BMJ Open

Protocol for a randomised controlled trial to evaluate the effectiveness of the diabetes community exercise and education programme (DCEP) for long-term management of diabetes

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To cite: Hale L, Stokes T, Scarth B, *et al*. Protocol for a randomised controlled trial to evaluate the effectiveness of the diabetes community exercise and education programme (DCEP) for long-term management of diabetes. *BMJ Open* 2019;**9**:e025578. doi:10.1136/bmjopen-2018-025578

► Prepublication history and additional material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2018-025578).

Received 22 July 2018
Revised 13 December 2018
Accepted 2 January 2019

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ABSTRACT

Introduction Type 2 diabetes is common in Māori and Pacific peoples and in those living in areas of high socioeconomic deprivation in New Zealand (NZ). People with type 2 diabetes often have multimorbidity, which makes their diabetes management more complex. The Diabetes Community Exercise and Education Programme (DCEP) is an interprofessional, patient-centred, whānau (family)-supported package of care specifically developed to engage with Māori and Pacific people and those living in deprived areas. We have previously demonstrated the feasibility and acceptability of the DCEP. This study aims to determine the effectiveness and cost-effectiveness of the DCEP through a pragmatic randomised controlled trial (RCT).

Methods and analysis 220 adults (age ≥35 years) with type 2 diabetes will be recruited from general practices in the lower South Island of NZ (Dunedin and Invercargill) to participate in an RCT. Participants will be randomised to intervention (DCEP) and control (usual care) groups. The DCEP participants will have their exercise goals agreed on with a physiotherapist and nurse and will attend two 90 min exercise and education sessions per week for 12 weeks. The primary outcome measure is blood glucose control (glycated haemoglobin). Secondary outcome measures include quality of life assessed using the Audit of Diabetes-Dependent Quality of Life questionnaire. Data will be collected at four time points: baseline, end of the 12-week intervention (3 months), 6 months postintervention (9 months) and 12 months after the intervention ends (15 months). We will also conduct a cost-effectiveness analysis and a qualitative process evaluation.

Ethics and dissemination The study has been approved by the Health and Disability Ethics Committee, Ministry of Health (HDEC17/CEN/241/AM01). A key output will be the development of an evidence-based training package to facilitate implementation of the DCEP in other NZ regions.

Trial registration number ACTRN 12617001624370 p; Pre-results.

Strengths and limitations of this study

- The intervention—Diabetes Community Exercise and Education Programme (DCEP)—is an interprofessional, patient-centred, whānau (family)-supported package of care specifically developed to engage with Māori and Pacific people and those living in deprived areas.
- The DCEP has been the subject of an observational feasibility study in one region of New Zealand (Otago) which showed clinically significant improvements in a range of outcome measures at 3 months.
- A process evaluation will be undertaken to identify context-specific delivery factors, facilitators and barriers to implementation in the two study sites.
- A cost-effectiveness analysis comparing the DCEP with standard care will be conducted from a societal perspective on an intention-to-treat basis.

INTRODUCTION

Type 2 diabetes (T2D) is a substantial and increasing health problem internationally and in New Zealand (NZ). In NZ, approximately 200 000 people are estimated to have T2D (prevalence 6.5%), with a higher prevalence in Māori (9.1%) and Pacific (14.5%) peoples and those living in areas of high socioeconomic deprivation (9.5%).[1 2] People with T2D often have multimorbidity,[3–6] making management of their diabetes more complex. Lifestyle interventions (physical activity and/or diet) in those with T2D can improve blood glucose control and positively affect lipids, blood pressure (BP), cardiovascular events, mortality and quality of life.[7] Learning and adopting self-management skills and behaviours are also key to controlling T2D,[8] and these can be delivered using a group-based approach.[9] People with T2D who have

multimorbidity (the presence of two or more long-term conditions) benefit from safely prescribed exercise.[10] There is also a specific evidence base for the effectiveness of lifestyle interventions (diet and/or physical activity) for Māori[11] and Pacific[12] peoples with, or at risk of, T2D in terms of a reduction in systolic BP[11 12] with a more mixed picture regarding effect on weight loss and blood glucose (glycaemic) control.[12] Health-related quality of life is also important for people with T2D,[13] and there is evidence that physical activity can improve quality of life in this population.[14]

Given the high prevalence of T2D in Māori and Pacific peoples in NZ, the School of Physiotherapy (University of Otago, Dunedin) and WellSouth Primary Health Network (PHO) (Dunedin) developed an innovative package of care—the Diabetes Community Exercise and Education Programme (DCEP)—for adults living with T2D to take control of their health and live well with their long-term condition. The DCEP development included consultation and co-creation with local Māori and Pacific health providers, whānau (extended family) and other community partners to enhance the programme's ability to meet the health and cultural needs of participants. Māori are twice as likely to report the lack of community-based diabetes services as a barrier to engagement in exercise than NZ Europeans.[15] The DCEP is an interprofessional, coordinated, evidence-based, patient-centred, whānau-supported community-based package of care specifically developed to engage with Māori and Pacific people and those living in areas with high deprivation, with T2D, including those with multimorbidity. The DCEP combines twice-weekly education with tailored exercise for 12 weeks. An ongoing twice-weekly maintenance exercise class follows. An interprofessional health team (a physiotherapist and a nurse, with educational support from dietitians, long-term condition nurse specialists, pharmacists and podiatrists) provide a culturally appropriate and supportive environment to optimise exercise participation and self-management skills. Based on the values of partnership, acceptance and compassion, the patient drives the goal setting in this circuit-based class. This follows best practice for group self-management while offering patients an individualised session that meets their health, social and cultural perspectives.[16] Exercise is known to be beneficial, but how exercise is prescribed and the relationship between the healthcare provider and patient are the key to long-term engagement.[17]

The DCEP has been the subject of an observational feasibility study in one region of NZ (Otago), which showed clinically significant improvements in a range of outcome measures at 3 months.[18] A separate qualitative evaluation[19 20] demonstrated that it was highly acceptable to participants, who reported an increased motivation to exercise, a sense of community and acceptance, cultural suitability and enhanced diabetes knowledge. Given the success of the feasibility study, a randomised controlled trial (RCT) is required to determine the effectiveness of the intervention. The RCT will need to determine what the longer-term (1 year) health outcomes of DCEP are. A key health outcome to measure will be diabetes control. Good blood glucose control, as measured by glycated haemoglobin (HbA1c), reduces the risk of developing diabetic microvascular and macrovascular complications (retinopathy, nephropathy and neuropathy).[21] In addition, the RCT will need to assess whether the DCEP is a cost-effective approach to diabetes management compared with usual care and if the DCEP can be readily translated to other NZ regions.

OBJECTIVES

- To evaluate the health outcomes of the DCEP for individuals living with T2D. It is hypothesised that participating in the DCEP will be more effective than usual care in improving HbA1c levels, physical health outcomes and health-related quality of life at 1-year follow-up.
- To evaluate the cost-effectiveness of the DCEP.
- To conduct a process evaluation to identify context-specific delivery factors, facilitators and barriers to implementation of the DCEP in the two study sites.

METHODS

Study design

The study will be a two-arm, parallel group, open-label RCT conducted across two centres with blinding of the outcome assessor and data analyst to compare the DCEP with usual care. Figure 1 presents a detailed participant flow chart.

Setting

This is a community-based study. We will provide the DCEP in two separate urban centres in the lower South Island of NZ: Dunedin (Otago Region) and Invercargill (Southland Region) in community exercise venues, with centres, introduced sequentially.

Participants and recruitment

We will recruit adults with T2D via general practices and WellSouth PHO's Diabetes Education Self-Management Newly Diagnosed and Ongoing Diabetes (DESMOND)[22] waitlist in Dunedin and Invercargill. We will inform general practitioners (GPs) and nurse managers in local primary healthcare organisations about the study via in-service training (eg, Continuing Medical Education sessions), leaflets and flyers, and by personal contact, requesting them to provide study information sheets to potentially suitable participants. If an individual is agreeable, the GP or practice nurse will refer them to the study via the Electronic Referral Management System (ERMS), which is embedded within NZ GP electronic medical records. Advertising through Diabetes NZ, local public media and community notice boards, Runaka/Marae, churches, social media (eg, Facebook, LinkedIn and Twitter) and health agencies that work with Pacific and Māori communities will also be used for recruitment.

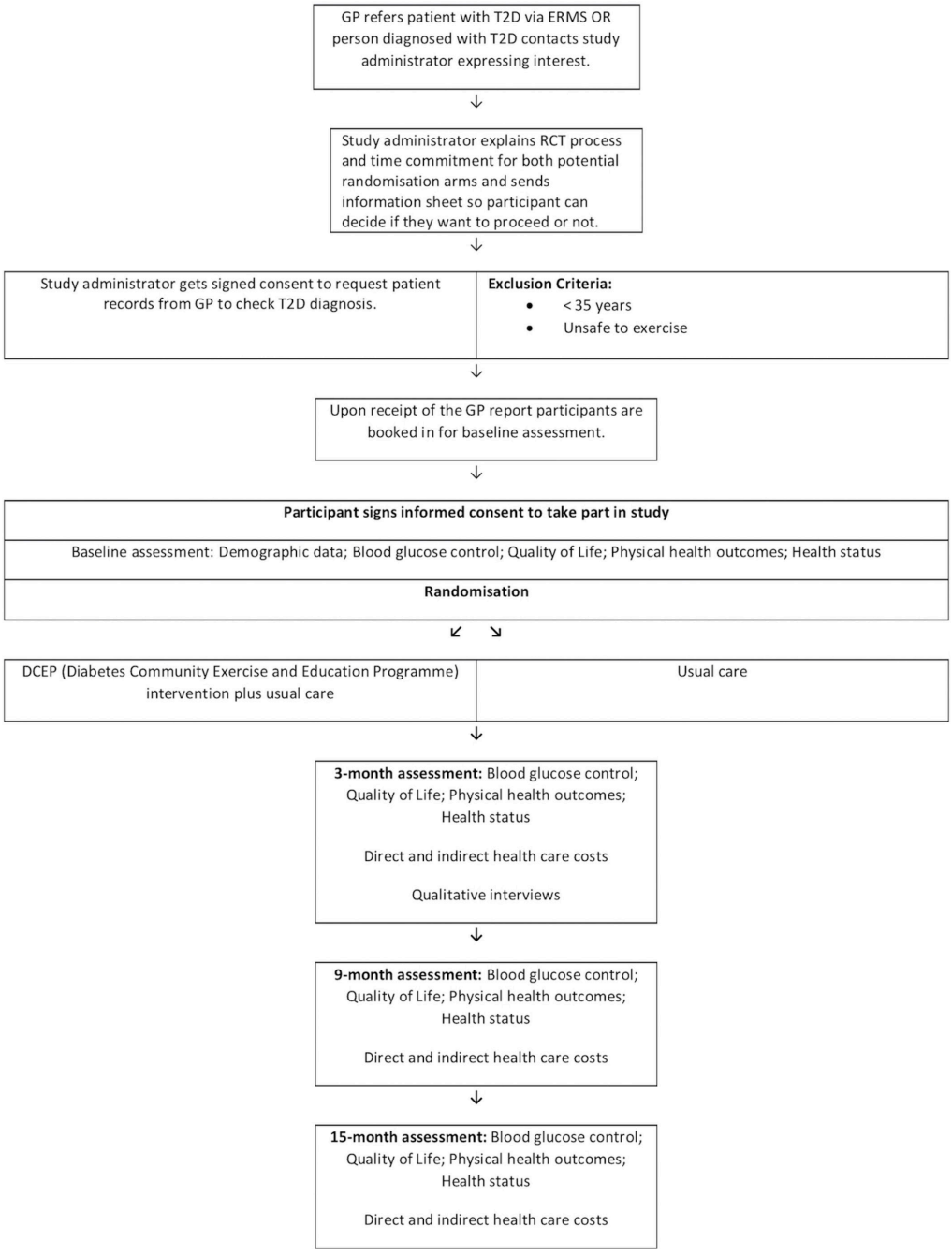

Figure 1 Flow chart of participant recruitment, randomisation and assessments. GP, general practitioner; RCT, randomised controlled trial; T2D, type 2 diabetes.

Participants recruited in this way will then be formally referred to the study using ERMS via their GP or practice nurse.

Inclusion criteria

Adults (age ≥35 years) will be considered eligible for the study if they have a diagnosis of T2D and live in either of the two study sites (Dunedin or Invercargill).

Exclusion criteria

We will exclude individuals if they have comorbid conditions that prevent safe engagement in exercise (any acute severe illness such as known active cancer, uncontrolled hypertension, uncontrolled chronic obstructive pulmonary disease (COPD), acute heart failure, acute pulmonary embolism or any unexplained excessive breathlessness with exertion or a very high falls risk).

Sample size

We based the sample size on the study's primary outcome measure of glycaemic control assessed using HbA1c. A commonly accepted minimal clinically important difference for HbA1c is a reduction in 5 mmol/mol (0.5%).[23] To provide 80% power to detect between-group differences in changes at any time using a two-sided test at

the 0.05 level for HbA1c of 5 mmol/mol[17] (assuming a cross-sectional SD of 10 mmol/mol and without making assumptions around correlations between repeated measures beyond r≥0.5), 64 participants per intervention and control groups are needed. Allowing for approximately 40% dropout (given longer follow-up to the prior observation study),[18] 110 participants will be needed in each group (220 in total) across the two centres.

Randomisation

We will randomly allocate participants following eligibility screening, consent and baseline assessment with equal probability to either the DCEP (intervention group) or usual care (control group). An independent administrator will randomise participants using centralised computer-generated random number tables, stratified by centre, with random block lengths (equally likely to be 2, 4 or 6) to preserve allocation concealment. To protect allocation concealment, the administrator will prepare opaque sealed randomisation envelopes containing the information for the participant regarding the allocation group and details around this (eg, where to go, when and so on). The assessor will give participants their envelope on completion of baseline testing and instruct them to open it at home, not to let the assessors know of their group allocation at any time and to phone the project manager if they have a problem or any questions. The nature of the research will prevent blinding of participants and the healthcare team to intervention. The researchers conducting the outcome assessments and data analysis will, however, be blinded.

With the higher prevalence of T2D in Māori whānau and Pacific families, it is likely that multiple eligible participants all from the same household will be interested in participating in the study. To ensure the cultural acceptability of the intervention for Māori and Pacific participants, and minimise contamination effects between the two arms, which would be increased if participants in the same household were allocated to different arms of the study, we will pragmatically allow participants who live together to be jointly allocated to the same group. The statistical analyses (discussed below) will use only the first enrolled participant from the household if fewer than 10 such clusters arise and will incorporate clustering within households through a household random effect otherwise.

Intervention: DCEP

We have structured the reporting of the DCEP intervention in line with the TIDieR (Template for Intervention Description and Replication) guide.[24 25] We will instruct participants to attend the DCEP and continue their usual care (as described below). Overall, this intervention was designed to be interprofessionally facilitated, and thus a physiotherapist and registered nurse attend all sessions, working consistently and collaboratively throughout the entire programme. Guest health professional educators feed into this collaboration, coordinating a package of care that includes a dietitian, diabetes nurse educator, podiatrist and pharmacist. Table 1 separately presents the exercise components of the programme (insert here). The educational components are set out below (online supplementary file 1 shows a typical education programme).

Intervention commencement

Participants are assessed by a physiotherapist and a nurse at a face-to-face assessment to identify individual goals, preferences and physiological profile for safe, individually prescribed exercise parameters (eg, cardiovascular fitness, muscle strength and flexibility), taking into account key safety considerations such as BP, comorbidities, pain and medications. This ensures that the intervention is patient-centred.

Intervention sessions

Each participant receives two 90 min sessions per week for 12 weeks. Each session will typically comprise 45 min of exercise, followed by 45 min of education on health-related topics. Each exercise session will include aerobic exercise warm-up (5 min), an aerobic and resistance exercise circuit with a focus on major muscle groups (30 min), and flexibility exercises (5 min). The degree of difficulty and intensity level is individually prescribed (taking into account comorbidities) based on accepted exercise prescription protocols. While each session is individualised, with exercises performed individually in a circuit, all participants attend at the same time creating a social group. Each education session focuses on a topic that supports self-management of diabetes, such as 'food portion size' and 'foot health', conducted by an appropriate health professional (eg, dietitian, podiatrist). At the final 12-week session, participants will receive a graduation certificate in a small ceremony. We will send a 'progress letter' detailing the main outcomes of the DCEP to the participant and their GP. Within a week, participants join the maintenance exercise classes (held twice weekly for 60 min) at the same venue, on the same day, with the same physiotherapy/nurse team, at a time slightly earlier or later time. The timing allows for mingling and story sharing between new programme participants and maintenance class attendees to facilitate ongoing adherence. We will record individualised exercise parameters, attendance and adverse events.

Cultural responsiveness

Based on stakeholder consultations (advisory group, consumers and decision-makers), the DCEP will be tailored to meet the needs of the local community to be culturally acceptable, safe and welcoming. For example, holding the DCEP in a church hall for a community that is predominantly Pacific Island or inviting participants to bring a support person/people/whānua to exercise alongside them should they so wish; the latter, a culturally inviting practice for both Māori and Pacific populations. The intervention will be discontinued on participant's

Table 1 Exercise intervention description (led by physiotherapist and supported by nurse)

Setting	Community hall
Number of participants	15–20
Preparticipation screening completed by physiotherapist	Adult pre-exercise screening tool (https://www.essa.org.au/wp-content/uploads/2011/09/Screen-tool-version-v1.1.pdf)
Equipment required	Cycle ergometers, exercise mats, medicine balls, dumbbells, gym balls, barbells, mini trampoline, wobble board, elastic resistance Bands, Rowing ergometers, benches, cones, stereo
Music	60's, 70's disco music
Time/Frequency	45 min twice per week for 12 weeks
Style	Circuit training
Exercise parameters[7]	
Aerobic exercise (20 mins)—repeated and continuous movement of large muscle groups to train fitness of cardiovascularpulmonary system	
Intensity: moderate	3–5 in Borg's Rating of Perceived Exertion (RPE) scale, category scale 0–10
Type	► Aerobic warm-up ► Cycling, brisk walking, rowing
Progression	Speed and distance covered provided within moderate intensity
Resistance exercise (20 mins)—repeated weighted movement of large muscle groups around shoulder, arm, thigh, leg, chest, back and abdomen	
Intensity: moderate	► 10–15 repetitions (of an exercise that can be repeated no >10–15 times) ► 1–3 sets
Type	► Body weight resistance, resistance band or free weight ► Up to 10 exercises including but not limited to: squat, lunge, supine bridge, push-up, prone hold, sit to stand, bicep curl, step-up, tricep dip, calf raise
Progression	When maximum number of repetitions (15) and sets (3) can consistently be exceeded, then increases in resistance are undertaken with a lower number of repetitions (8–10) and sets (1–2). Increases in repetition are then followed by a greater number of sets
Balance and flexibility exercise (5 mins)	
Flexibility	► Upper and lower limb and trunk static stretches ► Hold for 20 s, repeat twice
Balance	► Wobble board, mini trampoline ► Standing on one leg

request or reported adverse reactions (such as aggravated pain) as determined by regular reporting to the study Data and Safety Monitoring Board.

Control: usual care

The comparator is usual care. Participants will be instructed to manage their diabetes as usual (in other words, as their GP or Practice Nurse advises), which will include appropriate medication, advice regarding diet and physical activity participation and referral to Well-South PHO's DESMOND programme (a 1-day education programme designed to support people living with T2D).[22]

OUTCOME MEASURES

We will collect outcome measures at four time points: baseline, at the end of the 12-week intervention (3 months), 6 months after the intervention ends (9 months) and 12 months after the intervention ends (15 months) (see figure 1).

Primary outcome

Blood glucose control

This is defined as between-group differences in mean changes of HbA1c in mmol/mol from baseline to 15 months follow-up. HbA1c is recommended by national diabetes associations as a reliable, valid measure of

blood glucose control in diabetes[26] and is widely used as a primary outcome measure in diabetes research.[21–23] HbA1c testing will be undertaken using a cobas b 101 point-of-care analyser (Roche Diagnostics, Mannheim, Germany) in accordance with manufacturer's guidelines.[27] This point-of-care analyser has good validity when compared with venous blood glucose testing.[27]

Secondary outcomes

Physical health outcomes

Incremental Shuttle Walk Test (ISWT)

The ISWT is an externally paced maximal exercise test where the speed of walking increases each minute, controlled by a series of prerecorded beeps. The test continues until the participant can no longer keep up with the pace of the beeps. The ISWT is a valid and reliable (test–retest and intrarater) measure of cardiopulmonary exercise capacity in people who have COPD[28] or a heart condition.[29] The ISWT, although not previously used with a group of people with T2D, is the most pragmatic field-walking test of functional exercise capacity to use when minimal space requirements necessitate it. We will carry out the ISWT in accordance with current guidelines.[30]

Anthropometrics

Anthropometric data collection will follow the protocols documented in the Exercise and Sport Science Australia manual.[31] Body weight will be measured using SECA scales (seca 876), height will be measured using a SECA stadiometer (seca 217) and body mass index will be calculated. Waist circumference will be measured using a flexible, non-elastic tape measure (seca 201). Two measurements will be taken, and the mean of these results will be accepted provided they are within 1.5% of each other. A third measure will be taken if there is >1.5% difference between the first two measures and the mean taken of the two measurements with <1.5% difference. The Research Assistants will receive standardised training in anthropometric data collection with intertester and intratester comparisons conducted at regular time points.

Blood pressure

This will be measured and reported in line with international consensus standards (TRUE Consortium).[32]

Physical activity

Physical activity levels (frequency, duration and intensity) will be captured using the New Zealand Physical Activity Questionnaire-Short Form (NZPAQ-SF). Test–retest reliability and validity is good, although the instrument does underestimate energy expenditure relative to doubly labelled water (DLW) for high-intensity activity levels.[33 34] The DLW technique is the gold (criterion) standard: it assesses total energy expenditure through biological markers that reflect the rate of metabolism in the body.[34]

Quality of life

Diabetes health-related quality of life (HRQoL)

The Audit of Diabetes-Dependent Quality of Life (ADDQoL) Questionnaire[35] will be administered with the calculation of the difference in group mean changes in total score from baseline to 15-month follow-up. It is a measure of an individual's perception of the impact of diabetes on their quality of life and comprises 13 items relating to physical functioning, symptoms, psychological well-being, social well-being, role activities and personal constructs. It has good evidence of reliability and internal and external construct validities.[36]

Health status

The *EuroQol five dimensions questionnaire* (EQ-5D-5L), a standardised generic measure of health for clinical and economic appraisal, has good psychometric properties (construct validity, reliability and responsiveness) for a wide range of long-term disability,[37] including T2D.[38] It describes health status in terms of five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. We will administer the EQ-5D-5L questionnaire at each time point by interview.

HEALTH ECONOMIC EVALUATION

A cost-effectiveness analysis comparing the DCEP with standard care will be conducted from a societal perspective on an intention-to-treat basis. Direct costs will include service delivery costs, dispensed pharmaceutical costs, hospital inpatient costs and GP visits. Indirect costs will include out-of-pocket costs, such as transport costs, time off work and other personal costs associated with a person's diabetes status. Participants will be asked to keep a record of the costs associated with attending the DCEP. Outcomes will include changes in HbA1c and HRQoL (measured using the EQ-5D). Incremental cost-effectiveness ratios (ie, the difference in cost between the DCEP and standard care divided by the difference in outcome) will be calculated for HbA1c and Quality-Adjusted Life Years (using HRQoL). A sensitivity analysis will be conducted to assess how sensitive the cost-effectiveness results are to variation in key parameters including cost.

PROCESS EVALUATION

Qualitative process evaluation in line with current UK MRC complex intervention guidance on both fidelity of intervention delivery and how the intervention is delivered (context; implementation; mechanisms of impact) will be carried out.[39] An independent assessor will monitor intervention fidelity throughout the study using a checklist developed by the Clinical Advisory Group.

Implementation of the DCEP in the two regions will be explored using a well-known implementation science framework: the Consolidated Framework for Implementation Research (CFIR). The CFIR provides an overarching typology of implementation, providing a comprehensive,

standardised list of constructs, which identify variables most relevant to a particular intervention. The CFIR addresses intervention delivery (context; implementation; mechanisms of action) through five domains: intervention characteristics (eg, adaptability, complexity), outer setting (eg, external health policy, patient needs and resources), inner setting (eg, organisational culture and implementation climate), characteristics of the individuals involved (eg, self-efficacy) and the process of implementation (planning, engaging, executing, reflecting and evaluating).[40] The CFIR has been widely used to inform qualitative process evaluations across a range of complex interventions,[41] including interventions similar to those used in the DCEP.[42]

We will use the CFIR to inform a semistructured interview guide for both participants/whānau and staff at both study sites. After the 12-week intervention, we will invite for an interview a purposive sample of participants/whānau as well as healthcare professionals and staff involved in delivering the intervention (DCEP). We will interview the latter group on their experiences of implementing and administering the DCEP. Interviews will be audio-recorded and transcribed by a professional service. We describe the qualitative data analysis below. To explain how the DCEP has been implemented in the two regions, thus allowing comparison between the two settings, we will develop a logic model for each setting informed by the themes developed from the interviews which will be based on the CFIR Framework.

DATA COLLECTION AND SAFETY MONITORING

Trained Research Assistants (RA) in each study site, blinded to group allocation, will collect all data. Data will be collected at venues separate from the DCEP and DESMOND venues to ensure blinding of assessors. These data will be collected in person (ie, not online or over the telephone) and sufficient time will be allocated for this to ensure quality data especially from participants with low literacy. At each assessment point, the project manager organises data collection appointments at times convenient to participants and venues and reminds participants not to disclose their randomised group. Assessors will be asked to report incidents of disclosure. Assessors will be trained in test procedures at baseline and at again prior to each assessment point. Fidelity checklists by a research team member are randomly used to monitor testing. Assessors will input data directly into Research Electronic Data Capture (REDCap) via a tablet. REDCap is a web-based database that enables secure data collection, storage and maintenance and recommended for recording data, including personal information, which is either covered by Health Information Privacy Principles, The Privacy Act or Ethics Committee specifications that require a secure tool. All REDCap data are stored in the University of Otago data centres. REDCap allows multisite users to contribute via the internet to a secure database with one manager to oversee all data entries. Access is restricted and password protected. Independent access codes for different parts to the database ensure individuals only have access to the data they have consent to access. The Project Manager will oversee and manage the data spreadsheet and will maintain a data diary of any issues relating to data capture and fidelity.

No adverse events were reported in the feasibility study.[18] We will record any adverse events and report them via the Principal Investigator (PI) to the local organisation's Health and Safety monitoring processes. An independent Data and Safety Monitoring Board (DSMB) will review safety and make recommendations. The PI will report adverse events (as serious or non-serious) to the DSMB.

This study also has a Clinical Advisory Group comprising a physiotherapist (University of Otago), a nurse and a dietitian (WellSouth PHO).

STATISTICAL ANALYSIS

Analyses will be performed in accordance with modified intention-to-treat principles (based on group randomised to and using all available data but without being able to directly assess the impact of the intervention being offered to those for whom we do not have follow-up data and where their outcome data are not missing at random) using Stata V.15.1 and R V.3.5.1, or later versions, with two-sided $p<0.05$ considered significant. Reporting will adhere to all items in the CONSORT[43] statement, including a CONSORT flow diagram showing participant flow and reasons for exclusion and loss to follow-up where available. Those with and without follow-up data will be compared in terms of baseline data, including outcome variables as well as demographics. Linear mixed models will examine differences in changes over time between groups for continuous outcomes with group, time and centre as fixed effects, along with a group–time interaction, and a random participant effect to accommodate the repeated measures (at 0, 3, 9 and 15 months). Between-group differences in changes in HbA1c from baseline to 15 months will be used to determine programme effectiveness. If fewer than 10 households with multiple participants are enrolled in the study, we will select the first participant enrolled from each household for analysis. Otherwise, a random household effect will be added to all models described above. We will perform standard model diagnostics, including examining normality and homoscedasticity of residuals and linearity of associations involving continuous predictors. Where appropriate, transformations (most likely natural-logarithmic transformations of outcomes) and the addition of quadratic terms for continuous predictors will be investigated. As missing data is likely to include informative missingness, we will investigate the robustness of conclusions through scenarios involving modifying values from multiple imputation models (using chained equations, including the interim outcome measurements) in plausible ways. Uninformative group codes will be used to ensure that all described analyses are performed with blinding.

QUALITATIVE DATA ANALYSIS

We will use the general inductive approach[44] to analyse the data collected as part of the process evaluation. This approach answers specific study research questions by identifying the connections between the research objectives and the summary findings derived from the raw data. The analysis will embrace findings from both the CFIR domains (deductive) and those from the analysis of the raw data (inductive). In the analysis process, all researchers will systematically read all transcripts and develop a coding framework on the discussion. As new codes become evident on multiple readings, we will make further discussion and adjustments to the coding framework. On further deliberation, we will collapse the codes into categories, then conceptualised into the main themes. The Clinical Advisory Group and lay advisors will assist in the verification of emerging codes during the analysis process. A researcher not involved with the study will verify the categorisation of data (consistency check). We will ask participants to verify the preliminary results of the analysis (stakeholder checks). We will maintain audit trails and reflexive diaries.

Patient and public involvement

The DCEP was co-created by the School of Physiotherapy (Otago) and WellSouth (PHO) in Dunedin, a collaboration that facilitates access to the target population. Since 2008, the DCEP has been systematically developed, iteratively improved and evaluated.[18–20] Feedback from participants of the DCEP is that they enjoy the programme and gain health benefits from attending and want such a programme to be offered consistently and regionally. Feedback from current DCEP funders is that though the health improvements measured are noted to justify ongoing funding, it would be more beneficial to measure diabetes control rather than fitness and associated anthropometric measures and to include a cost-effectiveness evaluation. Two lay Māori lay advisors are involved in the study. The advisors are graduates of the existing DCEP and consistent attendees of the maintenance exercise class and advocate for the key ingredients essential for fidelity of delivery of the DCEP. Graduates of the DCEP will be encouraged to promote the research to their friends and family. We also piloted our data collection procedures on graduates of the DCEP, including the time taken and appropriateness of the questions and modifications were made accordingly with regards to questionnaire inclusion. Furthermore, consultation with local Māori and Pacific Island providers led to refinements of the DECP to ensure cultural acceptability and accessibility.

ETHICS AND DISSEMINATION

Ethical approval and trial registration

The Health and Disability Ethics Committees, Ministry of Health, NZ approved this study (HDEC17/CEN/241/AM01) and the trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12617001624370p).

Dissemination of findings

A key output of this project will be the development of an evidence-based resource-training package including case studies and tools for immediate implementation of the DCEP in other NZ regions. This output is in line with the NZ Ministry of Health's 2015–2020 plan 'Living Well with Diabetes',[45] which envisages that 'all New Zealanders with diabetes, or at high risk of developing T2D, are living well and have access to high-quality, people-centred health services'. The plan outlines six priority action areas guided by the following six principles: prevention and early intervention, reducing disparities, people and whānau (family)-centred services, sustainability, effective self-management and evidence informed. We will disseminate the findings of this study through peer-reviewed publications and conference presentations. We will also present our findings to WellSouth and partner Māori and Pacific Health Providers and Very Low Cost Access general practices in Otago and Southland, local rūnanga, Pacific Island Advisory and Cultural Trust, and Diabetes NZ. These organisations will guide us as to appropriate formats of dissemination, for example, verbal presentations, written summary findings and brochures for patients.

DISCUSSION

This pragmatic RCT aims to determine the effectiveness of a complex health intervention, the DCEP, to improve health outcomes for adults with T2D, in particular, Māori and Pacific peoples and those living in areas of high deprivation, with embedded cost-effectiveness and process evaluation. A key strength of this RCT is that it is designed to transfer evidence into practice, ensuring translation into other communities by incorporating prior stakeholder consultation (to ensure appropriate cultural and contextual delivery) and an embedded process evaluation (to carefully identify the key contextual factors). Co-creation of this intervention at each step with consumers, whānau and community end users will enhance the programme's ability to meet the health and cultural needs of adults living with T2D.

If the intervention is effective, then its results could reduce health inequalities for Māori, a key NZ health priority.[46] We developed the DCEP specifically to facilitate Māori and whānau living with diabetes to engage with exercise and healthy lifestyle choices.

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Acknowledgements The trial sponsor is the University of Otago, Dunedin, Otago, NZ.

Contributors LH, CH, TSt, RM, TSu, FD-N, PJ, ARG and JM: involved in the conception of the study. LH: wrote the grant application with input from CH, TSt, RM, TSu, FD-N, PJ, ARG and JM. BS and TSt: wrote the draft of the manuscript with input from CH. CH: contributed to the concept and design of the work and revising the draft for important methodological content. TSt: wrote the process evaluation component. TSu: wrote the economic evaluation component. ARG: the statistical methods section. LH, CH, TSt, BS, RM, TSu, FD-N, PJ, ARG and JM: reviewed and critiqued the manuscript and approved the final published version.

Funding This study is funded by the New Zealand Health Research Council (HRC Project Grant 17/233). The funding body has not had any role in the study design or outputs from the study. Funding was not provided by the trial sponsor.

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement As the paper relates to a study protocol, there are no datasets available as yet.

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