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Inclusion of indigenous and ethnic minority populations in intervention trials: challenges and strategies in a New Zealand supermarket study

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ABSTRACT

Background: The Supermarket Healthy Options Project (SHOP) is a large, randomised, controlled trial designed to evaluate the effect of tailored nutrition education and price discounts on supermarket food purchases. A key objective was to recruit approximately equal numbers of Māori, Pacific and non-Māori, non-Pacific shoppers. This paper describes the recruitment strategies used and evaluates their impact on recruitment of Māori, Pacific and non-Māori, non-Pacific trial participants.

Methods: Trial recruitment strategies included mailed invitations to an electronic register of supermarket customers; in-store targeted recruitment; and community-based recruitment.

Results: Of the 1103 total trial randomisations for whom ethnicity was known, 247 (22%) were Māori, 101 (9%) Pacific and 755 (68%) were non-Māori, non-Pacific shoppers. Mailed invitations produced the greatest proportion of randomisations (73% vs 7% in-store, and 20% from community recruitment). However, in-store and community recruitment were essential to boost Māori and Pacific samples. The cost of mailout (NZ\$40 (£14) per randomised participant) was considerably less than the cost of community and in-store recruitment (NZ\$301 (£105) per randomised participant).

Conclusions: The findings demonstrate considerable challenges and cost in recruiting indigenous and minority ethnic participants into intervention trials. Researchers and funding organisations should allocate more resources to recruitment of indigenous and minority populations than to recruitment of majority populations. Community recruitment and networks appear to be better ways to recruit these populations than passive strategies like mailouts.

In New Zealand, significant ethnic disparities exist for nutrition-related causes of death, in particular ischaemic heart disease (IHD) and stroke.^{1,2} Forty-seven per cent of deaths among Māori (indigenous New Zealanders, constituting 15% of the population) are attributable to nutrition-related risk factors compared with 39% among non-Māori.³ Among Pacific people in New Zealand (7% of the population), substantially more Pacific adults are overweight or obese than their total population counterparts and a similar pattern is seen in Pacific children whose rates of obesity are three times the national average for New Zealand children.⁴ Such ethnic inequalities make it imperative that health research in New Zealand is designed to maximise participation and opportunity for health gain among Māori and Pacific groups. Studies without

sufficient numbers of Māori and Pacific participants risk identifying interventions that work only for the majority population and may actually increase health disparities.

Most food expenditure in New Zealand takes place in supermarkets,⁵ which therefore have considerable potential for environmental nutrition interventions because of their significant capacity to influence the food purchases of a large section of the population. In 2005, a pilot study of interventions to promote healthier food purchasing among supermarket shoppers demonstrated difficulty recruiting Māori, Pacific and low-income shoppers using an electronic register and mailout.⁶ Based on these findings, recruitment strategies for the subsequent Supermarket Healthy Options Project (SHOP) intervention trial were modified with the aim of recruiting approximately equal numbers of Māori, Pacific and non-Māori, non-Pacific participants.

Despite recognition of Māori and Pacific peoples as priority populations in a number of national health strategies⁷⁻¹⁰ there is a lack of published data on recruitment of Māori and minority populations in New Zealand intervention trials. This paper describes various recruitment strategies used in the SHOP trial and evaluates their impact on recruitment rates. Key trial recruitment strategies included mailed invitations to an electronic register of supermarket customers; in-store targeted recruitment; and community-based recruitment.

METHODS

SHOP trial

SHOP is a large, randomised, controlled trial of the effect of tailored nutrition education and price discounts on supermarket food purchases. The trial is being conducted in eight supermarkets in the Lower North Island (Wellington, Wanganui and New Plymouth) in New Zealand. The University of Auckland Human Participants Ethics Committee approved the trial protocol and related documents.

SHOP team investigators comprise academics and community workers with combined expertise in clinical trials, social epidemiology, Māori health, Pacific health, nutrition and public health. The team was formed prior to trial design and funding applications in order to ensure representativeness at governance and decision-making levels as well as in trial conduct, analysis and dissemination.

Supermarkets included in the trial offer use of a system of handheld barcode scanning terminals

that allow registered customers to scan each item they select from the supermarket shelf before putting it in their trolley (Shop 'N Go). The advantages of the system to customers include the ability to track the cost of purchases as they shop and to save time at checkout. Most times Shop 'N Go customers can proceed to checkout without re-scanning chosen items although random re-scans are programmed to occur about 1 in 10 times it is used. Use of the barcode scanner, in conjunction with a personalised scannable card, allows collection of individualised electronic data on all food items purchased by a cardholder, providing an objective measure of supermarket food purchases.

The tailored nutrition education intervention consists of a paper-based package of dietary information tailored to ethnicity and usual supermarket food purchases (based on individualised electronic supermarket sales data).¹¹ The price discount intervention consists of an automatic 12.5% price reduction (equivalent to having Goods and Services Tax removed) on all eligible healthier food products. Discounts are implemented when randomised participants scan their personalised card at the checkout during the study intervention period.

The aim was to recruit and randomise 1200 supermarket customers to one of four intervention arms: (1) tailored nutrition education, (2) price discounts, (3) a combination of the two interventions or (4) a control group (no intervention).

Recruitment procedures

Recruitment took place over 9 months beginning in February 2007. To be eligible for inclusion in the trial participants had to meet all of the following criteria: main household shopper; aged 18 years or older; regular shopper at one of the eight participating supermarket stores (ie, shopped once every 2 weeks and spent a minimum of NZ\$150 per month); and either a registered user of the Shop 'N Go system or willing to sign up and use the system for the duration of the trial. Shop 'N Go use was essential to measure shopping habits and the impact of the intervention.

A variety of strategies were used to recruit participants, including mailouts to a random selection of regular supermarket customers registered to use the Shop 'N Go system, and targeted 'in-store' (supermarket-based) and community-based recruitment. Those contacted by mail were sent a pre-paid reply card to complete and return by mail to the study centre in order to indicate interest in finding out more about the trial. Alternatively they could call a local (free) telephone number to talk directly with project staff. We expected that mailouts would yield mainly non-Māori, non-Pacific participants⁶ so the community and in-store recruitment focused on Māori and Pacific shoppers.

Community recruitment consisted of raising awareness about the trial in Māori and Pacific communities in the vicinity of the trial supermarkets. A local Māori social and health service provider (Kokiri Marae) undertook the Māori community awareness-raising via community networks. Pacific community recruitment included awareness-raising by a number of Pacific recruiters in local church groups and sports clubs with support from the National Heart Foundation's Pacific Islands Heartbeat Unit. In-store recruitment involved the Māori and Pacific study recruiters approaching Māori and Pacific shoppers at the entrance to the supermarket informing them of the study, and asking them if they were willing to be involved. Since many of those recruited in-store or via community networks were not previously registered to use Shop 'N Go, new users were helped to sign up for the system and shown how to use it where

necessary. For both Māori and Pacific recruitment, the personality, networks and seniority of the Māori and Pacific people were considered critical to potential success.

Thus, specific strategies to enhance recruitment of Māori and Pacific shoppers were inclusion of Māori and Pacific researchers on the project team from inception; early consultation/focus groups with Māori and Pacific shoppers to obtain feedback on trial design, recruitment and interventions;¹² employment and training of Māori and Pacific recruiters; and community recruitment. Strategies to enhance general trial retention from the outset included regular mailed trial newsletters to all participants and inclusion in monthly draws for shopping vouchers.

Mid-way through trial recruitment (June 2007), monitoring of recruitment and enrolment rates indicated that targets for Māori and Pacific shoppers were unlikely to be met. In particular, Pacific recruitment was falling far short of targets. Thus, additional strategies were implemented. These included offer of an incentive of \$70 of shopping vouchers to all trial participants (\$20 on return of completed consent and baseline forms, and \$50 on completion of the study); a targeted media campaign, including media releases to local newspapers, radio and TV stations, and advertisements placed on bus shelters in areas with high proportions of Māori and Pacific residents; employment of three additional Pacific recruiters; and removal of non-essential and sensitive questions from forms to facilitate completion (see below for more details).

Data collection

The initial point of contact for trial staff with participants was either by telephone for shoppers who received a mailed invitation to participate in the SHOP trial or face-to-face for those approached in supermarket stores or via community networks. At this time, a brief registration form was completed comprising self-reported data on gender, age, ethnicity and the trial inclusion and exclusion criteria. The registration form was completed by research staff. Those who met inclusion and exclusion criteria were then either mailed or given a participant information sheet, baseline form and consent form, which they were asked to return by mail following self-completion. For those recruited in-store, study recruiters also offered assistance where necessary with completion of the baseline and consent forms.

The baseline questionnaire initially comprised 13 pages and 131 question items covering education, occupation, income, household composition, shopping and eating out habits, standard of living, and nutrition knowledge and food choices. When the questionnaire was streamlined to improve recruitment rates, it was shortened to four pages and 52 question items primarily by removing less critical sections relating to standard of living, nutrition knowledge and food choices.

Data analysis

Data on recruitment rates were collected from completed registration and baseline forms (where returned). Simple descriptive analyses were undertaken to describe recruitment rates by ethnicity, effectiveness of various recruitment strategies, demographic characteristics of study participants recruited in different ways, and the estimated costs per enrollee of different recruitment strategies.

RESULTS

Study recruitment rates over time by ethnicity

Over the 9-month recruitment period a total of 1926 potential participants were registered, of whom 1104 (57%) met trial

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inclusion and exclusion criteria and were randomised. Despite efforts to recruit approximately equal numbers across the main ethnic groups, clear differences emerged in numbers registered and randomised. Of the 1926 shoppers registered for whom ethnicity was known 622 (32%) were Māori, 402 (21%) Pacific and 899 (47%) were non-Māori, non-Pacific (table 1).

While additional strategies implemented mid-way through the trial recruitment period to improve recruitment of Māori and Pacific participants produced an increase in Māori and Pacific recruitment rates they also produced an even greater increase in non-Māori non-Pacific recruitment rates (fig 1).

Effectiveness of different recruitment strategies used

Overall, invitations sent by mail to registered Shop 'N Go users produced the greatest proportion of total trial registrations and randomisations. While the combination of community (n = 681) and in-store (n = 270) strategies almost matched the mailouts in registrations (n = 975), proportionally fewer participants registered using these methods progressed to randomisation.

Table 2 shows numbers randomised (and percentages of trial registrations) by ethnicity and recruitment strategy. Of the 1103 randomisations for whom ethnicity was known, 247 were Māori (22% of all randomisation, and 40% of Māori registrations), 101 Pacific (9% and 25%, respectively) and 755 (68% and 84%, respectively) were non-Māori, non-Pacific. Both ethnicity and recruitment strategy independently predicted successful randomisation. For example, within non-Māori non-Pacific, mailout (85%) was more successful than community (58%) and in-store (63%). Within community recruitment, non-Māori non-Pacific were more likely to be randomised (58%) than Māori (38%) and Pacific (25%).

Of those recruited via the community and in-store, the biggest reason by far for non-randomisation was not shopping regularly using Shop 'N Go (99% of non-randomisations),

whereas this accounted for a far smaller proportion of non-randomisations (14%) for those recruited via mailout.

Despite difficulties with community and in-store recruitment, without it Māori and Pacific recruitment would have been very poor (table 1). As expected, the large majority of shoppers recruited using the mailout were non-Māori non-Pacific (89%), while approximately 96% of those recruited using community or in-store recruitment was Māori or Pacific. Similarly, there were clear differences by strategy in education and income with more of those recruited via the community or in-store reporting no education (31% community, 32% in-store, 13% mailout) and lower household incomes (<NZ\$60 000 per year): 62% community, 76% in-store, 48% mailout). Unfortunately, because of income and education data being more likely to be complete for randomised versus non-randomised registrants, it was not possible to examine the predictive associations of socioeconomic position with randomisation.

Estimated costs of different recruitment strategies

The total cost of community and in-store recruitment was greater than the cost of mailout recruitment, mainly due to the higher staffing costs associated with the former (table 3). While the cost per registered participant was about three times greater for community and in-store recruitment than for mailout, the cost per randomised participant was almost eight times greater.

DISCUSSION

Recruitment for the SHOP trial demonstrates considerable challenges in recruiting indigenous and minority ethnic populations. Despite substantial investment in strategies aimed to improve recruitment of Māori and Pacific participants we did not reach our recruitment goal of approximately equal proportions of the three main ethnic groups in New Zealand.

Table 1 Demographic characteristics of registered participants by recruitment strategy (column percentages in parentheses)

	Mailout n = 975	Community n = 681	In-store n = 270	All N = 1926
Age, mean (SD)	46.3 (13.4)	39.5 (13.8)	38.4 (12.1)	42.8 (13.9)
Sex, n (%)				
Female	823 (84.4)	554 (81.4)	242 (89.6)	1619 (84.1)
Male	152 (18.5)	127 (18.6)	28 (11.6)	307 (19.0)
Ethnicity, n (%)				
Māori	79 (8.1)	352 (51.7)	191 (70.7)	622 (32.3)
Pacific	26 (2.7)	305 (44.8)	71 (26.3)	402 (20.9)
NMNP	867 (89.2)	24 (3.5)	8 (3.0)	899 (46.7)
Missing	3			3
Education, n (%)				
Primary or less	108 (13.0)	168 (31.0)	48 (31.8)	324 (21.2)
Secondary	298 (35.8)	154 (28.4)	60 (39.7)	512 (33.6)
University degree or diploma	311 (37.4)	175 (32.3)	37 (24.5)	523 (34.3)
Trade qualification	36 (4.3)	15 (2.8)	4 (2.6)	55 (3.6)
Other	79 (9.5)	30 (5.5)	2 (1.3)	111 (7.3)
Missing*	143	139	119	401
Household income, n (%)				
High (>\$60000/year)	402 (48.2)	85 (15.9)	32 (21.1)	519 (34.1)
Low (<\$60000/year)	402 (48.2)	331 (61.8)	115 (75.7)	848 (55.7)
Declined to answer	30 (3.6)	120 (22.4)	5 (3.3)	155 (10.2)
Missing*	141	145	118	404

*These questions were asked on the baseline form (ie, post-registration), which was not completed/returned by all registered participants.

NMNP, non-Māori, non-Pacific.

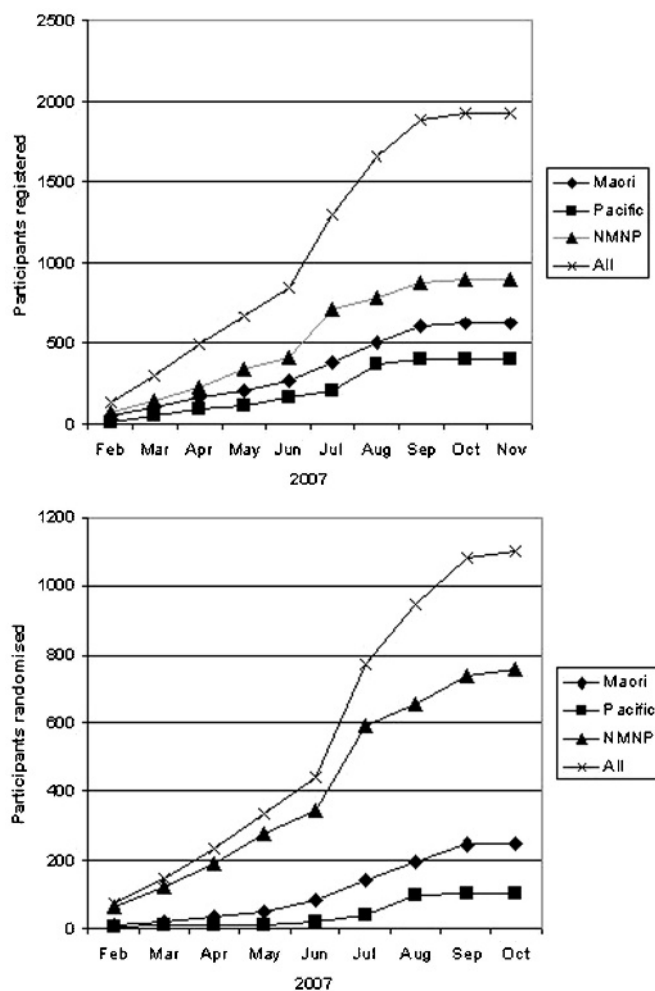


Figure 1 Cumulative registrations and randomisations. NMNP, non-Māori non-Pacific.

However, our findings provide insight into some more successful strategies that may aid other researchers with similar recruitment goals. In particular, community recruitment and networks appear to be a reasonably effective way of recruiting potential Māori and Pacific participants.

The first barrier to recruitment was simple demography. To have attained our goal of equal recruitment of Māori (15% of population), Pacific (7% of population) and non-Māori non-Pacific we would have needed to recruit over five times as many Māori per head of Māori population and over 10 times as many Pacific. The fact that the percentage distribution of Māori and Pacific in the final randomised sample (22% and 9%, respectively) exceeded the wider population prevalence is some measure of success.

The next biggest challenge to recruitment of Māori and Pacific participants for this trial appears to have been the requirement to use the electronic hand-held scanner system, Shop 'N Go. Although supermarkets do not collect data on ethnicity when shoppers register for the system, the low response to the mailout from Māori and Pacific shoppers suggests that relatively few Māori and Pacific shoppers overall use Shop 'N Go and/or that those who do are unlikely to respond to mailout as a method of recruitment.

While it was essential to use community and in-store recruitment to boost Māori and Pacific participation, these registrants were far less likely to already be registered users of Shop 'N Go than the mailout registrants. Thus, successful randomisation was lower among community and in-store recruits, including within the strata of ethnicity.

Randomisation for Māori and Pacific registrants, even within strata of recruitment strategy, was notably less (table 2). Some of these ethnic differences may have been due to underlying socioeconomic differences. Unfortunately, our socioeconomic data on those registered was not complete enough to allow robust assessment of any independent effect of socioeconomic position on randomisation, nor did we have socioeconomic data on all potential recruits (the community at large).

Informal feedback from potential Māori and Pacific trial participants who did not already use Shop 'N Go suggested reluctance to sign up for and use the system for a number of reasons, including apprehension regarding the use of technology and a perception of racism and 'increased surveillance' by supermarket staff. It was commonly believed that purchases of Māori and Pacific shoppers were more likely to be re-scanned than those of other shoppers.

A further challenge was the relative scarcity of Māori and Pacific expertise and workforce. While the study team includes Māori and Pacific co-investigators, a relatively small workforce and many competing demands on time limited the availability of Māori and Pacific researchers to actually undertake trial recruitment. Māori recruitment worked better because of the involvement of an established Māori social and health services provider with a proven track record. The challenges for Pacific recruitment were greater because there was no suitable local Pacific organisation available to take on a similar role, and Pacific recruiters were young without the necessary networks, expertise and skills.

Efforts were made to follow-up Māori and Pacific participants following registration, where possible, by their recruiters in order to maintain the relationship they had developed. However, because of resource constraints this task was also undertaken by non-Māori non-Pacific staff. This may have accounted for some of the attrition of Māori and Pacific participants between registration and randomisation. However, feedback also suggested that many potential participants misunderstood what they had signed up for, or didn't feel comfortable saying no at the point of registration.

Table 2 Randomisations by ethnicity and recruitment strategy

	Randomisations	Mailout	Community	In-store	All
Ethnicity	Māori, n (% Māori registrations)	48 (61)	132 (38)	67 (35)	247 (40)
	Pacific, n (% Pacific registrations)	16 (62)	76 (25)	9 (13)	101 (25)
	NMNP, n (% NMNP registrations)	736 (85)	14 (58)	5 (63)	755 (84)
	All, n (% all registrations)	800 (82)	222 (33)	81 (30)	1103 (57)

NMNP, non-Māori non-Pacific.

Table 3 Recruitment costs

Strategy	Staffing costs (NZ\$)	Postage costs (NZ\$)	Mileage and advertising costs (NZ\$)	Total costs (NZ\$)	Cost per registered participant (NZ\$)	Cost per randomised participant (NZ\$)
Mailout	24795	6961	–	31756	32.57	39.70
Community and in-store	80219	3295	7666	91180	95.88	300.92

Changes made mid-way through the trial to improve Māori and Pacific recruitment had the unexpected effect of increasing recruitment of all ethnic groups. Although this was not the aim it suggests opportunities to improve trial recruitment rates in general. The offer of incentives for trial participation and inclusion is commonly recognised as a way of increasing recruitment rates.¹⁵ Ensuring trial data collection is limited to essential information and questions are culturally appropriate is something all researchers should strive for, but particularly where they wish to recruit indigenous and minority ethnic groups.

The higher cost associated with community and in-store recruitment was not unexpected due to the higher staffing costs associated with these strategies. Since community recruitment was the most effective means to recruit Māori and Pacific participants for this trial it suggests that the greater resources and costs are crucial and should be factored into trial design and funding. In particular, funding organisations that prioritise inclusion of Māori and Pacific participants in health research need to be aware of the additional costs associated with effective recruitment. An important consideration is the feasibility of oversampling indigenous, ethnic minority or other priority populations for every research study. This simply may not be possible due to limited population numbers, and the inability of a relatively small health research workforce to provide sufficient input to all research.

What is already known on this subject

- ▶ In New Zealand, significant ethnic disparities exist in cause-specific mortality rates, with Māori and Pacific peoples suffering a disproportionate burden of cardiovascular disease and stroke.
- ▶ Health research should maximise participation and opportunity for health gain among Māori and Pacific groups.
- ▶ There is a critical lack of data on recruitment of these groups into intervention trials.

What this study adds

- ▶ The SHOP trial experienced considerable challenges in recruiting Māori and Pacific participants.
- ▶ Recruitment of these priority population groups was also associated with greater costs than recruitment of the majority population.
- ▶ Community recruitment and networks appear to be better trial enrolment strategies for indigenous and ethnic minority populations than passive strategies like mailouts.

In North America the National Institutes of Health Revitalization Act emphasises the scientific importance of the participation of women and minorities in clinical research. A large number of randomised, controlled trials from North America have published data on recruitment and retention strategies for racial and ethnic minorities.^{15–19} While some have been successful in their efforts to include minority populations,^{17–19} others have found it more challenging.¹⁶ There seems, however, to be broad agreement that successful strategies involve inclusion of target communities at the earliest opportunity and in all phases of design and research.^{15–17} One initiative based on this theory is the establishment of Resource Centers on Minority Aging Research.²⁰

Inclusion of indigenous and ethnic minority populations should be prioritised in intervention trials wherever possible in order to determine effectiveness of interventions for these high-risk groups. However, our experience in the SHOP trial demonstrates that recruitment of sufficient numbers to allow statistical analysis by ethnic group is a challenging and costly exercise. Ethnic differences in our trial recruitment may have been a function of a combination of factors, including underlying cultural factors, socioeconomic differences, technological barriers and perceived racism. Community-based recruitment involving key members of the target communities improves recruitment but is no panacea. To be maximally effective the community-based approach needs to be a true partnership and to allow sufficient time to build trusting relationships.¹⁷

Piloting of recruitment strategies and research methods should be undertaken in the contexts in which they are to be used to ensure acceptance by all ethnic groups. Interviews of trial non-participants to determine main reasons for non-participation could assist in identifying any factors requiring attention. If a similar supermarket trial were to be repeated in the future, we recommend the use of a simpler tracking system such as a personalised card that could be scanned at checkout to link individual shoppers to their food purchases.

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