Diabetologia (2020) 63:2559–2570
https://doi.org/10.1007/s00125-020-05261-x

ARTICLE

Impact of a comprehensive digital health programme on HbA_{1c} and weight after 12 months for people with diabetes and prediabetes: a randomised controlled trial

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Received: 14 April 2020 / Accepted: 20 July 2020 / Published online: 4 September 2020

Abstract

Aims/hypothesis The aim of this RCT was to evaluate the effectiveness of a digital health programme (BetaMe/Melon) vs usual care in improving the control of type 2 diabetes and prediabetes in a primary care population.

Methods We conducted a randomised parallel-group two-arm single-blinded superiority trial in the primary care setting in two regions of New Zealand. Eligible participants were identified through Primary Health Organisations and participating practices. Eligibility criteria were as follows: age 18–75 years, HbA_{1c} 41–70 mmol/mol (5.9–8.6%), not taking insulin, and daily access to the internet. BetaMe/Melon is a 12 month mobile-device and web-based programme with four components: health coaching; evidence-based resources; peer support; and goal tracking. Participants were randomised into the intervention or control arm (1:1 allocation) based upon baseline HbA_{1c} (prediabetes or diabetes range), stratified by practice and ethnicity. Research nurses and the study biostatistician were blind to study arm. Primary outcomes of the study were changes in HbA_{1c} and weight at 12 months, using an intention-to-treat analysis.

Results Four hundred and twenty-nine individuals were recruited between 20 June 2017 and 11 May 2018 ($n = 215$ intervention arm, $n = 214$ control arm), most of whom were included in analyses of co-primary outcomes ($n = 210/215$, 97.7% and $n = 213/214$, 99.5%). HbA_{1c} levels at 12 months did not differ between study arms: mean difference was −0.9 mmol/mol (95% CI −2.9, 1.1) (−0.1% [95% CI −0.3, 0.1]) for the diabetes group and was 0.0 mmol/mol (95% CI −0.9, 0.9) (0.0% [95% CI −0.1, 0.1]) for the prediabetes group. Weight reduced slightly at 12 months for participants in both study arms, with no difference between arms (mean difference −0.4 kg [95% CI −1.3, 0.5]).

Conclusions/interpretation This study did not demonstrate clinical effectiveness for this particular programme. Given their high costs, technology-assisted self-management programmes need to be individually assessed for their effectiveness in improving clinical outcomes for people with diabetes.

Trial registration www.anzctr.org.au ACTRN12617000549325 (universal trial number U1111–1189-9094)

Funding This study was funded by the Health Research Council of New Zealand, the Ministry of Health New Zealand and the Healthier Lives National Science Challenge.

Keywords Diabetes mellitus · eHealth · Mobile applications · Prediabetes · Randomised controlled trial · Self-management

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s00125-020-05261-x) contains peer-reviewed but unedited supplementary material, which is available to authorised users.

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Research in context

What is already known about this subject?

- Technology-assisted self-management programmes may improve glycaemic control and reduce weight in people with diabetes
- Programmes range from simple to multi-component, vary in the comparator of 'usual care', are commonly of short duration, and health gains are not always interpreted with respect to clinical significance
- Few studies have investigated the impact of technology-assisted self-management programmes in prediabetes or ethnic minority populations who suffer a greater burden of diabetes and its complications

What is the key question?

- How effective is the BetaMe/Melon programme vs usual care among primary care populations in improving the control of diabetes and prediabetes, as measured by changes in HbA_{1c} and weight over 12 months?

What are the new findings?

- Improvements in HbA_{1c} and weight did not reach levels of clinical significance, attenuated over time, and were lower for Māori and Pacific (ethnic minority) participants
- Intervention-arm participants had reductions in secondary outcomes for self-reported quality of life and confidence with self-management

How might this impact on clinical practice in the foreseeable future?

- Technology-assisted self-management tools continue to be funded despite their cost and a lack of evidence of benefit. The results of this study do not support such use

Abbreviations

MCID Minimal clinically important difference

Introduction

Type 2 diabetes mellitus is a common long-term condition affecting adults in New Zealand, with a prevalence of 6% in 2018/2019 [1]. Diabetes is associated with multiple long-term complications, higher mortality and substantial healthcare costs [2, 3]. The burden of type 2 diabetes is frequently unequal, with those in socially marginalised populations having higher rates. In New Zealand, the burden of diabetes is particularly high among Māori, Pacific and Indian people, who have up to three times the prevalence of those who self-identify with NZ European ethnicity [1].

Prediabetes is a precursor stage to type 2 diabetes, with up to 70% of affected individuals eventually progressing to type 2 diabetes; many with prediabetes already have complications seen with type 2 diabetes [2]. Self-management measures including appropriate diet, regular exercise and weight management are key to preventing the progression of prediabetes to type 2 diabetes, controlling existing type 2 diabetes and reducing complications [4–8]. While people with diabetes who undergo lifestyle interventions tend to have better glycaemic control and improved long-term outcomes [8], many people struggle to initiate and maintain these strategies [9, 10].

Technology-assisted self-management programmes are increasingly recommended to people with type 2 diabetes for delivery and support of lifestyle interventions. These scalable programmes offer the potential to reduce the burden of type 2 diabetes for populations, and improve health equity by addressing barriers to accessing healthcare, such as time and financial cost [11]. However, evidence is mixed as to whether these technology-based programmes are successful at improving glycaemic control, improving wellbeing or reducing complications [12–15]. A recent meta-review of type 2 diabetes self-management interventions found a diverse range of technology-assisted self-management programmes, ranging from simple text reminder to multi-model programmes [12]. Overall, technology-assisted programmes perform similarly to other self-management programmes. However, long-term adherence is problematic and observed short-term improvements tend to attenuate over time [12]. Other systematic reviews of technology-assisted interventions for diabetes have found that while improvements in glycaemic control are commonly achieved, effectiveness is sensitive to the amount of healthcare provider input, the degree of personalisation of the programme, and participant age (with greater gains seen in younger people with type 2 diabetes) [13, 15]. Similarly, potential improvements in wellbeing and quality of life are not consistently realised [14].

Given the excess burden among underserved populations, there is a critical lack of evidence relating to the usefulness of these programmes among these groups. In the absence of this evidence, poorly considered large-scale use of these tools may exacerbate inequities in diabetes-related outcomes or miss opportunities to reduce inequalities. The current RCT was intended to contribute to the evidence base for self-management of a comprehensive (multi-modal), patient-centred, technology-assisted self-management programme for individuals with prediabetes and diabetes (the BetaMe/Melon programme) compared with usual care within primary care services in New Zealand. We investigated the effect of this intervention on changes in HbA_{1c} and weight, as well as other secondary outcomes, for both a general population and for the minority Māori and Pacific population.

Methods

Study design This study was a randomised parallel-group two-arm single-blinded superiority trial. Participants were recruited from 25 general practices (primary care centres) in the greater Wellington and Waikato regions of the North Island of New Zealand, covering both urban and rural settings. The study was designed as an effectiveness trial [16], with an emphasis on recruitment that matched the real-world target population of people with diabetes or prediabetes, delivery of the intervention within the wider context of diabetes care in a primary care setting, and a long follow-up to examine clinically relevant outcomes in a sufficiently large sample of participants.

Ethical approval was obtained from the NZ Health and Disability Ethics Central Committee (HDEC: reference 17/CEN/49). Informed consent was obtained from all participants at the baseline assessment. The trial methods have been published as a protocol [17].

Participants All patients enrolled with participating practices were screened for eligibility for invitation into the study (for criteria that could be identified at screening), based on review of clinical database information.

Eligibility criteria were as follows: HbA_{1c} 41–70 mmol/mol inclusive (5.9–8.6%) at study enrolment (current or tested in preceding 3 months); not currently receiving insulin treatment; aged 18–75 years (inclusive); having daily access to the internet; and able to provide informed consent.

Exclusion criteria were as follows: pregnant at baseline; cognitive impairment that might make participating in the programme difficult; unable to read/write in English; and inability to use a phone or computer due to physical disability (e.g. poor eyesight).

Participants were recruited into either the diabetes-range group (baseline HbA_{1c} 50–70 mmol/mol inclusive; 6.7–8.6%) or prediabetes-range group (baseline HbA_{1c} 41–49 mmol/mol inclusive; 5.9–6.6%)), as defined by the New Zealand criteria [18]. Eligibility for the prediabetes-range group required that the participant had no previous diagnosis of type 2 diabetes (in clinical notes or reported by the participant).

Randomisation and masking Full details of randomisation are provided in the protocol [17]. Participants were individually randomised to the intervention (BetaMe/Melon programme) or control arm, using a pre-allocated computer-generated sequence stratified by key clinical and demographic variables (practice, prediabetes- or diabetes-range group, and ethnicity [Māori, Pacific and non-Māori/non-Pacific]). Allocation was conducted by the trial manager (MM) from within the REDCap system [19, 20], following confirmation of eligibility and consent. Participants could not be blinded to study arm following randomisation. Research nurses conducting follow-up assessments were blinded to study arm, although participants may have revealed their study arms during assessments.

The study statistician was blinded during data cleaning and statistical analysis. Results were unblinded following completion of main analyses; per-protocol and sensitivity analyses (noted below) could only be conducted following unblinding.

Procedures

Participants in the control and intervention arms received usual care, which at a minimum included annual checks of glycaemic control and, for those with type 2 diabetes, a review of treatment and checks for complications. Usual care varied across practices and could include education and advice on lifestyle factors.

In addition to usual care the intervention arm received the BetaMe/Melon programme over 12 months, delivered through mobile devices and web-based platforms. BetaMe/Melon was developed and delivered by Melon Health (New Zealand), a company with experience in developing and delivering evidence-based, innovative mobile health solutions in partnership with primary care clinicians. The BetaMe/Melon programme has foundations in behavioural change theory, using cognitive behavioural theory, motivation interviewing, goal setting, health tracking, reminders and intrinsic rewards to support and encourage positive behaviour change [21–23]. The BetaMe/Melon programme was piloted in 2015 [17]. Of the 108/117 individuals with prediabetes that completed the programme, 91% reduced their baseline HbA_{1c}, 94% lost weight (mean loss 4.2 kg), 87% had reduced waist circumference (mean reduction 4.2 cm) and 78% achieved HbA_{1c} levels in the normal range.

Table 1 Components of the BetaMe/Melon programme and evidence base

Element	What is provided	Evidence for effective self-management
Core only (weeks 1–16)		
Health coaching	Shared goal setting and personalised programme based on an individual's personal goals Regular input, encouragement and support via messaging and fortnightly video or audio meetings	Educational programmes and individual support through personalised coaches is effective at a level dependent on the intensity of the programme [25] Successful interventions include those providing access to an 'expert', such as a personal trainer or dietitian, coupled with support from health professionals [24, 26]
Health literacy	Fortnightly evidence-based resources and behaviour change tools delivered in consumer-centred formats (bite-size, simple messages, images and video)	Reminders or educational information sent via text or within applications on mobile telephones have proven beneficial in the management of chronic conditions such as diabetes [27] Positive outcomes include glycaemic control and patient satisfaction [29], self-efficacy [28], medication adherence [30], and reduced transition from prediabetes to diabetes as a result of weight loss [31]
Core and maintenance (12 months)		
Peer support	Online closed forum, monitored by a registered nurse	Peer support has been successful in improving glycaemic control [32–36]; participants regard this as being the most useful component of a self-management programme [33]
Goal tracking	Daily reminders via web-based devices Daily goal tracking of exercise, happiness, energy levels, food, glucose testing and medication adherence; weekly tracking of weight and waist measurements	Goal tracking, such as the regular monitoring of weight or laboratory data, has been identified as a key component of successful self-management programmes to achieve weight loss [38] and improved long-term outcomes [37]

BetaMe/Melon incorporates four evidence-based components (see Table 1): (1) individual health coaching [24–26]; (2) fortnightly provision of evidence-based resources [27–31]; (3) online peer support through a closed forum [32–36]; and (4) online goal tracking [37, 38]. The core part of the programme lasted 16 weeks (all four programme components), with the remaining 36 weeks comprising maintenance activities (web-based peer support and goal tracking only). Melon Health played no role in the RCT design, data collection or analysis.

Follow-up assessments were at 4 and 12 months following baseline assessment. Study data were collected and managed using REDCap electronic data capture tools [19, 20].

Data on participant engagement with the programme were provided to the Otago research team by Melon Health. From the data provided, we identified the number of completed initial health coaching sessions and measured 'active engagement' with the online programme (diary entries and posting or 'likes' on the peer support forum). We were unable to obtain data from Melon Health on the average number of health coach sessions completed per participant or on passive engagement with the online tool such as the opening of e-mailed fortnightly educational resources or browsing online. Participant engagement and satisfaction with the BetaMe/Melon programme are reported fully elsewhere.

Outcomes Co-primary outcomes were HbA_{1c} (analysed separately for diabetes- and prediabetes-range participants) and weight in kg (analysed across both groups combined). Standardised measurement procedures are described in the protocol [17]. The primary endpoint was the follow-up at 12 months.

Secondary outcomes included the following variables: HbA_{1c} and weight at interim follow-up (4 months); other physical measurements at both follow-up times (BMI, waist circumference, systolic and diastolic BP); and quality of life and self-management scales at both follow-up times (Partners in Health scale [39], Diabetes Distress Scale [40, 41], Diabetes Self-Care Activities [42] and EQ-5D [43]). Finally, diabetes medication receipt was reported at baseline and at each follow-up: participants were classified (relative to baseline) as to whether they had started insulin, started metformin or changed total daily dose, or started/changed daily dose for other glycaemic control agents. Baseline characteristics included New Zealand Index of Deprivation 2018 [44] as an area-based measure of socioeconomic deprivation, reported as quintiles.

Statistical analysis A statistical analysis plan was finalised before the trial statistician accessed the data (see electronic supplementary material [ESM] Methods). Main analyses were conducted following an intention-to-treat framework (see Sensitivity analyses below for per-protocol approach). Participants were included in a given analysis if they had at least one follow-up measurement for that outcome.

Comparisons of continuous outcomes (all primary and most secondary outcomes) used linear mixed models, looking at outcomes at follow-up (4 and 12 months) adjusted for baseline. These models adjusted for age group, sex and ethnicity (as a stratifying element in randomisation). All analyses examining the total group (diabetes- and prediabetes-range participants) further adjusted for HbA_{1c} range (stratifying element in randomisation). For the co-primary outcomes, HbA_{1c} was further adjusted for weight at baseline and weight analyses were adjusted for HbA_{1c} at baseline (pre-specified in protocol).

Assessment of baseline balance showed some differences in baseline diabetes medication use by study arm, so primary outcome analysis was adjusted for baseline diabetes medication (binary variable indicating whether a participant was taking hypoglycaemic control agent at baseline).

Results are presented as means at each follow-up (adjusted for baseline) and mean differences by study arm at each follow-up time, with 95% CI.

All statistical analysis was conducted using R 3.5 (R Institute, Austria). Linear mixed models were conducted using the nlme package [45].

Sample size calculations are given in full in the protocol, with the HbA_{1c} outcome having distinct minimal clinically important differences (MCIDs) for diabetes-range participants (5.5 mmol/mol, 0.5%; assumed SD of 15 mmol/mol, 1.4% [22]) and prediabetes-range participants (2.5 mmol/mol, 0.2%; assumed SD 5.5 mmol/mol, 0.5% [46]). Sample size was $n = 234$ for diabetes-range participants and $n = 152$ for prediabetes-range participants. This was inflated by 10% to allow for loss of information from incomplete follow-up, giving a final target of $n = 430$ participants.

For the weight outcome, the sample size required for 80% power to detect an MCID of 5 kg ($n = 284$, assuming SD 15 kg [47]) was well below the combined sample size calculated for HbA_{1c}.

Sensitivity analyses One pre-specified sensitivity analysis (ESM Methods/Statistical analysis plan) examined primary outcomes when restricting intervention participants to those with at least one health coaching session recorded. The first health coaching session was the only element of the programme that was required; all other components were optional.

Examination of raw data for objective measurements showed one participant with extreme weight gain of 60 kg between 4 months and 12 months. A post hoc analysis removed this participant from the analysis set before re-assessing the weight outcome.

Trial registration and data monitoring committee The trial was registered with the Australian New Zealand Clinical Trials Registry on 19 April 2017 (www.anzctr.org.au registration number ACTRN12617000549325 [universal trial number U1111–1189-9094]).

A data monitoring committee oversaw the study, with a remit to assess the effectiveness of study procedures, review any arising adverse events, and review and approve any amendments to study protocols.

Changes to methods after trial commencement A minor amendment to inclusion criteria was made after the trial commenced. The upper limit of baseline HbA_{1c} was increased for diabetic participants from 64 to 70 mmol/mol (from 8.0% to 8.6%). The rationale for this change was as follows: (1) recruitment of diabetic individuals had been slower than expected; (2) some diabetic participants had baseline measures in the range but were keen to be included in the study; and (3) participants in this range had not been started immediately on insulin. The rationale and decision were discussed and agreed by the study data monitoring committee, as well as clinical team members (AD, JK). The Clinical Trials Registry (ANZCTR) and Ethics Committee (HEDC) were advised of the change (date of approval by ANZCTR: 31 July 2017).

Results

Figure 1 shows participant flow from assessment for eligibility through to analysis. A total of 429 individuals were recruited between 20 June 2017 and 11 May 2018 ($n = 215$ and $n = 214$ for intervention and control arms, respectively); almost all were included in analysis of co-primary outcomes ($n = 423$ [98.6%] for HbA_{1c}; $n = 421$ [98.1%] for weight).

Balance at baseline The study arms were balanced on sociodemographic and clinical characteristics, and on baseline values of outcomes (Table 2, ESM Figs 1 and 2, and ESM Tables 1 and 2). There were some exceptions: the control arm had a higher proportion of participants taking metformin or another oral hypoglycaemic agent than the intervention arm (45.3% vs 39.5%; Table 2); the intervention arm had a higher proportion of current smokers than the control arm (12.6% vs 6.6%; Table 2); and a higher proportion of individuals in the intervention arm reported 'lung disease' comorbidity than in the control arm (16.3% vs. 12.6%; ESM Table 2).

Primary outcomes HbA_{1c} in the diabetes-range group (Fig. 2a, Table 3) was not different between study arms during follow-up: at the 12 month endpoint, the mean intervention effect was

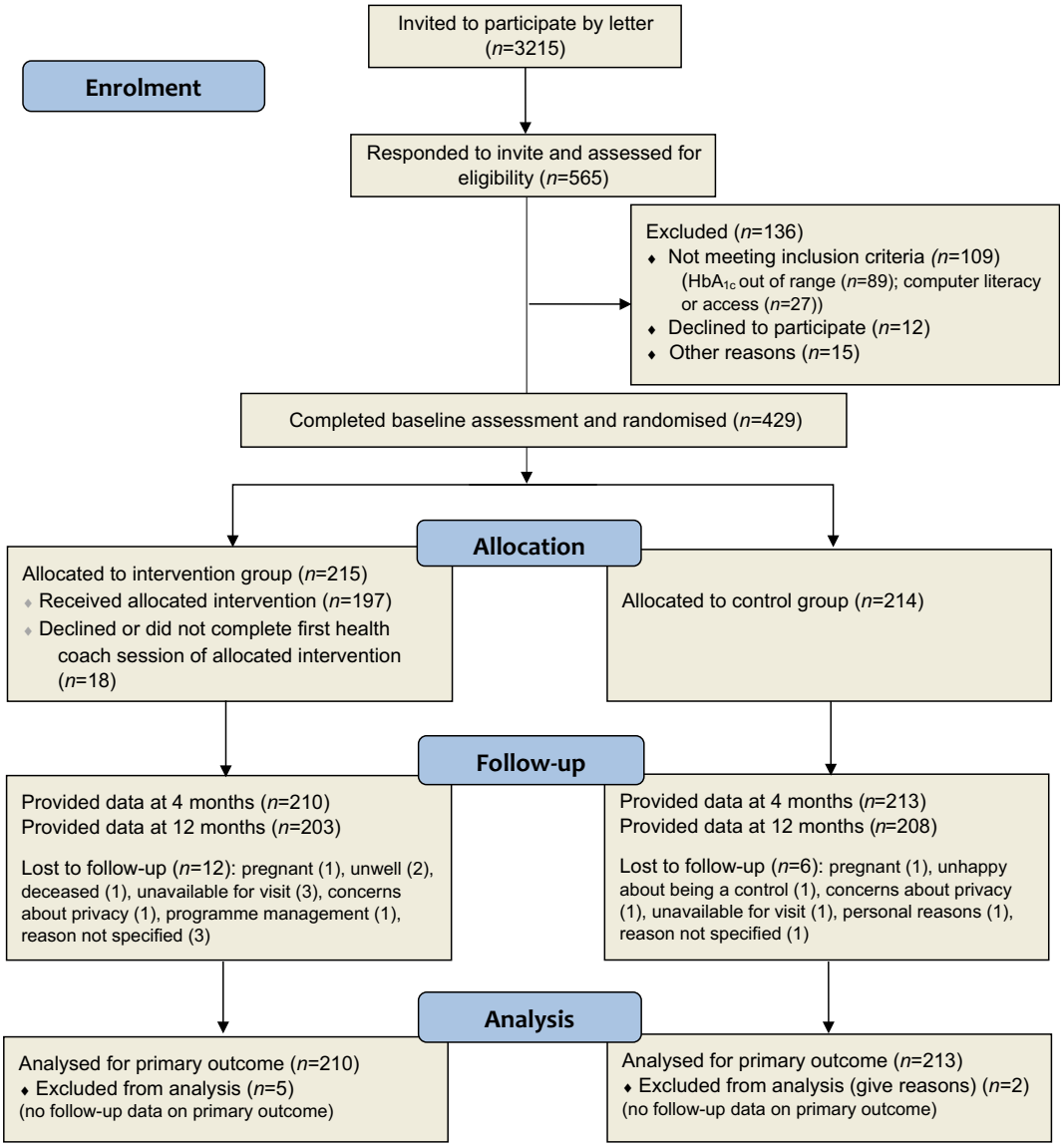

Fig. 1 Participant recruitment flowchart from invitation to analysis

−0.9 mmol/mol (95% CI −2.9, 1.1) (−0.1% [95% CI −0.3, 0.1]). For the prediabetes-range group (Fig. 2b, Table 3), there was no clinically important difference between study arms at 12 months: the mean difference in HbA_{1c} was 0.0 mmol/mol (95% CI −0.9, 0.9) (0.0% [95% CI −0.1, 0.1]).

Weight (analysed for the combined diabetes- and prediabetes-range groups; Fig. 3, Table 3) reduced slightly in both study arms but at 12 months there was minimal evidence of an intervention effect (mean difference −0.4 kg [95% CI −1.3, 0.5]).

Measured secondary outcomes At 4 months there was no strong evidence for a clinically important intervention effect on HbA_{1c} relative to the MCID of 5.5 mmol/mol (0.5%): difference in diabetes-range group −1.3 mmol/mol (95% CI −3.1, 0.5) (−0.1% [95% CI −0.3, 0.0]); difference in prediabetes-range group −0.2 mmol/mol (95% CI −0.8, 0.5) (0.0% [95% CI −0.1, 0.0]) (Table 3).

For weight, differences by study arm at 4 months were slightly larger than at 12 months (Fig. 3, Table 3) but the CI excluded the MCID of 5 kg (difference for all participants −0.7 kg [95% CI −1.2, −0.3]). Table 3 also reports results for BMI (calculated using height at baseline).

Separate analyses of weight for the diabetes- and prediabetes-range groups (ESM Table 3 and ESM Fig. 3) showed slightly greater weight loss at 4 months for the intervention arm and this was sustained for the prediabetes group at 12 months. Neither group achieved a mean weight loss at a clinically important level.

Intervention effects on weight for Māori/Pacific participants (ESM Table 4; $n = 79$ analysed) had wide CIs around point estimates, with slightly higher weight in the intervention

Table 2 Baseline comparison between intervention and control arm participants

Characteristic	Intervention	Control
n	215	214
Diabetes status, *n* (%)		
Diabetes range	105 (48.8)	99 (46.3)
Prediabetes range	110 (51.2)	115 (53.7)
Sex, *n* (%)		
Male	108 (50.2)	103 (48.1)
Female	107 (49.8)	111 (51.9)
Age group, *n* (%)		
25–44 years	10 (4.7)	14 (6.5)
45–54 years	33 (15.3)	40 (18.7)
55–64 years	76 (35.3)	71 (33.2)
65–75 years	96 (44.7)	89 (41.6)
Age, years	61.8 ± 9.5	62.4 ± 8.7
Ethnicity, *n* (%)		
Māori	32 (14.9)	33 (15.4)
Pacific	6 (2.8)	10 (4.7)
All others	177 (82.3)	171 (79.9)
NZ Dep quintile 2018, *n* (%)		
1 (least deprived)	49 (22.8)	45 (21.0)
2	43 (20.0)	41 (19.2)
3	41 (19.1)	40 (18.7)
4	49 (22.8)	51 (23.8)
5 (most deprived)	33 (15.3)	37 (17.3)
Smoking status, *n* (%)[a]		
Non-smoker	97 (45.1)	107 (50.7)
Ex-smoker	91 (42.3)	90 (42.7)
Current smoker	27 (12.6)	14 (6.6)
HbA_{1c}, mmol/mol	50.7 ± 7.8	50.8 ± 7.7
HbA_{1c}, %	6.8 ± 2.9	6.8 ± 2.9
Weight, kg	94.1 ± 21.0	92.4 ± 22.6
BMI, kg/m^2	33.5 ± 7.7	33.1 ± 7.1
Waist circumference, cm	108.1 ± 15.2	107.7 ± 16.2
Systolic BP, mmHg	127.3 ± 14.4	128.1 ± 15.2
Diastolic BP, mmHg	77.8 ± 9.5	77.7 ± 9.8
Medications at baseline, *n* (%)		
Metformin	80 (37.2)	95 (44.4)
Other oral glucose-lowering medication	29 (13.5)	35 (16.4)
Combined (either)[b]	85 (39.5)	97 (45.3)

Data are expressed as mean ± SD or *n* (%)

NZ Dep, New Zealand Index of Deprivation

[a] Data missing for *n* = 3 in the control arm

[b] The combined category groups those that are taking metformin and/or other oral glucose lowering medication

arm at both follow-up measurements (mean intervention effect 0.8 kg [95% CI −0.3, 1.8] at 4 months and 1.9 kg [95% CI −1.9, 5.7] at 12 months). The estimate at 12 months was strongly influenced by a single observation in the intervention arm (see Sensitivity analyses, above).

Other objective secondary outcomes are summarised in Table 3 (ESM Fig. 4). While systolic and diastolic BP both decreased over follow-up, there were no observed differences by between the study arms. Waist circumference decreased slightly more for the intervention arm than for the control arm participants.

Self-reported secondary outcomes Self-reported questionnaire measures are summarised in Table 4 (see ESM Figs 5–9). While the Partners in Health scores increased over follow-up in both study arms (indicating improved self-management), differences were small and slightly favoured the control arm (difference at 12 months −1.1 [95% CI −2.7, 0.5]). A similar pattern was seen for the Diabetes Distress Scale score, EQ-5D and EQ-5D Visual Analogue Scale (Table 4). For Diabetes Self-Care Activities, diet and exercise followed similar trajectories for intervention and control arms (excepting a slightly higher mean number of days of planned exercise at 4 months for the intervention arm).

Medication uptake/change following baseline (see ESM Table 5) showed few participants started insulin during follow-up (*n* = 4 [2.0%] in intervention arm; *n* = 1 [0.5%] in control arm). Starting metformin was slightly more common in the intervention arm (*n* = 11 [5.4%]) than in the control arm (*n* = 7 [3.4%]) and more people stopped metformin in the control than intervention arm (*n* = 6 [2.9%] in control arm; *n* = 0 [0.0%] in intervention arm). Uptake of other oral glucose-lowering agents was slightly higher in the control arm (*n* = 7 [3.4%]) than in the intervention arm (*n* = 4 [2.0%]) and discontinuation of these agents was similar in both groups (*n* = 2 [1.0%] in intervention arm; *n* = 3 [1.5%] in control arm).

There were no reported adverse events.

Sensitivity analyses Post hoc analysis (see ESM Table 6) included accounting for one participant with extreme weight gain between 4 and 12 months (weight gain of 60 kg: diabetes-range participant in intervention arm, Māori ethnicity). Removing this participant suggested the slight weight loss seen in the intervention group at 4 months (−0.7 kg [95% CI −1.2, −0.3]) was maintained to 12 months (−0.7 kg [95% CI −1.4, 0.0]). However the confidence intervals for these differences still excluded the MCID of 5 kg. Removing this participant's 12 month weight measurement had a similar impact on estimates for diabetes-range participants and the combined Māori/Pacific participant group.

Pre-specified per-protocol analysis for primary outcomes (ESM Table 7) restricted the intervention group to the 92% of participants that completed a first health coaching session. Among diabetes-range participants HbA_{1c} showed slightly greater differences favouring the intervention arm over the intention-to-treat analysis: −1.6 mmol/mol (95% CI −3.5, 0.2)

Table 3 Mean differences in measured outcomes from baseline to 4 months and 12 months (within condition) and mean difference by study arm at each follow-up

Outcome	Study arm	Mean (95% CI) difference from baseline[a]		Mean (95% CI) difference for intervention – control at indicated time point	
		4 months	12 months	4 months	12 months
Co-primary outcomes					
Diabetes range					
HbA_{1c}, mmol/mol	Intervention ($n = 108$)	−1.5 (−2.8, −0.3)	−0.4 (−1.9, 1.0)	−1.3 (−3.1, 0.5)	−0.9 (−2.9, 1.1)
	Control ($n = 114$)	−0.3 (−1.5, 1.0)	0.5 (−0.9, 1.9)		
HbA_{1c}, %	Intervention ($n = 108$)	−0.1 (−0.3, 0.0)	0.0 (−0.2, 0.1)	−0.1 (−0.3, 0.0)	−0.1 (−0.3, 0.1)
	Control ($n = 114$)	0.0 (−0.1, 0.1)	0.0 (−0.1, 0.2)		
p value intervention vs control				0.171	0.366
Prediabetes range					
HbA_{1c}, mmol/mol	Intervention ($n = 102$)	−0.4 (−0.8, 0.0)	0.0 (−0.7, 0.6)	−0.2 (−0.8, 0.5)	0.0 (−0.9, 0.9)
	Control ($n = 99$)	−0.2 (−0.7, 0.2)	0.0 (−0.7, 0.6)		
HbA_{1c}, %	Intervention ($n = 108$)	0.0 (−0.1, 0.0)	0.0 (−0.1, 0.1)	0.0 (−0.1, 0.0)	0.0 (−0.1, 0.1)
	Control ($n = 114$)	0.0 (−0.1, 0.1)	0.0 (−0.1, 0.2)		
p value intervention vs control				0.598	0.990
Weight, kg (all participants)	Intervention ($n = 208$)	−1.2 (−1.6, −0.9)	−1.1 (−1.8, −0.5)	−0.7 (−1.2, −0.3)	−0.4 (−1.3, 0.5)
	Control ($n = 213$)	−0.5 (−0.8, −0.1)	−0.7 (−1.4, −0.1)		
p value intervention vs control				0.003	0.396
Secondary outcomes (all participants)					
BMI, kg/m^2	Intervention ($n = 208$)	−0.4 (−0.5, −0.3)	−0.4 (−0.6, −0.1)	−0.3 (−0.4, −0.1)	−0.1 (−0.5, 0.2)
	Control ($n = 213$)	−0.2 (−0.3, 0.0)	−0.2 (−0.5, 0.0)		
p value intervention vs control				0.003	0.464
Systolic BP, mmHg	Intervention ($n = 207$)	−5.1 (−6.6, −3.6)	−4.0 (−5.6, −2.4)	−0.1 (−2.2, 1.9)	−0.1 (−2.3, 2.1)
	Control ($n = 212$)	−5.0 (−6.4, −3.5)	−3.9 (−5.5, −2.4)		
p value intervention vs control				0.915	0.924
Diastolic BP, mmHg	Intervention ($n = 207$)	−2.5 (−3.5, −1.5)	−1.7 (−2.8, −0.6)	−0.2 (−1.6, 1.1)	−0.5 (−2.0, 1.0)
	Control ($n = 212$)	−2.3 (−3.2, −1.3)	−1.2 (−2.3, −0.1)		
p value intervention vs control				0.727	0.535
Waist circumference, cm	Intervention ($n = 208$)	−3.1 (−3.6, −2.6)	−3.6 (−4.2, −3.0)	−1.1 (−1.7, −0.4)	−1.1 (−2.0, −0.3)
	Control ($n = 212$)	−2.0 (−2.5, −1.5)	−2.5 (−3.1, −1.9)		
p value intervention vs control				0.002	0.008

[a] Mean difference at follow-up relative to mean at baseline (across both groups)

(−0.1% [95% CI −0.3, 0.0]) at 4 months; and −1.0 mmol/mol (95% CI −3.0, 1.1) (−0.1% [95% CI −0.3, 0.1]) at 12 months. For prediabetes-range participants, intervention effects were still minimal: −0.3 mmol/mol (95% CI −0.9, 0.4) (0.0% [95% CI −0.1, 0.0]) at 4 months; and 0.0 mmol/mol (95% CI −1.0, 0.9) (0.0% [95% CI −0.1, 0.1]) at 12 months. In all these per-protocol analyses, point estimates and CIs excluded the MCIDs (5.5 mmol/mol for diabetes range, 0.5%; 2.5 mmol/mol for prediabetes range, 0.2%).

For weight (combined participant group), per-protocol analysis showed larger differences, favouring the intervention arm over the intention-to-treat analysis: −0.8 kg (95% CI −1.3, −0.3) at 4 months; and −0.4 kg (95% CI −1.4, 0.5) at 12 months. Removing the one participant with extreme weight gain suggested this difference was maintained across follow-up: −0.9 kg (95% CI −1.3, −0.4) at 4 months; and −0.8 kg (95% CI −1.5, −0.1) at 12 months.

Measures of engagement Initial engagement with the health coach was high, with 92% receiving an initial health coaching session. Seventy-four per cent of participants had any active engagement with the online programme in the 16 weeks of the core programme, primarily through diary completion (40% reducing to 20% during active phase), and a lower-level of engagement with the support forum (20% reducing to 5%). Overall, online engagement was lower for participants identifying as Māori, starting at 40% and dropping to only 3% at 4 months.

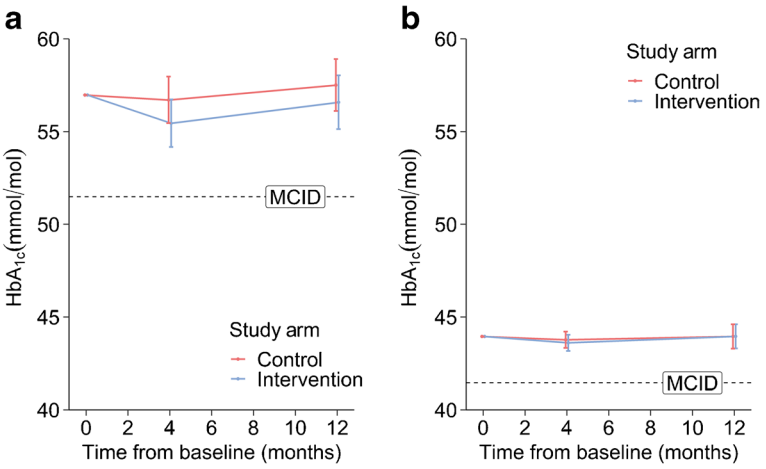

Fig. 2 Mean (95% CI) HbA_{1c} (mmol/mol) by study arm across follow-up for diabetes-range participants (**a**) ($n = 222$ analysed) and prediabetes-range participants (**b**) ($n = 201$ analysed)

Discussion

This RCT assessed an online self-management programme developed for type 2 diabetes and prediabetes (BetaMe/Melon) and found small improvements in HbA_{1c} and weight at 4 months that had largely attenuated by 12 months, a pattern seen in previous studies. Changes in HbA_{1c} and weight were greater for diabetes-range participants than for prediabetes-range participants, and greater for non-Māori non-Pacific people than for Māori and Pacific people. No group achieved clinically important mean improvements in glycaemic control (HbA_{1c}) or weight. Based upon these findings, the BetaMe/Melon programme in its current form cannot be recommended for use in the management of diabetes or prediabetes.

There is strong evidence for the role of self-management strategies in the management of type 2 diabetes [4–8] but mixed evidence as to whether web-based programmes are a useful platform to deliver these programmes [12–15]. The lack of effect of the BetaMe/Melon programme likely results from a combination of delivery of an inadequate dose of the programme, insufficient engagement of Māori and Pacific people in the programme design, a lack of connection to primary care, and the limited benefits of providing additional support to the relatively well controlled type 2 diabetes and prediabetes populations.

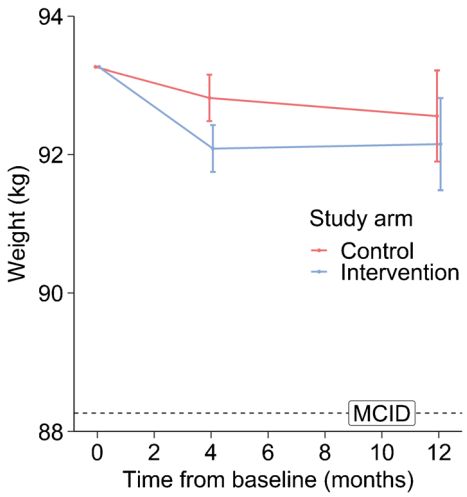

Fig. 3 Mean (95% CI) weight (kg) by study arm during follow-up for all study participants (intervention $n = 208$; control $n = 213$)

Engagement with technology-supported self-management programmes is critical to their success [11]. In this RCT, initial engagement with the health coach was high (92%) and 74% of participants had any active online engagement with the programme. However, it is likely that the high degree of programme flexibility (considering the intervention modules as optional) resulted in an inadequate overall 'dose' of the intervention and the loss of the potential benefits of a multimodal programme. The BetaMe/Melon programme was developed by a multidisciplinary team with Māori input [17] but achieved lower engagement from Māori people. Improved engagement and outcomes from technology-based healthcare programmes requires increased involvement of target populations (in this case Māori and Pacific) in the design and development phases [11].

Our recruited RCT population was chosen to represent the real population that this intervention targets: those with relatively well-managed type 2 diabetes (HbA_{1c} 50–70 mmol/mol, 6.7–8.6%) and prediabetes. The lack of an effect may reflect the limited additional benefit of self-management advice and support to that already provided 'as usual care' in primary care in this relatively well controlled population. In addition, previous studies have shown that active engagement of health providers with a programme increases the likelihood of patient improvements in glycaemic control [13]. The lack of a direct connection to the participant's primary care provider was a limitation of the assessed programme.

A major strength of this trial was the extremely high retention of participants (over 98% for primary outcomes). This was largely due to research nurse flexibility around appointments (including home visits) and multiple follow-up attempts. While there may have been changes in participant self-management driven by upcoming nurse assessments, we

Table 4 Mean differences in questionnaire outcomes, from baseline to 4 months and 12 months (within condition) and mean difference by study arm at each follow-up

Outcome measure	Study arm	Mean (95% CI) difference from baseline[a]		Mean (95% CI) difference for intervention – control at indicated time point	
		4 months	12 months	4 months	12 months
Partners in Health (total) all participants	Intervention ($n = 207$)	−0.3 (−1.5, 1.0)	1.4 (0.2, 2.5)	−1.2 (−2.9, 0.6)	−1.1 (−2.7, 0.5)
	Control ($n = 211$)	0.9 (−0.4, 2.1)	2.5 (1.3, 3.6)		
p value intervention vs control				0.195	0.182
Diabetes Distress Scale (two item) all participants	Intervention ($n = 206$)	−0.1 (−0.3, 0.1)	−0.1 (−0.3, 0.2)	0.2 (−0.1, 0.5)	0.26 (−0.1, 0.6)
	Control ($n = 211$)	−0.3 (−0.5, −0.1)	−0.3 (−0.6, −0.1)		
p value intervention vs control				0.283	0.137
EQ-5D all participants	Intervention ($n = 206$)	−0.02 (−0.05, 0.01)	−0.04 (−0.07, 0.00)	−0.02 (−0.07, 0.02)	−0.03 (−0.08, 0.01)
	Control ($n = 213$)	0.00 (−0.03, 0.03)	0.00 (−0.04, 0.03)		
p value intervention vs control				0.332	0.143
EQ-5D Visual Analogue Scale all participants	Intervention ($n = 206$)	−2.4 (−4.5, −0.4)	−2.2 (−4.3, −0.1)	−1.5 (−4.4, 1.3)	−3.4 (−6.4, −0.4)
	Control ($n = 214$)	−0.9 (−2.9, 1.1)	1.2 (−0.9, 3.4)		
p value intervention vs control				0.296	0.024
SCA: diet (days per week) all participants	Intervention ($n = 206$)	0.2 (0.1, 0.4)	0.3 (0.2, 0.5)	0.1 (−0.2, 0.3)	−0.1 (−2.3, 2.1)
	Control ($n = 211$)	0.2 (0.0, 0.3)	0.3 (0.1, 0.5)		
p value intervention vs control				0.549	0.675
SCA: any exercise (days per week) all participants	Intervention ($n = 207$)	0.3 (0.0, 0.5)	0.2 (−0.1, 0.5)	−0.1 (−0.4, 0.3)	0.0 (−0.4, 0.4)
	Control ($n = 212$)	0.3 (0.1, 0.6)	0.2 (0.0, 0.5)		
p value intervention vs control				0.741	0.861
SCA: structured exercise (days per week) all participants	Intervention ($n = 206$)	0.5 (0.3, 0.8)	0.1 (−0.2, 0.4)	0.3 (−0.1, 0.7)	0.2 (−0.2, 0.6)
	Control ($n = 212$)	0.3 (0.0, 0.5)	−0.1 (−0.3, 0.2)		
p value intervention vs control				0.878	0.380

[a] Mean difference at follow-up relative to mean at baseline (across both groups)

SCA, Diabetes Self-Care Activities scale

believe the impact of this on outcomes was likely to be small and non-differential. Over the course of the study the control group had little to no change in HbA_{1c} levels but did achieve some reduction in weight. Relatedly, while research nurses were blinded to participant study arm, participants could not be blinded (given the nature of the intervention) and in some cases chose to reveal their allocation to the nurses. Given the objective nature of the primary outcome measures (HbA_{1c}, weight) any potential arising bias is likely to be minimal.

Another strength was the range of secondary outcomes assessed in this study, including self-reported measures of quality of life. One concerning study finding was a reduction in quality of life for the intervention arm at 12 months (relative to the control arm): as a secondary outcome taken in the context of the entire trial, this result should be considered as an important outcome for follow-up in future research (including qualitative studies of participant experience). Previous studies of technology-assisted programmes have found either no impact or a small positive impact on measures of wellbeing [14]. It is possible that reports of lower quality of life may have been due to frustration or disappointment at the lack of progress with weight loss and glycaemic control while on the intervention. Finally, we assessed the impact of several design and analysis decisions on the results: these sensitivity analyses returned results broadly consistent with the main results.

Technology-assisted self-management tools, such as the programme assessed in this RCT, are promoted and used in healthcare settings based on mixed evidence of their effectiveness for the total population and scant evidence regarding subgroups within populations. In our study, even the small benefits that we detected appeared smaller in the groups most affected by diabetes. In the absence of demonstrated effectiveness, such programmes are problematic due to their costs and potentially negative effects on equity; the potential for unintended negative impacts for all or part of the population (e.g. negative impact on quality of life) needs to be examined further.

Conclusion This study did not support rollout of this self-management programme in its current state, based upon the lack of demonstrated effectiveness. Further research needs to

identify key elements of successful self-management programmes and investigate strategies to improve programme adherence. These lessons could help to improve future development or refinement of technology-assisted self-management programmes.

Acknowledgments The authors thank I. Osborne (Auckland, New Zealand) who designed the graphical abstract.

Data availability Data and analysis code are available on request from the authors.

Funding This study was funded by the Health Research Council of New Zealand, the Ministry of Health New Zealand and the Healthier Lives National Science Challenge, 16/727. The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Authors' relationships and activities The authors declare that there are no relationships or activities that might bias, or be perceived to bias, their work.

Contribution statement DS, MM and JaS led the study concept and design with input from VS, JK, RG and AD. MM managed the study. VS developed the study database with support from MM and JaS. MM, VS, DT and KH acquired and managed the data with support from JeS and CD. MM, JaS and DS led the analysis and interpretation of data. VS, JeS, JK, AD and RG contributed to data analysis and interpretation. MM and JaS wrote the first draft the manuscript with input from DS. MM, JaS, DS, VS, JeS, DT, KH, CD, JK, AD and RG provided critical revision of the manuscript draft. All authors gave final approval of the version to be published. MM is the guarantor of this work and had full access to all the data in the study and final responsibility for the decision to submit for publication.

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