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Published in:
The Lancet Digital Health

DOI:
10.1016/S2589-7500(19)30130-X

Publication date:
2019

Document Version
Publisher's PDF, also known as Version of record

A co-designed mHealth programme to support healthy lifestyles in Māori and Pasifika peoples in New Zealand (OL@-OR@): a cluster-randomised controlled trial

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Summary

Background The OL@-OR@ mobile health programme was co-designed with Māori and Pasifika communities in New Zealand, to support healthy lifestyle behaviours. We aimed to determine whether use of the programme improved adherence to health-related guidelines among Māori and Pasifika communities in New Zealand compared with a control group on a waiting list for the programme.

Methods The OL@-OR@ trial was a 12-week, two-arm, cluster-randomised controlled trial. A cluster was defined as any distinct location or setting in New Zealand where people with shared interests or contexts congregated, such as churches, sports clubs, and community groups. Members of a cluster were eligible to participate if they were aged 18 years or older, had regular access to a mobile device or computer, and had regular internet access. Clusters of Māori and of Pasifika (separately) were randomly assigned (1:1) to either the intervention or control condition. The intervention group received the OL@-OR@ mHealth programme (smartphone app and website). The control group received a control version of the app that only collected baseline and outcome data. The primary outcome was self-reported adherence to health-related guidelines, which were measured with a composite health behaviour score (of physical activity, smoking, alcohol intake, and fruit and vegetable intake) at 12 weeks. The secondary outcomes were self-reported adherence to health-related behaviour guidelines at 4 weeks; self-reported bodyweight at 12 weeks; and holistic health and wellbeing status at 12 weeks, in all enrolled individuals in eligible clusters; and user engagement with the app, in individuals allocated to the intervention. Adverse events were not collected. This study is registered with the Australian New Zealand Clinical Trials Registry, ACTRN12617001484336.

Findings Between Jan 24 and Aug 14, 2018, we enrolled 337 Māori participants from 19 clusters and 389 Pasifika participants from 18 clusters (n=726 participants) in the intervention group and 320 Māori participants from 15 clusters and 405 Pasifika participants from 17 clusters (n=725 participants) in the control group. Of these participants, 227 (67%) Māori participants and 347 (89%) Pasifika participants (n=574 participants) in the intervention group and 281 (88%) Māori participants and 369 (91%) Pasifika participants (n=650 participants) in the control group completed the 12-week follow-up and were included in the final analysis. Relative to baseline, adherence to health-related behaviour guidelines increased at 12 weeks in both groups (315 [43%] of 726 participants at baseline to 329 [57%] of 574 participants in the intervention group; 331 [46%] of 725 participants to 369 [57%] of 650 participants in the control group); however, there was no significant difference between intervention and control groups in adherence at 12 weeks (odds ratio [OR] 1·13; 95% CI 0·84–1·52; p=0·42). Furthermore, the proportion of participants adhering to guidelines on physical activity (351 [61%] of 574 intervention group participants *vs* 407 [63%] of 650 control group participants; OR 1·03, 95% CI 0·73–1·45; p=0·88), smoking (434 [76%] participants *vs* 501 [77%] participants; 1·12, 0·67–1·87; p=0·66), alcohol consumption (518 [90%] participants *vs* 596 [92%] participants; 0·73, 0·37–1·44; p=0·36), and fruit and vegetable intake (194 [34%] participants *vs* 196 [30%] participants; 1·08, 0·79–1·49; p=0·64) did not differ between groups. We found no significant differences between the intervention and control groups in any secondary outcome. 147 (26%) intervention group participants engaged with the OL@-OR@ programme (ie, set at least one behaviour change goal online).

Interpretation The OL@-OR@ mobile health programme did not improve adherence to health-related behaviour guidelines amongst Māori and Pasifika individuals.

Funding Healthier Lives *He Oranga Hauora* National Science Challenge.

Lancet Digital Health 2019; 1: e298–307

Published Online September 17, 2019 https://doi.org/10.1016/S2589-7500(19)30130-X

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Research in context

Evidence before this study

Mobile health (mHealth) programmes have been shown to produce modest improvements in several risk factors for non-communicable diseases (NCDs). We previously did a systematic review of co-designed mHealth interventions, to identify methods used in developing these interventions and to determine whether co-design with Indigenous and minority populations had been used. We searched six electronic databases (MEDLINE, Embase, PsycINFO, Scopus, CINAHL Plus, and Google Scholar) for relevant literature published between Jan 1, 2005, and Jan 31, 2016. Non-English language publications were excluded. We identified nine studies that used co-design or participatory methods to develop an mHealth intervention, three of which focused on health-related behaviours. Despite the alignment of co-design principles with the values of Indigenous and minority populations, we did not identify any previous studies that had used co-design to develop an mHealth intervention for these groups.

Added value of this study

The OL@-OR@ programme is unique in mHealth because it was co-designed with Māori and Pasifika communities in New Zealand to reduce the risk of NCDs by supporting healthy lifestyle behaviours. The communities participated in all stages of the study, including selection of the intervention approach, design of the app content and appearance, design of the randomised controlled trial (to evaluate the effectiveness of the programme), interpretation of trial findings, and dissemination activities. Our results, in conjunction with previous evidence on the modest effects of smartphone apps on health-related behaviours, suggest that app-based programmes that focus predominantly on individual behaviour change, have small effects on health-related behaviours at a population level.

Implications of all the available evidence

Comprehensive policies and programmes that include proven structural and system-level changes, in addition to supportive mHealth tools, are therefore required to achieve meaningful improvements in population health.

Introduction

Non-communicable diseases (NCDs) are a major contributor to the global burden of disease,[1] and they account for 88% of premature mortality and morbidity in New Zealand.[2] Tobacco use, unhealthy diets, obesity, physical inactivity, and alcohol use are all major risk factors for NCDs.[1] However, there are substantial inequalities in the prevalence of risk factors and health outcomes across population groups.[2] For example, Māori (the Indigenous people of New Zealand; 15% of the population) adults living in New Zealand show obesity rates 1·7 times higher than those of non-Māori peoples, and Pasifika (the collective term for peoples from different Pacific Island nations; 7% of the population) adults living in New Zealand show obesity rates 2·3 times higher than those of non-Pasifika peoples.[3] The drivers of these high rates of obesity are complex, but historical mistreatment of these communities, cultural disconnection, and structural racism have socioeconomic consequences that predispose Māori and Pasifika peoples to obesity and obesity-related illnesses.[4] Little research has been done to date on genetic or epigenetic factors that might increase susceptibility to obesity in Māori and Pasifika peoples, but lifestyle interventions indicate that clinically significant health benefits can be achieved through changes in diet and frequency of activity.[5]

Mobile health (mHealth) programmes use mobile and wireless technologies to support health and improve medical outcomes,[6] and they have been shown to be effective in supporting people to quit smoking,[7,8] lose weight,[9] become more physically active,[10] and improve other secondary risk factors for NCDs, such as increased blood pressure.[11] Although it is common for mHeath programmes to be developed with end-user input, few have been co-designed from conceptualisation and design to evaluation, and these programmes are often not tailored to specific cultural needs.[12,13] Co-designing an mHealth programme has the potential to increase its uptake by enabling this tailoring and by providing a sense of ownership among target end users.[12]

The OL@-OR@ mHealth programme was co-designed with Māori and Pasifika communities in New Zealand, to help individuals and their communities improve their health and wellbeing by making positive changes to health-related behaviours.[14] Co-design methods were used to understand the needs and aspirations of Māori and Pasifika communities.[15,16] Models of health and wellbeing that were specific to Māori and Pasifika peoples[17,18] were used to interpret focus group findings, and an mHealth tool was co-designed with these focus groups, that incorporated relevant content and features that aligned with the needs and wants of these communities. The theoretical domains framework[19] and behaviour change taxonomy[20] were then used to identify evidence-based behavioural determinants and behavioural change techniques that aligned with and could be incorporated into the content and features of the OL@-OR@ programme.

The aim of our study was to determine whether use of the co-designed OL@-OR@ mHealth programme improved adherence to health-related behaviour guidelines among Māori and Pasifika communities in New Zealand compared with a control group on a waiting list for the programme.

Methods

Study design and participants

The OL@-OR@ trial was a 12-week, two-arm, cluster-randomised controlled trial. This study design was considered the most appropriate way to evaluate the community-level intervention. A cluster was defined as any distinct location or setting in New Zealand where people with shared interests or contexts congregated. These clusters could include churches, *marae* (Māori meeting grounds), schools, workplaces, sports clubs, or community groups. Māori and Pasifika groups or communities were identified and recruited by community coordinators who were employed for this purpose by three Māori or Pasifika health provider organisation partners: Toi Tangata, The Fono Health and Social Services, and South Waikato Pacific Islands Community Services Trust. Community coordinators identified potential communities, many of which were groups already known to the three organisation partners. Word of mouth, and advertising on community organisation websites, in newsletters, and on Facebook, were also used for cluster recruitment. Coordinators would meet with the group leader, explain what was involved with the study, and give them a community information sheet and participant information sheets for individual participants. Small amounts of money (NZ$500 per cluster) were given to clusters whose members completed follow-up at 12 weeks.

Members of a participating cluster were eligible to participate if they resided in New Zealand; were aged 18 years or older; had regular access to a mobile phone, tablet, laptop, or computer; had regular access to the internet (at least once a week); were able to provide written consent electronically; and had an email address or were prepared to create an email account. Individuals were also able to enrol in the trial if they were invited by an existing trial participant via the OL@-OR@ tool, or if they shared a mobile phone with a trial participant who had downloaded the OL@-OR@ tool onto that device. Invitees were allocated to the same groups as the person who invited them.

All communities provided written informed consent, and individual participants provided informed consent via an online questionnaire completed at registration. The study protocol was approved by the Northern B Health and Disability Ethics Committee (reference 17/NTB/152), and it has been published previously.[21]

Randomisation and masking

Clusters of Māori and of Pasifika (separately) were randomly assigned (1:1) to either the intervention or control condition by use of a computer-generated randomisation list prepared by the study statistician (YJ). Participants in clusters assigned to the intervention condition received the OL@-OR@ programme (with smartphone app and website access), whereas those assigned to the control condition received a control version of the OL@-OR@ tool that was similar in visual design, but that only collected baseline and outcome data. We used block randomisation, with variable block sizes of two and four, stratified by locality (Auckland or Waikato) for Pasifika clusters and by region (rural, urban, or provincial) for Māori clusters. The randomisation list and codes were kept securely in a restricted-access computer file, which was only accessible by the project manager (JG) and project coordinator (JS), who disclosed allocation to the community coordinators at the time of randomisation.

Due to the nature of the intervention, it was not possible to mask study participants or research staff to cluster allocations. The risk of contamination between clusters was minimised by recruitment of distinct clusters located in different regions and communities around New Zealand.

Procedures

Participants in the intervention group clusters could download the OL@-OR@ app from the app store or they could access it via the internet with a login code that they received at study registration. The OL@-OR@ programme provided information on healthy eating and physical activity, culturally relevant information, and links to local activities and services. The programme supported users to set goals to change their health behaviours and to identify the steps needed to reach their goals. Users were also encouraged to invite other people from their community to join with them in changing their behaviour alongside them. Lifestyle trackers helped to monitor the progress of participants towards achieving their goals, and data could either be entered manually into trackers or users could sync the native health app on their mobile phone with the OL@-OR@ app. Regular culturally tailored tips on eating healthily, being more active, reducing stress, improving sleep, and managing weight were sent as app notifications (four to five tips per week). Participants who smoked also received a weekly message encouraging cessation of smoking. Regular motivational messages were sent to all intervention participants, which encouraged them to continue with changes they were making and to review or set new goals.

The app contained culturally relevant information, such as about activity groups specifically for Māori and Pasifika, promotion of wellbeing through *atua* (gods) concepts, *tikanga* (Māori customs), blessings, culturally relevant recipes, *whakatauki* (Māori proverbs), and culturally tailored motivational messages. Cultural icons, such as *flax kete* (bags) and *hei tiki* (a carved jade deity) and imagery were used as virtual rewards when participants achieved their goals.

The programme was designed to be fully customisable, allowing users to set their own healthy lifestyle challenges and share content with their community group. Although the app was pre-programmed with a list of generic

Figure 1: **Examples of OL@-OR@ app features**
(A) Tracking progress towards achieving goals. (B) Virtual rewards. (C) Food record. (D) Culturally relevant information on healthy food practices (Food of the Gods).

behaviour change goals (eg, to walk for 30 min five times per week, to increase their fruit and vegetable intake to five servings per day, and to get 8 h of sleep per night), participants could set individually defined goals and update their own progress towards goals. When a goal was achieved, the participant received a virtual reward. For example, Pasifika participants who achieved one goal would receive one virtual coconut, and each subsequent goal achieved would result in another reward reflecting a further part of the coconut life cycle, until five goals had been achieved and a coconut tree was fully grown and added to their virtual plantation. Several OL@-OR@ programme features are shown in figure 1, indicating how cultural relevance was reflected in the content. Questionnaires completed by all participants at baseline, 4 weeks, and 12 weeks collected information on sociodemographic factors (baseline only), self-reported weight and height, health status, physical activity, smoking behaviour, alcohol intake, fruit and vegetable consumption, and holistic wellbeing.

Participants in clusters assigned to the control condition received a control version of the OL@-OR@ app, which collected baseline and outcome data via baseline, 4-week, and 12-week questionnaires and provided a countdown to the end of the study, when control participants could download the OL@-OR@ app to use for as long as they wished. The control group questionnaires were the same as those completed by the intervention group, but they did not include questions about the OL@-OR@ programme.

We based our measurement of adherence to health-related behaviour guidelines on the self-reported composite health behaviour score used by the European Prospective Investigation into Cancer-Norfolk Prospective Population Study,[22] which we adapted for New Zealand.[23] Scores range from 0 to 4, dependent on the number of health guidelines met. Individuals were classified as adherent if they scored 3 or more (out of a maximum score of 4) and non-adherent if they scored 2 or less. The health behaviours that we assessed were smoking, measured as a 7-day point prevalence of self-reported smoking abstinence (as scores of 1 [not currently smoking] or 0 [had at least one cigarette in the past 7 days]); fruit and vegetable intake, measured by questions used in the New Zealand Health Survey[3] (scores of 1 [at least five daily servings] or 0 [four or fewer daily servings]); alcohol intake, measured with the Alcohol Use Disorders Identification Test[24] (scores of 1 [13 units or fewer per week] or 0 [at least 14 units per week]); and physical activity, measured by the Godin Leisure-Time Physical Activity Questionnaire[25] (scores of 1 [at least 24 units of moderate-to-vigorous activity per week] or 0 [23 units or fewer of moderate-to-vigorous activity per week]). Scoring of the Godin Leisure-Time Physical Activity Questionnaire adds the reported weekly frequency of participation at each of three physical activity levels (strenuous, moderate, or light), and multiplies this value by the corresponding metabolic equivalent of task (MET) value (9, 5, or 3 METs).

Holistic health and wellbeing status was measured in Māori people by use of 16 questions that were informed by Māori health models[17] and adapted from the Hua Oranga Māori Mental Health Assessment Questionnaire.[26] Holistic health and wellbeing status was measured in Pasifika people by use of ten questions that were informed by a Pacific health model,[18] the Ottawa Charter,[27] and Hua Oranga.[26]

Although we used a relatively short follow-up period (12 weeks), user engagement with apps is typically higher in the short term and tends to wane over time. For example, the average period of app use is 2 months,[28] and only 27% of participants in another study[29] were still using the app at a 14-week follow-up. We therefore reasoned that we were likely to see greater effects over the short term than long term.

This study was a large mHealth intervention trial, and data collection was undertaken entirely via the study app and website. This study design, along with the geographic spread of the communities across New Zealand, meant that physiological measurements were impracticable. With large-scale population studies that involve low face-to-face contact with participants, self-report measures, such as those used here, are generally well accepted.[30]

Outcomes

The primary outcome was self-reported adherence to health-related behavioural guidelines (physical activity, smoking behaviour, alcohol intake, fruit and vegetable consumption (primary outcome was a composite measure of all four behaviours) at 12 weeks. The secondary outcomes were self-reported adherence to health-related behaviour guidelines at 4 weeks; self-reported bodyweight at 12 weeks; holistic health and wellbeing status at 12 weeks; and 12-week user engagement in all intervention participants. Consent was sought for longer-term follow-up of participants (beyond the 12-week follow-up period of the trial) via the New Zealand Integrated Data Infrastructure (IDI). Further funding will be required to enable such follow-up via the IDI.

We assessed user engagement and interaction with the OL@-OR@ app with an accepted engagement index.[31] However, it proved impossible to use the index because the necessary Google Analytics data were not available at unique individual user level. As such, a decision was made to define user engagement with the programme as having set at least one behaviour change goal within the app or website (ie, system-recorded). All measures were assessed at an individual level, but they were analysed and reported at the cluster level.

Detailed analyses of holistic wellbeing status for Māori and Pasifika are planned and will be published separately. Adverse events were not collected.

Statistical analysis

We aimed to recruit 1280 participants from 64 community clusters (32 Māori, 32 Pasifika), with an average of 20 participants per cluster. Our sample size calculation was based on self-reported adherence to health-related behaviour guidelines (the primary outcome). We estimated that recruitment of 32 clusters (16 clusters per group) with 640 individual participants (20 individuals per cluster) would provide 80% power at a 5% level of significance (two-sided) to detect a between-group absolute difference of 15% in the primary outcome 12 weeks after randomisation, assuming 30% of individuals in the control group were adherent and an intracluster correlation coefficient of 0·05. To have sufficient power to undertake separate subgroup analyses for Māori and Pasifika clusters, we aimed to recruit 64 clusters (32 Māori, 32 Pasifika) with a total of 1280 participants.

The effect of the intervention was evaluated with an intention-to-treat analysis, including all clusters in the group that they were randomly assigned to, irrespective of whether the participants in each cluster received or used the intervention. Clusters that withdrew from the study or did not register any participants at baseline were excluded before participant recruitment. The proportion of participants who were adherent to health-related guidelines (defined as three or more of four behaviours) at the end of the 12-week intervention period was compared between the two treatment groups by use of generalised linear mixed models with a random cluster effect and adjustment for baseline outcome, cluster region, and ethnicity (stratification factors). Clusters with fewer than five participants were excluded from the final analysis to minimise bias. Missing participant data were incorporated into the mixed model estimates by maximum likelihood, based on the assumption that data were missing at random. Similar regression analyses were undertaken for secondary outcomes and intracluster correlation coefficients were estimated. Prespecified subgroup analyses were done for Māori and Pasifika clusters separately. An exploratory analysis was also done, which only assessed the subset of intervention group participants who engaged with the OL@-OR@ programme (ie, set at least one behaviour change goal). Statistical analyses were done with SAS version 9.4. All statistical tests were two-tailed, and a p value of less than 0·05 was considered statistically significant. This study is registered with the Australian New Zealand Clinical Trials Registry, ACTRN12617001484336.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Between Jan 22 and July 31, 2018, community coordinators invited 83 community clusters to participate in the study, all of whom agreed, were enrolled into the trial, and were

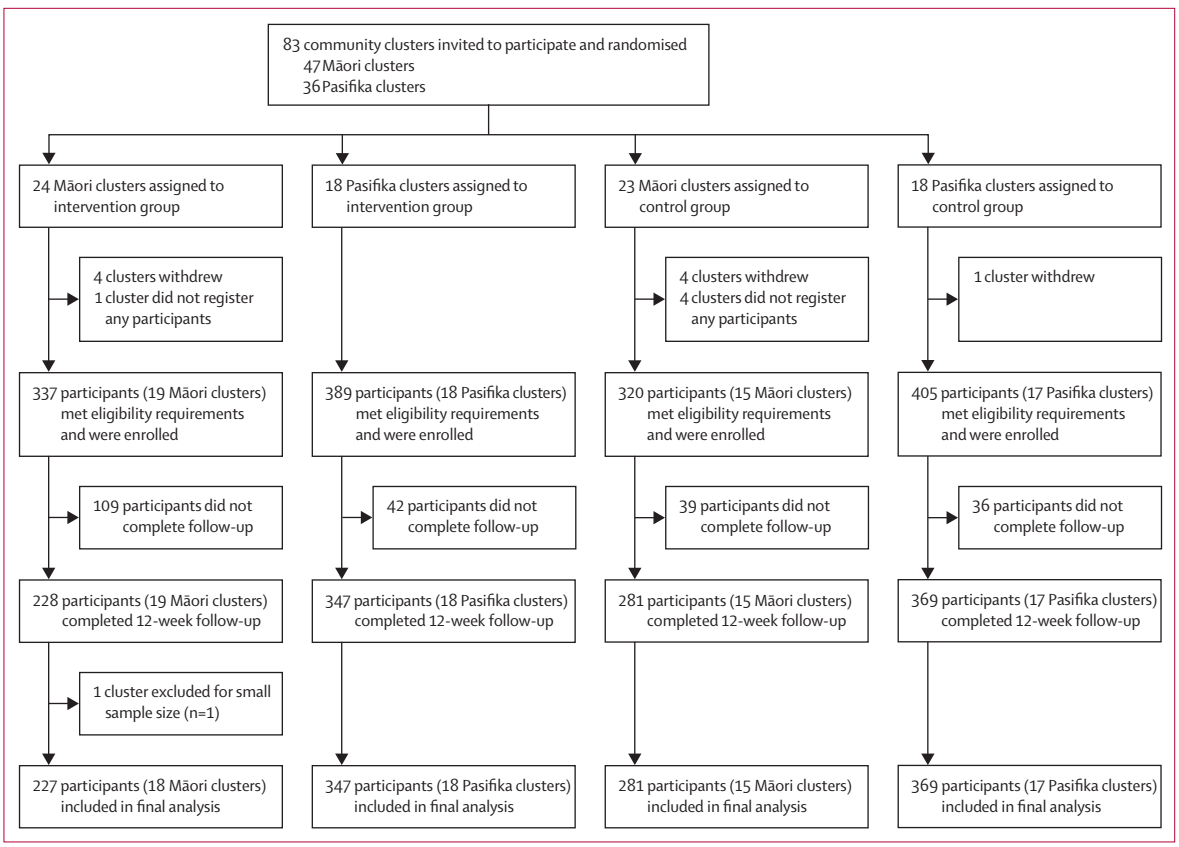

Figure 2: **Trial profile**

randomly assigned to groups (24 Māori and 18 Pasifika clusters to the intervention group and 23 Māori and 18 Pasifika clusters to the control group; figure 2). Four clusters in the intervention group (all Māori) and five clusters in the control group (four Māori and one Pasifika) withdrew after randomisation, and one cluster in the intervention group (Māori) and four clusters in the control group (all Māori) did not register any participants at baseline. Between Jan 24 and Aug 14, 2018, we enrolled 337 Māori participants from 19 clusters and 389 Pasifika participants from 18 clusters (n=726 participants) in the intervention group and 320 Māori participants from 15 clusters and 405 Pasifika participants from 17 clusters (n=725 participants) in the control group. Of these participants, 227 (67%) Māori participants and 347 (89%) Pasifika participants (n=574 participants) in the intervention group and 281 (88%) Māori participants and 369 (91%) Pasifika participants (n=650 participants) in the control group completed the 12-week follow-up and were included in the final analysis. Only one (<1%) participant of those who completed follow-up (from one cluster in the intervention group, among the Māori participants) was excluded from the final analysis, because the cluster only contained one participant.

The 14 clusters who withdrew or did not register participants did not significantly differ from those that remained in the study regarding key cluster-level characteristics, such as geographical region (p=0·57) or group type (p=0·50). The 69 study communities were predominantly located in urban areas, and the predominant cluster types included social community groups (n=20), sports or fitness groups (n=18), and church communities (n=11; table 1). The mean age of study participants was 38·9 years (SD 13·4) in the intervention group and 36·3 years (12·1) in the control group. 69% of the intervention group participants and 70% of the control group participants were female.

Over the 12-week intervention period, 23 233 notifications were sent to intervention group participants (mean 40 notifications per participant [SD 37]), of which 1631 (7%) notifications were logged as opened or read. 352 (61%) participants did not open any notifications, and the proportion of individuals opening these notifications were similar between Māori and Pasifika participants (140 [62%] participants *vs* 212 [61%] participants). However, the number of notifications opened might not reflect the actual number read because it is possible to read notifications on-screen and remove them from the screen without viewing them in-app (which would not have been logged as read).

Relative to baseline, adherence to individual health-related behaviour guidelines increased at 12 weeks in

	Māori		Pasifika		All	
	Intervention group (19 communities, 337 participants)	Control group (15 communities, 320 participants)	Intervention group (18 communities, 389 participants)	Control group (17 communities, 405 participants)	Intervention group (37 communities, 726 participants)	Control group (32 communities, 725 participants)
Community characteristics						
Group type						
Community group	4 (21%)	3 (20%)	7 (39%)	6 (35%)	11 (30%)	9 (28%)
Fitness or sports group	6 (32%)	7 (47%)	2 (11%)	3 (18%)	8 (22%)	10 (31%)
Church group	0	1 (7%)	7 (39%)	3 (18%)	7 (19%)	4 (13%)
Extended family	4 (21%)	2 (13%)	0	0	4 (11%)	2 (6%)
School or kindergarten	1 (5%)	0	0	2 (12%)	1 (3%)	2 (6%)
Other group or social network	4 (21%)	2 (13%)	2 (11%)	3 (18%)	6 (16%)	5 (16%)
Location						
Urban area	12 (63%)	12 (80%)	12 (67%)	10 (59%)	24 (65%)	22 (69%)
Rural area	7 (37%)	3 (20%)	6 (33%)	7 (41%)	13 (35%)	10 (31%)
Participant characteristics						
Age, years	38·2 (12·2)	36·3 (11·9)	39·6 (14·4)	36·4 (12·3)	38·9 (13·4)	36·3 (12·1)
Sex						
Female	242 (72%)	230 (72%)	260 (67%)	280 (69%)	502 (69%)	510 (70%)
Male	94 (28%)	89 (28%)	128 (33%)	125 (31%)	222 (31%)	214 (30%)
Gender diverse	1 (<1%)	1 (<1%)	1 (<1%)	0	2 (<1%)	1 (<1%)
Qualification after secondary school	192 (57%)	180 (56%)	157 (40%)	186 (46%)	349 (48%)	366 (50%)
Weight, kg	95·2 (22·0)	93·6 (22·8)	102·0 (25·2)	102·4 (26·8)	98·8 (24·0)	98·6 (25·5)
Body-mass index, kg/m²	33·1 (7·2)	33·1 (8·3)	35·5 (10·0)	36·3 (10·4)	34·4 (8·8)	34·8 (9·6)
Physical activity						
Godin score	27·1 (24·0)	30·4 (24·9)	27·9 (30·4)	29·8 (31·2)	27·5 (27·6)	30·0 (28·6)
Meets physical activity guideline (Godin score ≥24)	157 (47%)	170 (53%)	192 (49%)	208 (51%)	349 (48%)	378 (52%)
Smoking						
Current smoker	91 (27%)	57 (18%)	78 (20%)	94 (23%)	169 (23%)	151 (21%)
Meets smoking guideline (no cigarettes in the past 7 days)	240 (71%)	259 (81%)	302 (78%)	301 (74%)	542 (75%)	560 (77%)
Alcohol						
Number of alcoholic drinks per week	6·2 (6·9)	4·6 (6·7)	2·9 (4·7)	3·7 (6·2)	4·4 (6·1)	4·1 (6·4)
Meets alcohol guideline (<14 drinks per week)	300 (89%)	282 (88%)	364 (94%)	368 (91%)	664 (91%)	650 (90%)
Fruit and vegetable intake						
Number of servings of fruit and vegetables per day	3·3 (2·0)	3·3 (2·1)	3·2 (2·2)	3·0 (1·9)	3·2 (2·1)	3·1 (2·0)
Meets fruit and vegetable intake guideline (at least five fruit or vegetable servings per day)	86 (26%)	77 (24%)	100 (26%)	79 (20%)	186 (26%)	156 (22%)
Adherence to guidelines						
Composite health behaviour score	2·4 (0·8)	2·5 (0·9)	2·5 (0·9)	2·4 (0·8)	2·5 (0·9)	2·5 (0·9)
Adherent (meets criteria for at least three behavioural guidelines)	134 (40%)	154 (48%)	181 (47%)	177 (44%)	315 (43%)	331 (46%)

Data are n (%) or mean (SD). Godin score was measured with the Godin Leisure-Time Physical Activity Questionnaire.[25]

Table 1: **Baseline community and participant characteristics**

both groups (table 2). However, the proportion of participants adhering to guidelines on physical activity (351 [61%] of 574 intervention group participants *vs* 407 [63%] of 650 control group participants; odds ratio [OR] 1·03, 95% CI 0·73–1·45; p=0·88), smoking (434 [76%] participants *vs* 501 [77%] participants; 1·12, 0·67–1·87; p=0·66), alcohol consumption (518 [90%] participants *vs* 596 [92%] participants; 0·73, 0·37–1·44; p=0·36), and fruit and vegetable intake (194 [34%] participants *vs* 196 [30%] participants; 1·08, 0·79–1·49; p=0·64) did not differ between groups. Similar results were obtained in Māori and Pasifika

subgroup analyses. Overall, 329 (57%) intervention group participants and 369 (57%) control group participants adhered to the guidelines for three or more health-related behaviours at 12 weeks (OR 1·13, 95% CI 0·84–1·52]; p=0·42; table 3).

	Intervention, n (%)	Control, n (%)	Odds ratio (95% CI)	p value	Intraclass correlation coefficient
Māori*					
Physically active (Godin score ≥24)	145 (64%)	190 (68%)	0·95 (0·61–1·47)	0·81	0·01
Non-smoker (no cigarettes in the past 7 days)	166 (73%)	221 (79%)	1·13 (0·53–2·41)	0·75	<0·0001
Low alcohol intake (<14 drinks per week)	202 (89%)	260 (93%)	0·62 (0·22–1·74)	0·36	0·01
Five or more servings of fruit or vegetables per day	79 (35%)	93 (33%)	0·96 (0·60–1·54)	0·86	0·02
Pasifika†					
Physically active (Godin score ≥24)	206 (59%)	217 (59%)	1·05 (0·65–1·69)	0·84	0·05
Non-smoker (no cigarettes in the past 7 days)	268 (77%)	280 (76%)	1·15 (0·54–2·45)	0·72	0·02
Low alcohol intake (<14 drinks per week)	316 (91%)	336 (91%)	0·92 (0·34–2·52)	0·88	<0·0001
Five or more servings of fruit or vegetables per day	115 (33%)	103 (28%)	1·21 (0·80–1·84)	0·37	0·02
All‡					
Physically active (Godin score ≥24)	351 (61%)	407 (63%)	1·03 (0·73–1·45)	0·88	0·05
Non-smoker (no cigarettes in the past 7 days)	434 (76%)	501 (77%)	1·12 (0·67–1·87)	0·66	0·01
Low alcohol intake (<14 drinks per week)	518 (90%)	596 (92%)	0·73 (0·37–1·44)	0·36	<0·0001
Five or more servings of fruit or vegetables per day	194 (34%)	196 (30%)	1·08 (0·79–1·47)	0·64	0·02

Godin score was measured with the Godin Leisure-Time Physical Activity Questionnaire.[25] *Of 227 participants from 18 communities (intervention group) versus 281 participants from 15 communities (control group). †Of 347 participants from 18 communities (intervention group) versus 369 participants from 17 communities (control group). ‡Of 574 participants from 36 communities (intervention group) versus 650 participants from 32 communities (control group).

Table 2: **Adherence to health-related behaviour guidelines at 12 weeks**

We found no significant differences between intervention and control groups in self-reported adherence to health-related behaviour guidelines at 4 weeks, self-reported bodyweight at 12 weeks, nor in holistic health and wellbeing status at 12 weeks (data not shown).

147 (26%) intervention group participants engaged with the OL@-OR@ programme (ie, set at least one behaviour change goal online, via the programme app or website). The exploratory analysis, which compared engaged participants with the control group, indicated that those who engaged with the programme showed significantly greater adherence to health-related behaviour guidelines at 12 weeks than the control group (94 [64%] of 177 engaged intervention group participants *vs* 369 [57%] control group participants; OR 1·88, 95% CI 1·19–2·98; p=0·0069; table 3). We also observed a significant effect relative to the control group in engaged Pasifika subgroup participants (50 [66%] of 76 participants *vs* 201 [55%] of 369 participants; 2·94, 1·50–5·78; p=0·0018), but not for engaged Māori participants (44 [62%] of 71 participants *vs* 168 [60%] of 281 participants; 1·14, 0·57–2·30; p=0·71).

Discussion

In this large cluster-randomised controlled trial, which evaluated an mHealth programme to support healthy behaviour change that was co-designed with the relevant communities, the OL@-OR@ mHealth programme did not significantly improve adherence to health-related behaviour guidelines by Māori and Pasifika adults compared with a control group with an app that simply collected outcome data. The co-design method that we used throughout the study led to a strong sense of ownership and investment in the OL@-OR@ tool by the community coordinators, who were key to the rapid recruitment of a large number of Māori and Pasifika communities into the trial. However, co-design of the programme did not lead to more positive outcomes in the intervention group relative to the control group. We found low engagement of intervention participants with the programme: only approximately one-quarter of participants set a behaviour change goal in the app or online.

	Intention-to-treat analysis					Exploratory analysis based on level of engagement				
	Intervention, n (%)	Control, n (%)	Odds ratio (95% CI)	p value	Intraclass correlation coefficient	Intervention, n (%)*	Control, n (%)	Odds ratio (95% CI)	p value	Intraclass correlation coefficient
Māori†	131 (58%)	168 (60%)	1·05 (0·64–1·73)	0·85	0·02	44 (62%)	168 (60%)	1·14 (0·57–2·30)	0·71	0·0235
Pasifika‡	198 (57%)	201 (55%)	1·16 (0·81–1·65)	0·42	<0·0001	50 (66%)	201 (55%)	2·94 (1·50–5·78)	0·0018	0
All§	329 (57%)	369 (57%)	1·13 (0·84–1·52)	0·42	0·01	94 (64%)	369 (57%)	1·88 (1·19–2·98)	0·0069	0·0144

Data are individuals who were adherent to at least three guidelines. Intervention data in the per-protocol analysis only include participants who set at least one behaviour change goal. *Of 71 participants from 15 communities (Māori); 76 participants from 16 communities (Pasifika); or 147 participants from 31 participants (all). †Of 227 participants from 18 communities (intervention group) versus 281 participants from 15 communities (control group). ‡Of 347 participants from 18 communities (intervention group) versus 369 participants from 17 communities (control group). §Of 574 participants from 36 communities (intervention group) versus 650 participants from 32 communities (control group).

Table 3: **Composite adherence to health-related behaviour guidelines by analysis method**

Strengths of the OL@-OR@ trial include its large sample size with sufficient power to undertake separate analyses for Māori and Pasifika, use of a rigorous randomised controlled design with high internal validity, and high follow-up rates. To our knowledge, this study is the first to co-design and evaluate an mHealth programme in partnership with Indigenous populations who are disproportionally affected by NCDs and their risk factors.[12] Community feedback on the co-design approach and the experience of these communities of being involved in the research was uniformly positive, which was reflected in excellent recruitment and high follow-up rates (in terms of study questionnaire completion) among communities that often do not have positive experiences with mainstream research approaches.

Some limitations should be considered. First, the study control communities might have been so-called active controls, the behaviours of whom might not be reflective of real-world behaviour in the absence of engagement by the study team. Community coordinators engaged regularly, in person and by telephone, with both intervention and control clusters throughout the 12-week trial. There were three purposes of this engagement: to support individual participants to access the programme (via smartphone or online) and to troubleshoot any problems encountered with the app, to remind participants to complete study questionnaires, and to maintain existing important relationships with all study communities. Study logs indicate that coordinators spent an average of 21 h per community in face-to-face community engagement (both intervention and control) over the 11-month trial, which they supplemented with telephone calls and text messages. The regular contact might have increased awareness of health in the control communities, and thus motivated control participants to make behaviour changes during the 12-week study. This premise could describe the observed increase in self-reported adherence to guidelines over time in the control communities, even though they did not have access to the OL@-OR@ programme. Nevertheless, the mHealth intervention did not have a substantial effect beyond that achieved through coordinator engagement with the communities.

Second, the large number of study participants who reported relatively high adherence to some health-related behaviour guidelines at baseline (eg, in smoking and hazardous drinking) suggests a selection bias in our study population that might have led to a ceiling effect in the primary outcome, whereby it was more difficult to detect improvements in behaviour by individuals who were already following a healthy lifestyle. In our sample size calculation, we assumed the proportion of individuals in the control group who were adherent to guidelines would be 30%. However, at baseline, 44% of the study sample was adherent to three or more guidelines, and this proportion increased over time in both groups. Greater impact might be possible among programme users with less healthy lifestyles and in individuals with health conditions that might provide a greater incentive for behaviour change.

Third, unlike short message service-based mHealth programmes, which push messages and content to recipients, smartphone apps require active engagement for users to derive maximal benefit from their features and content. Additionally, apps require data access, adequate storage capacity on mobile phones, and a level of digital literacy and digital confidence, all of which can contribute to low engagement.[32] Our findings are consistent with other studies[33,34] of healthy lifestyle behaviour apps, which show modest effects on health-related behaviours and that engagement with the intervention is linked to intervention efficacy.

Finally, other potential study limitations include our use of self-reported behaviour outcome measures and the short duration of follow-up. Although each of these factors could either augment or ameliorate the measured effect of the study intervention, the rigorous randomised controlled study design means that the limitations affected both intervention and control groups equally, and we can be confident of the validity of the between-group comparisons reported.

In conclusion, at the low level of engagement observed in this trial, participation in the OL@-OR@ programme did not significantly affect adherence to health-related behaviour guidelines relative to that in the control group. These results, in conjunction with previous evidence on smartphone apps, suggest that app-based tools, which tend to focus predominantly on individual behaviour change, have small effects on health-related behaviours at a population level. In the absence of structural changes to make healthy behaviours the easy option, educational mHealth tools will probably only have a low impact, irrespective of the degree of participation of the target populations in their design. Comprehensive policies and programmes that include proven structural and system-level changes, in addition to mHealth tools, are therefore required to achieve meaningful improvements in population health.

Contributors

CNM, AJ, and RW formulated the study concept and designed the research. CNM, LTM, and RT-F oversaw and executed the study. RD, MV, GH, and DG designed the intervention and developed the programme features. JG and JS managed the daily conduct of the study. SD, TF, EH, AH, LL-T, CP, DP-H, and MT oversaw recruitment and data collection. YJ did the statistical analyses of the study data. CNM wrote the paper and had primary responsibility for its final content. All authors interpreted the data, provided critical review and commentary on the draft manuscript, and approved the final manuscript.

Declaration of interests

We declare no competing interests.

Data sharing

The research team will consider reasonable requests to share deidentified patient-level data from the study, which will be made available with publication. Requests should be made to the corresponding author after approval of a proposal with a signed data access agreement. Consent from participants for data sharing was not

obtained, but the data are anonymised, and the risk of identification is low. The original protocol will be made available from the corresponding author on request, and has previously been published.

Acknowledgments

This investigator-initiated study was funded by a Healthier Lives *He Oranga Hauora* National Science Challenge project grant. We are indebted to our 69 community clusters and 1451 study participants. We would also like to thank Koda Web Design, who developed the OL@-OR@ wireframes, staff at the National Institute for Health Innovation who were involved in data management, app and web development, and contracting (John Faatui, Michelle Jenkins, Manoj Alwis, Mahfuz Rahman, Dongho Park, Sarah Douglas, and Karen Carter), Valery Yi-Zhuo Liu who assisted with assessing user engagement with the app, and Ralph Maddison, who advised on assessment of compliance with physical activity guidelines.

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