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An Aotearoa New Zealand diet for metabolic health and whanau wellbeing: He Rourou Whai Painga

Submission date
02/06/2022

Recruitment status
No longer recruiting

Registration date
14/06/2022

Overall study status
Completed

Last Edited
14/08/2024

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cardiovascular disease and diabetes are common in New Zealand and good nutrition plays a role in decreasing the risk of developing these diseases. This research will test whether the consumption of foods which are mostly vegetables, fruit, legumes (beans and peas), fruits, unrefined cereals, nuts, seafood and smaller portions of lean red meat and dairy, offers health benefits to people at risk of cardiometabolic disease and their families. Research has shown that such eating patterns can improve metabolic, cardiovascular, and wellbeing profiles in people at risk of these diseases, but this concept has not been studied in the New Zealand population using New Zealand foods and beverages. The aim of this study is to evaluate the effect, over 12 months, of 12 weeks of nutritious food and dietary support, and whether it will improve the health of adults living in New Zealand and their families.

Who can participate?
Any adult between 18-70 years can volunteer to participate. They will be assessed to see if they meet the eligibility criteria and if so, they are welcome to take part. Each participating adult can invite up to five members of their household to take part.

What does the study involve?
The study involves attending the research centre between 5-6 times over a period of about a year. Participants will undergo clinical assessments and will be asked to complete questionnaires about their health and wellbeing. They will receive up to 75% of the weekly food in addition to behaviour change support for the first or second 12 weeks of the study. They may also be invited to take part in focus groups or interviews to describe their experiences.

What are the possible benefits and risks of participating?
Eating the foods provided may improve the health and wellbeing of participants. There are small risks related to the blood tests such as bruising, fainting or light-headedness. Also, when people change what they eat to include more fibre, they might have some extra flatulence or loose

bowel motions. The radiation from the DXA scan is very low risk. Whilst processes will be in place to protect data, no system is completely failsafe. and there is a very small risk of breach of privacy.

Where is the study run from?
University of Otago (New Zealand)

When is the study starting and how long is it expected to run for?
January 2020 to June 2024

Who is funding the study?
High Value Nutrition National Science Challenge (New Zealand)

Who is the main contact?
Dr Fiona Lithander, fiona.lithander@auckland.ac.nz

Contact information

Type(s)
Scientific

Contact name
Dr Fiona Lithander

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
ACTRN12622000906752

Study information

Scientific Title
An Aotearoa New Zealand Diet for Metabolic Health and Whanau Wellbeing: He Rourou Whai Painga (HRWP); a randomised controlled trial of a dietary pattern in adults at metabolic risk and their whanau and the effect on metabolic syndrome z score

Acronym
HRWP

Study objectives
A 12-week dietary intervention incorporating nutritious New Zealand food and beverage products will improve metabolic health in individuals at risk of developing metabolic disease and their whānau and, with targeted dietary change support, lead to long-term adoption of a healthy plant-rich dietary pattern.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/05/2022, Northern B Health and Disability Ethics Committee (Health and Disability Ethics Committees, Ministry of Health, 133 Molesworth Street, PO Box 5013 Wellington 6011, New Zealand; +64 (0)4 819 6877; hdecs@health.gov.nz, hdecs@moh.govt.nz), ref: 2022 FULL 12045

Study design
Multicentre interventional randomized controlled trial combined with a 12-month longitudinal observation study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Metabolic syndrome

Interventions
This is a randomised controlled trial of food provision and dietary change support (Group A) compared with a self-selected habitual dietary intake (Group B) for 12 weeks.

Randomisation will be via a computer-generated sequence. The group randomised to the self-selected habitual dietary intake (Group B) will, after 12 weeks, receive the food provision and dietary change support phase for 12 weeks.

In both groups, the 12-week intervention phase will be followed by a secondary randomisation to receive continued dietary change support for a further 12 weeks or enter directly into an observational maintenance phase. This will be followed by a longitudinal observational follow-up of all participants out to a total of 52 weeks from the initiation of the intervention diet.

Index participants will be adults at risk of metabolic and cardiovascular disease and up to five members of their household/whanau will be invited to also take part in the study.

The food provision means that participants and their household/whanau will receive up to 75% of their weekly food delivered to their home for 12 weeks. The food, which together forms a dietary pattern, is rich in fruit, vegetables, whole grains, olive oil and seafood with limited red meat and dairy.

The dietary change support includes a participant-facing study website with guidance on how to change dietary behaviour, recipes and meal plans, and information about the metabolic syndrome and the foods provided. The support includes access to Facebook groups and peer-support online activities. The online support is designed and delivered by research dietitians with a minimum of 5 years of experience.

The intervention itself (food provision and dietary change support) is delivered over a period of 12 weeks. Participants and their household/whanau will receive the food at their homes on a weekly/fortnightly basis. The dietary change support will be available at all times through the intervention and beyond, as necessary.

The research visits will take place in four research centers across New Zealand. Depending on whether participants have been randomised to Group A or Group B determines how many times they and their household/whanau participants will visit the research; either 5-6 times. Each visit will last 1-3 hours, depending on the measurements to be undertaken at that visit. Visits will take place virtually or in the participant's homes if regulations specify this at the time.

Intervention adherence will be measured through the collection of dietary intake data and the assessment of it against a Mediterranean diet score.

(added 24/06/2022): To understand participants' experiences in this study, a full integrated qualitative consumer insights study will be undertaken concurrently to the other assessments. The purpose of this part of the study is to gain insights into the perceptions, attitudes and emotions of participants and to corroborate behavioural data gained in the quantitative study with respect to the adoption and maintenance of the intervention diet. This component is delivered by experts in qualitative research methodology.

Intervention Type
Mixed

Primary outcome(s)
Metabolic syndrome severity z-Score (MetS-z) measured using a fasted blood sample (for glucose and lipids), blood pressure and waist circumference at 12 weeks

Key secondary outcome(s))
1. Weight measured using a weighing scales at 12 weeks
2. Body composition (body mass index [BMI], fat mass and lean mass) measured using a DXA scan, weighing scales and a stadiometer at 12 weeks
3. Dietary pattern among index participants measured using dietary pattern analyses at 12 weeks
4. Change from baseline in metabolic syndrome severity z-score (MetS-z) in full cohort measured using a fasted blood sample (for glucose and lipids), blood pressure and waist circumference at 24 and 52 weeks
5. Individual components of MetS z score measured using a fasted blood sample (for glucose and lipids), waist circumference and blood pressure at 12 weeks
6. Change in individual components of the MetS z score (fasting glucose, waist circumference, blood pressure, lipid profile) in full cohort at 24 weeks

7. Change in individual components of the MetS z score (fasting glucose, waist circumference, blood pressure, lipid profile) in full cohort at 52 weeks
8. Dietary pattern after secondary randomisation to continued support vs no ongoing support measured using dietary pattern analyses from 12 weeks to 24 weeks

(added 24/06/2022):
Qualitative component outcome measures, measured using NVivo software to assist with a thematic analysis using open and axial coding after the end of the intervention:
1. Participants' reported on their understanding of what a healthy way of eating is.
2. Participants' reported on the application of the 'tools' they are learning from the programme to assist them in adopting this healthy eating programme.
3. Participants' reported on any empowerment in their ability to follow this new way of healthy eating.
4. Participants reported on their ability to encourage their family to follow this new way of healthy eating.
5. Participants reported their feelings of wellbeing.
6. Participants reported on their ability to follow this new way of healthy eating.
7. Participants reported their intentions regarding following this new way of healthy eating.

Completion date
10/06/2024

Eligibility

Key inclusion criteria
For index individuals:
1. Adults aged 18-70 years
2. Metabolic syndrome severity z-score (MetS-Z) >0.35
3. In addition to the index individual, a minimum of one other whanau member in the household agrees to participate (these additional household members, if they qualify, may also be enrolled as an index individual). Up to five whanau are eligible to take part
4. Participants and their whanau are planning to live together for the duration of the study
5. Access to the internet at home
6. Able and willing to attend all site visits
7. Is willing to adhere to local health and safety regulations
8. For the consumer insights study there needs to be a willingness to be interviewed

For household/whanau members:
1. Living in the same household as the index individual
2. Consent/assent to consume the intervention diet
All household/whanau members who qualify for inclusion will: a) complete age-appropriate questionnaires; b) be invited to undertake clinical measurements; and c) be invited to provide blood samples if aged 11 years and over.

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group

All

Lower age limit
18 years

Upper age limit
70 years

Sex
All

Total final enrolment
200

Key exclusion criteria
For index individuals:
1. Previous bariatric surgery, or pre-existing Type 1, or Type 2 diabetes. Where a previous diagnosis of type 2 diabetes mellitus (T2DM) is uncertain, this will be defined as ever having had two consecutive HbA1c results greater than or equal to 50 mmol/mol that are at least 3 months apart
2. Total cholesterol greater than or equal to 8 mmol/l
3. Chronic severe renal disease (eGFR <30 ml/min/1.72m^2)
4. Current pregnancy or breastfeeding, or planning to conceive during the study (due to impact on interpreting outcome measures)
5. Unstable body weight (active weight loss/gain >5 kg in the prior 3 months)
6. Gastrointestinal disorder that alters the digestion and absorption of nutrients (e.g. ulcerative colitis, Crohn's disease, coeliac disease, an ileostomy or colostomy)
7. Severe food allergies (anaphylaxis) or intolerances in any household member
8. Medication use – current use of medications that modify blood sugar levels, or anticipated regular use of oral or injected steroids
9. Does not agree to refrain from donating blood for three months prior to each study visit (due to impact on HbA1c)
10. Is participating in, or has recently participated in another research study involving an intervention which may alter outcomes of interest to this study
11. Any other condition or situation, which in the view of investigators would affect the compliance or safety of the individual taking part

For household/whanau members (blood samples):
1. Age <11 years
2. Pre-existing Type 1 diabetes
3. Chronic severe renal disease (eGFR <30 ml/min/1.72 m^2)
4. Current pregnancy or breastfeeding, or planning to conceive during the study (due to impact on interpreting outcome measures)
5. Unstable body weight (active weight loss/gain >5 kg in prior 3 months)
6. Gastrointestinal disorder that alters the digestion and absorption of nutrients (e.g. ulcerative colitis, Crohn's disease, coeliac disease, an ileostomy or colostomy)
7. Medication use – current use of medications that modify blood sugar levels, or anticipated regular use of oral or injected steroids
8. Does not agree to refrain from donating blood for three months prior to each study visit (due to impact on HbA1c)
9. Is participating in, or has recently participated in another research study involving an

intervention which may alter outcomes of interest to this study
10. Any other condition or situation, which in the view of investigators would affect the compliance or safety of the individual taking part
11. Children living in the household but who do not have a legal guardian also living in the household
12. Severe food allergies (anaphylaxis) or intolerances in any household member

Date of first enrolment
20/06/2022

Date of final enrolment
28/02/2023

Locations

Countries of recruitment
New Zealand

Study participating centre
Centre for Endocrine, Diabetes and Obesity Research (CEDOR)
Level 5, Grace Neill Block
Wellington Regional Hospital
Riddiford St, Newtown
PO Box 7902, Wellington South
Welington
New Zealand
6021

Study participating centre
University of Auckland
Department of Nutrition and Dietetics
85 Park Road
Grafton
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New Zealand
1142

Study participating centre
University of Otago
Department of Medicine
2 Riccarton Avenue
PO Box 4345
Christchurch
New Zealand
8140

Study participating centre
Kokiri Marae Keriana Olsen Trust
7-9 Barnes Street
Seaview
Lower Hutt
New Zealand
5010

Sponsor information

Organisation
University of Otago

ROR
https://ror.org/01jmxt844

Funder(s)

Funder type
Research organisation

Funder Name
High Value Nutrition National Science Challenge

Results and Publications

Individual participant data (IPD) sharing plan
De-identified data that underlie the results may be available in published study results including but not limited to reports to the funder, peer-reviewed publications, clinical trial registry websites, scientific meetings, and regulatory/marketing submissions.

The name and email address for the investigator/body who should be contacted for access to the datasets: Prof. Jeremy Krebs (Jeremy.krebs@otago.ac.nz).
The type of data: de-identified data.
When the data will become available and for how long: beginning 9 months following article publication and ending 36 months following article publication.
By what access criteria data will be shared including with whom: Investigators whose proposed use of the data has been approved by the Senior Leadership Team of the current trial.
For what types of analyses: for the purposes outlined in the proposal received from the

applicant who wishes to use the de-identified data.
Whether consent from participants was obtained: No. Any data shared would be de-identified.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/07/2024	14/08/2024	Yes	No
Protocol article		11/12/2023	27/12/2023	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes