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Participant Information Sheet

STUDY TITLE: OL@-OR@
FUNDED BY: Healthier Lives He Oranga Hauora National Science Challenge
LEAD INVESTIGATORS: Professor Cliona Ni Mhurchu
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Talofa lava, Kia Orana, Malo e lelei, Fakaalofa lahi atu, Malo Ni, Ni Sa Bula Vinaka, Namaste, Mauri, Ia Orana,
Fakatalofa atu, Aloha, Halo olaketa

We invite you to take part in a research study called **OL@-OR@ (pronounced as 'OLA-ORA')**. The study wants to find out how useful a new mobile health tool is for Māori and Pasifika in New Zealand. The tool consist of a smart phone app and a website, and provides health information and support. It was created by Māori and Pasifika communities, together with researchers from three universities across New Zealand. You can use the app on your smart phone or tablet, or you can access a web version from a laptop or computer.

The following communities and organisations were involved in creating the OL@-OR@ tool:

- Waiwhetū Community
- South Waikato Pacific Islands Community Services Trust
- The Fono
- Te Rūnanga Ngāti Whātua
- Toi Tangata

What does the OL@-OR@ tool do?

- Helps you and your family to improve your health and wellbeing
- Helps you to make small positive Pasifika-centred changes to your lifestyle.
- Helps you in setting health goals and making small steps to reach those goals.
- Encourages you to invite others to join you on this journey.
- Rewards you with tokens as you achieve goals.
- Sends regular reminders and motivational messages to help you reach your goals.
- Gives you culturally-tailored information about food, physical activity, local activities and health services.
- Helps you to track your progress using lifestyle trackers.

Aim of the study

We would like to find out what you think of the OL@-OR@ tool. We are keen to see if it helps you, your family and/or friends to lead healthier lives, such as eating more healthily and being more active.

About the study

From November 2017 to July 2018, we plan to enroll 64 groups of people in the study (32 Māori groups and 32 Pasifika groups). A group (or cluster) can be for example a church community, sports club or school. Each group will consist of around 20 people.

We are looking for people who are interested in improving their wellbeing or making healthy lifestyle changes, either personally or for their family, friends and/or community. Recruitment will be led by Pasifika Community Coordinators. They will identify the groups and approach the people within these groups.

If you decide to take part in the study, you and your group will be randomly allocated (like the toss of a coin) to one of the following two study conditions: an intervention or control condition. The table below shows what it means when you and your group are allocated to one of these conditions:

	Intervention condition	Control condition
What tool will my group and I receive?	The new OL@-OR@ tool.	A basic version of the tool, which will send you a weekly motivational message and will ask you to complete several questions during the study.
How long will my group and I be in the study for?	12 weeks	12 weeks
What questionnaires will my group and I need to complete and when?	At the start of the study we will ask you to complete some questions about yourself, your health and wellbeing. Additional questions will be asked at 4 and 12 weeks after registration. We will ask you for feedback on using the tool at the end of the study (after 12 weeks).	At the start of the study we will ask you to complete some questions about yourself, your health and wellbeing. Additional questions will be asked at 4 and 12 weeks after registration.
Can I use the OL@-OR@ tool after the study?	Yes, you can continue to use the tool after the study.	Yes, once you have completed your 12 week questionnaire you can download and the full OL@-OR@ app.

Who can take part in this study?

You can take part in this study if you:





- Are a member of Māori or Pasifika group or community who has signed up to take part in the study
- Are aged 18 years or older
- Have access to a smartphone/tablet (preferred), laptop or computer with regular access to internet (at least 1x per week as a minimum)
- Have an email address or prepared to create an email account.

Where will the study be undertaken?

The study will be undertaken throughout New Zealand. All information will be delivered and collected through your phone, tablet or computer. There is no need to attend face-to-face visits.

What will I be asked to do?

Your Community Coordinator will contact you and your group and ask you to join the study. They may invite you to a group session to give you more information about the study. You can also contact your local Community Coordinator and ask them to sign you up for the study. The Community Coordinator can support you with registering for the study and using the tool during the study period. If you take part in the study, we would ask you to follow these steps:

STEP 1: Register and download the tool onto your smartphone or tablet 	<ul style="list-style-type: none">• Sign up to the study with your Community Coordinator.• You will receive an email from olaora@auckland.ac.nz with your registration details.• Click on the link in the email and fill in the registration form, consent form, health questionnaire and terms of use (you will need access to internet).• Download the OL@-OR@ tool (if intervention condition) or basic app (if control condition) onto your phone or tablet (preferred), or use the web version on a laptop/computer.
STEP 2: Use the tool 	<ul style="list-style-type: none">• Use the app or web version for 12 weeks.• It is up to you how much time you spend each week using the app.• Leave the OL@-OR@/basic app running on your phone or tablet for the whole 12-week period.
STEP 3: Answer the questions 	<ul style="list-style-type: none">• After 4 weeks, answer the questions about your health and wellbeing on the app/website• After 12 weeks, answer the questions about your health and wellbeing.
STEP 3: Provide your feedback 	<ul style="list-style-type: none">• After 12 weeks, give feedback on the app/web tool.• You can continue using the tool after this time if you would like to.• If you are assigned to the control condition you will be able to download the full app once you have completed all the questions at 12 weeks.• You may be invited to also attend a focus group in your local community to provide further feedback.

Will it cost me anything to be in the study?

No, the OL@-OR@ app/website is free of charge.

Will I be paid?

Yes, there will be koha for your group for participating in the study.

What are the possible benefits?

This study is about examining the effects of a healthy lifestyle support tool designed *by* and *for* Māori and Pasifika communities. It is possible you may not notice any improvement in your health and wellbeing after the study, or you/ your family may improve your health and wellbeing and gain new knowledge and skills about how to improve your lifestyle.

What are the possible risks?

We do not think there will be any risks for those who take part in this study. However, if you were injured in this study, which is unlikely, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted.

What are my rights during the study?

Your participation in this study is entirely voluntary (your choice). You do not have to take part. If you choose not to take part in this study you will not be affected in any way. You can pull out at any time. Your withdrawal from the study will not affect your future health care or your relationship with the University of Auckland. This Participant Information Sheet and the study brochure will help you decide if you would like to take part. Your local Community Coordinator can also give you further support on using the tool. Before you decide you may want to talk about the study with other people, such as family, friends, or healthcare providers. If, after reading this information sheet, you wish to take part we will need you to give us your permission. This will be done through the app or web tool in an electronic consent form.

Will the information about me be kept confidential?

All information that you provide will remain strictly confidential. We need to collect personal details such as your name, and contact details to communicate with you throughout the study. This information will be stored separately from any other personal data we collect like your ethnicity and age. No material that could personally identify you will be used in any reports on this study. All information collected during the study will be stored securely by the National Institute for Health Innovation, The University of Auckland for 6 years. All computer records will be password protected. All future use of the information collected will be strictly controlled in accordance with the Privacy Act, 1994. If you wish, we can also send you a summary of the results.

Follow-up

We also would like to find out if the OL@-OR@ tool has a positive influence on your health in the long-term. Therefore we would like to link your study information to the National Health Databases. We will only do this if you give us your written consent to do so. If you decide not to give consent, you can still be part of this study.

If you do give consent, you will be asked for your National Health Index (NHI) number. If you don't know your NHI number the researchers can look it up using your name, date of birth, address and GP details if you give us your consent to do so.

We will use your NHI number to look up health information that may be influenced by this study and relates to your 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

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 you such as your name and contact details.

Who do I contact for more information?

If you have any questions or concerns about the study at any stage, you can contact:

Community Coordinator

The Fono

olaora@thefono.org

Tel: 021 512 213 or 09 216 4640

OL@-OR@ Project Manager:

Jacqui Grey

olaora@auckland.ac.nz

Tel: 09 923 8210

Pasifika investigator:

Dr Tupa'ilevaililigi Ridvan Tupa'i-Firestone

r.t.firestone@massey.ac.nz

Tel: 04 801 4987

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050

Fax: 0800 2 SUPPORT (0800 2787 7678)

Email: advocacy@hdc.org.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS

Email: hdecs@moh.govt.nz

Electronic Consent Form

This form will be completed online at registration. Please carefully read the following statements and tick 'Yes' if you agree. Ask your Community Coordinator if you have any questions

		YES	NO
1.	I have read and I understand the Participant Information Sheet.	<input type="checkbox"/>	<input type="checkbox"/>
2.	I have been given enough time to consider whether or not to participate in this study.	<input type="checkbox"/>	<input type="checkbox"/>
3.	I have had the opportunity to use family support or a friend to help me ask questions and understand the study.	<input type="checkbox"/>	<input type="checkbox"/> N/A <input type="checkbox"/>
4.	I am satisfied with the answers I have been given regarding the study and I have a copy of this Consent Form and Participant Information Sheet (this maybe an electronic copy or can be a hard copy if required from your Community Coordinator).	<input type="checkbox"/>	<input type="checkbox"/>
5.	I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting me.	<input type="checkbox"/>	<input type="checkbox"/>
6.	I consent to study staff collecting and using my information.	<input type="checkbox"/>	<input type="checkbox"/>
7.	I understand that my participation in this study is confidential and that no information which could identify me personally, will be used in any reports on this study.	<input type="checkbox"/>	<input type="checkbox"/>
8.	I understand the compensation procedures in case of injury during the study.	<input type="checkbox"/>	<input type="checkbox"/>
9.	I know who to contact if I have any questions about the study in general.	<input type="checkbox"/>	<input type="checkbox"/>
10.	I understand my responsibilities as a study participant.	<input type="checkbox"/>	<input type="checkbox"/>
11.	I agree to be re-contacted by the study team in the future for more information or follow up.	<input type="checkbox"/>	<input type="checkbox"/>
12.	I wish to receive a summary of the study results.	<input type="checkbox"/>	<input type="checkbox"/>
13.	I consent to study staff linking my study information to national databases in order to look at the long-term effect of the OL@-OR@ app on health.	<input type="checkbox"/>	<input type="checkbox"/>