Protocol

Supporting healthy lifestyles: A Māori and Pasifika mHealth approach
Phase 2: a cluster-randomised controlled trial.

Trial Registration Number: ACTRN12617001484336

(Universal Trial Number U1111-1199-5010)

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Project Sponsors

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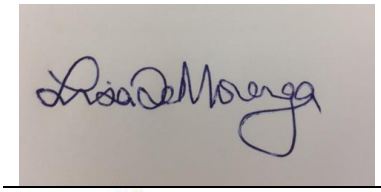
Signature Page

Coordinating investigator(s):

Name	Signature:	Date:
Prof Cliona Ni Mhurchu		27 July 2017
Dr Lisa Te Morenga		27 July 2017
Dr Tupa'ilevaililigi Ridvan Tupa'i-Firestone		27 July 2017

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Version 1.0	27/07/2017	Final
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Version 3.0	11/04/2018	Final
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1. Overview

Title of study: OL@-OR@ Trial

Investigators and study centres: This study has been designed jointly by independent investigators at the National Institute for Health Innovation (NIHI), University of Auckland, Auckland; Centre for Public Health Research, Massey University, Wellington; Department of Human Nutrition, University of Otago, Dunedin; and partners at Toi Tangata, The Fono, and South Waikato Pacific Islands Community Services Trust. The overall design and conduct of this trial is the joint responsibility of the Principal Investigators and project team. Publication of data from this trial will be the responsibility of members of the university team. The study will be co-ordinated by NIHI.

Study period: November 2017 – December 2018

Objectives: The primary objective of this trial is to determine the effects of a co-designed, culturally-tailored, lifestyle support mHealth tool (smartphone app and web version) on important health behaviours associated with an increased risk of non-communicable disease (diet, physical activity, smoking and alcohol consumption) compared to a control condition.

Duration of intervention: Twelve weeks

Study design and methodology: The OL@-OR@ trial is a pragmatic, community-based, two-arm, cluster randomised trial. Clusters will be randomly assigned (1:1 ratio) to one of two groups: 1) the full OL@-OR@ app, or 2) a simplified version of the app (data collection only plus a weekly notification), stratified by community type for Pasifika clusters and by region for Māori clusters. All participants will be followed for 12 weeks with assessments at baseline, 4 and 12 weeks.

Study population: Participants will be adults (≥ 18 years old) who identify with either Māori or Pasifika ethnicity, live in New Zealand, are interested in improving their health and wellbeing or making lifestyle changes, have regular access to a smartphone, tablet or laptop/computer and regular access to internet (at least once a week), and are members of a group or community who has signed up to take part in the study. Clusters are identified by Community Coordinators affiliated with Māori and Pasifika health care/ health promotion providers who have been involved in the co-design phase of the intervention.

Number of subjects: 1280 participants in total; 64 clusters with 20 participants per cluster (32 Māori clusters and 32 Pasifika clusters).

Main criteria for inclusion:

- Member of a Maori or Pasifika group or community who has signed up to take part in the study
- Live in New Zealand;
- Aged ≥ 18 years old;
- Regular access to a smartphone, tablet or laptop/computer and regular access to internet (at least once a week);
- Able to provide written consent (e-consent);
- Have an email address or able to create an email address for the trial.

Criteria for evaluation:

Primary outcome
The primary outcome is adherence to healthy lifestyle behaviours measured using a self-reported composite health behaviour score at 12 weeks, including smoking, fruit and vegetable intake, alcohol intake, and physical activity.

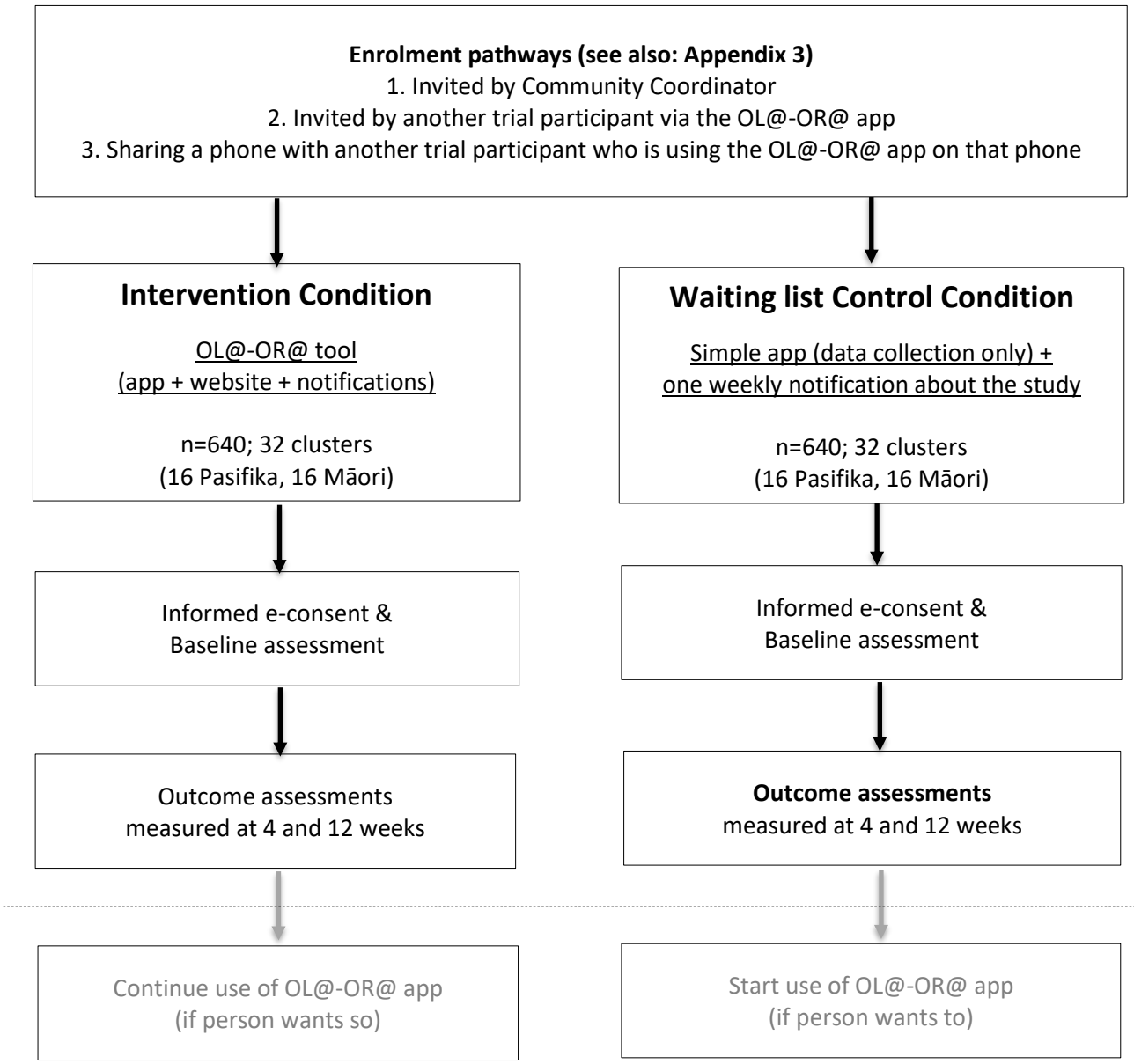
Secondary outcomes
Measured at twelve weeks post-randomisation:

- Anthropometry (self-reported)
- Health and wellbeing status
- Medication use
- User engagement with OL@-OR@ app

Statistical methods:
Data from this trial will be entered into the Drupal database, and imported to SAS version 9.4 (SAS Institute Inc. Cary NC) for data analysis at NIHI. All statistical tests will be 2-sided at a 5% significance level. Baseline data collected from all participants will be summarised by treatment group, overall and by ethnicity (Māori and Pasifika). Information collected at the cluster level will also be reported. The effect of intervention will be evaluated on the intention-to-treat (ITT) population using generalised linear mixed models, adjusting for important baseline confounders, accounting for the cluster effect and missing data. Similar regression analyses will be conducted on secondary outcomes using the link function appropriate to a continuous or categorical variable. Intra-cluster correlation coefficient will be estimated. The analysis will be conducted for the full sample and by ethnicity. A full statistical analysis plan will be developed *a priori* to guide final analysis and reporting.

Funding: This project is funded by the Healthier Lives *He Oranga Hauora* National Science Challenge.

2. Study Plan Schematic



3. Background

Almost one in three adults in New Zealand is obese (31.2%), which places New Zealand third in the developed world for obesity rates[1]. Substantial health inequities exists among different population groups, with Māori (indigenous New Zealanders; 15% of total population) and Pasifika (collective group of people representing different Pacific Island nations predominately from the South Pacific region; 7% of total population) adults living in New Zealand experiencing obesity rates 1.7 and 2.4 times higher respectively than those of non-Māori, non-Pasifika adults[2]. Unhealthy diets and physical inactivity are common preventable risk factors for obesity and increase risk of non-communicable diseases (NCDs) as well as impacting on wider population economic and social functioning[3]. The scope and scale of the problem indicates an urgent need for well-crafted evidence-based behavioural interventions.

Culturally adapted or tailored behaviour change interventions have shown beneficial effects[4-7]. Although effective, traditional face-to-face behavioural interventions are resource intensive and have limited reach and hence uptake by some population groups. The broad population penetration of mobile and wireless technologies as well as advancements in their application may offer a solution. Mobile health (mHealth) programmes - i.e. the usage of mobile and wireless technologies designed to achieve medical objectives[8] - have been shown to effectively help people quit smoking[9-11], lose weight[12,13], become more physically active[14,15], and improve other secondary risk factors for cardiovascular diseases, such as blood pressure and medication adherence[16]. Nevertheless, most mHealth interventions are designed with minimal input from end-users and lack tailoring to specific (cultural) needs. Consequently such interventions often have poor uptake and low rates of use by these communities and end-users[17].

The OL@-OR@ project consists of two phases, a co-design phase and a trial phase. The first phase of the OL@-OR@ project consisted of the development of a culturally-tailored, lifestyle support mHeath tool for Māori and Pasifika communities in New Zealand using co-design (this phase of the project was approved on 19/04/2016 by the New Zealand Northern A Health and Disability Ethics Committees [reference 16/NTA/29]). Co-design - also called participatory design or co-creation - originated in the late 1960s in the industry sectors, such as manufacturing and transport. Since then co-design principles and practices have been used in a range of other domains, including healthcare. This relatively novel but emerging methodology is complementary to other participatory approaches and overlaps with a number of other user-centric research design disciplines and methods (e.g. user-centred design, experienced-based design, and participatory action research). However, co-design differs from other user-centred approaches in going beyond consultation and seeking active contribution of users as co-designers or co-researchers throughout the whole design process. As a result, interventions or services are not only developed *for,* but also *with,* users. Such a community-academic partnership enables and empowers users to tailor the intervention to their specific needs (cultural) and contexts (social, economic).

The OL@-OR@ project was envisioned as part of a National Science Challenge project that involved the academic researchers over a two-year internal development period. As the project evolved into a proposal focused on Māori and Pasifika and using co-design, the initial team was broadened to include academic Māori and Pasifika researchers. Subsequent to the project being funded a research collaboration between academics and Māori and Pasifika community partners was formed and an

approach agreed. *Toi Tangata*, a Māori health promotion provider, agreed to lead the engagement process with Māori (involving two communities one each in the Wellington and Auckland regions) and two Pasifika health providers, *The Fono* in Auckland, and *South Waikato Pacific Islands Community Services Trust* in Tokoroa agreed to lead engagement processes with their communities.

Various co-design methods were used to collaboratively capture and understand the needs of target end-users of the mHealth intervention, i.e. members of Māori and/or Pasifika communities. These methods fostered expression, reflection and sharing, and informed the development of the intervention. Whereas traditional ethnographic methods, such as in-depth interviews and observations, only give access to explicit and observable sources of information, co-design methods - also known as generative methods - aim to go beyond the explicit and observable and provide insight in the implicit aspects of people's lives [18]. By creating a setting for collective reflection, ideas for intervention development were generated from gained insights.

By using ethnic-specific models of health for interpreting the data gathered from the co-design, we ensured that the selected determinants, behaviour change techniques, and intervention features align with the cultural needs and wants of users. Use of the Theoretical Domains Framework (TDF) and Behavioural Change Taxonomy - two Western-oriented frameworks for the development of behaviour change interventions – to map similarities and differences in identified behavioural determinants and change techniques confirmed that our intervention aligns with evidence-based behaviour change principles

The next step in the OL@-OR@ project will be the trial phase. This phase will determine the impact of the smartphone app (and web version) on preventable risk factors for non-communicable disease among our target communities, including diet, physical activity, smoking, and alcohol use in a pragmatic, community-based, two-arm, cluster-randomised controlled trial.

4. Rationale for the Present Study

New Zealand urgently needs effective healthy lifestyle and obesity management programmes. Currently funded research largely focuses on population and policy interventions, and government funding has been directed to the Healthy Families initiative. However, there are no scalable, evidence based notational programmes and tools to support individuals who want to improve their diet, lose weight, or be more active. This study aims to address this gap and provide new knowledge in the field of mHealth, especially as it will examine a novel, co-designed, culturally-tailored mHealth tool in a large-scale cluster-randomised controlled trial. If effective, this study will contribute to the improvement of health outcomes of Māori and Pasifika by providing them with a tool to support healthy behaviour change. In addition, because this study will focus on Māori and Pasifika, this study has potential to improve health equity in New Zealand.

5. Study Objectives

The primary outcome is participant adherence to recommended health guidelines at 12 weeks, measured by a self-reported composite health behaviour score, consisting of smoking, fruit and vegetable intake, alcohol intake, and physical activity. We hypothesize that using a culturally-tailored, co-designed, lifestyle support smartphone app for 12 weeks will be more effective than using a basic, data-collection version of the app in improving important lifestyle behaviours in Māori and Pasifika that pose a risk for non-communicable disease.

6. Study Design

6.1 Inclusion criteria

Participants recruited into the trial will be members of a Māori or Pasifika group or community who has signed up to take part in the study, reside in New Zealand, be aged ≥ 18 years, have regular access to a smartphone, tablet, laptop or computer and regular access to internet (at least once a week), are able to provide written consent (e-consent), and have an email address or are prepared to create an email account.

6.2 Exclusion criteria

Participants will not be able to enrol in the trial if they are aged less than 18 years old, do not have access to smartphone, tablet, laptop or computer or do not have access to internet, and if they are a member of a cluster that has already been randomised to another study condition.

6.3 Recruitment

Recruitment will be led by Māori and Pasifika Community Coordinators who have identified the clusters and will approach potential participants within these clusters who are interested in making lifestyle changes (Appendix 3; Process Diagram 1). Our community partners have existing relationships with many of the clusters identified. Although people within clusters may self-identify as Māori and Pasifika, they will analysed as Māori if they are part of a Māori cluster and as Pasifika if they are part of a Pasifika cluster.

Once initial contact has been made with the identified cluster leads, they will be given information on what is required to be involved with the study, including outlining the possibility of being randomised to control or intervention conditions. Cluster leads will then provide informed consent for their participation in the study.

The next step will be for the cluster leads with the support from a Community Coordinator to start recruiting participants for the trial. Specific recruitment methods will be decided by each cluster, including:

- Inviting potential participants to face-to-face information sessions on the trial
- Using social media e.g. Facebook
- Using posters, brochures and other advertising material
- Word of mouth
- Inviting potential participants through the OL@-OR@ app by others from the same cluster who are already participating in the trial.

People will also be able to enrol in the trial if they are invited by another trial participant via the OL@-OR@ app or if they share a phone with a trial participant who has downloaded the OL@-OR@ app on that phone. These processes are outlined in Appendix 3.

6.4 Study procedures

Clusters will be randomly assigned to either the intervention or control condition. People who are identified as part of a cluster by their local Community Coordinator will be invited to participate in the study. An information meeting will be organised to provide information about the study and answer any questions potential participants may have. Potential participants will be provided with a copy of the Patient Information Sheet and brochure. People who are interested and meet the inclusion criteria may sign up for the study with their local Community Coordinator and be part of the cluster.

Potential participants who indicate interest will receive an email with study registration details. By clicking on a link in the email they will be able to fill in their registration details and provide e-consent (participants consenting using computer based consent form). They will then complete baseline questions online. Once all questions are complete participants will be able to download the OL@-OR@ app (intervention) or the data collection version of the app (control) on their device. If they do not have a smartphone or tablet they will be able to access the web version through a link provided. All participants will be asked to use the app (or web version) for 12 weeks and keep the app running on their device for (at least) the whole 12-week period. At 4 and 12 weeks, follow-up assessment will take place.

After 12 weeks, participants in intervention clusters can continue using the app if they wish to. Participants assigned to control condition will be able to download the full app or use the web version once they have completed all the 12-week questionnaire. There is also an opportunity at the end of the trial for participants to be invited to attend a focus group in their local community to provide further feedback on the tool. This will be led by our Community partners as an opportunity for our partners to gain further insights from communities involved in the trial to benefit their organisation/services they provide.

If the results look favourable and we are able to source additional funding we may look to extent the follow up and measure longer term follow ups.

6.5 Randomisation

Clusters will be randomly assigned at a 1:1 ratio to either the intervention or control condition using computer-generated randomisation lists. Randomisation will be stratified by type of community (e.g. locality – Auckland or Waikato) for Pasifika clusters and by region (rural, urban or provincial) for Māori clusters, to ensure a balance between the intervention and control group within each stratum.

6.6 Blinding

Randomisation lists will be concealed until the point of randomisation for all clusters. Due to the nature of the intervention it will not be possible to blind participants or research staff to the use of the different intervention conditions (full versus basic (data-collection only) version of the smartphone app).

6.7 Study intervention

The OL@-OR@ tool (app/ web version) is designed to help Māori and Pasifika and their whānau/family to improve their health and wellbeing by making small positive, culturally relevant changes to their lifestyle. The tool supports users to set goals and make small steps to reach those goals. It encourages the user to invite others to join them on their journey and allows them to collect reward tokens as they

achieve their goals. The tool also provides information about diet, physical activity, local activities and health services. Lifestyle trackers help users monitor their progress.

The tool sends regular culturally-tailored reminders and motivational messages to help users reach their goals. There will be 4-5 messages each week. These messages include:

- At the beginning of each week a motivational message (whakatauki) will be sent – 1 per week
- Lifestyle messages: these will include tips on eating more healthily, doing more physical activity, reducing stress, improving sleep and weight loss tips. Users will receive 1 lifestyle message per week.
- In addition, those who have specified that they smoke will receive messages specifically about smoking cessation 1x per week.
- Function messages – these will highlight how to use specific features of the tool and will be sent to users 1x per week highlighting a different feature each week.
- Goal reminders – at the end of each week a message will be sent a reminder to review or set goals.

Clusters that are assigned to the waitlist control condition will be asked to use a basic data collection version of the OL@-OR@ tool, either on their phone or tablet (preferred) or via the web on a laptop or computer. This version of the tool will only collect data and will provide a weekly motivational message thanking participants for taking part in the study and counting down the weeks until they receive the OL@-OR@ tool. At the end of the study participants in the control clusters will be able to download the full OL@-OR@ tool to use it for as long as they wish.

6.8 Payments for involvement in the study

To acknowledge participants' time and involvement in the study koha will be available for each cluster which will be around $500* per cluster (pro-rated per number of participants recruited up to 20 participants). The Community Partners will decide the best way to provide koha to the communities involved however this will likely be through a voucher, cash for the community, donation to a named charity, or through purchasing of equipment. Some clusters may elect to share the koha equally between enrolled participants.

*As sample size has reduced from 40 to 20 participants per cluster, so clusters have already achieved over 20 participants and understood they would be receiving up to $1000 pro-rated per number of participants recruited up to 40 participants. For those who achieve this prior to amendment being approved this will be honored.

6.9 Withdrawal criteria

Reasons for withdrawal include:

- The participant makes a voluntary decision to withdraw; a participant who wishes to withdrawal will be made inactive and reason for withdrawal if given will be noted in the Drupal system.
- The study is terminated for any reason.

6.10 Baseline assessments

At baseline assessment, the following data will be collected:

- **Socio-demographic data:** date of birth, gender, ethnicity, hapu and iwi (where relevant), highest education level, and annual household income;
- **Anthropometry:** self-reported weight (in kilograms) and height (in centimetres);

- **Health status:** self-reported health condition(s) defined as being told by a doctor that they have this condition, including high blood pressure, high cholesterol, diabetes, and heart disease; permission to obtain NHI number.
- **Physical activity:** measured by the Godin Leisure Time Physical Activity Questionnaire[19];
- **Smoking behaviour:** Measured by 7-day point prevalence of smoking abstinence;
- **Alcohol intake:** Measured by the Alcohol Use Disorders Identification Test Consumption (AUDIT)[20];
- **Fruit and vegetable consumption:** Measured by items from the New Zealand Health Survey[21];
- **Kava consumption:** questions include 'Do you consume Kava?', 'How often do you consume Kava?', and 'How many Kava drinks do you consume in a typical week?';
- **Holistic wellbeing (for Māori participants):** Tūhononga (cultural connections, Mauri and wellbeing, whanaungatanga (whānua wellbeing and social connectedness) and Rangatiratanga (self-determination, motivation and management) measured by 16 questions based on Māori health models Te Whare Tapa Whā[22] and Te Pae Mahutonga[23] and adapted in part from the Hua Oranga Māori mental health assessment questionnaire[24]. Answer categories consist of a 6-point Likert scale;
- **Holistic wellbeing (for Pasifika participants):** spiritual, physical, mental and family wellbeing measured by 10-items based on the Fonofale Model[25], the Ottawa Charter and Hua Oranga[24] designed for the purpose of this study. All answers are measured on a 5-point Likert scale.
- **Pacific and Kiwi-New Zealand Heritage and Lifestyle (Pasifika participants only):** Attitudes and beliefs about Pacific and Kiwi/New Zealand heritage and lifestyle measured using an 8-item cultural affiliation questionnaire designed by the Kohala Health Reseach Project[26]. Answer categories consist of a 5-point Likert scale (ranging from 1=very knowledgeable to 5=not at all knowledgeable);

6.11 Primary outcome measure

The primary outcome is 12 week participant adherence to recommended health guidelines, as defined by a self-reported composite health behaviour score based on the European Prospective Investigation into Cancer (EPIC)-Norfolk Prospective Population Study[27]. This composite score includes: smoking (1=not currently smoking; 0=had ≥1 cigarettes in past 7 days); fruit and vegetable intake (1 = ≥5 servings daily; 0 = ≤4 servings daily); alcohol intake (1 = ≤13 units per week; 0 = ≥14 units per week); and physical activity (1 = ≥14 units of moderate-to-vigorous activity/week; 0 = ≤13 units of moderate-to-vigorous activity/week). Scores range from 0 to 4 based on the number of health guidelines met. Participants are classified as adherent if they score 3 or more out of 4 and non-adherent if they score 2 or less. These measures are measured at an individual leave but analysed and reported at a cluster level (as are the secondary measures).

6.12 Secondary outcome measures

Post-randomisation, 4 and 12 week follow-up assessments will be undertaken via the smartphone app or web version and will relate to the composite health behaviour score. These questions will include:

- **Physical activity:** measured by the Godin Leisure Time Physical Activity Questionnaire[19];
- **Smoking behaviour:** Measured by 7-day point prevalence of smoking abstinence;
- **Alcohol intake:** Measured by the Alcohol Use Disorders Identification Test Consumption (AUDIT)[20];
- **Fruit and vegetable consumption:** Measured by items from the New Zealand Health Survey[21];
- **Holistic wellbeing (Māori participants):** Tūhononga (cultural connections, Mauri and wellbeing, whanaungatanga (whānua wellbeing and social connectedness) and Rangatiratanga (self-determination, motivation and management) measured by 16 questions based on Māori health models Te Whare Tapa Whā[22] and Te Pae Mahutonga[23] and adapted in part from the Hua Oranga

Māori mental health assessment questionnaire[24]. Answer categories consist of a 6-point Likert scale and 4 open ended questions;

- **Holistic wellbeing (Pasifika participants):** spiritual, physical, mental and family wellbeing measured by 10-items based on the Fonofale Model[25], the Ottawa Charter and Hua Oranga[24] designed for the purpose of this study. All answer categories are measured on a 5-point Likert scale.

At 12 week follow-up, user engagement and interaction with the smartphone app will be quantified using an Engagement Index (EI)[28]. The EI is an adapted version of the Web Analytics Demystified visitor EI[29]. Web metrics will be used to develop a composite measure of engagement for users of the OL@-OR@ app. The EI will be based on include the following sub-indices:

- **Click-Depth Index:** the number of pages participants viewed per session in the app;
- **Loyalty Index:** frequency of participants accessing the app from when they commenced the intervention**;**
- **Interaction Index:** Number of push notification opened from those sent through the app;
- **Recency Index:** Time difference between each session the participant accessed the app;
- **Feedback index:** Subjective 20 items measure of participant's satisfaction with the app assessed in the app's 12 month follow-up assessment (examples of questions include: ease of navigation, usefulness of information, helpfulness of notifications, satisfaction with look of the app)[28].

The overall EI summarises the sub-indices from date of registration through to 12 weeks follow-up. The EI will provide a score for each participant that measures their overall engagement with the app during this period. Cut-off points will be developed based on the distribution of the total sample's EI scores using quartiles. Participants will then be categorised as either poorly, moderately, or highly engaged.

6.13 Data linkage to New Zealand Integrated Data Infrastructure

In order to examine the long-term impact of the OL@-OR@ tool on Māori and Pasifika health we aim to link the data gathered in this study to the New Zealand Integrated Data Infrastructure (IDI) using the participant's unique National Health Index (NHI) number. The IDI is a large national database containing microdata about people and households in New Zealand. Data is derived from a range of government agencies, Statistics New Zealand surveys including the 2013 Census, and non-government organisations. We will use participants NHI number to look up health information that may be influenced by this study and relates to participants risk of illnesses such as heart disease and diabetes, including:

- Blood tests (blood glucose and cholesterol)
- Visits to health professionals
- Diabetes and heart disease medication use

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We may look at this information up to once per year for a maximum of five years after the study ends. All information will be anonymized and won't be linked to information that could identify participants. Written consent will be sought from study participants in order to do this (see section 8.3 for more details on the consent process).

6.13 Schedule of intervention and follow-up data collection

Outcome assessments will be measured at 4 and 12 weeks post-randomisation (Table 1).

Table 1: Details of data collection

Timing	Week 0	Week 0	Week 4	Week 12
Description	Registration	Baseline data collection	Follow-up data collection	Follow-up data collection
General data				
E-consent	✓			
Eligibility	✓			
Age, sex, ethnicity		✓		
Socioeconomic details		✓		
Contact details**	✓			
Primary outcome data				
Smoking behaviour		✓	✓	✓
Physical activity		✓	✓	✓
Alcohol intake		✓	✓	✓
Fruit and vegetable intake		✓	✓	✓
Secondary outcome data				
Anthropometry (weight, height)		✓		✓
Health status		✓		✓
Medication use		✓		✓
Kava consumption		✓		✓
Holistic wellbeing		✓		✓
Pacific and New Zealand Heritage and Lifestyle (Pasifika only)		✓		
Engagement Index				
Click-Depth Index				✓
Loyalty Index				✓
Interaction Index				✓
Recency Index				✓
Feedback Index				✓

6.14 Sub-study: Key stakeholder interviews

Ascertaining a programme's effectiveness is key to informing whether it should be made available to end-users outside the research environment. However, transitioning effective tools outside the research environment also requires consideration of implementation barriers and enablers, preferred methods and processes for end-users, and the best platforms for delivery. Further, we need to explore how delivery and maintenance of the programme could be supported once research is complete. This sub-study aims to explore and collate a range of perspectives on ways to roll out OL@-OR@ more widely, enablers/barriers to implementation, and the best ways to implement the programme in the health system and real world. The results will inform the development of an implementation model and a business case to support implementation of the programme.

6.14.1 Procedures

We will undertake interviews with 8-12 key stakeholders to obtain information and perspectives on potential pathways to implementation of OL@-OR@. Key stakeholders include members of the communities involved in development and testing of OL@-OR@ and other potential implementation partners and funders. Interviews will be approximately 45 minutes in duration and conducted at a

time or location of the interviewees choosing. Participants will be provided the option of completing the interviews in person or over phone/video conference. The interviews will be semi-structured and cover the following topics:

- Feedback on the OL@-OR@ app
- Potential changes or enhancements to the app or its content needed prior to implementation
- Logistics of making OL@-OR@ available to communities (e.g. when, where and how?)
- Suggestions for integration with existing practices and systems
- Barriers and enablers to successful implementation
- Perceptions of successful implementation
- Arrangements for ongoing maintenance and ownership of the app
- Potential funding models for ongoing delivery
- Ongoing monitoring and evaluation needs

6.14.2 Analysis

The data will be analysed using a simple, general inductive thematic approach to identify common themes and meanings from the data. The findings will inform an implementation model for the OL@-OR@ programme. The model will in turn inform the development of a business case to support future implementation of the OL@-OR@ programme. The nature of the business case will depend on the outcome of the interviews including consideration of who the business case is aimed at, the target audience for the proposed service, and who will host, deliver, and maintain the programme.

7. Statistical Considerations

7.1 Sample size

We aim to recruit 1280 participants in total; 64 clusters with 20 participants per cluster (32 Māori clusters and 32 Pasifika clusters). This sample size will have sufficient power for the analysis of Māori and Pasifika participants separately. More specifically, a total sample size of 640 participants (n=20 per cluster, 16 clusters per treatment group; 32 clusters in total i.e. each ethnic-specific sample) will have 80% power at 5% level of significance (two-sided) to detect a between-group difference of 15% in the primary outcome at 12 weeks post intervention, assuming the proportion of participants adherent to healthy lifestyle behaviours in the control group is 30%[30] and an intracluster correlation coefficient (ICC) of 0.05[31].

7.2 Statistical analyses

Data from the trial will be entered into the Drupal database, and imported to SAS version 9.4 (SAS Institute Inc. Cary NC) for data analysis at NIHI. All statistical tests will be 2-sided at a 5% significance level. A full statistical analysis plan will be developed *a priori* by the study statistician to guide final analysis and reporting. No interim analyses will be undertaken during the trial. The CONSORT 2010 statement: extension to cluster randomised trial[32], will be followed.

7.2.1 Baseline characteristics

Baseline data collected from all participants will be summarised by treatment group, overall and by ethnicity (Māori and Pasifika). Information collected at the cluster level will also be reported. Continuous variables will be presented as numbers observed, means and standard deviations. Categorical variables will be presented as frequencies and percentages. Since any differences between randomised groups at baseline could only have occurred by chance, no formal significance testing will be conducted.

7.2.2 Intervention effects

The effect of the intervention will be evaluated using an intention-to-treat (ITT) analysis, including all study participants in the group they are randomised to, regardless of whether they receive or complete that treatment. The proportion of participants who are adherent to lifestyle change (≥3 of 4 behaviours) at the end of the 12-week intervention period will be compared between two treatment groups using generalised linear mixed models, adjusting for important baseline confounders (including the stratification variable) and accounting for the cluster effect. Similar regression analyses will be conducted on secondary outcomes using the link function appropriate to a continuous or categorical variable. Intra-cluster correlation coefficient will be estimated. The analysis will be conducted for the full sample and by ethnicity. Note: although people within clusters may self-identify as Māori and Pasifika, they will analysed as Māori if they are part of a Māori cluster and as Pasifika if they are part of a Pasifika cluster.

7.2.3 Engagement Index (EI)

Basic descriptive data analysis will be performed on the metrics and components of the EI as well as the final EI score, following previous research[28]. To analyse the EI score, cut-off points will be developed based on the distribution of the total samples' EI scores using quartiles. Participants will be categorised as either poorly, moderately, or highly engaged. Group comparisons between poorly, moderately, or highly engaged participants will be conducted using generalised linear mixed models. Additional analyses will be performed to determine the association between the EI and socio-demographic characteristics of the participants, including their education level, ethnicity, age, annual household income, device type (android or iOS), and system type (app only, web only, or app and web).

7.2.4 Procedures to account for missing data

Missing data will be taken into account in the estimates of generalised linear mixed models by maximum likelihood, assuming data are missing at random. It has optimal statistical properties if assumptions are met, with several advantages over multiple imputation when both approaches are asymptotically efficient[33].

7.3 Data management

Information about study subjects will be kept confidential in keeping with the obligations set out in the Privacy Act 1993, the Health Information Code 1994 and Section 22B to 221 of the Health Act 1956. Data will be entered, stored and backed-up in a secure manner on a server at NIHI. Access to all study data will be restricted to research staff directly involved in conducting or monitoring the study. Confidentiality will be protected by the use of study registration numbers, and only aggregated and anonymous data will be reported. Personal information will be kept confidential and stored securely. Computerised information will be password protected and hard copy information kept in a locked filing cabinet. All reports from the study will be written in a way such that no individuals can be identified.

7.3.1 Record retention policy

Paper records, electronic files, and source documents will be retained for 6 years from the termination date of the study, in accordance with the requirements of the Privacy Legislation and the Health (Retention of Health Information) Regulations 1996.

8. Ethical Approval and Consent

8.1 National ethics approval

Ethical approval will be sought from the Health and Disability Ethics Committee. This study will conform to standards of good clinical research practice (GCP) where applicable. All participants will receive a participant information sheet and consent information (however the consenting process will be via e-consent) prior to taking part in the study. All participant data collected will be treated as confidential and stored securely at NIHI.
Ethics approval was received on 14th August 2017 subject to minor amendments
Minor amendments were approved on 17th November 2017

8.2 SCOTT committee approval

No medication will be administered as part of this study, therefore SCOTT approval is not required.

8.3 Informed consent

Maintenance of confidentiality and compliance with the Privacy Act will be emphasised to all study participants. Participation in the study will be entirely voluntary and participants may withdraw from the study at any time without having to give a reason by contacting the research team. A Participant Information Sheet and Consent Form will be given to participants who are identified as being part of cluster by the local Community Coordinator during an information meeting. E-consent will be obtained at the time of registration once participants have had the opportunity to read the Participant Information Sheet and ask any questions to their local Community Coordinator or other members of the study team. Participants will be asked to provide electronic consent to link their study information to the IDI. If participants give their consent for this they will be asked to provide their NHI number. If they do not know their NHI number, participants will be asked permission for the research team to access their NHI number using their name, date of birth and address details. In addition, GP details will be requested (i.e. GP name and practice name).

9. Assessment of Safety / Adverse Event Reporting

No adverse or serious adverse events are anticipated and thus these data will not be collected in this trial.

10. Clinical Supplies

No clinical supplies are used in this study.

11. Relevance to Health

Poor health resulting from unhealthy diets and inadequate physical activity will overtake tobacco as the leading risk factor for ill health by 2016. Moreover, there are important health inequalities, with Māori and Pasifika experiencing a greater burden of obesity and nutrition-related disease. The scope and scale of this problem indicate an urgent need for well crafted, scalable, evidence-based interventions to support individuals in communities to improve their diet, lose weight, or be more active. Culturally-tailored behavioural programmes have been shown to be effective in reducing weight and type 2 diabetes. However, face to face behavioural treatments are costly and difficult to implement on a large scale.

The broad population penetration of mobile and wireless technologies and advancements in their application offers a potential solution. Ninety two percent of New Zealanders own a mobile (67% have a smart phone) and 80% have internet access. Further, there are no significant differences in smartphone ownership or internet access by ethnicity or education, and few differences by age (for those <65 years). Formative research in New Zealand indicates the majority of Māori would be keen to use a mHealth intervention for weight loss, and systematic reviews indicate mHealth interventions can create behaviour change.

Since most mHealth interventions are designed with minimal input from end-users and lack tailoring to specific (cultural) needs, a culturally-tailored smartphone app was developed by both an academic research team and community partners. This co-design phase of the OL@-OR@ project informed a theory-driven approach to content development, including identification of key themes and content domains, selection of behavioural determinants and change techniques, and development of features and functionalities of the smartphone app. The proposed trial will evaluate the effectiveness of the OL@-OR@ tool.

12. Dissemination of Results

12.1 Trial registration

The trial will be registered online on the Trials Registry (www.clinicaltrials.gov).
Trial was registered with ACTRN on the 20th October 2017. ACTRN12617001484336

12.2 Study participants

Study participants will be informed about the trial results by being sent a plain language summary of the results just prior to the publication of the study results. A plain language summary will also be published on the study website.

12.3 The general public

The general public will be informed about the trial via posting of the research findings on the University's and other relevant websites, both national and international. Opportunities to make presentations to local, national and international audiences will be actively pursued. Another dissemination pathway will be media releases (national and international) at the time of journal publication.

12.4 Academic/professional colleagues

Academic/professional colleagues will be informed about the trial via publication in international journals. Less formal feedback will be given to researchers via the investigators' participation in the national and international research community. Opportunities to make presentations to local, national and international audiences will be actively pursued, including the Healthier Lives Kōrero Tahi.

12.5 Health service funders and providers

Academic papers and summary reports will be distributed to key stakeholders. In New Zealand this will include but is not limited to the Ministry of Health, Health Promotion Agency, District Health Boards, Primary Health Organisations, non-government organisations, and health professionals. Internationally this will include groups such as the WHO.

12.6 Iwi/Māori

Dissemination of findings to Māori organisations, media and community groups will be guided by our Maori community partners involved in this project. Likely dissemination for a include Toi Tangata Hui-a-Tau, the annual Activity and nutrition Aotearoa (ANA) conference and Māori Public Health Association symposium.

12.7 Pacific Island communities

Dissemination of findings to Pacific Island Community organisations, media and community groups will be guided by our Pasifika community partners involved in this project.

13. Administrative Section

13.1 Adherence to the protocol

Except for a change that is intended to eliminate an immediate hazard to participants, the approved protocol will be conducted as described. Any significant protocol deviation will be documented.

13.2 Protocol revision procedures

All revisions will be discussed with, and approved by, the Principal Investigators and project team. If the revision is an "administrative letter", the Principal Investigator will submit it to the National Ethics Committee for their information. If the revision is an "amendment", the Principal Investigator will sign it. The Principal Investigator will submit the amendment to the National Multi-Regional Ethics Committee for review and approval or favourable opinion prior to implementation. Documentation of approval signed by the chairperson or designee of the National Multi-Regional Ethics Committee will be sent to the principal investigator.

If an amendment substantially alters the study design or increases the potential risk to the subject:

- the consent form will be revised and submitted to the National Multi-Regional Ethics Committee for review and approval or favourable opinion;
- participants currently enrolled in the study, if they are affected by the amendment, will be contacted by telephone and the amendment discussed and verbal consent re-obtained;
- the revised consent form will be posted to participants currently enrolled in the study if they are affected by the amendment;

13.3 Case report form procedures

All questionnaire information will be collected via the app and web versions of the tool and directly entered into the study database.

13.4 Monitoring/ Source document verification

No medication will be administered as part of this study, therefore monitoring/source document verification is not required.

13.5 Reporting schedule

The principal investigator will provide annual reports on the progress, or completion, termination or discontinuation of the study to the Health & Disability Ethics Committee and to the funder of this trial.

13.6 Record retention policy

The project co-ordinator will retain study records for the maximum period required by the Privacy Legislation and the Health (Retention of Health Information) Regulations 1996 (10 years from data lock). Staff involved in the trial will not destroy any records associated with the trial, without the prior approval of the project manager. If the Principal Investigator or any co-investigators withdraw from the study (e.g. relocation, retirement), any records they hold will be transferred to a mutually agreed upon designee (e.g. another co-investigator). Notice of such transfer will be given in writing to the Director of NIHI.

13.7 Insurance

Participants may be considered for coverage under accident compensation legislation, for any injury caused as a result of their participation in this research.

13.8 Ownership of data and publication policy

Individual study data will remain the property of individual study participants. NIHI will have the responsibility for storage, protection and retrieval of study data. The University team will have the responsibility for the safe guardianship and use of the data in consultation with the wider project team. All access, analyses and dissemination of Māori -specific data will be the joint responsibility of the University team and the Māori Community Partners. All publications will be approved by members of the University team. Study participants, and any members of the project team who are not named on the report will be acknowledged in the final report and in publications and presentations resulting from this trial.

13.9 Intellectual Property

Below are the IP project agreements with the community partners:

- Nothing in this Subcontract shall change ownership of any Background IP. The Collaborating Organisation hereby grants to the Subcontracting Party a non-exclusive, royalty-free, non-transferrable license to its relevant Background IP to the extent required to deliver the subcontracted activity. The Subcontracting Party hereby grants to the Collaborating Organisation a non-exclusive, royalty-free license to its relevant Background IP to the extent required to deliver the Project and to use and commercialise the Project IP.

- Any new Project IP developed under this Subcontract shall be owned by the Collaborating Organisation who will be responsible for ensuring such Project IP is developed in a manner that advances the mission of the Challenge. The Collaborating Organisation grants the Subcontracting Party (as research partner to the co-design process) a non-exclusive, royalty-free license to use the Project IP developed under this Subcontract for any purpose that is consistent with the mission of the Challenge. The parties will consult with each other in good faith to ensure that any future use of the Project IP by either party is designed to promote the rights, aspirations and wellbeing of Māori.

- Notwithstanding clause above, nothing in this Subcontract gives the Collaborating Organisation or the Challenge Contractor ownership of mātauranga māori shared by māori and iwi for the Project. The Collaborating Organisation recognises that mātauranga māori provided for the project is a taonga of the originating māori and iwi and that the originating parties have the primary interest as kaitiaki over the mātauranga māori. The Collaborating Organisation will ensure that it's use of mātauranga māori respects and enhances the cultural and spiritual integrity of mātauranga māori and the originating māori and iwi.

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15. Study Acknowledgement

STUDY ACKNOWLEDGMENT

I have read the protocol and agree that it contains all necessary details for carrying out the study as described. I will conduct this protocol as outlined therein and will make a reasonable effort to complete the study within the time designated.

I will provide copies of the protocol and access to all information to study personnel under my supervision. I will discuss this material with them to ensure that they are fully informed about the treatment and the study.

Professor Cliona Ni Mhurchu	27 July 2017
_____	_____
Investigator's printed name and signature	Date
Dr Lisa Te Morenga	27 July 2017
_____	_____
Investigator's printed name and signature	Date
Dr Tupa'ilevaililigi Ridvan Tupa'i-Firestone	27 July 2017
_____	_____
Investigator's printed name and signature	Date

16. Appendix 1 – Informed Consent Procedures

E-consent will be obtained from all participants. For consent to be valid the participant must be suitably informed of the study so that they can make an independent choice about whether to participate. During a study information meeting prior to enrolment, the potential participant will be provided with a copy of the patient information sheet and the consent form. Issues to be covered in the information sheet will be reviewed carefully with each participant. It will not be assumed that every person has read the information sheet or that they can read.

The potential participant will be given details (refer information sheet) regarding:

- The purpose of the study.
- An explanation of who the researchers are.
- An explanation of why the participant qualifies for the study.
- The type of participants studied and the number likely to be involved.
- The length of the study.
- The length of time and the procedures.
- The potential risks/benefits to the person.

The potential participant will be informed (refer information sheet) that:

- The supply of information provided by them is entirely voluntary.
- They may refuse to answer any of the questions. They do not have to give a reason for doing so.
- They have the right to access their data and/or to remove it from the study.
- They have the right to have questions answered.
- A person outside of the study is available to be contacted should they have any concerns i.e. a health advocate.

The participant will be made aware (refer information sheet) that:

- Personal information will be collected about them but that this information will be kept strictly confidential.
- That copies of this information may be completed and will be kept securely at NIHI.
- All computerised information will be password protected on a computer.
- No one, other than the study investigators and people that may audit the data (e.g. the study monitor, relevant regulatory bodies, and the trial sponsors) will have access to these data.
- All information will be published or presented in a way that no individual can be identified.

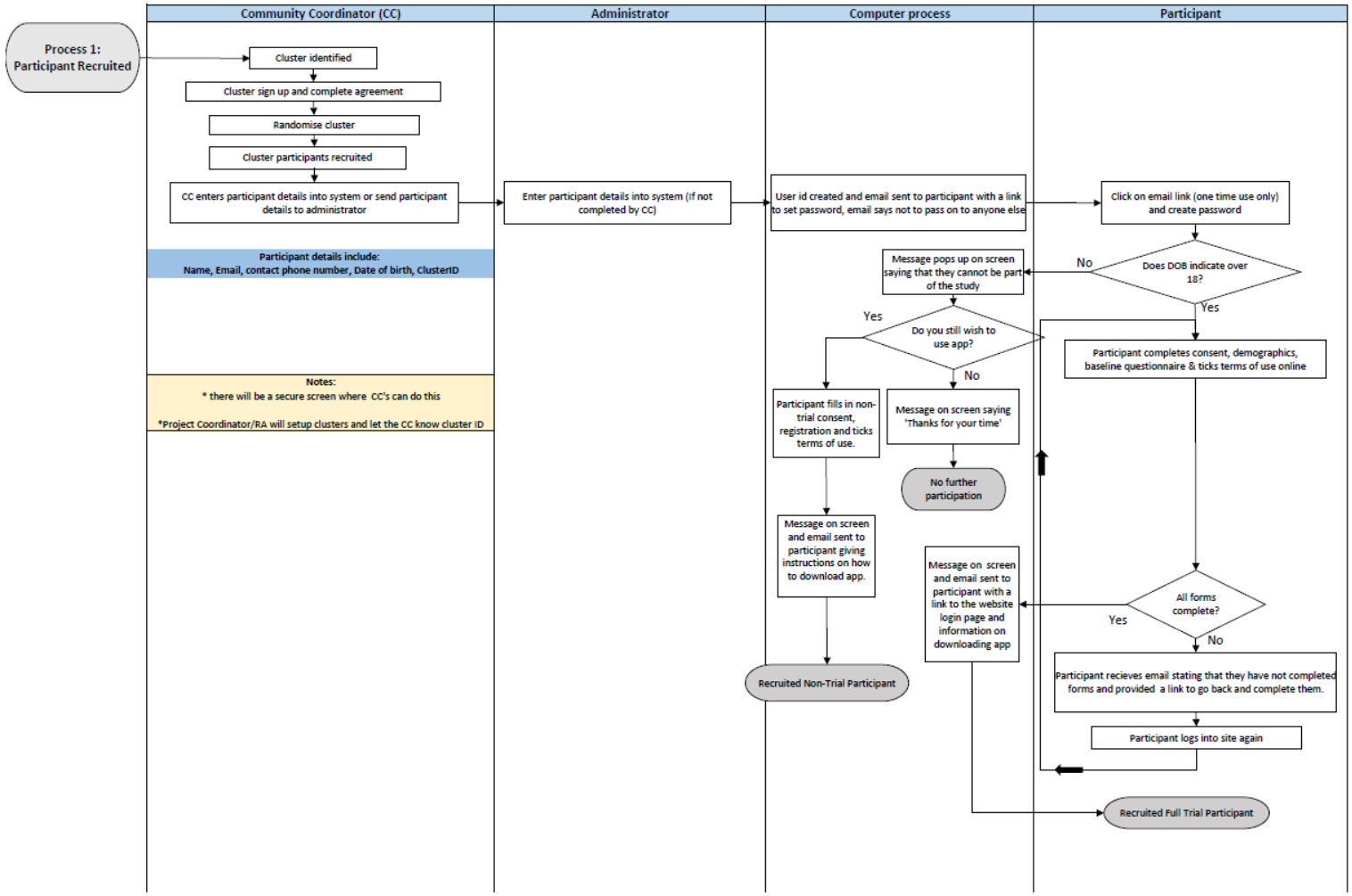
The fact that the participant has given (or declined) consent will be recorded on the computer programme at the time of enrolment.

17. Appendix 2 – Key Milestones

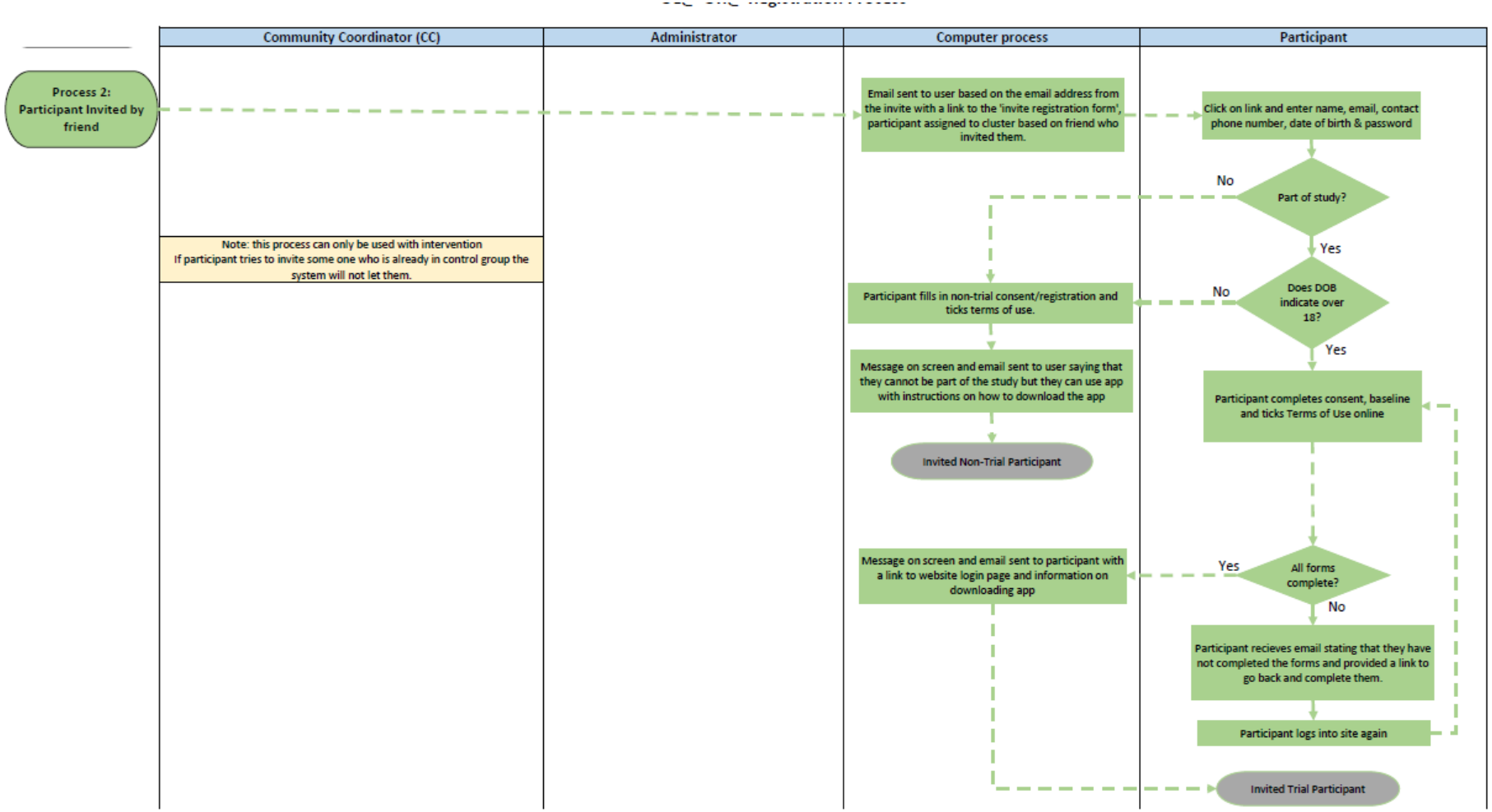
Date	Milestone
01/01/16	Project start date
22/04/16	Contract between Sponsor and University finalised
01/12/16	First (co-design) phase of the project completed
27/07/17	Submit application for ethics approval for cluster RCT
31/08/17	Final prototype of mHealth tool finalised
30/10/17	Recruitment of clusters begins and agreements signed
From 22/01/18	Recruitment of participants begins
From 22/01/18	Study enrolment begins
From 30/04/18	12-week follow-up completed (those who started in Jan)
31/07/18	Recruitment completed and all participants started trial
31/10/18	All 12-week follow-up completed
15/11/18	Data lock
19/12/18	Data analysis complete
01/02/19	Results submitted for publication
After 01/01/19	Dissemination of findings to partner communities and other stakeholders

18. Appendix 3 – Process Diagrams

Process Diagram 1: Registration process for participants are recruited through clusters and Community Coordinators



Process Diagram 2: Registration process when participants are invited to join through friends already using the app.



19. Appendix 4 – Summary of Protocol Amendments

Page	Section heading	Amendment
9	Statistical methods	Redcap changed to drupal
19	Statistical analysis	Redcap changed to drupal
17	Study design	Added section in about Data linkage to New Zealand Integrated Data Infrastructure
21	Ethical Approval and consent	Add information in about consent about providing their NHI number for long term follow up.
1	Heading	Trial registration added
17	Study design	Added further information on NHI collection, how long and how often
32	Appendix 3	Process diagram 3 deleted
30 - 31	Appendix 3	Updated process diagrams 1&2
10	Study plan schematic	4. Downloading the OL@-OR@ app on own initiative (from app store) – as users who download app are unable to use it unless they have been recruited through cluster.
14	6.5 Randomisation	Example of Pasifika strata changed to locality Auckland or Waikato instead of church, sports centre etc
15	6.8 Payment for involvement in study	Changed to around $1000 to bring in line with what has been agreed in partner contracts. Also added pro-rated up to 40 participants
15	6.9 Withdrawal criteria	Added the following information - A participant who wishes to withdrawal will be made inactive and reason for withdrawal if given will be noted in the Drupal system.
29	17: Appendix 2 – key milestones	Updated dates of key milestones
3	Project team members	Project team updated
9	Overview	Amended number of subjects based on updated agreed sample size calculation
11	Study plan schematic	Amended sample size, cluster and participant numbers
16	Payment involved for participants in the study	Koha has been reduced to $500 for up to 20 participants and information regarding clusters who have achieved more participants already included.
20	Sample size calculation	This has been amended based on agreed sample size calculation
22	Ethics approval	Updated section to state when ethics approval was received
23	Trial registration	Updated with when trial was registered
29	Key milestones	Updated timeframes to reflect increase in recruitment by 1 month.
18-19	6. 14 Sub-study: Key stakeholder interviews	Added section to describe key stakeholder interviews
