THE EFFECT OF AN EXERCISE AND LIFESTYLE MANAGEMENT PROGRAMME ON CARDIOVASCULAR RISK REDUCTION: RATIONALE AND DESIGN OF A CLUSTER CONTROLLED TRIAL USING A KAUPAPA MĀORI PHILOSOPHY

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ABSRACT

Background: Māori, the indigenous population of New Zealand, are disproportionately affected by cardiovascular disease. Innovative approaches that acknowledge a Māori worldview of health are required to address this inequity. Methods: A 12-week exercise and lifestyle management controlled trial, using kaupapa Māori methods and a cluster wait-list design, will be used. Participants will be enrolled in clusters and must be aged over 18 years, of Māori descent, and have at least two risk factors for cardiovascular disease. Once assigned to the intervention, participant clusters are able to redevelop a usual-care 12-week exercise and lifestyle management programme to embed a Māori worldview. The redevelopment process will occur within a focus group setting with each cluster. Clinical measures are assessed pre- and post- 12-week programme. An evaluation focus group will be held to assess acceptability of the programme. Discussion: The significance of this project is the ability to provide an intervention for the prevention of cardiovascular disease that draws from both a western medical and a kaupapa Māori knowledge base. Acknowledgment of the worldview of the participant group and having a usual care programme reshaped by that participant group based on their unique perspective is novel in health. Trial Registration: Registered with the Australia and New Zealand Clinical Trials registry on 13 October 2015. Trial ID: ACTRN12615001077550

KEYWORDS

Cardiovascular disease, prevention, lifestyle management, kaupapa Māori.

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BACKGROUND

Cardiovascular disease (CVD) remains the leading cause of premature death and disability for all New Zealanders, accounting for 30% of deaths annually (1). Māori are the indigenous people of New Zealand and are disproportionately affected by CVD which is the principal reason for the difference in life expectancy between Māori and non-Māori (2,3). Life expectancy at birth is 76.5 years for Māori women and 72.8 years for Māori men, compared with 83.7 years for non-Māori women and 80.2 years for non-Māori men (4). Innovative approaches, focusing on prevention and management of CVD and using principles associated with a Māori worldview, are required to improve cardiovascular health outcomes and life expectancy for Māori. Kaupapa Māori is an accepted framework for health research in Aotearoa / New Zealand and is underpinned by critical theory (5,6). Māori beliefs and values are placed at the centre of the research process and findings are applied based on Māori views of the world. Māori health is holistic, considering more than just the physical aspects of a person, and a number of Māori health models exist (7,8,9) The most commonly referenced model is Mason Durie's Whare Tapa Whā (8). The model is symbolised as a wharenui (meeting house) with the four walls of the whare (house) representing the four dimensions of Māori health: Taha hinengaro (mental health), Taha wairua (spiritual health), Taha whānau (health of the family) and Taha tinana (physical health). Each wall is essential for the strength and symmetry of the whare and as such each dimension of health must be balanced for an individual to be well.

In addition, there must be stable whenua (land) on which the house stands thus the importance of connection to land for Māori is also a key component to consider in health.

Kaupapa Māori health research therefore works innately within a Māori model of health and, in contrast to western science, emphasises relationships and is cross disciplinary rather than based on categorisations and disciplinary divisions. Kaupapa Māori research is based on whakapapa (genealogical) relationships and is accountable to those relationships (10). Māori in Aotearoa are a modern people who interact with their environment in different ways depending on the context. Society as a whole is based on a western system, yet a Māori person may navigate modern society while being engaged in the traditions and processes of an ancient Māori worldview. Many Māori function within a set of socially acceptable rules while still adhering to the processes that are innate to the Māori world. The Treaty of Waitangi is the founding document of New Zealand and is an agreement between the government and Māori outlining principles of partnership, participation and protection for Māori. The Treaty of Waitangi dictates a basis from which western society ensures that Māori are acknowledged in societal processes and that the importance of a Māori way of life is upheld. The western medical system and western science are an integral part of the management of Māori health, but Māori have poor outcomes in Aotearoa and an approach which acknowledges and incorporates the traditional health and wellness values within the Māori world is needed.

The marriage between modern science and medicine and traditional Māori health values is a positive way forward for Māori in Aotearoa.

A previous project piloted an innovative approach to CVD management for Māori. In New Zealand the Treaty of Waitangi guarantees tino rangatiratanga (Māori control over Māori things) and the pilot programme was an acknowledgement of that indigenous right. The methodological approach used in the pilot has been published, as has a paper reporting the positive clinical outcomes from the pilot (11,12). A 12-week exercise and lifestyle management programme for cardiac risk reduction was embedded with a kaupapa Māori philosophy and Māori participants were involved in its development and management, as well as dissemination of the findings afterward. The key concept of the pilot was that the programme was developed based on Māori needs to create structure for a 'by Māori, for Māori' programme. Essentially, key components of a usual care programme were integrated with kaupapa Māori concepts so that western science and medicine as well as Māori values were acknowledged and Māori had control over the process. A kaupapa Māori project that has produced positive clinical outcomes has never been re-tested with another group of Māori to determine if findings can be replicated when a potentially different programme is developed,

based on the Māori consultation process.

A subsequent study is therefore essential for extending knowledge about kaupapa Māori programmes. The purpose of this study was to integrate kaupapa Māori and medical science within a practice-based research setting. The concept of an interface space, in which the Māori researcher or health professional functions, has been introduced by Durie (13). The interface space describes a 'third space' between the Māori world and, in this case, the medical, scientific world where a 'new' philosophy is created that takes the best of both worlds and moulds those concepts to

create an innovative way forward. In a health environment where the uptake of alternative and complementary therapies is increasing (14) and an anecdotal dissatisfaction with a rigid western medical model is becoming apparent (15), understanding different approaches to achieve improved health can only be positive. This is especially the case for Māori and other indigenous cultures whose health worldview is typically disparate from the western medical perspective (16) and health outcomes are poor in comparison

to the dominant culture (17). The primary purpose of this study is to determine the effect of a 12-week exercise and lifestyle management programme that is imbedded with a kaupapa Maori philosophy on cardiac risk reduction.

The specific aims of the project are:

1) To determine the effect of a 12-week kaupapa Māori exercise and lifestyle management programme on CVD risk factors (cholesterol profile, blood pressure, glucose tolerance, waist circumference)

2) To understand what worked well from the perspective of participants in the kaupapa Māori programme and to analyse examples of how participants adapted the programme.

METHODS

Project Design

The study protocol is in accord with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 Statement (18) and was prospectively registered in the Australian New Zealand Clinical Trials Registry 13/10/2015. TrialID: ACTRN12615001077550. The intervention is described according to the Consolidated Standards of Reporting Trials (CONSORT)- eHealth Checklist (19). The trial schedule is presented in Figure 1.

The study is a controlled trial using a kaupapa Māori approach with a cluster wait-list design (20). A wait-list design enrols participants to the "wait-list" of no intervention, where they accrue until the conditions are met that allow them to be allocated to the intervention. In this study, participants are assigned to a cluster, consisting of 4-7 people. A cluster enters the wait-list for a minimum of 6 weeks before the intervention is administered. The next cluster can be assigned to the wait-list after the first cluster has begun the wait list period. This process of uni-directional crossover continues until the required number of participants has been recruited. The specific advantages of this design are that each participant acts as their own control, and administration of the intervention is sequential and so more able to be managed in clinical practice. An individual randomised controlled trial is often considered to be the 'gold standard' in medical science however in this project, of practice-based research, individual randomisation is not appropriate as 1) the Māori worldview is collectivistic as opposed to individualistic and clusters allow integration of whānau (family) into the project, and 2)

	Study Period						
	Enrolment	Control Baseline	Intervention Baseline	Intervention Complete	Follow-up		
Duration (weeks)	0	0	6	12	12	24	52
Time point		T0	T1	T2	T3	T4	T5
Eligibility screen	X						
Informed consent	X						
Allocation	X						
Control Period		X					
Intervention			X	X			
Follow-up					X	X	X
Primary Outcomes							
Waist circumference		X	X	X	X	X	X
HDL cholesterol		X	X	X	X	X	X
Secondary Outcomes							
Cardiorespiratory fitness		X	X	X	X	X	X
Systolic blood pressure		X	X	X	X	X	X
LDL cholesterol		X	X	X	X	X	X
Total:HDL cholesterol		X	X	X	X	X	X
Hip circumference		X	X	X	X	X	X
Waist:hip		X	X	X	X	X	X
Body weight		X	X	X	X	X	X
Forced vital capacity		X	X	X	X	X	X
Quality of life		X	X	X	X	X	X

Figure 1: Consolidated Standards of Reporting Trials (CONSORT)-eHealth Checklist

indigenous groups are typically at high risk of disease and it is not ethical to assign such groups to a non-intervention control (21). Allocation to the intervention in clusters acknowledges the collective nature of the Māori world and is integral to the kaupapa Māori CVD risk management intervention. A cross-over design allows all participants to receive the intervention while retaining a control aspect.

Participants are enrolled into the study as a group and start the minimum wait-list period of 6 weeks, which is considered the time needed to achieve physiological stability. Clinical measurements are taken at the beginning and at the end of the wait-list period (T0, T1), and again at the end of the 12-week intervention (T2). Follow-up measurements occur at 3-, 6- and 12-months post intervention (T3, T4, T5 respectively). The time on the wait-list will vary and the actual time for each person will be taken into account in the analysis.

The co-primary end-points are the change in: High density lipoprotein (HDL) cholesterol and waist circumference.

The secondary end-points are the change in: Systolic blood pressure (SBP), Rate pressure product (RPP), Total cholesterol to HDL cholesterol ratio (TC:HDL), Low density lipoprotein (LDL) cholesterol, Maximal oxygen carrying capacity (VO2max), Body weight, Hip circumference, Waist to hip ratio (WHR), Forced vital capacity (FVC), Forced expiratory volume in one second (FEV1)and Quality of life (QoL)

Recruitment and Sample Size

Inclusion criteria will be Māori individuals with two or more cardiac risk factors, excluding ethnicity (22). Exclusion criteria will be previous myocardial infarction, previous stroke, unstable angina pectoris, hypertrophic cardiomyopathy, decompensated heart failure, symptomatic aortic stenosis and severe pulmonary hypertension (23). Recruitment will be through Māori health providers and the Māori community within the Bay of Plenty.

There is a paucity of relevant quantitative data on community dwelling Māori with 2 or more CVD risk factors on which to estimate sample size with any accuracy. The pilot study obtained complete data on 9 people and so was felt to represent the highest variance that could be obtained. Consequently, larger studies among non-Māori were also assessed to obtain an estimate of the variance of the change in measurements over a similar timeframe as the current study (24, 25). To represent the quantitative outcomes, a biomarker (HDL cholesterol) and a metric of body size (waist circumference) are the basis of the sample size estimates. HDL is cardioprotective and is positively affected by exercise. Findings from the pilot project reported a significant increase in HDL in response to the intervention therefore using HDL as a primary endpoint is efficacious. In clinical practice, waist circumference is used as an indirect measure of visceral fat content, which when increased, is associated with an elevated risk for metabolic abnormalities including those related to CVD risk (obesity, diabetes). To detect a difference in HDL of 0.1 mmol/L with the intervention (SD 0.163 mmol/L) (24), with 80% power and α=0.05, at least 42 participants would be required (when participants act as their own control). A participants are assigned to the intervention in clusters, and there may be high intra-cluster correlation as recruitment of whānau members as a group is encouraged, a design effect of 2 will be used. Estimates of a specific intra-cluster co-efficient were not available. On this basis, 84 participants would be required. Similarly, to detect a difference in waist circumference of 3cm (SD 5.86) (25, 26), 120 participants would be required after applying the design effect.

Consultation

Consultation with key stakeholders in the Māori community is integral to kaupapa Māori research methodologies. Consultation is the process of engaging with Māori health providers, community members, and iwi (tribe) organisations to discuss the proposed research and to obtain feedback. The consultation process allows Māori the avenue to shape research to fit those who will benefit most and to support the integration of a Māori worldview into work that has a western medical component.

There is full support for an integrated kaupapa Māori approach to CVD prevention and management in the Bay of Plenty. The consultation process included an assessment of the requirement for a kaupapa Māori programme for CVD prevention and risk management, input into the methodology, including suggestions for ways to modify the usual care programme to include Māori-specific content, and guidance regarding how and when to disseminate. Once recruitment has occurred, the participants will be able to have input into the methodology and will become the main stakeholders, guiding the kaupapa Māori process.

Kaupapa Māori Programme Design

To design the kaupapa Māori programme a usual care programme is modified to incorporate Māori values. The usual care programme used here is an exercise and lifestyle management programme that adheres to the guidelines provided by the American College of Sports Medicine (ACSM) (27). Participants exercise 3 days per week on a Monday, Wednesday and Friday either at The Centre for Health or at a place of their choice i.e. home, workplace or gym. Individualised programmes are prescribed based on an assessment by a clinical exercise physiologist. The pre-programme assessment includes measurements of body weight, waist circumference, hip circumference, forced vital capacity (FVC), forced expiratory volume in one second (FEV1) (Cardinal Health Micro-Gold standard), resting blood pressure (average of 3 measurements), total cholesterol, HDL cholesterol and LDL cholesterol (CardioChekÒ PA). The point-of-care CardioChekÒ PA system has good accuracy compared to clinical diagnostic laboratory methods and has reasonable compliance for coefficients of variation and bias measurements (28). Body mass index (BMI), waist:hip ratio and total:HDL cholesterol ratio will be calculated. QoL was measured using a non-validated questionnaire that was designed during the pilot study that preceded this work (11). In the pilot project, Māori participants indicated that the validated questionnaires often used to determine QoL (SF-36 (29) and WHOQOL-SRPB (30)) did not reflect a Māori worldview and were not an appropriate measure of QoL for Māori. Therefore, a questionnaire that reflected a Māori worldview was developed in consultation with Māori stakeholders and used in the pilot. The pilot questionnaire was modified again with Māori stakeholders and will be used in its final iteration with six questions under four domains; 1) physical, 2) mental and emotional, 3) family, and 4) spiritual wellbeing. In addition, participants will perform a graded exercise ECG test on a treadmill using XScribe ECG system (Mortara Instrument Inc.) and the modified Naughton treadmill protocol (31). Maximal oxygen carrying capacity (VO2max) will be assessed during the exercise test with a Metalyser 3B gas analyser. Blood pressure, heart rate and rating of perceived exertion will be recorded in the final 30 seconds of each stage of the exercise test. Rate Pressure Product (RPP) will be calculated for each stage of the test. Key findings from the exercise test such as heart rate and blood pressure response, cardiorespiratory fitness, injury status will be used to prescribe the first day of

exercise for each participant. Participants will perform a progressive, combined aerobic and resistance training programme from week 1 through to 12. Six education sessions will be offered at fortnightly intervals. The topics for the usual care programme education sessions are: exercise, nutrition, breathing, stress management, yoga and goal setting. These are offered to the group in addition to Māori specific education sessions e.g. traditional Māori healing, Māori models of health, Māori spirituality. Education sessions will be facilitated in an environment chosen by the group such as the marae, workplace or The Centre for Health. Post-programme assessment is the same as the pre-programme assessment.

The important structural components of the usual care programme are the: exercise prescription (frequency, intensity and modality),
monitoring and supervision of the exercise, provision of education (but not the topics of the education), and clinical measurements (e.g. stress test, blood pressure, cholesterol, lung function, anthropometric measures).

The development of the kaupapa Māori programme will be within an interface space where the important structural components (see above) are managed along with concepts that reflect the Māori worldview. An approach utilising Duries 'interface space' ideal ensures the integrity of the programme from the two perspectives (western medicine and kaupapa Māori in this case) (13). Participants will be grouped into clusters and participate in a consultation focus group on enrolment into the project. At that focus group, each participant in the cluster will be given their individual test results and exercise programmes in a private and confidential manner. The participants will have the opportunity to adapt their programme and determine how they would like a Māori worldview to be embedded. For example each cluster of participants will guide the research team about the content of education sessions, involvement of their whānau within the programme and any cultural practices they believe to be important. Previous consultation for this study and for the pilot programme (11, 12) has provided modifications to the current model of intervention (see examples in Table 1 below). These modifications will be discussed with the participant clusters to incorporate the Māori world into their programme, although participants will be able, and encouraged, to include their own ideas.

Recording of kaupapa Māori methods

For Maori participants, the story of their journey through the programme is important (32). Our

Table 1:Potential Suggested Modifications to the Usual Care Programme

	Usual Care Programme Structure	Potential Kaupapa Māori Programme Modifications
Programme Development	-No involvement in programme structure	-Full involvement in programme structure
Exercise Sessions	-Attend for exercise Mon/Wed/Fri -Attend as an individual -Exercise prescription based on ACSM guidelines	-Exercise Mon/Wed/Fri at a place of choice i.e. home or clinic -Attend as a collective -Exercise prescription based on ACSM guidelines
Nutrition	-3-day written food recall -Individualised menu plan and recommendations	-Whānau focussed menu plan and recommendations -Ad hoc provision of 'bite-sized' nutrition advice throughout the programme
Education sessions	-Classroom based sessions: exercise, nutrition, breathing, stress management, goal setting and yoga	-Options for specific Māori content including but not limited to: Māori models of health, concepts of hinengāro and wairua, rongoa Māori, and gardening. -Whānau welcome to attend -Option to have skype education sessions for remote dwelling participants
Clinical Assessment	-Standard clinical measures as per protocol -SF-36 quality of life questionnaire used	-Standard with acknowledgement of cultural values around blood collection and appropriate practices allowed as requested -Kaupapa Māori QoL questionnaire used
Post-programme debrief	-Standard clinical report	-Tailored holistic report -Focus group evaluation -Celebration with food

jinvestigation will include a qualitative component, recording and analysing the discussions at the beginning of six clusters. Clusters will be selected from those participating at the beginning of the project, in the middle, and towards the end, for formal analysis, although observations and notes from the facilitators of all cluster discussions will also contribute to the research. The recorded discussions will be transcribed. NVivo11, a qualitative data analysis software package, will be utilised to organise qualitative data and then the research team will collaborate to analyse the transcripts, identify patterns and themes across the data and organise into thematic categories and narrative analysis (engaging with the stories and narratives created by the participants during collective discussions) (33).

Evaluation focus groups

Following the kaupapa Māori programme, each cluster will have a focus group evaluation of which six (as above) will be used to formally evaluate the experience of participants and to establish guidelines for kaupapa Māori service provision in health care. The focus group discussion will be a conversation guided by the
research assistant, covering areas such as peoples' journey into and through the programme, the overall benefit of participation to participant and whānau, positive aspects of the programme, and suggestions for change. The evaluation focus groups have the potential to become an integral part of the programme as
the process is aligned with a kaupapa Māori philosophy and allows for ongoing reflection and development. The evaluation focus group hui will be transcribed and inserted into NVivo for thematic analysis.

3-, 6- and 12-month follow-up

Once each participant has completed their 12-week programme there are 3-, 6- and 12-month follow-up assessments to determine sustainability of exercise and lifestyle change. These follow-up assessments are the same as the pre- and post-programme assessments.

Statistical analyses of quantitative outcomes

The intra-individual difference of all primary and secondary endpoints after the 12-week intervention programme will be compared using paired Student t-tests. Similarly, the change in measurements from start to end of the control period (T0 to T1) and from the end of intervention to each follow-up (T1 to T3, T4, T5) will also be assessed.

Dissemination

Dissemination of individual findings will occur to participants on completion of the 12-week programme. All participants will receive a full report detailing their pre and post programme results. Dissemination to stakeholders within the Māori community will occur at the completion of the project by way of a formal report in either written or presented format depending on what stakeholders request. Findings from both pre- and post-programme focus groups, for each cluster, will be provided in report form on completion of the project and followed up by a presentation if requested along with any
other requests for dissemination that are made. Full project dissemination will be through peer reviewed publications. Presentation at appropriate NZ based conferences and international indigenous conferences will be a priority.

DISCUSSION

The significance of this project is multifaceted including 1) the acknowledgment of a Māori worldview of health, 2) the importance of a methodology being able to adapt to fit a cultural context as opposed to the context having to adapt to fit the methodology, and 3) the potential impact on equitable health outcomes for Māori. There are expected clinical health improvements from participation in the 12-week exercise and lifestyle change programme but additionally, and arguably more importantly, there is an expected improvement in health as defined by Māori from within a Māori worldview.

The project is the continuation of a pilot programme that successfully integrated a kaupapa Māori methodology within a clinical setting. The pilot programme identified that the acknowledgement of culture within a health setting and allowing aspects of that culture to be embedded into a clinical programme was important for Māori. Providing programmes that allow Māori self-determination of health is a significant and positive step forward for a population that has failed to thrive under a western medical and scientific approach to health. From a research perspective a kaupapa Māori project that has produced positive clinical outcomes has never been re-tested with another group of Māori to determine if findings can be replicated. This subsequent project is therefore essential for extending knowledge about successful kaupapa Māori health programmes and their ability to effect positive health change in a practical and sustainable manner.

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