Family Diabetes Intervention Programme (FDIP)

Protocol

Co-design & Implementation of a Pacific Family Diabetes Intervention: pilot approach

Trial Registration Number: *registration submitted to ANZCTR*

(Universal Trial Number U1111-1266-0219)

Principal Investigators:

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**Coordinating Centre**

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# Project Team Members

**University Team**

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| **Name** | **Institution** | **Role** |
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| Ms Akarere Henry | South Waikato Pacific Island Community Inc, Tokoroa | Associate Investigator |
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**Project Support Staff**

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# Contact Details

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**Project Management**

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**Project Sponsors**

The principal financial sponsor of this intervention is the Healthier Lives National Science Challenge - *He Oranga Hauora*, hosted by the University of Otago, PO, Box 56 Dunedin 9054, New Zealand. The design, conduct, analyses and interpretation of trial results are independent of the trial sponsor.

# Signature Page

Coordinating investigator(s):

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| Name | Signature: |  | Date: |
| Dr Riz Tupa’i-Firestone | C:\Users\jlis004\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.Outlook\EUIKVWSN\riz_signature.jpg |  | 12/03/2021 |

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| Revision Chronology: | Date | Type |
| Version 1.0 | 12/03/2021 | Final draft |
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# Overview

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| **Title of study**: Family Diabetes Intervention |
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| **Investigators and study centres:** This study has been designed jointly by independent investigators at the Research Centre for Hauora and Health (RCHH) Massey University, Wellington; School of Health, Victoria University of Wellington; Department of Nutrition and Behavioural Science, University of Utah; and the South Waikato Pacific Islands Community Services Trust. The overall design and conduct of this study will be the joint responsibility of the Principal Investigator and the project team. Publication of data from this study will be the responsibility of members of the university team. The study will be co-ordinated by RCHH. |
| **Study period: February 2021-January 2023** |
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| **Objectives:** The primary objective of this project: Can we co-design an effective approach to family-centred diabetes prevention for Pacific families that is capable of being tested in a larger population? |
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| **Duration of intervention:** 24 weeks (6 months) |
| **Study design and methodology:** The FDIP is a pragmatic, community-based intervention (no control group). All participants will be followed for 24 weeks with assessments at baseline and at the end of the intervention (weeks 25 and 26). |
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| **Study population:** Participants will be adults (≥ 18 years old) who identify with being Pacific ethnicity, live in the South Waikato region, New Zealand, and are interested in improving their health and wellbeing or making lifestyle changes. The participants are identified by the Community Coordinator affiliated with the Pacific health care provider who have been involved in the co-design phase of the intervention. |
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| **Number of subjects:** Phase 1 = 20 individuals with prediabetes or diabetes (newly diagnosed); Phase 2 = 100 people (approximately 20 families). |
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| **Main criteria for inclusion:** |
| * Pacific ethnicity (self-identified) * at least one family member at high risk of developing diabetes (defined by having a BMI>30 and high blood-pressure) * diagnosed as having type 2 diabetes (<12 months diagnosis) * resides in a moderate-high deprivation area |
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| **Criteria for evaluation:** |
| Primary outcome  The primary outcome is adherence to the family healthy lifestyle behaviours (intervention) to reduce the risk factors of/and diagnosed type 2 diabetes, over a 24 week period using:   * anthropometry (measured using BMI, blood pressure) * HbA1c blood test (at the end of the intervention, carried out at their GP clinic) * Family and health wellbeing status * Physical activity |
| Secondary outcomes  Measured at 26 weeks using talanoa meetings with all families to evaluate the F-DIP to better understand ‘user-engagement’ of the intervention programme. |
| **Analyses:**  Data from this intervention will be entered into a managed database, and imported to SAS version 9.4 (SAS Institute Inc. Cary NC) for data analysis at RCHH. We propose to use Exploratory Factor Analyses (EFA) to analyse dietary factors to examine consumed dietary patterns for all individuals within families. Logistic regression will be used to examine associations between participants (with diabetes) dietary patterns and co-variates (gender, wellbeing status, and other risk factors for diabetes), adjusting for known confounders. A full statistical analysis plan will be developed a priori to guide final analysis and reporting. |
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| **Funding:** This project is funded by the Healthier Lives *He Oranga Hauora* National Science Challenge. |
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# Study Plan Schematic

**Enrolment pathway**

1. Invited by Community Coordinator (phase 1)

2. Invited by participant (phase 1 and Community Coordinator)

3. Invited by another participant from the same community region

Talanoa sessions to evaluate the intervention, measured from 26 weeks

Outcome assessments

measured at 25 weeks

**Phase 2**

Informed consent from heads of families

Baseline assessment

Start Intervention for 24 weeks

**Phase 1**

Co-design F-DIP

n=20 individuals

# Background

Non-communicable diseases (NCD) account for a large proportion of the disease burden worldwide. The recent Global Burden of Disease Study shows that chronic conditions make up over 87% of the total health burden in New Zealand (NZ)1. Several NCD conditions including cardiovascular disease, cancers, mental illness and diabetes are the most common diseases affecting the adult population, with Pacific peoples experiencing the highest levels of inequities from these conditions, compared to other NZ ethnic groups2. Of these NCDs, type two diabetes (T2DM) is the fastest growing long-term condition. From the Ministry of Health’s virtual diabetes register 2005-20173, the number of people with undiagnosed T2DM has been estimated between 5,300 and 22,900 people nationally. Additionally, the prevalence of T2DM is highest among the older age groups, approximately 15-20% in people aged over 65 years, albeit, the prevalence is also increasing among younger people (25-39 years), particularly among Pacific peoples, where the prevalence is three times higher than NZ Europeans4. Furthermore, Pacific peoples have a greater rate of progression from prediabetes to T2DM than the total population because they had more advanced prediabetes at the time it was diagnosed (by higher HbA1c)5. It has been estimated that the health cost of T2DM is projected to rise to $1.8 billion by 2021/22. The high health and economic cost of the growing T2DM epidemic requires a critical focus on implementing effective prevention programmes, especially for high risk population groups4. There has been limited intervention-based research that have focused on reducing the prevalence of T2DM for Pacific peoples and adequately addressing known barriers associated with social, economic and cultural issues that preclude independent healthy living. It is now timely, that a specific focus on Pacific peoples and T2DM prevention be appropriately addressed.

Previous preventative approaches have attempted to take into account ethnic and socio-economic inequalities in risk factor exposures6. Several well documented government initiatives include: (1) Healthy Families NZ, a community leadership approach to prevent chronic illnesses and address health system inequities7. Healthy Families NZ has identified that localised level improvements are needed, particularly in how use of local data and knowledge are managed and made accessible to enable greater insights into community contexts8; (2) NZ Green Prescription primary health care exercise initiative (GRx), aimed at regulating better standards and improving access to physical activities and healthier lifestyles, targeting patients at risk of metabolic syndrome. Findings at a 2-3 year-follow-up highlighted that the GRx was effective long-term for men and women who completed the 12-week programme. However, it was noted that compliance could be improved with better communication and collaboration between provider and community, and a more tailored approach for Māori and other indigenous groups9.

There have been several research programmes that have highlighted community-based approaches as being important to enabling behavioural change, particularly where communities are partnered with health services developing healthier lifestyle programmes. Examples such as Ngāti and Healthy10, and community church-based initiatives, like the LotuMoui Health programme11, highlighted the need for communities to be key stakeholders as part of the design and implementation of programmes. National-based preventative programmes addressing the T2DM burden primarily through lifestyle and behavioural changes10 12 alongside a few international studies also suggest some success with such approaches in reducing the progression to T2DM13 14.

Small scale piloted projects in NZ (eg. Choose Change Project, Active Families) employed mainstream community-based programmes focusing on lifestyle behavioural changes15 16, however, reported barriers and challenges such as costs and transport issues [to the programme] were noted as common barriers preventing Pacific peoples from participating15 16. Recent findings from the BetaMe randomised controlled trial highlighted a 16-week individualised lifestyle programme compared to ‘usual care’ among primary care populations in improving T2DM control and prediabetes risk, measured by changes in HbA1c and weight-loss over a 12-month lifestyle maintenance period17. Their pilot work showed reduced HbA1c levels among 117 patients with prediabetes over a four-month period. The 12-month results are not yet available, but if effective, the BetaMe programme may be well-placed to be applicable within a primary healthcare provider context17. The Mana Tū project was developed in response to current ethnic and social inequities facing patients with high prevalence rates of T2DM and wider social-cultural determinants18. Mana Tū was an attempt to address health system, service and patient factors that impact on the whānau’s ability to ‘stand with authority’ when living with NCDs. Key learnings from Mana Tū highlighted the capacity development of people with skills that can be used for life, and which establish a framework for change that brings individuals, whānau, services and systems together to improve short- and long-term outcomes. The Pasifika Prediabetes Youth Empowerment Programme (PPYEP) piloted a co-designed approach involving empowering youth (15-24yrs) located within two large Pacific communities (HRC 16-713)19, addressing prediabetes risk among Pacific adults (aged 25-44 years) in their respective communities. Preliminary [unpublished] findings showed significant improvements over an 8-week intervention period in: reduced total body weight (>-2.4%,p=0.0004); decreased waist circumference (-1.6%, p=0.0491); and improved levels of physical activity (47,252 steps, p=<0.001)20. Qualitative findings [unpublished] also highlighted the effectiveness of the co-designed approach. Intervention participants identified four enablers of the programme: (i) community-centred focus utilising the community strengths and resources; (ii) group-based activities preferred over individual programs; (iii) knowledge translation through empowerment; and (iv) family-focused intervention is essential to benefit the whole family health and wellbeing21.

In February 2020, a Pacific Fono was held with representatives from Pacific communities and providers, District Health Boards (DHBs), Pacific health researchers, academics and members of the Challenge Senior Leadership Team. At the Fono, several major themes were identified: a focus on Pacific peoples and T2DM prevention that must be family-centred; empowerment of Pacific communities; research to understand better how to address health system inequities for Pacific peoples; and the need to enhanced health literacy and education for communities. Therefore, this proposal was borne out of the [above] themes collectively identified and agreed by the community and stakeholders at this Fono.

Pacific families are the nucleus that make up Pacific communities, and often determine how communities operate collectively. Building on the established community partnerships and capacity development work from project HRC16-71322, the overall purpose of this proposal is to co-design and evaluate a unique Pacific family-centred diabetes prevention programme. Of note, this proposal differs from the previously funded study (PPYEP) because the focus is on families and T2DM prevention, although we will utilise the same co-design and empowerment approach that was piloted from the PPYEP study. This proposal is ‘implementation research’ that inherently seeks to provide a documented method, that a co-designed prevention and evaluation programme should be well-placed in a community context (intended outcome), hence our strong engagement with the community stakeholder, who are also named AIs.

# Rationale for the Present Study

There is a lack of appropriate approaches that focus on supporting Pacific families with members who have or are at high risk of diabetes. Thus, the overall purpose of this proposal is addressing this gap and to develop a programme that is culturally relevant to Pacific families focused on diabetes prevention in the community. The specific aims include: (1) co-designing and implementing a diabetes intervention programme that is family-centred and tailored to the realities of Pacific families; (2) evaluating the impact of the prevention programme from a systems (health and communities) perspective using developmental reflective evaluation and talanoa approaches. The pragmatic outcome of this research will be evident in a documented methodology, that includes programming and resources established from the co-design approach, that will provide actionable knowledge on how to address health inequities for Pacific families managing and living with diabetes in a community context.

# Study Objectives

**Objectives:** The primary objective of this project: Can we co-design an effective approach to family-centred diabetes prevention for Pacific families that is capable of being tested in a larger population?

We hypothesize that using a culturally-tailored, co-designed, *lifestyle family diabetes intervention programme* for 24 weeks will be effective in improving and supporting important lifestyle behaviours that pose a risk for those with diabetes.

# Study Design

## Inclusion criteria

Participants recruited into the intervention will be members of a Pacific family who has high risk of, or recently diagnosed type 2 diabetes and signed up to take part in the study, reside in the South Waikato region, be aged ≥ 18 years, are able to provide written consent.

Exclusion criteria

Participants will not be able to enrol in the trial if they are aged less than 18 years old, do not have high risk of developing or long-term diagnosis of type 2 diabetes.

## Recruitment

Recruitment will be led by the Community Coordinator who have identified the families and will approach potential participants within the region who are interested in making lifestyle changes. Our community partner has existing relationships with Pacific communities as the main Pacific health provider.

Once initial contact has been made (face-to-face), the participant will be given information on what is required to be involved with phase 1 of the study, including outlining the possibility of being invited to participate in phase 2. The coordinator will then provide informed consent for their participation in the whole study.

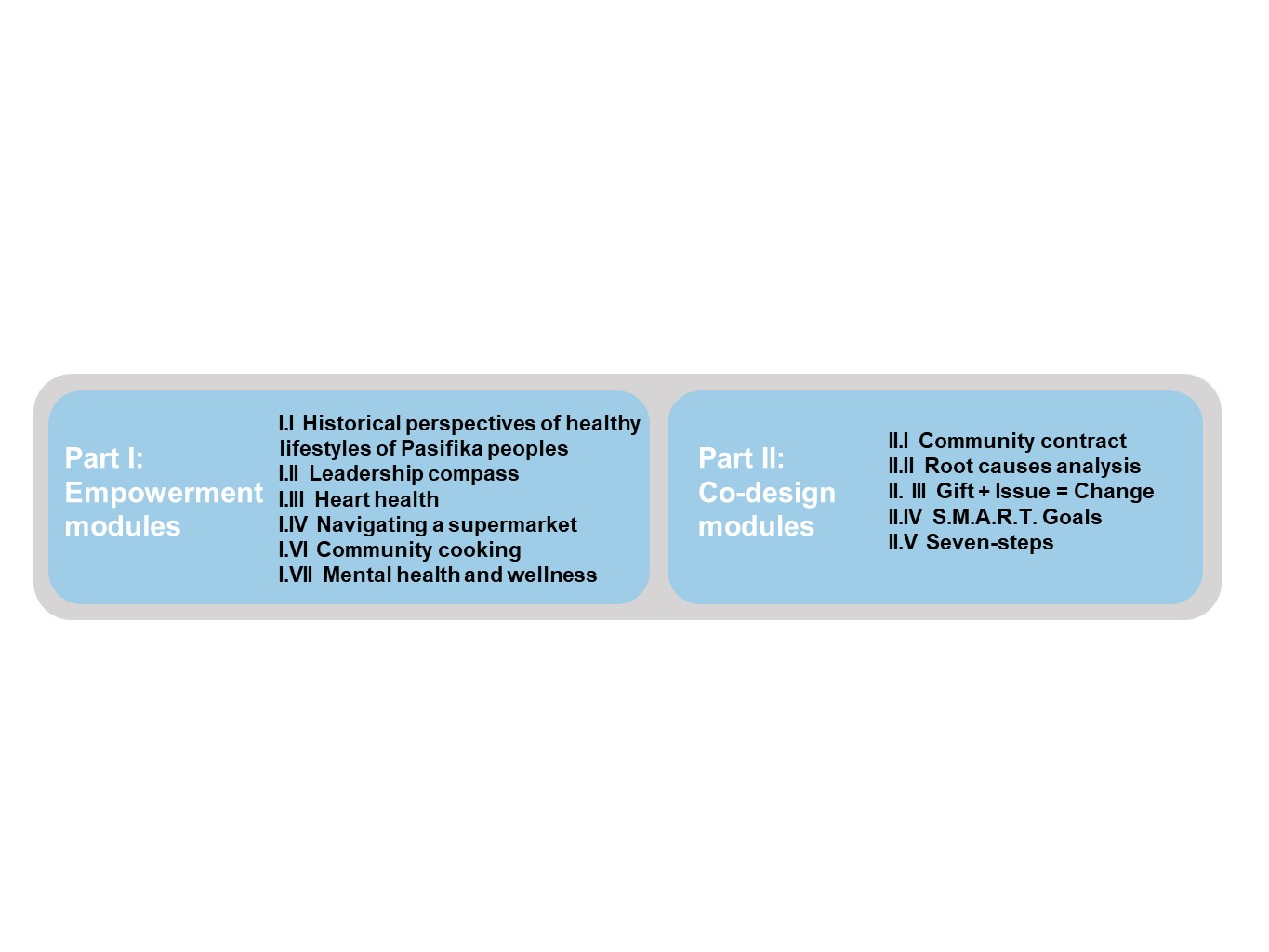
The next step will be for the Community Coordinator to start recruiting participants for the phase 2 of the trial – naturally this recruitment will be through the participants from phase 1. Specific recruitment methods will be decided by the Pacific health provider, including:

* Inviting potential participants to face-to-face information sessions on the intervention
* Word of mouth

## Study procedures

People who are identified by their local Community Coordinator will be invited to participate in the study. An information meeting may be organised to provide information about the study and answer any questions potential participants and their families may have. Potential participants will be provided with a copy of the Information Sheet and consent forms. People who are interested and meet the inclusion criteria may sign up for the study with the Community Coordinator.

**Phase 1:** Potential participants (n=20) who consent to participate will participate in several research workshops to co-develop the F-DIP using an established model (see Figure below).

**Phase 2:** The co-designed intervention programme will run for 24 weeks, and participants in intervention can continue using the intervention programme, if they wish to.

At the end of the intervention period, each family will be invited to attend a mini focus group with another family to talanoa (consult) on the learnings and potential long-term uptake of the intervention. This will be led by our Community partner as an opportunity for our partners to gain further insights from the wider community involved in the intervention to benefit their organisation/services they provide.

If the results look favourable and we are able to source additional funding we may look to scale up the intervention to other Pacific and Maori communities, and measure longer term follow ups.

## Payments for involvement in the study

To acknowledge participants’ time and involvement in the study me’alofa (koha) will be available for each family which will be around $1700 per cluster (pro-rated per number of participants recruited). The Community Partner will decide the best way to provide me’alofa to the communities involved however this will likely be through a voucher, cash for the community, or they may elect to share the me’alofa equally between enrolled participants.

## Withdrawal criteria

Reasons for withdrawal include:

* The participant makes a voluntary decision to withdraw;
* The study is terminated for any reason.

## Baseline assessments

At baseline assessment, the following data will be collected:

* **Socio-demographic data:** date of birth, gender, ethnicity, 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 (eg high cholesterol, diabetes – including date of diagnosis);
* **Risk factors:** BMI, high blood pressure;
* **Physical functioning:** measured by the 6 minute walking test at baseline and post-intervention;
* **Smoking and alcohol consumption:** Measured by items from the New Zealand Health Survey[21](#_ENREF_21);
* **Holistic wellbeing:** spiritual, physical, mental and family wellbeing measured by 10-items based on the Fonofale Model[25](#_ENREF_25), the Ottawa Charter and Hua Oranga[24](#_ENREF_24) designed for the purpose of this study. All answers are measured on a 5-point Likert scale.

## Primary outcome measure

The primary outcome is 24 weeks participant adherence to a family co-designed diabetes intervention programme. Measurements (listed above) are measured at an individual level but analysed at a group level.

## Secondary outcome measures

We will use mini-focus groups to examine the secondary outcome, using talanoa approach which is a well-used Pacific methodology. The data will be transcribed and analysed according to Braun and Clark’s 6 steps of qualitative research25.

## 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 RCHH. 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.

### Record retention policy

Paper records, electronic files, and source documents will be retained for 10 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.

# Ethical Approval and Consent

## 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 prior to taking part in the study. All participant data collected will be treated as confidential and stored securely at RCHH.

## SCOTT committee approval

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

## 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 the Community Coordinator during an invitational meeting.  Informed consent will be obtained at the time of registration once participants have had the opportunity to read the Information Sheet and ask any questions to Community Coordinator or other members of the study team.   In addition, GP details will be requested (i.e. GP name and practice name), so that information about the study can be shared, as appropriate.

# Assessment of Safety / Adverse Event Reporting

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

# Clinical Supplies

No clinical supplies are used in this study.

# Relevance to Health

Pacific peoples have one of the highest rates of type 2 diabetes, predominantly resulting from unhealthy diets and inadequate physical activity. Moreover, there are important health inequalities, with Pacific peoples experiencing a greater burden of obesity and nutrition-related disease. The scope and scale of this problem indicate an urgent need for culturally-tailored, evidence-based interventions to support individuals and their families 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.

This co-design phase of the project will be informed by a Pacific framework that will ensure that the intervention content and approach, selection of behavioural determinants will be culturally-tailored and feasible within a Pacific family environment.

# Dissemination of Results

## Trial registration

The intervention has been registered online on the Australian New Zealand Clinical Trials Registry.

## Study participants

Study participants will be informed about the project 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. We will also host dissemination workshop and present the overall results back to the community.

## The general public

The general public will be informed about the intervention 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.

## Academic/professional colleagues

Academic/professional colleagues will be informed about the intervention 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 website.

## 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, and the Pacific Islander Center of Primary Care Excellence (PI-COPCE). PI-COPCE is an innovative network that includes representatives from local ministries, departments of health, national Pacific Islander Diabetes Prevention Program (DPP) partners, and the Association of Asian Pacific Community Health Organisations (AAPCHO).

## Iwi/Māori

Dissemination of findings to Māori organisations, media and community groups will be guided by our Māori Advisor (Dr Te Morenga) and in consultation with the Healthier Lives Challenge Kahui group.

## Pacific Island communities

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

# Administrative Section

## 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.

## Protocol revision procedures

All revisions will be discussed with, and approved by, the Principal Investigator 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-RegionalEthics Committee for review and approval or favourable opinion prior to implementation. Documentation of approval signed by the chairperson or designee of the National Multi-RegionalEthics 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-RegionalEthics 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;

## Case report form procedures

All questionnaire information will be collected and directly entered into the study database.

## Monitoring/ Source document verification

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

## 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 intervention.

## Record retention policy

The project manager 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 intervention will not destroy any records associated with the trial, without the prior approval of the project manager. If the Principal Investigator or any associate-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 RCHH.

## Insurance

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

## Ownership of data and publication policy

Individual study data will remain the property of individual study participants. RCHH 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 Pacific-specific data will be the joint responsibility of the University team and the Pacific Community Partner. 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.

## Intellectual Property

Below are the IP project agreements with the community partner:

* 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 Pacific peoples.
* 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 any interested mana whenua where the research is conducted.

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# 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 intervention and the study.

Dr Ridvan Firestone 19 March 2021

Investigator's printed name and signature Date

# Appendix 1 – Informed Consent Procedures

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 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 RCHH.
* 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.

# Appendix 2 – Key Milestones

|  |  |  |
| --- | --- | --- |
| **Milestones** | **Related objectives** | **End Date** |
| 1. Inform the mana whenua in of the participating community area about the research to ensure they are aware of the research and have an opportunity to collaborate with the research team. | All | 30 June 2021 |
| 1. Submit Ethics application to HDEC |  |
| 1. Phase 1 - Identify family participants via SWPICs network |  |
| 1. Phase 1 - (Family mentor training component) started |  |  |
|  |  | 30 June 2022 |
| 1. Submit a Project Communications Plan(using template supplied) | All |
| 1. Phase 1 of the study (Co-design component) started. |  |
| 1. Phase 2 of the study (implementation) started. |  |
|  |  |  |
| 1. Phase 1 & 2 findings analysed | All | 31 Jan 2023 |
| 1. Plans for dissemination started, including engagement with other stakeholders (other PHOs, NGOs, etc) |  |
| 1. Provide final report. |  |