


BMJ Open What predicts regression from pre-diabetes to normal glucose regulation following a primary care nurse-delivered dietary intervention? A study protocol for a prospective cohort study

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ABSTRACT

Introduction Pre-diabetes is a high-risk state for the development of type 2 diabetes mellitus (T2DM) and cardiovascular disease. Regression to normoglycaemia, even if transient, significantly reduces the risk of developing T2DM. The primary aim of this mixed-methods study is to determine if there are clinically relevant differences among those with pre-diabetes and excess weight who regress to normoglycaemia, those who have persistent pre-diabetes and those who progress to T2DM following participation in a 6-month primary care nurse-delivered pre-diabetes dietary intervention. Incidence of T2DM at 2 years will be examined.

Methods and analysis Four hundred participants with pre-diabetes (New Zealand definition glycated haemoglobin 41–49 mmol/mol) and a body mass index ≥ 25 kg/m² will be recruited through eight primary care practices in Hawke's Bay, New Zealand. Trained primary care nurses will deliver a 6-month structured dietary intervention, followed by quarterly reviews for 18 months post-intervention. Clinical data, data on lifestyle factors and health-related quality of life (HR-QoL) and blood samples will be collected at baseline, 6 months, 12 months and 24 months. Sixty participants purposefully selected will complete a semi-structured interview following the 6-month intervention. Poisson regression with robust standard errors and clustered by practice will be used to identify predictors of regression or progression at 6 months, and risk factors for developing T2DM at 2 years. Qualitative data will be analysed thematically. Changes in HR-QoL will be described and potential cost savings will be estimated from a funder's perspective at 2 years.

Ethics and dissemination This study was approved by the Northern A Health and Disability Ethics Committee, New Zealand (Ethics Reference: 17/NTA/24). Study results will be presented to participants, published in peer-reviewed journals and presented at relevant conferences.

Trial registration number ACTRN12617000591358; Pre-results.

Strengths and limitations of this study

- This mixed-methods study follows a pragmatic non-randomised pilot study which showed that a primary care nurse-delivered 6-month dietary intervention for people with pre-diabetes and body mass index ≥ 25 kg/m² was feasible in a primary care setting, and weight loss was achieved in the intervention group.
- The study is set in a geographical region where approximately 21% of the population is Māori, the indigenous peoples of New Zealand, who have high rates of pre-diabetes and type 2 diabetes mellitus.
- Following the 6-month dietary intervention, participants will be reviewed every 3 months by primary care nurses for 18 months.
- A possible limitation is that the study is taking place in a real-world setting, and health sector changes influencing the primary care environment may influence the study outcomes.
- This study is limited as it will not include a control group.

INTRODUCTION

The prevalence of diabetes and concomitant costs continue to increase.^{1–4} Diabetes now affects an estimated 8.8% of adults globally.⁵ Pre-diabetes, a condition in which blood glucose levels are higher than normal, but not high enough to be classified as diabetes, is more common, affecting as many as 30%–50% of some adult populations.^{6–9} Without treatment, about 5%–10% of those with pre-diabetes will progress to type 2 diabetes mellitus (T2DM) annually, and most will eventually develop T2DM.^{10–11} Lifestyle modification and weight loss can prevent or delay progression,^{12–18} with the overall risk being approximately halved.¹⁹ Medication

has also been shown to prevent T2DM in people with pre-diabetes enrolled in clinical trials.^{12 19–21}

Implementing diabetes prevention lifestyle interventions in primary care: the challenges

Implementing diabetes prevention lifestyle clinical trial evidence into real-world settings is challenging, particularly in primary care settings,^{22–24} where those with pre-diabetes are typically a more heterogeneous group compared with those participating in clinical trials.²⁵ Further, the cost of delivering lifestyle interventions in primary care can be a barrier.²⁶ The Diabetes Prevention Program (DPP) lifestyle intervention costs US\$1399 per participant in the first year.²⁷ A significant proportion of this cost was specialist lifestyle intervention staff, who are often employed in diabetes prevention lifestyle programmes, irrespective of the setting.^{12–17 28–35} Few studies have specifically employed primary care nurses to deliver lifestyle advice,^{36–39} although dietary advice given by an appropriately trained nurse can be as effective as that given by a dietitian in the primary care setting,³⁸ and is potentially more sustainable and cost-effective.⁴⁰

Furthermore, as pre-diabetes increases the risk of not only T2DM, but also cardiovascular disease,^{6 11 41} and the microvascular complications associated with diabetes,^{6 42} the goal of pre-diabetes screening and treatment should arguably be regression to normoglycaemia.^{11 21 43} Even if transient, regression to normoglycaemia is associated with a significantly reduced risk of developing T2DM, independent of whether this occurs spontaneously or in response to lifestyle advice or metformin therapy.⁴⁴ Greater insulin secretion, lower baseline glucose concentrations, younger age, weight loss and intensive lifestyle modification predict restoration of normoglycaemia,^{45–47} but other factors such as sociocultural, economic and health service delivery, which have not been previously examined, may also be important.

Pre-diabetes lifestyle interventions have been implemented in primary care

The primary care-based Pre-diabetes Intervention Package (PIP) is a feasible primary care nurse-delivered 6-month pre-diabetes lifestyle intervention with a focus on diet, sociocultural context and goal setting, for overweight and obese patients with pre-diabetes.⁴⁸ In this pragmatic mixed-methods non-randomised pilot study conducted in the Hawke's Bay region, New Zealand (NZ), intervention implementation fidelity was high and after adjustment, the intervention group lost a mean 1.3 kg more than the control group ($p < 0.001$). The mean glycated haemoglobin (HbA1c) decreased in the intervention group and increased in the control group, but the difference was not significantly different. Extending the study and offering the intervention to all study practices, alongside exploring clinical, as well as sociocultural, economic and genetic variables, provides an opportunity to determine if there are clinically relevant differences among those with pre-diabetes who regress to normoglycaemia, who have

persistent pre-diabetes and who progress to T2DM. It is anticipated that these prospectively collected data will contribute to limited international data on sociocultural factors that may be associated with regression from pre-diabetes to normoglycaemia,⁴⁵ and to clinical decision-making risk assessments in the primary care setting.^{21 49}

The primary aim of this study is (1) to determine if there are clinically relevant differences among those with pre-diabetes who regress to normoglycaemia, those who have persistent pre-diabetes and those who progress to T2DM at 6 months following participation in a structured primary care nurse-delivered pre-diabetes dietary intervention in the primary care setting. The secondary aims are (2) to quantify the reduction in incident T2DM at 2 years in participants who regressed to normoglycaemia at 6 months compared with the other participants; (3) to qualitatively explore and examine barriers, challenges and facilitators of clinically meaningful lifestyle changes between those who regress to normoglycaemia and those who do not; (4) to explore whether a T2DM genetic risk score of common genetic variants might influence regression to normoglycaemia at 2 years in a sub-sample, (5) to describe changes in HR-QoL at 2 years and (6) to estimate the potential cost savings to the health sector associated with a reduction in T2DM.

METHODS AND ANALYSIS

This extension of the PIP pilot study is a mixed-method prospective cohort study with pre-intervention and post-intervention measures and a qualitative study.^{50 51}

NZ context

In NZ, among adults aged 15 years and over, the prevalence of diabetes is 7.0% and the prevalence of pre-diabetes is 25.5%.⁷ Māori, the indigenous people of NZ, and Pacific people have higher rates than the NZ European and Other ethnic group, with diabetes rates of 9.8%, 15.4% and 6.1%, respectively, and pre-diabetes rates of 30.4%, 29.8% and 24.6%, respectively.⁷ Screening for diabetes and pre-diabetes is recommended as part of cardiovascular risk assessment.⁵² For those with no symptoms and no known risk factors, screening is recommended from 45 years for men and 55 years for women, with Māori, Pacific, Indo-Asian peoples, and those with known cardiovascular risk factors or at high risk of developing diabetes to be screened 10 years earlier, *or even younger* if there is particular clinical concern regarding unfavourable risk factors.⁵²

Study setting

The study will be conducted in general practices in the urban zones of two neighbouring provincial cities (Napier and Hastings) in the Hawke's Bay region, NZ. Napier had a population of 57240 (18.2% Māori) and Hastings District had a population of 73245 (23.0% Māori) in 2013.⁵³ Māori comprise 15% of the NZ population.⁵⁴ The general practices will be members of the Health

Hawke's Bay Primary Health Organisation (PHO). PHOs are not-for-profit organisations that provide primary health services either directly or through their provider members. Health Hawke's Bay is the only PHO in the study region.

Patient and public involvement

The PIP was designed in collaboration with the Health Hawke's Bay PHO.⁴⁸ The intervention was first pre-tested with members of the public, then primary care nurses reviewed and contributed to the implementation and research protocols at a meeting. The process evaluation by an independent researcher⁴⁸ enabled views about the intervention and its implementation from patient participants, participating nurses and Health Hawke's Bay PHO staff involved in the design and implementation to be incorporated into the planning of this study. Results of the pilot study and process evaluation were presented and discussed at a forum to which all participants (patients and professionals) were invited.

Participant eligibility

General practices who use the Medtech patient management system and employ primary care nurses will be invited to participate in the study. The reason for including general practices using Medtech is that this is the dominant patient management system in Hawke's Bay, and study data collection systems had been modified for Medtech only in the pilot study. The demographic description of practice populations will be reviewed to ensure that patients with different sociocultural backgrounds are offered the opportunity to participate.

Adults aged 18–69 years with pre-diabetes (defined as HbA1c 41–49 mmol/mol according to the NZ diagnostic criteria)⁵² and a body mass index (BMI) ≥ 25 kg/m² will be included. Pre-diabetes will have been diagnosed following screening (at the time of a recommended cardiovascular risk assessment or because they are deemed to be at risk).⁵² We set a lower age limit of 18 years to reflect the high prevalence of pre-diabetes in young adults in NZ, particularly in high-risk ethnic groups including indigenous Māori and Pacific.⁷ Those with a history of diabetes, prescribed metformin, unable to communicate in English, with a terminal illness or planning to move from the area during the first 6 months of the study and women pregnant at the time of study enrolment will be excluded.

Identification of potential participants and recruitment

General practice patient management systems will be used to identify potential eligible participants. Queries will be conducted using the HbA1c, BMI, age and metformin status criteria to generate lists of potential participants. The queries will not be time-constricted. Primary care nurses will review these lists to check eligibility status including co-morbidities, current medications, confirmation of English-speaking ability and pregnancy status. The lists will be generated in no particular order.

Potential participants will be recruited sequentially according to the random lists generated, in order to minimise selection bias. The research nurse will check these lists regularly to assess who has been invited, who has declined and who is yet to be invited. A letter inviting participation and information about the study will be sent to potential participants in blocks to manage nurse's workload. Potential participants will be contacted by their primary care nurse 5–7 days later to determine participation status and to make a baseline study appointment for those choosing to participate. For those who decline to participate, the nurse will record the reason(s). Those diagnosed with pre-diabetes after recruitment begins and those who meet the eligibility criteria will be invited to participate at the time of their diagnosis.

Intervention

The intervention will be delivered by trained primary care nurses in the general practice setting. The key underpinning principle of the intervention is to provide participants (and their family) with an understanding of the principles of healthy eating and to deliver consistent evidence-based dietary messages, so they are empowered to make good dietary choices; that is, the dietary advice will not be prescriptive. This pragmatic intervention package has six components⁴⁸:

Health Professional Training and Support

Primary care nurses will undertake an intensive 3–4 hour theoretical and practical training course. The course content will include the rationale for the study, key nutritional concepts, dietary assessment in the primary care setting (using Starting the Conversation (STC)⁵⁵ modified for the NZ context),⁴⁸ healthy conversations and goal setting. The nurses will be instructed how to use the PIP study-structured dietary tool,⁴⁸ and about the necessary research processes (informed consent and data collection). They will also be instructed on standard practices for measuring anthropometry and blood pressure. The course will be delivered by study investigators and a local dietitian. A training manual will provide reference material for both primary care nurses and participants, as well as research protocols. A half-day update course will be run at 6 months.

The local dietitian will be available by email and phone to answer any queries or discuss specific clinical cases. The dietitian will also arrange monthly clinical case review meetings for 6 months at each practice. Both the primary care nurses and dietitian found that dietitian's support and guidance was only required for up to 6 months in the pilot study.⁴⁸ A research nurse will also visit participating practices to provide support and advice, as needed, to maximise intervention fidelity.

Individualised dietary assessment, goal setting and dietary advice sessions

The intervention goal is a 10% wt loss over 6 months. After providing informed written consent, participants

will be offered an initial 30 min individualised dietary session with their primary care nurse. They will be encouraged to bring family to the session. A brief structured dietary assessment will be undertaken. STC:Diet, a validated eight-item simplified food frequency instrument designed for use in primary care and health-promotion settings, will be used.⁵⁵ STC:Diet was minimally modified, with permission, for the NZ context. Specifically, the word 'sodas' was changed to 'soft drinks', and a traffic light system was added to indicate healthy, not-so healthy and unhealthy dietary habits. The nurse will review the STC:Diet responses; ask additional dietary prompt questions; seek additional contextual information, such as household membership and budget, who purchases household foods and specific dietary requirements/choices such as vegetarianism and take anthropometric measures (height, weight and waist circumference) using calibrated equipment. The additional questions are called the Detailed Dietary Assessment (DDA). A 10% wt loss goal over 6 months will be calculated. Responses to the STC:Diet and DDA will inform three dietary goals negotiated with the participant, and individualised dietary advice. Participants will be given the standard 'Be Active Every Day' pamphlet, which advises 30 min of physical activity of moderate intensity on most, if not all, days of the week.⁵⁶ Follow-up intervention appointments will be arranged at 2–3 weeks, 6 weeks, 3 months, 4 months and 6 months, then 3-monthly appointments for a 'weigh-in' and provision of ongoing brief targeted dietary advice and support for 18 months. Intervention appointments at 6 weeks and 4 months were added, following feedback from both participants and nurses in the feasibility study.⁴⁸ All study appointments will be at no cost to the participant.

Key messages and consistent opportunistic reminders

Each participant's three dietary goals will be recorded in the practice patient management system. These goals and accompanying clinical notes will facilitate opportunistic targeted advice and guidance by GPs, thus reinforcing dietary advice and support provided by the nurses. The goals will be reviewed and updated accordingly at follow-up nurse appointments.

Nutritionally supportive primary care environment

Prior to the beginning of this study, each intervention practice will be visited to discuss ways to enhance dietary messages provided by nurses. Specifically, the dietary information provided in pamphlets, magazines and posters in the waiting rooms will be reviewed and updated, if necessary, so dietary messages are appropriate and consistent. Provision of magazines that support reputable dietary messages and active living, hobbies and sports and posters promoting fruit and vegetables, such as those offered by Vegetables.co.nz (www.vegetables.co.nz), will be encouraged.

Community-based group education for participants and their family
At the 2–3 week intervention appointment, nurses will refer participants to the Kia Ora programme, a community group nutrition education course consisting of six weekly sessions of 2.5 hours. The Kia Ora programme is an approved Stanford chronic disease self-management programme.^{57 58} The education sessions will be delivered by lay trainers, and topics will include healthy eating, label reading, problem solving and making action plans.

Written patient resources

Readily available patient resources will be utilised. The key resource will be the Diabetes New Zealand booklet, *Diabetes and healthy food choices*,⁵⁹ a clearly presented and easily understood source of dietary information. The booklet was used successfully in the LOADD study,⁶⁰ and the PIP pilot study.⁴⁸

Data collection

Data will be collected as part of the intervention appointments with primary care nurses, as was done in the pilot study.⁴⁸ Study data collection forms have been incorporated into the Medtech patient management system. Additional data will be collected by a research nurse at separate study-specific visits. Recruitment began August 2017, and it is expected that data collection will be completed December 2021. The type and frequency of measurements are shown in [table 1](#). These include:

Routine clinical data

Clinical data will be collected by primary care nurses. These data will include demographics, medical history, family history, social history, brief dietary assessment, height, weight, waist circumference, blood pressure and bloods (HbA1c, total cholesterol, high-density lipoprotein cholesterol, triglycerides, liver enzymes (alanine aminotransferase, aspartate aminotransferase and gamma-glutamyl transferase) and urate. Known data such as date of birth and ethnicity will pre-populate the study data collection sheets and additional pre-diabetes clinical management data (eg, brief dietary assessment details) will be added by the primary care nurses during the intervention consultations.

Additional study-specific quantitative data

A research nurse will administer a questionnaire and arrange for a fasting blood sample to be taken. The questions will explore areas known to influence pre-diabetes lifestyle management. Data will be collected on self-monitoring activities (self-weighing at home, food diaries and self-initiated attendance at support groups), social support systems,^{61 62} sleep patterns,⁶³ stages and processes in weight management,^{64 65} physical activity (the International Physical Activity Questionnaire (IPAQ) long)⁶⁶ and HR-QoL using the EQ-5D.^{67 68} The additional non-routine blood tests will include fasting insulin and fasting glucose (to enable calculation of homeostatic model assessment (HOMA)⁶⁹ and the McAuley Index,⁷⁰ both measures



normoglycaemia ($\text{HbA1c} < 41 \text{ mmol/mol}$), pre-diabetes ($41 \text{ mmol/mol} \leq \text{HbA1c} \leq 49 \text{ mmol/mol}$) and diabetes ($\text{HbA1c} > 49 \text{ mmol/mol}$).⁵² Providing the number of transitions between each pair of states is sufficient, multistate models will initially be used to describe transition probabilities between these states over all measurement times (all three transitions are possible) with an absorbing state of death also reachable from any of these three states. Factors associated with transitions between these three glycaemic states (but not between these states and death) are the focus of this study and these prognostic variables will be used to construct models of the relative risks for transitions between each pair of stages. Initially, these factors will be evaluated independently and Hosmer–Lemeshow’s criteria for logistic regression of unadjusted $p < 0.25$ will be used to identify candidate predictors for further (adjusted) modelling.⁷⁵ The number of potential predictors included in adjusted models will be limited by the number of transitions providing data for parameter estimates. Peduzzi *et al*’s heuristic for logistic regression of 10 events (and 10 non-events) per parameter estimated will be used to determine the maximum model complexity when identifying predictors for further examination.⁷⁶ If more factors are identified than can be modelled using the Hosmer–Lemeshow screening heuristic, selection will be based on favouring modifiable factors which could be used to inform interventions over non-modifiable factors. Similarly, where multiple predictors are identified that are highly correlated, only one will be retained for further modelling. If data allow estimation of the necessary number of parameters, time-dependent transition probabilities will be estimated in similar ways.

A genetic risk score will be compiled from common variants identified as T2DM-associated from a NZ genome-wide association study of T2DM currently in progress. The genetic risk score will be tested for association with the outcomes of the intervention in the sub-sample of participants with genetic information.

Qualitative component

Inclusion of qualitative approaches in the design and reporting of evaluations of complex health interventions is relatively uncommon and rarely reported, although qualitative components offer opportunities to enhance the interpretation of the quantitative outcome data.^{77–79} The qualitative component of this study will provide important insight into the psychosociocultural factors that influence lifestyle change in relation to regression to normoglycaemia. It will specifically explore the experience of being diagnosed with pre-diabetes and how both those who regress to normoglycaemia at 6 months and those who do not describe the process in relation to barriers to and facilitators of lifestyle changes.

A purposive sample of 60 participants who have completed the 6-month intervention will be sought (30 people who regressed to normoglycaemia and 30 people who did not). The sample will be stratified to include equal numbers of participants by gender and half of the sample

will comprise indigenous Māori to ensure that a meaningful level of analysis can be undertaken. Participants will be selected from those who agreed to participate in further research when first recruited into the main study. Those purposively selected will be contacted shortly after completion of the 6-month measures to arrange a face-to-face interview if willing to participate in this part of the study. Written consent will be obtained immediately prior to this interview, which will last approximately 60 min. The interviewer (SA), who has, with co-author (DT-L), worked and published extensively in projects where the cross-cultural context is central, will ensure cultural safety throughout the interview process with Māori and Pacific participants.^{80–81} With permission, all interviews will be audio recorded and transcribed.

Analysis will be completed by a sub-team (SA, LW, DT-L and KC) using thematic analysis.⁸² This will involve multiple reading of transcriptions followed by the development and description of a priori and emergent themes and concepts. Further analysis will explore interconnections between themes. The thematic findings will also be triangulated with the quantitative data to assist interpretation of results and provide descriptive context.⁸³

Economic analysis

Using the EQ-5D scores, the number and percentage of participants reporting each level of problem on each dimension of the EQ-5D will be described by age, gender and ethnicity, and compared across time and groups (ie, those who regress to normoglycaemia, those who have persistent pre-diabetes and those who progress to T2DM). Participants’ self-reported health status as measured on the EQ Visual Analogue Scale will also be reported. An estimate of *potential* cost savings (acknowledging that any change in glycaemic status cannot be attributed to the programme with certainty) will be calculated from a funder’s perspective using average cost estimates and the expected rate of progression to T2DM.

ETHICS AND DISSEMINATION

Local consultation with Māori was facilitated via Health Hawke’s Bay’s Operational Māori Advisor and was undertaken at the outset of study planning, particularly in relation to the genetic studies. The study was endorsed by the Priority Population Committee of the regional primary health organisation, Health Hawke’s Bay. This committee is tasked with ensuring programmes contribute to equitable access and health gains for Māori, Pacific and other populations living in high deprivation areas (NZ deprivation score 9–10).⁸⁴ Study author, DT-L (Māori public health physician), performed an advisory role across all appropriate planning components of the study and will be in-field cultural advisor across the project, in particular for the research nurse and the qualitative researcher. The study was also endorsed by the University of Otago Ngāi Tahu Research Consultation Committee.

Further consultation was undertaken specifically with respect to taking blood for genetic analysis. Families will be interested in learning if there is a genetic link with a higher risk of T2DM. The most obvious outcome would include a more responsive health system with early detection, destigmatisation, early ‘no blame’ intervention and prevention programmes for family who are at risk of developing T2DM. As part of the study, participants will be given a choice on consenting as to the disposal of body fluids/parts as per the University of Otago’s and Hawke’s Bay District Health Board’s Policies and Procedures.

The main study results will be first presented to participating GPs and participating patients. The results of the study will be written and published in peer-reviewed journals and presented at relevant conferences. A written summary of the results will also be distributed to participants, participating GPs, and published on Health Hawke’s Bay website for their members.

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Contributors KC conceived the study. KC and TF initiated and led the pilot study from the outset. KC, SA, LW, AG, TM, TS, JK and LP contributed to the study design, with DT-L providing cultural guidance. AG wrote the statistical analysis plan and estimated the sample size. KC wrote the first draft of the manuscript with contributions from SA, LW, AG, TM, JK and TS. All authors revised the manuscript for important intellectual content, and read and approved the final version of the manuscript.

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Competing interests TF is employed by Health Hawke’s Bay who co-ordinates the general practitioners participating in the research. JK reports receiving personal fees for consulting or speaking from MSD and Novartis. LP reports receiving personal fees for consulting or speaking from Novo Nordisk, Sanofi, Astra Zeneca, Boehringer-Ingelheim, Merck, Janssen, WebMD, Medscape and UpToDate.

Patient consent for publication Not required.

Ethics approval This study has received ethics approval from the Northern A Health and Disability Ethics Committee, New Zealand (Ethics Reference: 17/NTA/24). The study is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12617000591358).

Provenance and peer review Not commissioned; externally peer reviewed.

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