	19 (90.5, 77.9 to 100)	160 (93.6, 89.9 to 97.2)
ACE inhibitor	19 (65.5, 48.2 to 82.8)	31 (56.4, 43.3 to 69.5)	27 (67.5, 53.0 to 82.0)	17 (65.4, 47.1 to 83.7)	12 (57.1, 36.0 to 78.3)	106 (62.0, 54.7 to 69.3)
Beta blocker	15 (51.7, 33.5 to 69.9)	40 (72.7, 61.0 to 84.5)	28 (70.0, 55.8 to 84.2)	12 (46.2, 27.0 to 65.3)	9 (42.9, 21.7 to 64.0)	104 (60.8, 53.5 to 68.1)
Aspirin	23 (79.3, 64.6 to 94.1)	46 (83.6, 73.9 to 93.4)	36 (90.0, 80.7 to 99.3)	20 (76.9, 60.7 to 93.1)	15 (66.7, 46.5 to 86.8)	140 (81.9, 76.1 to 87.6)
Number of CVD medications classes, n (%, 95% CI)						
One	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Two	11 (37.9, 20.3 to 55.6)	15 (27.3, 15.5 to 39.0)	7 (17.5, 5.7 to 29.3)	10 (38.5, 19.8 to 57.2)	11 (52.4, 31.0 to 73.7)	54 (31.6, 24.6 to 38.5)
Three	8 (27.6, 11.3 to 43.9)	22 (40.0, 27.1 to 52.9)	18 (45.0, 29.6 to 60.4)	12 (46.2, 27.0 to 65.3)	7 (33.3, 13.2 to 53.5)	67 (39.2, 31.9 to 46.5)
Four	10 (34.5, 17.2 to 51.8)	18 (32.7, 20.3 to 45.1)	15 (37.5, 22.5 to 52.5)	4 (15.4, 1.5 to 29.3)	3 (14.3, 0.0 to 29.3)	50 (29.2, 22.4 to 36.1)
Allergy/side effect, n (%, 95% CI)						
Statin	0 (0)	1 (1.8, 0.0 to 5.3)	1 (2.5, 0.0 to7.3)	1 (3.8, 0.0 to 11.2)	2 (9.5, 0.0 to 22.1)	5 (2.9, 0.4 to 5.4)
ACE inhibitor	0 (0)	2 (3.6, 0.0 to 8.6)	1 (2.5, 0.0 to7.3)	0 (0)	1 (4.8, 0.0 to 13.9)	4 (2.3, 0.1 to 4.6)
Beta blocker	1, (3.4, 0.0 to 10.1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.6, 0.0 to 1.7)
Aspirin	0 (0)	0 (0)	0 (0)	1 (3.8, 0.0 to 11.2)	2 (0.0 to 22.1)	3 (1.8, 0.0 to 3.7)

Continued

Table 3 Continued

	Australia	NZ rural	NZ urban	Canada A	Canada B	Total
Systolic BP mm Hg, mean (95% CI)	130.2 (124.3 to 136.0)	131.5 (127.8 to135.2)	134.7 (128.8 to 140.6)	131.4 (125.4 to 137.4)	129.5 (123.1 to 136.0)	131.6 (129.3 to 133.8)
Systolic BP (range)	87–154	97–161	111–172	111–73	103–166	87–173
Diastolic BP, mean (95% CI)	82.0 (77.8 to 86.2)	79.0 (76.9 to 81.1)	81.7 (78.1 to 85.3)	77.0 (73.4 to 80.6)	74.2 (69.7 to 78.7)	79.0 (77.6 to 80.5)
Diastolic BP (range)	65–112	57–99	60–03	63–98	52–87	52–112
Lipids mmol/L, mean (95% CI)						
LDL	2.32 (2.01 to 2.63)	2.82 (2.58 to 3.05)	2.31 (2.04 to 2.58)	2.34 (1.86 to 2.81)	2.40 (1.96 to 2.84)	2.50 (2.36 to 2.64)
LDL (range)	1.05–3.55	1.10–5.05	0.75–3.90	0.73–4.68	0.50–4.23	0.50–5.05
HDL	1.10 (1.01 to 1.20)	1.14 (1.07–1.20)	1.10 (1.00–1.20)	1.08 (0.96–1.20)	1.19 (1.05–1.33)	1.12 (1.08–1.16)
HDL (range)	0.60–1.65	0.80–1.85	0.78–1.94	0.50–1.66	1.97–1.19	0.50–1.97

BP, blood pressure; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; CVD, cardiovascular disease; HDL, high-density lipoprotein; LDL, low-density lipoprotein; MI, myocardial infarction; NZ, New Zealand; TIA, transient ischaemic attack.

access and use health information; however, only data about the primary outcome (medication knowledge) are presented in this paper.

The findings in regard to medication knowledge were observed in all four medication classes. At baseline, knowledge of all four medication classes was low. The intervention resulted in significant increases in knowledge that were largest in the first session but were also observed in subsequent sessions, and were sustained between sessions, suggesting that participants were retaining and spontaneously recalling information. Our findings are consistent with previous research that has demonstrated that there are clear benefits to culturally appropriate and community-specific interventions. Culturally appropriate interventions have previously demonstrated an association with improved health knowledge about diabetes and CVD.[45 46] Counselling that incorporates successful adult education techniques such as reinforcement and feedback, teachback, assessing and confirming patients' understandings, and patient-tailored information all build health literacy.[44 47] Research involving pill cards for health literacy has tended to focus on pill cards as a management tool for low health literate populations as opposed to assessing how they build health literacy skills and capabilities. These studies have demonstrated effectiveness in improving adherence among low health literacy populations when used as a stand-alone tool[48] and when used in combination with counselling by a health professional trained in adult education techniques.[49]

Kripalani *et al*[44] demonstrated that training increased physicians' confidence to counsel patients with low health literacy about medication use.[44] In this study we provided training to the Indigenous health practitioners who delivered the intervention.

Inadequate knowledge about medications is associated with intermittent or non-adherence to medications, which in turn is associated with worse outcomes including poorer control of risk factors, and increased hospitalisations, morbidity and mortality.[22 25 50] This study showed that baseline knowledge about cardiovascular medicines was low among Indigenous people in Australia, Canada and NZ. This low baseline knowledge is consistent with published information about health literacy levels in Indigenous populations.[36] However, this finding is unlikely to be unique to these populations as poor health literacy also is seen in significant proportions of the non-Indigenous populations.[36] The reported low baseline medication knowledge in this study is also congruent with studies for non-Indigenous populations where low medication knowledge has been reported.[50 51]

This study has several strengths, including very good retention rates across the intervention period. Intervention trials located within Indigenous communities are rare. Brega *et al*[45] found that the 'Honouring the Gift of Heart Health' intervention increased knowledge about CVD, symptoms associated with MI and stroke, and CVD risk factor control, in both high and low health literacy groups of American Indian and Alaska Native peoples.[45]

Table 4 Unadjusted mean per cent correct items in knowledge questionnaire, by medication

	n	Presession knowledge Mean (95% CI)	Postsession knowledge Mean (95% CI)	% Difference (95% CI)
Statin				
Session 1	160	34.0 (30.1 to 38.8)	90.6 (88.0 to 93.3)	56.7 (49.0 to 64.3)
Session 2	155	85.4 (81.9 to 88.8)	96.1 (94.1 to 98.1)	10.7 (5.8 to 15.5)
Session 3	151	92.3 (89.9 to 94.7)	98.2 (97.2 to 99.3)	6.0 (2.2 to 9.7)
Aspirin				
Session 1	140	29.4 (27.4 to 31.4)	92.9 (90.8 to 95.1)	63.5 (55.5 to 71.5)
Session 2	134	87.1 (83.7 to 90.5)	96.3 (94.6 to 98.0)	9.2 (4.3 to 14.1)
Session 3	129	91.5 (89.0 to 94.1)	98.6 (97.6 to 99.7)	7.1 (2.6 to 11.6)
ACE inhibitor				
Session 1	106	22.7 (19.7 to 25.8)	87.0 (83.6 to 90.5)	64.3 (55.2 to 73.4)
Session 2	102	83.0 (78.8 to 87.3)	94.3 (91.9 to 96.6)	11.3 (5.1 to 17.4)
Session 3	95	90.2 (87.1 to 93.3)	96.5 (94.5 to 98.5)	6.3 (1.4 to 11.2)
Beta blocker				
Session 1	104	26.0 (21.9 to 30.2)	88.8 (85.7 to 92.0)	62.8 (53.5 to 72.1)
Session 2	101	85.8 (81.6 to 90.0)	96.1 (94.3 to 98.0)	10.4 (4.4 to 16.3)
Session 3	97	89.2 (86.0 to 92.5)	97.7 (96.2 to 99.1)	8.4 (2.9 to 14.0)

The current study and that of Brega *et al* demonstrate that appropriately designed interventions can be successfully implemented in Indigenous communities. This study is imbued with Indigenous research principles and practices, including Indigenous leadership, partnership with Indigenous health services, incorporation of local Indigenous design features in the intervention, embedding of culturally appropriate processes and protocols within the design and conduct of the trial, and the development of the Indigenous health professionals' and services' capacity to undertake research and to respond to health literacy needs within their communities.[38–40 52–54] While Indigenous-led, participatory research is increasing, there are a few existing examples involving a complex multisite intervention trial. Furthermore, there has been a strong shift in Indigenous-led research towards strength-based

Table 5 Multivariable analysis for cardiovascular disease medications change in % items correct in knowledge questionnaire*

	n	Preknowledge score Mean (95% CI)	Postknowledge score Mean (95% CI)	B (95% CI)	P value
Statin					
Session 1	160	37.4 (34.3 to 40.9)	87.8 (84.9 to 90.9)	3.50 (3.06 to 3.01)	<0.001
Session 2	155	84.0 (80.5 to 87.7)	94.9 (92.1 to 97.8)	1.14 (1.09 to 1.19)	<0.001
Session 3	151	91.2 (88.8 to 93.7)	97.5 (96.1 to 98.9)	1.07 (1.04 to 1.10)	<0.001
Aspirin					
Session 1	140	30.7 (28.9 to 32.6)	92.4 (89.9 to 94.9)	3.01 (2.83 to 3.20)	<0.001
Session 2	134	86.5 (83.1 to 90.0)	96.0 (93.9 to 98.1)	1.11 (1.07 to 1.15)	<0.001
Session 3	129	91.3 (88.8 to 93.9)	98.5 (96.8 to 100)	1.08 (1.05 to 1.11)	<0.001
ACE inhibitor					
Session 1	106	24.5 (21.7 to 27.7)	84.7 (80.6 to 89.0)	3.50 (3.06 to 3.91)	<0.001
Session 2	102	81.6 (77.4 to 86.1)	93.2 (90.3 to 96.2)	1.14 (1.09 to 1.19)	<0.001
Session 3	95	89.5 (86.6 to 92.4)	95.9 (94.2 to 97.8)	1.07 (1.04 to 1.10)	<0.001
Beta blocker					
Session 1	104	27.9 (24.3 to 32.0)	84.0 (79.5 to 88.9)	3.01 (2.60 to 3.49)	<0.001
Session 2	101	84.6 (80.0 to 89.4)	94.4 (91.4 to 97.5)	1.12 (1.07 to 1.16)	<0.001
Session 3	97	88.8 (85.7 to 92.1)	97.4 (95.4 to 99.5)	1.10 (1.06 to 1.13)	<0.001

*Model included site and diabetes comorbidity.

approaches rather than focusing on disparities and deprivation experienced by Indigenous people; accordingly the latter are not a focus of the research presented here. Communities in each country were engaged throughout the research process, and their experiences, culture and values incorporated in the design of the intervention. Heterogeneity between the communities was accounted for by enabling communities to design an approach that was tailored to them.

Much of the current health literacy literature is descriptive. The intervention described here offers solutions to improving Indigenous health and experiences with the health system. Although CVD is common, this study is one of the first to examine the effect of an intervention to improve CVD medication health literacy in any population group. Many measures of health literacy, for example, the Test of Functional Health Literacy in Adults and the Rapid Estimate of Adult Literacy in Medicine, are based on generic language and numeracy skills. However, knowledge has been shown to provide a strong indication of health literacy for specific conditions.[33] This study measured health literacy in terms of knowledge about CVD medication. Other measures of health literacy, for example, use of different types of health information resources, were collected but are not reported in this paper.

There are three other potential limitations to this study. First, we have not used a control group. There was a high risk of contamination between intervention and control groups because the small, close-knit nature of the communities meant it would be difficult to prevent sharing of information and project resources. Contamination was also possible if the nurses/educators inadvertently used skills/information acquired during training when providing usual care to the control group. Furthermore, to obtain an appropriate sample size, all eligible participants in the health services had to receive the intervention. Ascertaining whether the observed effects were due to the intervention or to other unmeasured factors is challenging given the lack of a control group. The pattern of change within sessions supports an intervention effect, as does the relatively short time (1 month) from sessions 1 to 3. The intervention was delivered at five sites in three countries, and the results are remarkably consistent across all sites, providing further support for intervention effect rather than unmeasured factors, which are unlikely to be the same in all three countries. Although the findings were similar across all sites in the three countries and between an urban and rural site in NZ, further studies could assess whether the intervention is as effective in Indigenous populations who receive care from non-Indigenous health services and on the effect of the intervention with non-Indigenous population groups. Second, follow-up data assessing changes in knowledge beyond the immediate duration of the programme have not been collected. The purpose of the project was to assess the effectiveness of a customised, structured medication education programme that incorporated strategies based on adult education principles to support the development of participants' health literacy. Accurate retention of information requires regular reinforcement of knowledge. Future implementation of the programme should occur within long-term CVD management in primary care services where patients are seen regularly, providing ongoing opportunities for reassessment, reinforcement of existing knowledge and, where indicated, the provision of new information. Thus, the immediate effect of the programme is of more interest than longer term follow-up for a 'one off' programme. Finally, we have not assessed the effect of improved knowledge on clinical outcomes or behavioural measures such as medication adherence. Assessment of these outcomes requires a much larger sample size and/or longer time frame than that used in this study. Furthermore, literature discussing the impact of health literacy interventions on adherence suggests that, although increasing health literacy skills and knowledge contributes to improvements in adherence,[48 55] other factors such as self-efficacy also play an important role.[56–58] Future research that addresses a wider range of these factors could investigate the effects of health literacy interventions like this on clinical outcomes for patients.

Health professionals and healthcare organisations play a central role in ensuring that the needs of patients with low health literacy are being met. By adapting current systems of care for patients with low health literacy, health professionals and healthcare organisations can support the development of Indigenous patients' CVD medication knowledge and health literacy practices. The evidence presented here suggests that systematic approaches operating at the interface of health professional and patient are likely to improve the health literacy of Indigenous people and in turn improve health equity. The findings from this study have important implications for populations with low health literacy more generally.

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sites and collaborated in drafting the manuscript. JKS led the Canadian research team. MK participated in design, led the Australian research, undertook data analysis and collaborated in drafting the manuscript. All authors read and approved the final manuscript.

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