The diabetes community exercise programme plus usual care versus usual care in patients with type 2 diabetes: A randomised, two-arm, parallel, open-label trial

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Summary

Background Exercise is important in type 2 diabetes (T2D) management. Focussing on Māori and Pacific people and those from deprived circumstances, the Diabetes Community Exercise Programme (DCEP) was developed to engage people with T2D in exercise. We report the evaluation of whether being offered DCEP (plus usual care) was more effective than usual care in improving glycaemic control at 1-year.

Methods A randomised, two-arm, parallel, open-label trial with blinding of outcome assessor and data analyst. Adults (age ≥35 years) with T2D recruited from two New Zealand (NZ) communities were randomised, using opaque sealed envelopes and stratified by centre with random block lengths, to DCEP or usual care. DCEP comprises twice-weekly, two-hour sessions of exercise and education over 12-weeks, followed by a twice-weekly maintenance exercise class. The primary outcome was between-group differences in mean changes of glycated haemoglobin (HbA1c) from baseline to 1-year follow-up with intention-to treat analysis. This trial is registered with the Australian NZ Clinical Trials Registry (ANZCTR): ACTRN12617001624370p and is closed to new participants.

Findings From 2018 – 2019, of 294 people screened, 165 (mean age 63·8, SD16·2 years, 56% female, 78·5% European, 14% Māori, 6% Pacific, 27% most deprived) were baseline evaluated, randomised, and analysed at study end (DCEP = 83, control = 82). Multimorbidity (≥2) and polypharmacy (>5 medications) were high (82%, 69%). We found no statistically significant between-groups differences in HbA1c (mmol/mol) change at 15 months (mean 3% higher in DCEP, 95% CI 2% lower to 8% higher, $p = 0{\cdot}23$). Twelve-week intervention adherence was good (41% attended >80% available sessions). No adverse events were reported.

Interpretation DCEP was not effective in improving glycaemic control, possibly due to insufficient exercise intensity. Our attendance demonstrated DCEP's cultural accessibility. DCEP might be good to engage in exercise marginalised people with high Hb1Ac levels, multimorbidity, and high polypharmacy.

Funding Health Research Council of New Zealand.

Keywords: Type 2 diabetes; Exercise; Education; Self-management support; Ethnicity; Health equity

Introduction

Type 2 diabetes (T2D) is a highly prevalent long-term condition worldwide[1,2] that significantly impacts on health and quality of life.[3] People with T2D frequently present with multimorbidity which further complicates health outcomes.[4,5] Evidenced guidelines detailing the overall management of T2D are available. Guidelines for the non-pharmaceutical management of T2D include lifestyle changes focusing on healthy eating,

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Research in context

Evidence before this study

Despite evidenced guidelines detailing the management of type II diabetes (T2D), health inequities remain in New Zealand with the high prevalence of diabetes amongst Māori (7.9%) and Pacific (13.6%) adults. Needed are studies evaluating culturally appropriate programmes that focus on increasing physical activity participation. A search of OVID from 2000 until study commencement in 2017 using the key words "physical activity" or "exercise" and "diabetes" or "diabetes mellitus" and "Maori or Pacific" found seven related New Zealand studies. The evaluated programmes were found acceptable but their impact on health outcomes were unsubstantiated.

Added value of this study

Our study evaluated the effectiveness of the Diabetes Community Exercise Programme (DCEP) specifically designed to enable access for all ethnic groups. DCEP was not effective in improving glycaemic control; possibly due to insufficient exercise intensity. Our study adds value by informing ways in which marginalised people with high glycated haemoglobin levels, multimorbidity, and high polypharmacy can be engaged in exercise.

Implications of all the available evidence

For a long-term health condition such as T2D, people need access to an intervention that they are comfortable to engage with lifelong. Perhaps for populations where equity and cultural accessibility are important, lifestyle interventions for T2D (such as exercise, diet, mental health) should first focus on wellbeing indicators and include outcomes of wellbeing, measures of confidence to take control of their own health and an indicator of long-term programme engagement.

engagement in physical activity, and diabetes education and support.[3,6]

The prevalence of T2D in New Zealand (NZ) is as high as elsewhere worldwide, but particularly high amongst Māori and Pacific people, and people living in low socioeconomic circumstances.[7] Amongst adults aged over 15 years, the prevalence of self-reported diabetes in NZ in 2019/2020 was 5·9% (7·9% Māori, 13·6% Pacific, 10·4% living in most deprived areas). The adjusted (gender and age) ratio comparisons (statistically significant) were 1·74 for Māori versus non-Māori and 3·22 for Pacific versus non-Pacific and 2·62 for those living in the most deprived versus least deprived areas of NZ (adjusted for gender, age, and ethnic group).[8] Accessing appropriate, quality health care is challenging for these populations, including that which supports non-pharmaceutical management and people's efforts to self-manage.[9] One reason offered for very high prevalence of T2D amongst Māori and Pacific people is the cultural inaccessibility of lifestyle programmes, largely developed along Western guidelines, with little consideration of cultural appropriateness and acceptability[9–15]; an approach too often propagated worldwide.[16] To enable cultural access, several NZ programmes have been developed in consultation with Māori[9–11] and Pacific communities.[12–15] Although these programmes were found acceptable to their target populations, their impact on health outcomes were unsubstantiated.

In response to the growing numbers of people living with T2D in the city of Dunedin (South Island, NZ) in 2008 we developed the Diabetes Community Exercise Programme (DCEP). The programme has been described previously.[17,18] Its overarching aim is to support adults living with T2D to take control of their health and to live well with their long-term condition. It focuses on enhancing self-efficacy to engage in exercise and to do so long-term. DCEP incorporates two-hourly sessions of exercise and education twice weekly over 12-weeks, followed by a maintenance exercise class that attendees can continue to attend twice weekly. Although the exercise component of DCEP was based on the findings of a 2006 Cochrane review,[19] the programme was specifically designed by a Pākeha (non-indigenous) physiotherapist and a Māori community diabetes nurse, informed by extensive community consultation, to enable access for all ethnic groups and for those living in low socioeconomic circumstances. Access is facilitated by it being community-based, culturally appropriate (for Māori and Pacific), and free.[20–22]

In a single-group pre-post trial, DCEP demonstrated beneficial health outcomes and acceptability to attendees.[20–22] Additionally, there was 33% (n = 12/36) combined representation of Māori and Pacific participants during the 12-week programme.[19] This was an over-representation of Māori and Pacific people, as according to the 2013 NZ census[23] 10% of the Dunedin city population identify as either Māori or Pacific ethnicity. These data suggest that our programme was considered culturally safe and accessible. In a qualitative evaluation, participants' perceptions of benefits included increased motivation to exercise, social community and acceptance, cultural appropriateness, and enhanced diabetes knowledge.[18,21,22] Further, there was good long-term uptake of the maintenance class following the initial 12-week programme (n = 22/57, 39%) and no adverse events were reported.[24] DCEP, therefore, warranted formal evaluation, including its effectiveness not only on physical health outcomes but on blood glucose control (measured by glycated haemoglobin (HbA1c)) as controlling blood glucose is important to reduce the risk of developing diabetic microvascular and macrovascular complications.[25]

This paper reports a randomised controlled trial (RCT) addressing the hypothesis that being offered

DCEP plus usual care is more effective than usual care alone in improving HbA1c levels, physical health outcomes, and health-related quality of life at 1-year follow-up.

Method

Study design

This study's protocol has been previously published[17] and only essential details from this are presented here along with information not provided in the protocol. The design was a two-arm, parallel group, open-label RCT conducted across two centres with blinding of the outcome assessor and data analyst to compare DCEP plus usual care with usual care alone. A nested qualitative process evaluation was undertaken and will be reported elsewhere. The study was approved by NZ Health and Disability Ethics Committee (17/CEN/241) and all participants signed informed consent via forms approved by this committee. The study was conducted in compliance with the Declaration of Helsinki. This trial is registered with the Australian NZ Clinical Trials Registry (ANZCTR): ACTRN12617001624370p. The study protocol[17] can be found at http://dx.doi.org/10.1136/bmjopen- 2018–025,578.

Study setting

DCEP intervention and data collection were community-based in two urban centres in the lower South Island of NZ. We began in Dunedin (Otago Region) and 12 weeks later started the trial in Invercargill (Southland Region). This sequential introduction of the trial allowed for context specific modifications of DCEP for implementation into the new centre of Invercargill to ensure appropriate delivery and successful uptake (for example, local needs and cultures, and idiosyncrasies of local health systems and processes).

Participants and recruitment

As described previously[17] we recruited widely via general practices (GP), Diabetes NZ, public media advertising, and health agencies that work with Māori and Pacific communities. Potential participants were then formally referred to the study using the Electronic Referral Management System (ERMS, a GP electronic medical records referral system) via their GP or their health centre's practice nurse.

Inclusion criteria were adults (age ≥35 years) with a GP confirmed diagnosis of T2D, living in Dunedin or Invercargill. In NZ, an HbA1c ≥50 mmol/mol in symptomatic individuals confirms the diagnosis of T2D.[26] Individuals were excluded if they had comorbid conditions that would prevent safe engagement in exercise (for example, any acute severe illness such as known active cancer, uncontrolled hypertension or chronic obstructive pulmonary disease (COPD), acute heart failure or pulmonary embolism, any unexplained excessive breathlessness with exertion or a very high falls risk).

Randomisation

Following eligibility screening, consent, and baseline assessment, each participant was randomly assigned to either the DCEP or control group (with equal chance) by opening a sealed opaque envelope containing their allocation. The envelopes were prepared by an independent administrator based on lists prepared by the study biostatistician. These lists were generated using computer software (in Stata, using the ralloc function) using pseudo-random numbers and stratified by centre with random block lengths (equally likely to be 2, 4, or 6) to preserve allocation concealment. Research assistants handed the sealed envelopes to participants at the end of the baseline assessment session with instructions to open at home. During the study, an error in one centre lead to the randomisation sequence being altered through 44 envelopes being skipped. After accounting for this, checks of the participant order for baseline questionnaires against the randomisation sequences found that some participants did not appear to answer this questionnaire in the same order as the randomisation schedule (n = 50, 30·3% over both centres). Some of these might have been the result of participants completing the questionnaire in a different order to their allocation or to envelopes being handed to participants out of order, but some (n = 7, two in one centre and five in the other) occurred when only one participant was allocated within that centre on that day and in other cases, the study biostatistician was unable to reconcile the lists for participants allocated in the same centre on the same day through re-ordering. To enable DCEP to be culturally accessible, Māori whānau and Pacific families could attend DCEP together. If eligible participants with T2D attended from the same household, they were jointly allocated to the same group. This pragmatic approach also served to minimise contamination effects between the two arms if participants in the same household were allocated to different arms of the study. In the statistical analyses, only data from the first enroled participant from the household were used (see details below).

Sample size

Based on a minimal clinically important difference for HbA1c of 5 mmol/mol (0·5%)[25] with 80% power to detect between-group differences in changes using a two-sided test at the 0·05 level (assuming a cross-sectional SD of 10 mmol/mol and without making assumptions around correlations between repeated measures beyond $r \geq 0{\cdot}5$), we calculated that 64 participants per intervention and control groups were needed

at follow-up. Allowing for approximately 40% dropout, 110 participants per group (220 in total) were sought. Based on our previous studies and on the nature of the intervention delivery, we did not anticipate any therapist clustering which may be present with individualised randomisation, and thus we did not factor a clustering effect into our sample size calculations.[27] We did anticipate the possibility of centre clustering and this was accounted for in the statistical analysis as described later.

Intervention: DCEP

DCEP has been detailed previously.[17,18] Briefly, each participant was first assessed by a physiotherapist and a nurse to identify individual goals, preferences, and physiological profile for safe, individually prescribed exercise parameters (e.g. cardiovascular fitness, muscle strength and flexibility), considering key safety considerations such as blood pressure, comorbidities, and medications. Participants then attended two 90-min sessions per week for 12 weeks. Sessions comprised 45 min of exercise, followed by 45 min of education on health-related topics. Each exercise session included 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 exercise degree of difficulty and intensity level was individually prescribed (considering comorbidities) based on accepted exercise prescription protocols.[25] Each education session focused on a topic to support self-management of diabetes, such as 'food portions' and 'foot health', conducted by an appropriate health professional (e.g. dietitian, podiatrist) and delivered in a manner enabling flexibility, tailored to attendee requests and incorporating participant-driven discussions. Participants in this group also received "usual care" (described below). DCEP session attendance and adverse events occurring or reported by participants were recorded by the session physiotherapist (as detailed in our published protocol).[17] Although this was a low risk intervention,[20] anticipated adverse events included falls, physical events (e.g. musculoskeletal injuries or discomfort) or minor medical events (e.g. hypoglycaemia).

Control: usual care

Participants randomised to the control group received "usual care" and were instructed to manage their diabetes as usual, based on what their GP or Practice Nurse advised, which would normally include appropriate medication, advice regarding diet and physical activity participation, and referral to the Diabetes Education Self Management Newly Diagnosed and Ongoing Diabetes (DESMOND) programme (a 1-day self-management education programme designed to support people living with T2D).[28]

Outcome measures

Participants were evaluated at baseline, post 12-week intervention (3 months), and then 9 months and 15 months post baseline. Blood glucose control was the primary outcome measure, defined as between-group differences in mean changes of HbA1c in mmol/mol from baseline to 15 months follow-up. Secondary outcomes, described previously, included changes in the Incremental Shuttle Walk Test (ISWT), waist circumference, body mass index, blood pressure, the NZ Physical Activity Questionnaire-Short Form (NZPAQ-SF), the Audit of Diabetes-dependant Quality of Life (ADDQoL) Questionnaire, and the EuroQol five dimensions questionnaire (EQ-5D-5 L).[17]

Data collection, cleaning, checking, and safety monitoring

Trained research assistants in each study site, blinded to group allocation, collected all data. To ensure blinding of assessors, data were collected at alternative venues than those where DCEP and DESMOND took place. Data were collected in person with enough time allowed for quality data to be collected from participants with low literacy. Participants were reminded not to disclose their randomised group and assessors were asked to report incidents of disclosure. Fidelity checklists by a research team member (CH) were randomly used to monitor testing and DCEP delivery. Assessors inputted data directly into Research Electronic Data Capture (REDCap) via a tablet. All REDCap data were stored in the University of Otago data centres.

Ethnicity was assessed using the standard NZ census question (NZ European, Māori, Samoan, Cook Island Māori, Tongan, Niuean, Chinese, Indian, and Other). The free text option for participants selecting the option of "Other" to indicate their ethnicity was inadvertently not included. Of the 11 participants selecting "Other", for six their exact ethnicity could be found in their referral documentation to the study, with five remaining unknown. One participant refused to answer this question and one provided no information about their ethnicity, resulting in seven participants with unknown/missing ethnicity. For participants with ethnicity data, their ethnicity data was coded into a single identity using the prioritisation of Māori, then (in order) Pacific, Asian, MELAA (Middle Eastern, Latin American, and African in Statistics NZ's classification), Other, and finally European.

In univariate exploration of the data, one participant was noted to have an implausibly low HbA1c (11.6 mmol/mol) and this was treated as missing instead. A further two participants did not have baseline HbA1c values and so were not able to be included in analyses adjusting for this variable. In multivariate exploration of the data, some implausible combinations of data were noted, but it was unclear which values were

most likely to be questionable and so no further changes to the data were made.

Data analysis

All primary statistical analyses were performed with Stata 16.1 and R 4.1.1 (with software defaults used in all cases where not noted below) using uninformative group codes and following a modified intention-to-treat principle (with all available data included). A two-sided $p < 0{\cdot}05$ was considered statistically significant with no allowance for multiplicity when looking at secondary outcomes. Appropriate summary statistics were calculated. Linear mixed models then examined differences in changes over time between groups for continuous outcomes adjusting for baseline values and with group, time and centre as fixed effects, along with a group −time interaction, and a random participant effect to accommodate the repeated measures. REML was used to estimate random effects and reported tests of fixed effects were performed as z-tests (the default in Stata). Between-group differences in changes in HbA1c from baseline to 15 months were used to determine programme effectiveness. As described in the protocol, if fewer than 10 households with multiple participants were enroled in the study, we selected the first participant enroled from each household for analysis. Otherwise, a random household effect would have been added to all models described above. Standard model diagnostics were performed, including examining normality and homoscedasticity of residuals and linearity of associations involving continuous predictors. Where appropriate, transformations (natural-logarithmic transformations) were investigated. Where this did not resolve concerns with model diagnostics, mixed quantile regression modelling medians was performed instead. Two per-protocol analyses were also conducted, using levels of attendance decided after the main analyses were completed (two-thirds of the 12-week intervention sessions and, separately, two-thirds of the maintenance sessions) with the biostatistician still blinded as to the group codes.

Māori advisory committee

A Māori Advisory Committee informed the trial at key points, for example, participant recruitment. This Committee comprised the key Māori advisor of the largest regional Primary Healthcare Organisation, the District Manager from the local District Health Board Māori Health Directorate, representatives from Māori Health care providers in the two cities, and two Māori researchers.

Role of funding source

This study was funded by Health Research Council of New Zealand. All authors had access to the dataset and all authors were responsible for deciding to submit for publication and had final responsibility for the submitted paper.

Results

Study participants and baseline characteristics

From 2018 to 2019, 294 people volunteered and were screened for inclusion, with 169 evaluated and randomised at baseline and 165 analysed at 15 months (from 2019 to 2020) follow-up (DCEP = 83, control = 82). Four participants (two from each group) were excluded from the final analysis as they were household members of another participant). See Figure 1 for participant flow through the study. The COVID-19 pandemic only minimally impacted this trial. NZ was in level 4 lockdown April-May 2020. This lockdown only impacted the HbA1c and physical data collection at the 6-month and 12-month assessment points of 13 and 44 participants, respectively. These data were collected later (a delay of 6 weeks) when NZ moved into level 2 lockdown. The questionnaire data were collected at the planned time but online with follow-up phone calls. The maintenance classes for 22 participants were disrupted during the April-May 2020 period. These participants kept in touch with the therapists via a WhatsApp messenger group and were encouraged to participate in physical activity (which included been allowed to walk in their local neighbourhood). These amendments to protocol were approved by the funding body.

Table 1 summarises baseline characteristics (see supplementary Table 1 for summarised data by centre). Mean age was 64.2 (SD, 15.7) years; 56·4% were female and 78·5% were NZ European, 13·9% were Māori, and 3·8% of Pacific Island heritage. The NZ Deprivation Index data showed that 27·8% of participants lived in areas considered to be in the most deprived deciles (deciles 9 and 10). The majority did not smoke (89·7%) and did not, or seldom drank, alcohol (63·7%). Multimorbidity was high (≥2 long term conditions 81·8%) as was polypharmacy (>5 medications 68·9%).

As no statistically significant between-group differences in the outcome measures (primary or secondary) were found, and the intervention was more costly than usual care (i.e. the cost of intervention included all costs associated with running DCEP plus the cost of usual care), a cost-effectiveness analysis was not conducted.

Attrition rate and treatment adherence

Attrition from the trial was low (Figure 1). Treatment adherence for the 12-week DCEP intervention was 41% for ≥20/24 sessions, 15% for 15–19/24 sessions, 21% for 2–15/24 sessions, and 23% for none to one session. The maintenance attendance was 23% for attending >50% of available sessions and 35% for 10–40% of

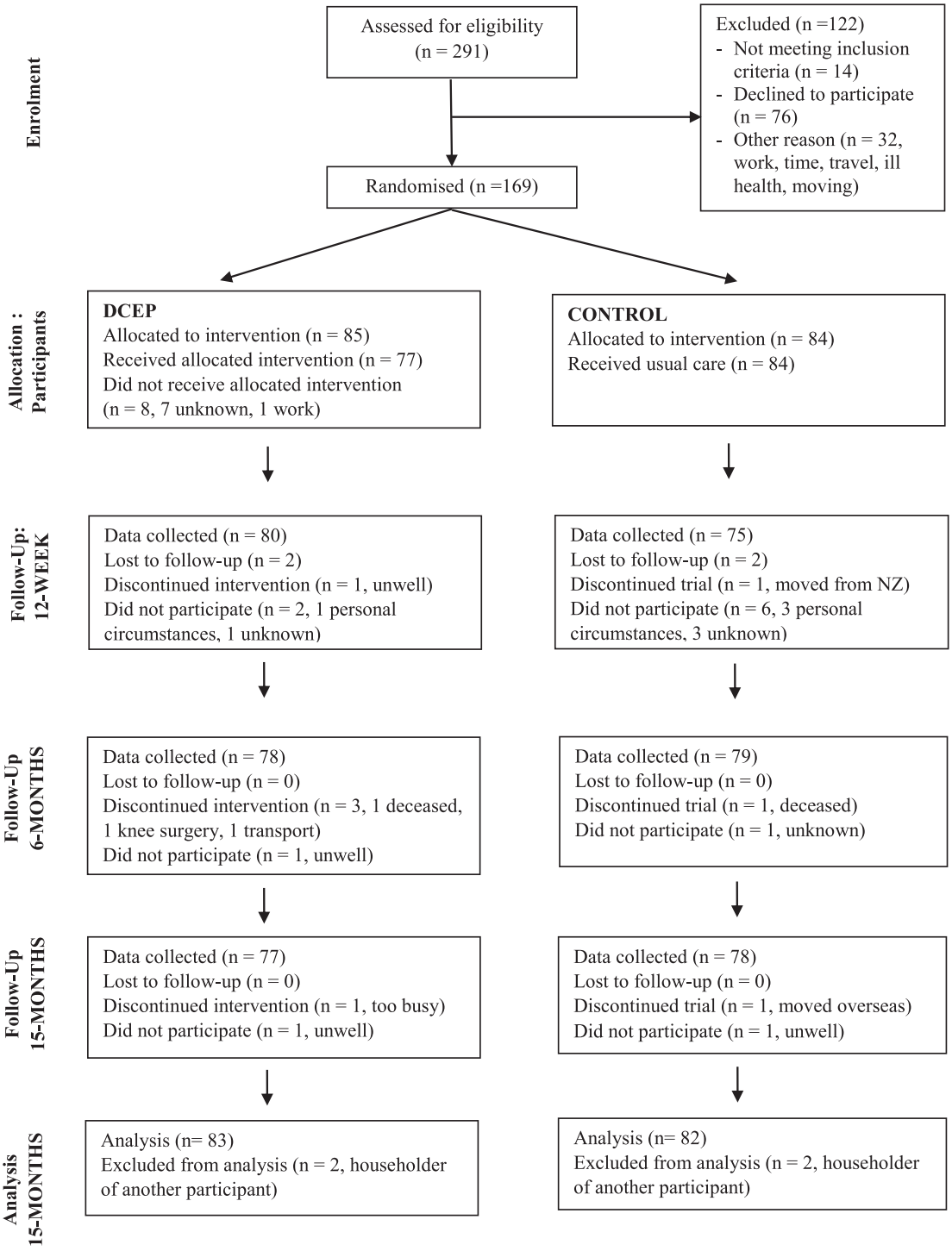

Figure 1. Trial profile.
The CONSORT flowchart of the participant flow throughout the study.

Characteristic	Overall Median (IQR)	DCEP (*n* = 83) Median (IQR)	Control (*n* = 82) Median (IQR)
Age, years	64·2 (15·7)	62·7 (15·3)	65·2 (17·7)
Problem areas in diabetes	20·0 (28·8)	21·3 (31·3)	19·4 (27·5)
Self-efficacy for managing chronic disease	44·0 (15·0)	43·0 (15·0)	45·0 (17·0)
Self-efficacy for exercise and physical activity	16·0 (9·0)	16·0 (7·0)	17·0 (10·0)
	n (%)	n (%)	n (%)
Sex			
Male	72 (43·6)	39 (47)	33 (40)
Female	93 (56·4)	44 (53)	49 (60)
Ethnicity (prioritised)			
NZ European	124 (78·5)	64 (80)	60 (77)
Māori	22 (13·9)	10 (13)	12 (15)
Pacific	6 (3·8)	2 (3)	4 (5)
Asian	4 (2·5)	4 (5)	0 (0)
Other	2 (1·3)	0 (0)	2 (3)
Missing / unknown	7	3	4
NZ Deprivation groups (based on deciles)*			
1 & 2	28 (17·0)	14 (17)	14 (17)
3 & 4	22 (13·3)	9 (11)	13 (16)
5 & 6	32 (19·4)	16 (19)	16 (20)
7 & 8	39 (23·6)	23 (28)	16 (20)
9 & 10	44 (26·7)	21 (25)	23 (28)
Multi-morbidity (number of self-reported conditions)			
1	30 (18·3)	11 (13)	19 (23)
2	53 (32·3)	26 (31)	27 (33)
3	36 (22·0)	22 (27)	14 (17)
4	21 (12·8)	11 (13)	10 (12)
5	18 (11·0)	9 (11)	9 (11)
6+	6 (3·7)	4 (5)	2 (2)
Missing/unknown	1	0	1
Polypharmacy			
≥ 5 medications	113 (68·9)	64 (77)	49 (60)
Missing/unknown	1	0	1
Education			
No formal qualifications	33 (20·4)	15 (19)	18 (22)
Trade (e.g. apprenticeship, chef)	28 (17·3)	14 (18)	14 (17)
Year 10 or equivalent (school certificate)	37 (22·8)	19 (24)	18 (22)
University degree/higher University degree	44 (27·2)	20 (25)	24 (29)
Other	20 (12·3)	12 (15)	8 (10)
Missing/unknown	3	3	0
Employment			
Working in paid employment (includes self-employment)	73 (44·5)	39 (48)	34 (41)
Not in paid work, and looking for a job	16 (9·8)	9 (11)	7 (9)
Not in paid work, and not looking for a job	75 (45·7)	34 (41)	41 (50)
Missing/unknown	1	1	0
Smoking			
No	148 (89·7)	74 (89)	74 (90)
Yes	17 (10·3)	9 (11)	8 (10)
Drinking			
Never	45 (27·3)	16 (19)	29 (35)
Monthly or less	60 (36·4)	35 (42)	25 (30)
2–4 times a month	35 (21·2)	18 (22)	17 (21)
2–3 times a week	16 (9·7)	9 (11)	7 (9)
4 or more times a week	9 (5·5)	5 (6)	4 (5)

***Table 1*: Baseline characteristics by treatment group of the intent-to-treat sample.**
DCEP: Diabetes Community Exercise Programme; NZE: New Zealand European; IQR: Interquartile range (the difference between the 25th and 75th percentiles).

* The New Zealand (NZ) Deprivation groups is an area-based measure of socioeconomic deprivation in NZ. It measures the level of deprivation for people in each small area. It is based on nine Census variables and is displayed as deciles. Each decile contains about 10% of small areas in NZ.

available sessions, with 42% attending no sessions (data not shown).

Primary outcome

There was a pattern of worse values for at baseline, outcomes, including for baseline HbA1c, in the DCEP intervention group (see Table 2 and Figs. 2–10). There was no statistically or clinically significant difference in HbA1c (mmol/mol) change between groups at the end of the study (15 months) (geometric mean 3% higher in the DCEP group, 95% CI 2% lower to 8% higher, $p = 0{\cdot}23$).

Secondary outcomes

Secondary outcomes are reported in Table 2. No statistically significant between group differences were found. Amongst the 146 participants in our study with both physical activity and HbA1c data at both baseline and follow-up, there was no evidence for a correlation between changes in these variables overall (Spearman's Rho = −0·136, $p = 0{\cdot}10$), although evidence for such an association was observed for the DCEP group ($n = 73$, Rho = −0·299, $p = 0{\cdot}01$) and not the control ($n = 73$, Rho = −0.016, $p = 0{\cdot}90$).

Per-protocol analyses

Per-protocol analyses of those participants who attended over two-thirds of available 12-week DCEP sessions ($n = 45$) showed no statistically significant between group differences for all outcomes, except for weight, for which the control group weighed significantly less. Likewise, there were no statistically significant between group differences for all outcomes for the maintenance class ($n = 8$), except for ADDQoL (see Supplementary Tables 2 and 3).

Safety

No adverse events were reported.

Role of funding sources

The funding agency had no role in study design, data collection, data analysis, data interpretation, or writing of this report.

Discussion

This trial found a lack of evidence for the hypothesis that being offered DCEP, a programme developed to enable access for all ethnic groups and for those living in low socioeconomic circumstances (in addition to usual care), would be more effective than usual care in improving HbA1c levels, physical health outcomes and health-related quality of life at 1-year follow-up. DCEP endeavoured to be culturally accessible for Māori and Pacific people. Our findings reflect those of a 2018 systematic review of lifestyle interventions for people with, and at risk of, T2D in Polynesian communities ($n = 8$, four RCTs, four pre-post studies).[29] This review reported, that apart from evidence for modest reductions in systolic blood pressure, there were no significant changes in other health outcomes (body mass index, waist circumference, weight, and glycated haemoglobin (HbA1c).) All included studies, unlike our study, primarily focussed on dietary control, with additional encouragement to increase physical activity levels in only four of the five included NZ studies.[11,13–15,30] In one NZ study, weekly aerobic sessions were built into the regular programme of church activities and several walking groups began; however, attendance appeared poor with, on average, 23 people (out of 365) attending sessions.[15]

There is strong evidence in extant literature that exercise significantly reduces Hb1Ac.[31] A 2018 systematic review of 37 studies ($n = 2208$ people with T2D) showed that a supervised combined programme of aerobic and resistance exercises significantly reduced HbA1c compared to no exercise or either form of individualised exercise.[32] It appears intense exercise regimens are required to attain glycaemic control. In one study, the Diabetes Aerobic and Resistance Exercise (DARE) study,[33] exercise group participants exercised three times weekly, and training progressed gradually in duration and intensity. The aerobic training comprised exercise on treadmills or bicycle ergometers and progressed from 15 to 20 min per session at 60% of the maximum heart rate to 45 min per session at 75% of the maximum heart rate. In the resistance training, in each session seven different exercises on weight machines were performed, progressing from two to three sets of each exercise at the maximum weight that could be lifted, to seven to nine sets. The total exercise duration built up to 90 min. Participants were aged 39 to 70 years, were cleared to exercise from a negative stress test result or by a cardiologist and had proven adherence to exercise during a 4-week run-in period. The median exercise training attendance from baseline to 26 weeks was 86% (interquartile range, 74% to 92%).

It is thus likely that our twice weekly, 45-min exercise programme, whilst combining aerobic and resistance training, did not achieve the level of intensity required to bring about the necessary physiological changes to impact Hb1Ac. To enable access and encourage attendance, we created a socially supportive environment and allowed participants to self-select their exercises from a programme of prescribed exercises; the DCEP physiotherapist then encouraged appropriate exercise intensity progression. Qualitative evaluation of DCEP showed that attending participants valued the social atmosphere and that is what kept them coming during the initial 12-week programme and facilitated exercise engagement.[18] This congenial environment

Outcome	Time	DCEP		Control		Between group differences at final follow-up	
		n	Geometric mean (geometric SD) or median (IQR)	n	Geometric mean (geometric SD) or median (IQR)	Ratio or difference (DCEP) and 95% CI	p-value
Primary Outcome							
HbA1c, mmol/mol *	Baseline	81	61·8 (1·25)	81	56·7 (1·23)		
	Post-intervention	78	58·3 (1·24)	74	54·1 (1·26)		
	9 month follow-up	76	59·0 (1·22)	76	54·1 (1·23)		
	15 month follow-up	75	61·6 (1·22)	74	55·2 (1·25)	1·03 (0·98, 1·08)	0·23
Secondary Outcomes							
Incremental Shuttle Walk Test, m **	Baseline	69	290 (230)	71	300 (190)		
	Post-intervention	70	325 (170)	61	330 (190)		
	9 month follow-up	68	330 (165)	62	330 (140)		
	15 month follow-up	65	310 (160)	62	305 (180)	7·8 (−36·0, 51·5)	0·72
Weight, kg *	Baseline	83	100·2 (1·25)	82	95·7 (1·24)		
	Post-intervention	78	98·9 (1·26)	74	94·5 (1·24)		
	9 month follow-up	75	98·2 (1·25)	74	94·3 (1·24)		
	15 month follow-up	72	97·8 (1·25)	73	93·9 (1·24)	1·01 (0·99, 1·02)	0·28
Waist Circumference, cm *	Baseline	83	115·5 (1·17)	82	111·5 (1·17)		
	Post-intervention	78	113·5 (1·16)	73	109·7 (1·14)		
	9 month follow-up	74	112·9 (1·15)	74	109·5 (1·15)		
	15 month follow-up	72	113·4 (1·15)	73	109·4 (1·14)	1·02 (0·99, 1·04)	0·16
Systolic Blood Pressure, mmHg *	Baseline	83	136·6 (1·13)	82	135·0 (1·11)		
	Post-intervention	78	135·7 (1·11)	74	134·0 (1·13)		
	9 month follow-up	74	132·3 (1·11)	74	134·3 (1·13)		
	15 month follow-up	72	136·1 (1·12)	73	134·9 (1·13)	1·01 (0·97, 1·04)	0·73
Diastolic Blood Pressure, mmHg *	Baseline	83	80·5 (1·14)	82	79·8 (1·12)		
	Post-intervention	78	79·4 (1·13)	74	78·3 (1·13)		
	9 month follow-up	74	77·8 (1·13)	74	77·3 (1·14)		
	15 month follow-up	72	77·7 (1·12)	73	78·6 (1·14)	0·99 (0·96, 1·02)	0·58
Audit of Diabetes-dependant Quality of Life **	Baseline	78	−1·197 (2·667)	77	−1·000 (1·526)		
	Post-intervention	75	−0·875 (1·789)	74	−0·515 (1·530)		
	9 month follow-up	74	−0·864 (2·094)	74	−0·764 (1·316)		
	15 month follow-up	72	−1·173 (1·766)	76	−0·690 (1·493)	−0·172 (−0·551, 0·207)	0·37
Health Status (EuroQol five dimensions) **	Baseline	83	0·823 (0·261)	82	0·873 (0·244)		
	Post-intervention	78	0·870 (0·246)	74	0·856 (0·299)		
	9 month follow-up	76	0·856 (0·180)	77	0·873 (0·244)		
	15 month follow-up	75	0·839 (0·248)	76	0·820 (0·243)	−0·011 (−0·070, 0·048)	0·71

Table 2 *(Continued)*

Outcome	Time	DCEP		Control		Between group differences at final follow-up	
		n	Geometric mean (geometric SD) or median (IQR)	n	Geometric mean (geometric SD) or median (IQR)	Ratio or difference (DCEP) and 95% CI	p-value
Total Physical Activity after truncation, mins **	Baseline	83	60 (155)	82	88 (120)		
(NZ Physical Activity Questionnaire-Short Form)	Post-intervention	78	90 (140)	74	68 (120)		
	9 month follow-up	76	90 (133)	77	90 (130)		
	15 month follow-up	75	50 (115)	76	60 (88)	−15·9 (−51·1, 19·3)	0·37

***Table 2*: Descriptive statistics for outcomes and intention to treat analyses.**
Models adjust for centre and baseline values; SD: standard deviation; IQR: Interquartile range (the difference between the 25th and 75th percentiles).
* Geometric mean and geometric standard deviation, and ratio of means.
** Median and IQR, and difference of medians.

however, may not have been conducive to intense exercising, with both staff and DCEP attendees commenting that many did not exercise much at sessions.[18] Further to this, 49.5% of our cohort living with ≥3 long term health conditions and high polypharmacy and would most likely not have met the inclusion criteria of the DARE study. It is noteworthy, however, that the DARE study calculated that the monthly cost of the combined intervention (exercise facility membership fee plus trainer time) was $197 (Canadian).[33] We purposefully, to enable our target group to participate, ensured our intervention was free for participants and low cost for us to deliver; in fact, attendees commented that they would not attend if there was any cost to them.[18] For some, they could not even afford the transport or petrol to attend.[18]

The strength of this study was that DCEP specifically focussed on equity, enabling attendance of those that experience inequities in health delivery and poor health outcomes. In our trial, we reached ethnic representation with the percentage of Māori (13·9%) and Pacific peoples (3·8%) in our study reflecting the ethnic mix of these populations in our Southern District Heath Board (DHB) (Māori 10·8%, Pacific peoples 2·3%)[34] and the known prevalence of self-reported diabetes in NZ for Māori (8·4%). Although the Southern DHB is reported to have a high proportion of people in the least deprived sections of the NZ population and a low proportion in the most deprived section,[34] our cohort had 30% living in the most deprived section. Further to this we reached our targeted sample size (based on our statistical power calculations) with a low drop-out rate (2.4%). Given that our initial 12-week programme was relatively well attended, with 41% attending over 80% of available sessions, perhaps our primary achievement was that we got a cohort with high HbIAc levels, multimorbidity, and high polypharmacy to start to engage in physical activity. Indeed, contemporary idioms are now stating that some physical activity engagement is better than none.[35] This success is potentially attributable to the extensive consultation and relationship building conducted prior to trial commencement.

Study limitations included not collecting dietary and nutritional data, and so we cannot infer the interaction of exercise and diet on our outcomes. Additionally, the twice weekly frequency of exercise may have been insufficient to utilise the postprandial effects of aerobic exercise on glycaemic control.[36] Physical activity data collected demonstrated no statistically significant between group differences. Although the levels of activity appeared to increase for those attending DCEP, we do not know if this was offset by increased sedentary behaviour at home in between classes. Further, as noted in our earlier qualitative evaluation,[18] whilst we did train the healthcare professionals involved in delivering DCEP, the high turnover of staff and the subtle nature of how we delivered the exercise and education in a

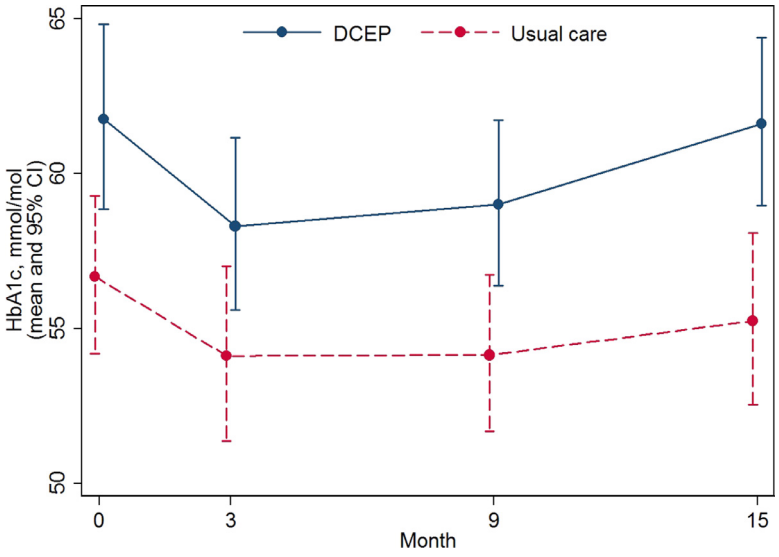

Figure 2. HbA1c outcomes baseline to 15-month follow-up.

The Diabetes Community Exercise Programme (DCEP) group (blue line) and usual care control group (red dashed line) mean and 95% confidence intervals (CI) for glycated haemoglobin (mmol/mol) outcomes shown at baseline, 3, 9 and 15 months follow-up (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.).

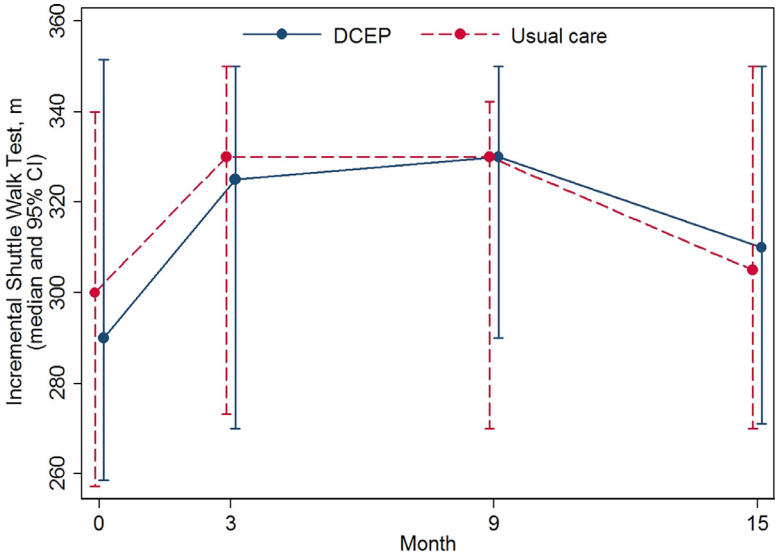

Figure 3. Incremental Shuttle Walk Test outcomes baseline to 15-month follow-up.

The Diabetes Community Exercise Programme (DCEP) group (blue line) and usual care control group (red dashed line) median and 95% confidence intervals (CI) for the Incremental Shuttle Walk Test (m) outcomes shown at baseline, 3, 9 and 15 months follow-up (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.).

tailored, person-centred way, appeared to require additional training and resources, a finding highlighted in a previous study.[37] The timing of our DCEP classes prevented many attendees from maintaining attendance in the maintenance classes, especially if they were employed or working multiple jobs.[18] We were unable to collect HbıAc data at baseline for two participants due to a device malfunction and for one participant their baseline HbıAc was inexplicably low. Data were missing for the shuttle walk test as 25 participants were experiencing too much pain or deemed too unwell (blood sugar levels and/or blood pressure too high) to enable safe testing at the time. Despite randomisation, the imbalances in baseline measures between the

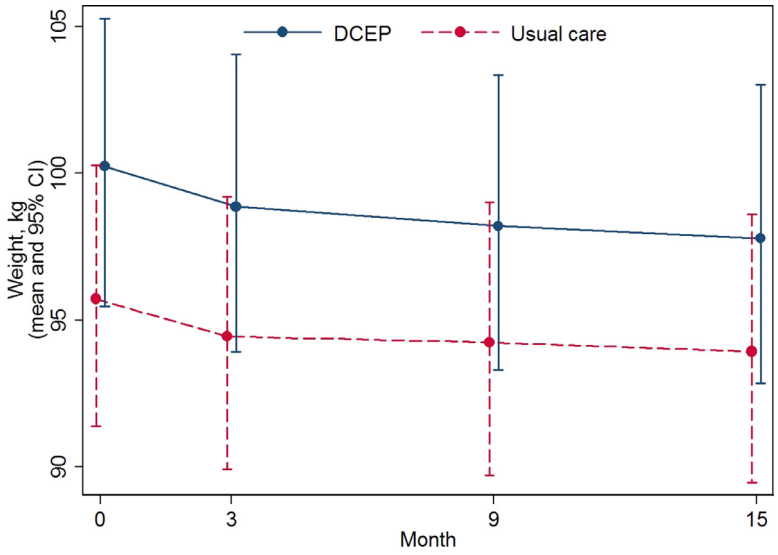

Figure 4. Weight outcomes baseline to 15-month follow-up.

The Diabetes Community Exercise Programme (DCEP) group (blue line) and usual care control group (red dashed line) mean and 95% confidence intervals (CI) for the Weight (kg) outcomes shown at baseline, 3, 9 and 15 months follow-up (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.).

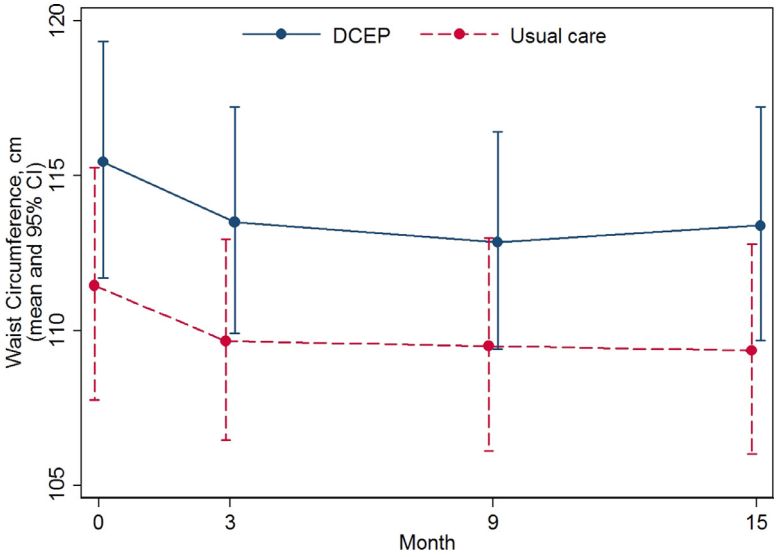

Figure 5. Waist Circumference outcomes baseline to 15-month follow-up.

The Diabetes Community Exercise Programme (DCEP) group (blue line) and usual care control group (red dashed line) mean and 95% confidence intervals (CI) for the Waist Circumference (cm) outcomes shown at baseline, 3, 9 and 15 months follow-up (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.).

groups, particularly for our primary outcome HbA1c, were large, and while we adjusted for these in analyses, we cannot rule out differential regression to the mean effects between groups.

When trials report lack of effect on outcomes, the subsequent debate is often whether this is due to an implementation failure or intervention failure.[38] In our case, we will report a detailed implementation analysis elsewhere, but here it raises the question, did our intervention fail? When viewed with the Western, medical model lens, possibly yes. We argued for exercise and education as a means of effectively improving glycaemic control, and we did not demonstrate this. Possibly viewed through an equity lens, while prolonged and

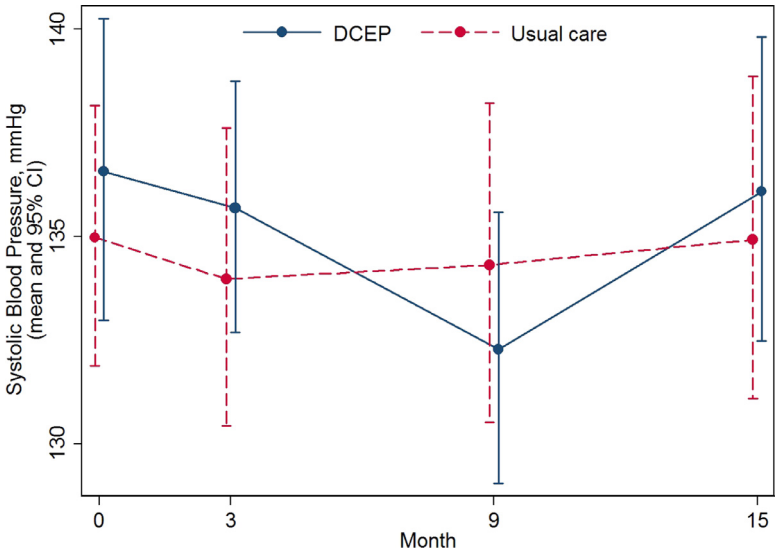

Figure 6. Systolic Blood Pressure outcomes baseline to 15-month follow-up.

The Diabetes Community Exercise Programme (DCEP) group (blue line) and usual care control group (red dashed line) mean and 95% confidence intervals (CI) for the Systolic Blood Pressure (mmHg) outcomes shown at baseline, 3, 9 and 15 months follow-up (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.).

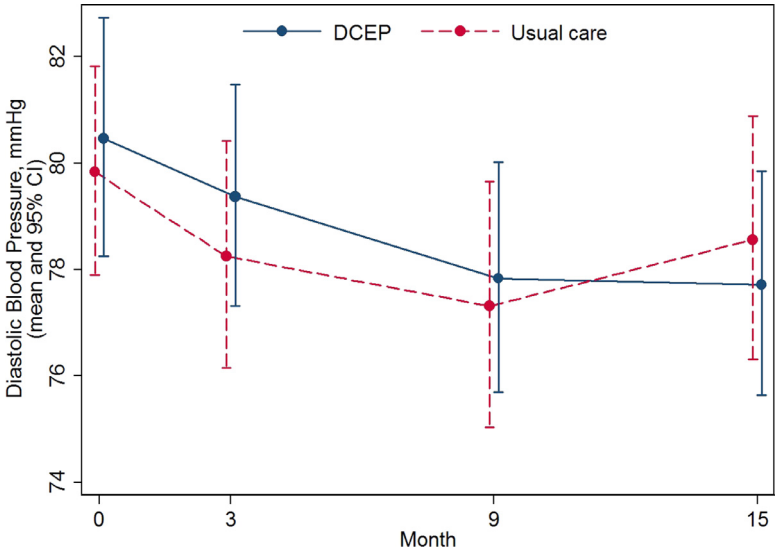

Figure 7. Dystolic Blood Pressure outcomes baseline to 15-month follow-up.

The Diabetes Community Exercise Programme (DCEP) group (blue line) and usual care control group (red dashed line) mean and 95% confidence intervals (CI) for the Dystolic Blood Pressure (mmHg) outcomes shown at baseline, 3, 9 and 15 months follow-up (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.).

intense exercise engagement may improve glycaemic control, if target groups are unable or do not want to attend such programmes due to the high costs or potential pretentiousness of such programmes,[18] then intense programmes may not be acceptable to these groups.

Perhaps for populations where equity and cultural accessibility are important, lifestyle interventions for T2D (such as exercise, diet, mental health) should first focus on wellbeing indicators. Then over time, alongside good and appropriate pharmaceutical care, exercise intensity can gradually increase. Using this stepwise approach to building physical activity behaviour change is pragmatic given that in a 2019/2020 NZ Ministry of Health report only 52% of all adults did at least 2.5 h of

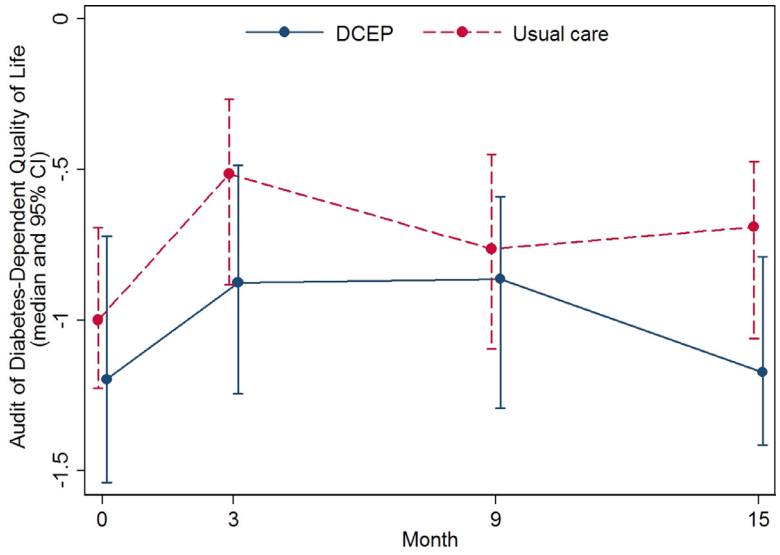

Figure 8. Audit of Diabetes-dependant Quality of Life outcomes baseline to 15-month follow-up.

The Diabetes Community Exercise Programme (DCEP) group (blue line) and usual care control group (red dashed line) median and 95% confidence intervals (CI) for the Audit of Diabetes-dependant Quality of Life outcomes shown at baseline, 3, 9 and 15 months follow-up (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.).

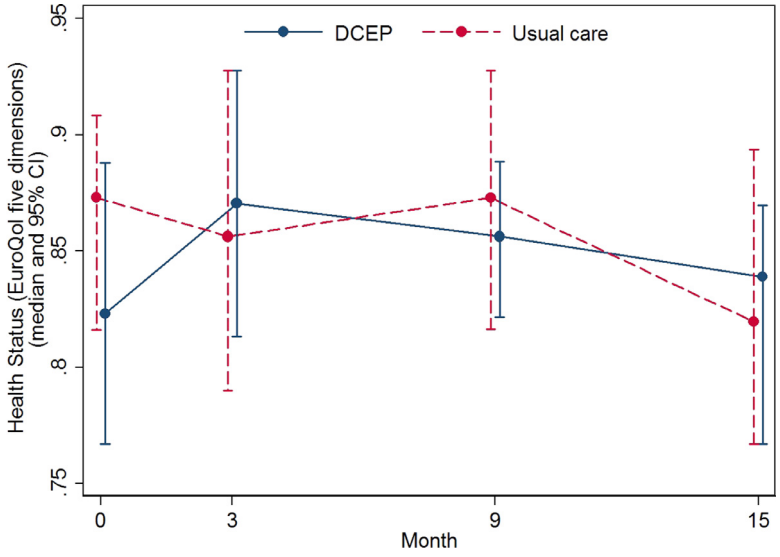

Figure 9. EuroQol five dimensions outcomes baseline to 15-month follow-up.

The Diabetes Community Exercise Programme (DCEP) group (blue line) and usual care control group (red dashed line) median and 95% confidence intervals (CI) for the Health Status (EuroQol five dimensions) outcomes shown at baseline, 3, 9 and 15 months follow-up (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.).

activity in the past week, 12.5% of adults were only physically active for less than 30 min per week, and Pacific and Asian adults are less likely to be physically active than non-Pacific, non-Asian adults.[39] Further to this, participants should be encouraged to be physically active more frequently, beyond the twice-a-week attendance at DCEP to benefit from postprandial glucose metabolism.[35] Our study perhaps should have focused on a well-being outcome or included outcomes of community participation, diabetes distress, or self-compassion. In the meantime, we appear to be achieving desirable wellness goals, adding life to years as

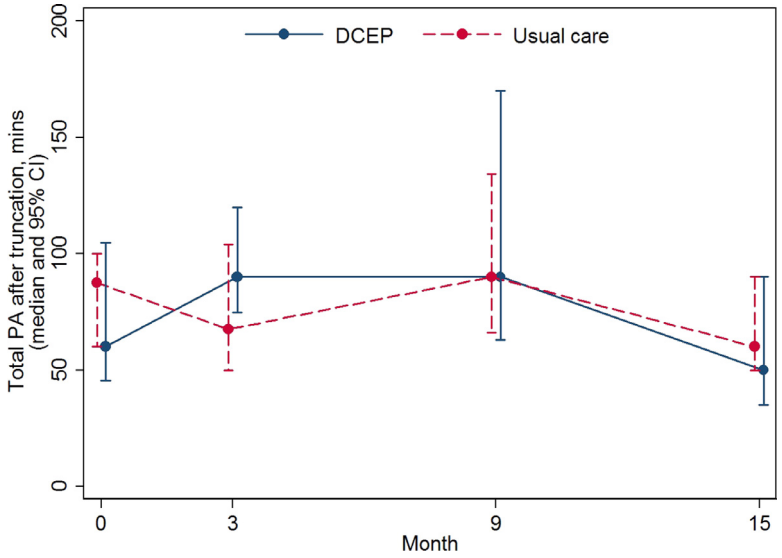

Figure 10. New Zealand Physical Activity Questionnaire-Short Form outcomes baseline to 15-month follow-up.

The Diabetes Community Exercise Programme (DCEP) group (blue line) and usual care control group (red dashed line) median and 95% confidence intervals (CI) for the Total Physical Activity (PA) after truncation (mins) outcomes shown at baseline, 3, 9 and 15 months follow-up (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.).

opposed to years to life.[40] For a long-term (often lifelong) health condition such as T2D, people need to be able to access an intervention that they are comfortable to engage with lifelong. Future lifestyle programmes for Māori and Pacific people and those living in low socioeconomic circumstances with T2D should also include outcomes of wellbeing, measures of confidence to take control of their own health and an indicator of long-term programme engagement.

Author contributions

The authors' contributions were as follow:

LH: principle investigator - conceptualisation, formal analysis, funding acquisition, investigation, methodology, project administration, wrote original draft and finalised manuscript

ARG: biostatistician - formal analysis, funding acquisition, investigation, methodology, writing - review and editing

CH: physiotherapy clinical investigator - conceptualisation, formal analysis, funding acquisition, project clinical administration, data interpretation, writing - review and editing

JM: medical advisor - conceptualisation, funding acquisition, data interpretation, writing - review & editing

RM: conceptualisation, funding acquisition, investigation, methodology (secondary outcomes), data interpretation, writing - review and editing

TS: health economist - conceptualisation, funding acquisition, investigation, methodology, data interpretation, writing - review and editing

JT: data curation and management, project administration, writing - review and editing

DK: project administration, conceptualisation, funding acquisition, data interpretation, writing - review and editing

TS: medical advisor - conceptualisation, funding acquisition, data interpretation, writing - review and editing

All authors reviewed and critiqued the manuscript and approved the final published version. All authors critically edited and reviewed the manuscript. All authors had full access to the data in the study and accept responsibility to submit for publication.

Data sharing statement

All relevant data are included in this manuscript. The data that support the findings of this study are available from the corresponding author upon reasonable request.

Declaration of interest

All authors have nothing to declare.

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