**TRIAL PROTOCOL**

**BetaMe. Impact of a comprehensive digital health programme on HbA1c and weight at 12 months for people with diabetes and prediabetes: a randomised controlled trial**

Sarfati D, McLeod M, Stanley J, , Signal V, Stairmand J, Krebs J, Dowell T, Leung W, Davies C, Grainger R.

**Protocol version control:**

|  |  |  |  |
| --- | --- | --- | --- |
| Protocol Master version number | Date | Comments/ Amendments  | Author (initials) |
| V1.1 | 19 April 2017 | Registered on Australian New Zealand Clinical Trials Registry. ACTRN: ACTRN12617000549325. See <http://www.ANZCTR.org.au/ACTRN12617000549325.aspx> | All |
| V1.2 | 1 Aug 2017 | Minor amendment to inclusion criteria: upper limit of baseline HbA1c increased for diabetic participants from 64 to 70. Rationale: 1) recruitment of diabetic patients has been slower than expected; 2) some diabetic patients have baseline measures in the range, but are keen to be included in the study; 3) participants in this range have not been started immediately on insulin. Rationale and decision discussed and agreed by Data Monitoring Committee, as well as clinical team members (TD, JK). NZCTR and HEDC advised (approval dates: ANZCTR: 31 July 2017). | DS, MM |
|  |  |  |  |

Notes:

All amendments must be reported in writing to Australian and New Zealand Clinical Trials Registry and the Health and Disability Ethic Committee

Update date and version number on footer in document

Contents

[1 Investigators 1](#_Toc476232868)

[2 Background 2](#_Toc476232869)

[2.1 Why do we need to undertake an RCT? 5](#_Toc476232870)

[3 Intervention 7](#_Toc476232871)

[3.1 Initiating the BetaMe programme 9](#_Toc476232872)

[3.2 Health coaching 7](#_Toc476232873)

[3.3 Health literacy 7](#_Toc476232874)

[3.4 Goal tracking 8](#_Toc476232875)

[3.5 Peer support 9](#_Toc476232876)

[3.6 Timing of intervention 9](#_Toc476232877)

[3.7 Technical features of the intervention 9](#_Toc476232878)

[4 Methods 11](#_Toc476232879)

[4.1 Aims 11](#_Toc476232880)

[4.2 Study Design 11](#_Toc476232881)

[4.3 Setting 11](#_Toc476232882)

[4.4 Participants 11](#_Toc476232883)

[4.4.1 Inclusion criteria 11](#_Toc476232884)

[4.4.2 Exclusion criteria 12](#_Toc476232885)

[4.4.3 Recruitment 12](#_Toc476232886)

[4.4.4 Intervention group 12](#_Toc476232887)

[4.4.5 Control group 13](#_Toc476232888)

[4.5 Blinding 13](#_Toc476232889)

[4.5.1 Randomisation 13](#_Toc476232890)

[4.5.2 Allocation concealment 13](#_Toc476232891)

[5 Outcome measures 15](#_Toc476232892)

[6 Adverse health events 17](#_Toc476232893)

[7 Data monitoring committee 18](#_Toc476232894)

[8 Sample size and analysis 19](#_Toc476232895)

[9 Process evaluation measures 20](#_Toc476232896)

[10 Cost-effectiveness analysis 22](#_Toc476232897)

[11 Ethical considerations 23](#_Toc476232898)

[12 Trial registration 24](#_Toc476232899)

[13 References 25](#_Toc476232900)

[14 Appendices 29](#_Toc476232901)

[Appendix 1: Coaching guidelines for first health coach session 29](#_Toc476232902)

[Appendix 2: Draft Practice Nurse Scripts 31](#_Toc476232903)

[Appendix 3: Participant Information and Consent Form 34](#_Toc476232904)

[Appendix 4: Research nurse baseline measure guidance 40](#_Toc476232905)

[Appendix 5: Participant baseline and follow up questionnaire 44](#_Toc476232906)

[Appendix 6: CONSORT 2010 checklist of information to include when reporting a randomised trial\* 56](#_Toc476232907)

[Appendix 7: mHealth evidence reporting and assessment (mERA) guidelines, including mHealth essential criteria88 59](#_Toc476232908)

# Investigators

Prof Diana Sarfati

Epidemiologist, Public Health Physician, Director of C3 Research Group

Dr Melissa McLeod

Public Health Physician, Māori health researcher

Dr James Stanley

Biostatistician

Dr Virginia Signal

Public Health researcher, nurse

Jeannine Stairmand

Māori health researcher, nurse

Associate Professor Jeremy Krebs

Endocrinologist

Professor Tony Dowell

Professor of Primary Care, General Practitioner

William Leung

Health economist

Cheryl Davies

Māori health researcher, primary care

Dr Rebecca Grainger

Physician and eHealth researcher

# Background

Long-term health conditions (chronic physical and mental disorders) are by far the largest contributor to health loss in New Zealand (NZ), accounting for 88% of disability–adjusted life years.1 The economic cost and burden on the health system is substantial and growing.1,2 There are important inequities both in the incidence and the outcomes from long-term conditions (LTCs).3-5 In order to create sustainable health systems with empowered patients and communities, we need a radical change in our approach to managing these conditions. There are global calls to shift the focus from clinical management in the surgery or clinic, to prevention and management in the hands of the people living with these conditions.6-9 Self-management strategies offer a potential way to reduce the pressure on health services, by working alongside individuals and whānau to support and equip them to take an active role in the management of their LTCs.

Prior to the wholesale roll-out of self-management strategies across the health sector, it is critical to assess the likely effectiveness, cost-effectiveness and acceptability of these strategies for the general population, and also specifically to Māori and Pacific. This research aims to make a significant contribution to the evidence base for self-management through: a **randomised controlled trial** (RCT) of a comprehensive, patient-centred, self-management intervention for patients with prediabetes and diabetes (the BetaMe programme) compared with ‘usual care’ within two Primary Health Organisations (PHOs) and a large Māori provider (Whai Oranga o Te Iwi); a **process evaluation** of the BetaMe programme to assess accessibility and acceptability to participants; and a **cost-effectiveness analysis** of the BetaMe programme. The PHOs and Māori provider involved in this research have expressed strong interest in a wider roll-out of the intervention following these evaluations.

Type 2 diabetes mellitus (T2DM) is one of the most common LTCs affecting NZ adults, with a prevalence of around 7% based on HbA1c data from the 2008/09 NZ Adult Nutrition Survey.10 Furthermore, the prevalence of T2DM is rapidly increasing in NZ at a rate of 7% per annum.2 Māori, Pacific and Indian people have particularly high rates of T2DM with rates up to three times higher than European New Zealanders.2,10 Diabetes is associated with multiple long-term complications, higher mortality and substantial healthcare costs.2,11 Prediabetes is a precursor stage to T2DM with up to 70% eventually progressing on to T2DM; many people with pre-diabetes already have some of the complications of T2DM.12-15 The estimated prevalence of prediabetes in NZ adults is 26%.2

Self-management measures such as a healthy diet, regular exercise and weight management are key to preventing the progression of prediabetes to T2DM, to controlling T2DM, and reducing complications.16-20 For example, the Diabetes Prevention Program (DPP) study found that a lifestyle intervention resulted in a reduction of incidence of diabetes by 58% among a high-risk population without diabetes, and that even short term reversion to normal glucose control among pre-diabetic patients substantially reduced the likelihood that the person would progress to diabetes.19,20 Similarly, diabetic patients who undergo lifestyle interventions tend to have better glycaemic control and improved long-term outcomes.16 However, many people struggle to initiate and maintain these strategies.21,22 For these reasons, two of key strategies identified in the recent report from the Ministry of Health on “Living Well with Diabetes” were to identify programmes that aim to prevent high-risk people developing T2DM, and to support those with T2DM in their efforts to self-manage.2 The BetaMe programme does both.

Self-management strategies for T2DM have resulted in improvements in glycaemic control23-25, weight loss24,25, patient satisfaction with healthcare24 self-efficacy26 and adherence to medication.27 There is relatively less evidence for self-management programmes in those with prediabetes. One study assessed the two-year outcomes of an internet-based diabetes prevention programme for people with prediabetes that was of a similar duration and had similar components to the BetaMe programme (health coaching, small group discussion and health tracking). This programme resulted in clinically significant reductions in body weight and HbA1c at two years after entry into the programme.28 There is limited evidence from NZ on the effectiveness of self-management programmes for T2DM. There are studies investigating educational interventions for diabetes in NZ, including a study led by Jeremy Krebs that examined the effectiveness of a six-week programme that involved group education sessions for T2DM.29 Positive outcomes were recorded at six months, with improvements in glycaemic control, weight, blood pressure and confidence in managing diabetes. Most of these benefits had disappeared by nine months. A second study assessed the effectiveness of a series of educational sessions (4-6 in total) for newly diagnosed people with diabetes and those with established diabetes identified by their health provider as requiring assistance with effective self-management.30 This study also demonstrated improvements in glycaemic control, and attitudes towards diabetes three months after the programme but outcomes were not measured beyond this short period of follow-up.

A randomised controlled trial of a text-message intervention to improve blood glucose monitoring and provide diabetes-related educational material in NZ is currently underway (SMS4BG).31 The pilot study for the SMS4BG intervention demonstrated improvements in HbA1c at three months, and was reported to be useful and acceptable to participants.31 The SMS4BG study examines a target population of people with diabetes with poor glycaemic control (HbA1c greater than 65 mmol/mol), and uses a more self-directed intervention (text-based reminders and educational resources). In contrast, the current RCT is for an intervention (BetaMe) that has demonstrated positive outcomes for both people with diabetes (with varying levels of glycaemic control) as well as people with prediabetes (with the possibility of preventing their progression to diabetes). Assessing the effectiveness across this **full spectrum of glycaemic control** is important, and more reflective of clinical practice. The BetaMe programme is also **personalised** to individual participants, who works with a health coach to set goals and a programme specifically for them. BetaMe is a comprehensive programme offering a community support platform through the online forum with peers; integrates with other technology including wearables (e.g. Fitbit), and can provide data directly to clinicians allowing direct integration with clinical care (Table 1). Multi-modal programmes such as BetaMe have been shown to be more effective than interventions that use a single delivery mode (e.g. text messaging).32,33

The BetaMe Programme is an integrative evidence-based self-management programme for T2DM and prediabetes. It was developed with a strong emphasis on engagement, education and activation of patients with LTCs. Its foundations are based in behavioural change theory using cognitive behavioural theory, motivational interviewing, goal setting, health tracking, reminders and intrinsic rewards to support and encourage positive behaviour change.23,34,35 It incorporates access to expert one-on-one coaching, decision support and peer support all of which are evidence-based approaches to increasing the effectiveness of self-management support (see Table 1).

BetaMe was developed by Melon Health, a company with substantial experience in developing and delivering evidence-based, innovative mobile health solutions for the prevention and management of LTCs, in partnership with primary care clinicians based in both Midlands and Wellington regions, with a multidisciplinary team that included Māori and Pacific health expertise (e.g. Faimafili Tupu, Pacific portfolio manager for planning and funding at Auckland and Waitemata DHBs, and Paula Snowden, GM at Raukawa Whānau Ora), clinical health psychologist (Dr Cheryl MacDonald36), Chris Beaty (ex CEO of Diabetes NZ) alongside input from patients. The team was part of the Mayo Techstars Partnership programme offered to only three companies each year in the US resulting in further input and feedback from endocrinologists and obesity experts, Professors James Levine and Frederick Schwenk (Mayo Clinic), Prof Victor Montori (Mayo Clinic Center for Clinical and Translational Science) and Prof John Hixson (mHealth specialist at University of California, San Francisco).37 The BetaMe programme has been developed with explicit consideration of how to address the disproportionate burden of LTC for Māori and Pacific peoples. A core component of BetaMe is a web-based application. This is an important mode of delivery of health information and support for Māori and Pacific that requires further investigation. There is a high level of smartphone ownership in NZ (70% in 2015) 38, and even higher for Māori and Pacific.38 In addition, Māori and Pacific coaches are available, and feedback from Māori participants on an earlier pilot of the BetaMe programme suggested that it was acceptable and appropriate. The peer support component enables connections with other participants and ‘virtual whānaungatanga’.39

BetaMe is a 12-month programme, delivered using both mobile and web-based platforms, with four key evidence-based components: health coaching, provision of evidence-based resources, peer support and goal tracking. Each component has demonstrated benefits for improved outcomes for diabetic or pre-diabetic individuals (summarised in Table 1). The first 16 weeks form the core part of the programme, with the remaining 36 weeks covering the maintenance (web-based peer support and goal-tracking only).

Table 1: Components of the BetaMe programme, and evidence of their effectiveness

|  |  |  |  |
| --- | --- | --- | --- |
| Stage | Element | What is provided | Evidence–based for effective self-management |
| Core only (weeks 1-16) | Health coaches | Shared goal setting, and personalised programme based on that person’s personal goals. Provide regular input, encouragement and support via messaging and fortnightly video or audio meetings | Educational programmes and individual support through personalised coaches has been shown to be effective, with the level of effectiveness dependant on the intensity of the programme.40 A number of successful interventions have provided access to an ‘expert’ such as a personal trainer or dietician, coupled with support from health professionals.41,42 |
| Health literacy  | Fortnightly evidence-based resources and behaviour change tools delivered in consumer-centred formats (bite size, simple messages, images and video). | Mobile phones to send reminders or educational information via text, or within applications, have proven beneficial in the management of chronic conditions such as diabetes43 with positive outcomes relating to glycaemic control and patient satisfaction,24 self-efficacy 26 medication adherence.27 and as a result of weight loss, reduced transition from prediabetes to diabetes.44 |
| Core and maintenance(12 months) | Goal tracking  | Daily reminders via web-based devices. Daily goal tracking of exercise, happiness, energy levels, food and weekly tracking of weight and waist measure. | 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 45, and improved long-term outcomes.46  |
| Peer support  | Online closed forum, monitored by a registered nurse | Peer support has been successful in improving glycaemic control 47-51 and has been identified by participants, to be the most useful component of a self-management programme.47 |

BetaMe has been designed to align with the key principles and approaches for effective self-management outlined by the Ministry of Health.52 The BetaMe programme is *patient and whānau centred*: it provides health coaches to work with individuals to undertake shared *goal setting*, and develop a personalised programme and an *action plan* to achieve these goals. *Psychological support* is provided by the health coaches, and also through the peer support components of the programme in a *culturally relevant way*.

The BetaMe programme underwent substantial pre-testing and a full pilot in 2015 demonstrated extremely positive results. In the pilot evaluation, 117 people with prediabetes participated from five practices within the Midlands Health Network. Baseline and follow up measures at 16 weeks included HbA1c, weight, waist circumference, prediabetes status (defined as HbA1c 41-49 mmol/L) and blood pressure. Of the 117 patients, 108 completed the programme (92%). Of these, 91% reduced their HbA1c, 94% lost weight (mean=4.2Kg), 87% had reduced waist circumference (mean=4.2cm), and a stunning 78% had HbA1c levels below the pre-diabetic range.

The feedback from pilot participants was extremely positive. Participants strongly endorsed both the coaching and community aspects of the programme (77% found these the most helpful aspect), and 84% said they were likely to recommend BetaMe to someone else (only 2% said they were unlikely to do so). Comments included: “It’s immensely helped with my health”, “I know I can continue to stay healthy”, “Please ensure this program continues, it is an extremely valuable tool for people in need”, and “Now I’ve started, there’s no going back”. Participants provided feedback on how they would like the intervention to be improved, which allowed further refinements. In a recent US review of digital diabetes prevention and self-management solutions in the workplace, the BetaMe programme ranked top for patient engagement and was in the top five overall.53

While the BetaMe programme has been developed specifically for individuals with T2DM, and prediabetes, the potential benefits of the intended outcomes from the intervention (weight loss, improved nutrition, lower blood pressure and improved health literacy) are not limited to diabetes. This is important because diabetes often coexists with other health conditions,22 firstly because diabetes and prediabetes are themselves risk factors for other conditions (such as cardiovascular and kidney disease) and secondly because T2DM and prediabetes share risk factors with other conditions (for example, obesity is a risk factor for diabetes and also cardiovascular disease and several cancers). This program will therefore potentially positively impact many other coexistent conditions among those with diabetes or prediabetes. Furthermore, the BetaMe programme has been specifically designed to be easily modified for delivery to patients with other LTCs (including, in development, programmes for COPD, ischaemic heart disease and chronic kidney disease). If this intervention is demonstrated to be beneficial to those with prediabetes and T2DM, it will likely also be beneficial to people with other conditions. This then, is a potential shift from a condition-specific intervention to one that improves the health of people with LTCs more generally.

## Why do we need to undertake an RCT?

RCTs are considered the gold standard method to assess the effectiveness of interventions. We will undertake an RCT to compare the BetaMe programme with usual primary care for patients with T2DM and prediabetes, examining the impact on HbA1c as well as on weight, waist circumference, blood pressure and a number of self-reported measures of effectiveness at 12 months. This work will address a number of gaps in the current knowledge base around **comprehensive** self-management programmes for diabetes. First, this will allow us to provide robust evidence on the effectiveness of the intervention over a full 12-month period. Second, it will address a lack of evidence on the effectiveness of self-management programmes for Māori and Pacific. Third, most existing studies examine one part of what is considered to be a self-management programme. For example, a 2011 meta-analysis of 22 trials with 1657 participants concluded there was evidence that mobile phone applications led to significant improvements in glycaemic control (a mean reduction in HbA1c of 6 mmol/mol over a mean 6 months duration)23 However, most of the programmes studied were not comprehensive in that their interventions focused solely on monitoring reminders or entering glucose measurements; did not involve providers or current clinical practice; or did not personalise the programme to individuals. Fourth, unlike most other studies that focus on ‘people with diabetes’ or ‘pre-diabetics’ our RCT will include patients with both prediabetes and diabetes, and will measure the effectiveness of the intervention for both of these groups. This will be more representative of the effectiveness of this intervention in the real clinical setting, and will give a better idea of the relative benefits for those with prediabetes compared to those with diabetes.

# Intervention

For this RCT, Melon Health Ltd has been subcontracted to deliver the BetaMe programme to those in the intervention arm of the trial. The BetaMe programme is an integrative evidence-based self-management programme for T2DM and prediabetes. As outlined above, it consists of four separate components; health coaches, provision of evidence-based resources, goal tracking and peer support. BetaMe is internet-based and delivered using both mobile and web-based platforms. The BetaMe intervention aims to strike a balance between ‘tailoring’ to individuals and delivering an intervention that is applied consistently enough to allow us to measure its impacts.

This section describes the components of the intervention: other elements such as patient identification and eligibility, the outcome measures used, and the timing of the intervention within the RCT, are covered in the Methods section (Section 4.) In brief, participants will be screened for eligibility based on clinical records and invited into the study by a practice nurse at their usual primary care provider. A study research nurse will ask for consent, at which point baseline measures will be taken. Final eligibility is dependent on baseline HbA1c levels: once eligibility has been determined, each patient will be randomised to either the control or intervention arm.

## Health coaching

The health coaches are all either qualified personal trainers or registered nurses trained in motivational interviewing, cognitive behavioural therapy, and nutrition, and have completed the Heart Foundation Pacific Heartbeat Community Nutrition course. Health coaches will arrange the first one-on-one session with participants. The purpose of this first one-hour session is so that health coaches can work with participants to develop goals that are tailored according to their needs and values. The session follows a set format. Coaches use a number of standard conversation starters, and activities to work through with participants to establish what their values are, in order to develop goals that are relevant and meaningful to them (Appendix 1: Coaching guidelines for first health coach session ). Māori and Pacific coaches will be available.

Once these goals have been set and agreed on, participants’ goals are entered into their profile on the BetaMe system. Coaches will then continue to work with participants. Coaches will message participants weekly to check on their progress, reinforce information from the modules and arrange further meetings at frequencies that suit the participant (these can be weekly of fortnightly or less frequently if preferred). These subsequent meetings are generally around 15-20 mins in length. All meetings with the coaches will be by audio or video, as per the participant’s preference. Participants are able to make appointments with or send messages to their coach through the BetaMe app.

Clinical Governance of the health coaches will be provided by Cheryl MacDonald (health psychologist), who will spend one-on-one time with each coach on a fortnightly basis. Coaches will have access to the wide range of coaching resources purchased by Melon Health, and will be supported by Dr Chris Masters (project mental health lead) and Sam Rodney-Hudson (experienced health coach). Coaches also regularly interact with one another via an online forum (separate from patient forums) to share any problems they are having and solutions.

## Health literacy

There are eight key education modules introduced to participants through an introduction to the module via the web and mobile platform with attached resources (videos, infographics, articles, tips, tools, meal ideas and mini-quiz). The time spent on the modules is up to the participant, but would typically be less than two hours. The key messages in the modules are also reinforced in corresponding email newsletters, discussions on the newsfeed initiated by the Community Manager and by the participant’s coach. Every two weeks, a new module is released that presents participants with a range of topics that offer key messages to help them to learn about and manage their own health. The modules are:

**Week 0:** Introduction to BetaMe and risk factors of prediabetes and Diabetes. This module includes an overview of what prediabetes and diabetes are in plain language including risk factors, signs and symptoms, what lifestyle factors can prevent or modify diabetes and prediabetes. There is also an introduction to physical activity, the food diary and tracking.

**Week 1-2:** Healthy Eating, Healthy Moving. This module provides support to participants to change their eating and physical activity patterns. It encourages them to get support and encouragement from the BetaMe community, and offers other techniques including visualisation, meditation and goal setting.

**Week 3-4:** Triggers and Habits. This module encourages participants to identify when and why they make less healthy decisions, and how to establish healthy habits. It reinforces the importance of tracking.

**Week 5:** Review your progress. This module offers a quiz on key learning points about healthy eating and activity.

**Week 6-7:** Eating for Health. This module identifies cheap, convenient and tasty meal ideas, and reinforces the importance of exercise.

**Week 8-9:** Drinks, Sleep and Shift Work. This module identifies alternatives to sugary drinks, and focuses on the importance of sleep.

**Week 10:** Recap & Refresh, Meal Planning and Budgeting Tips.

**Week 11-12:** Problem Solving. This module provides participants with skills and confidence to make informed decisions about food and activity.

**Week 13-14:** Healthy Coping & Mindfulness. This module identifies self-defeating thoughts and provides strategies on how to break them including breathing exercises, affirmations, mindfulness and visualisation.

**Week 15-16:** Reflection and Celebration. Transitioning to the maintenance phase. This module reinforces key messages, provides a quiz, and the process to identify next steps to ongoing success.

The content of these modules aligns with the Ministry of Health Guidelines for health eating and the Heart Foundation guidelines.54,55 Participants will have the option for one-on-one on-line chats with their coach to discuss each new module.

## Goal tracking

Participants are encouraged to track their progress towards their goals (including healthy eating, physical activity, weight, happiness and sleep).

They will be provided with a set of digital scales and a tape measure so they can take their own measurements and track their progress

They will be able to share these data with their health coach at any time, or with their doctor by email or at their next appointment.

## Initiating the BetaMe programme

Those participants randomised to the BetaMe programme (intervention arm) will be contacted by a health coach within ten working days of having their baseline blood test taken. The health coach will inform them that they will be taking part in the BetaMe programme and will provide detail for patients to access an online tutorial about the BetaMe programme, including a short video orientating participants to the app and how to use it.

## Peer support

The programme also includes peer support with real-time chat within a private and secure online social network monitored by a Community Manager who is a registered nurse trained in nutrition. This person monitors the community to ensure nothing unsafe (like personal details, or negative health messages) is shared, and that people are supported and supportive. They will also reinforce key messages, highlight local events in the area, start conversations and welcome new people to the community. They also provide a point of contact for technical support, and more generally after the first 16 weeks of the programme when the health coaching module is completed.

## Timing of intervention

In the first 16 weeks of the programme, participants will set goals, work with health coaches, receive the evidence-based modules and be encouraged to use goal tracking and participate in the peer support programme. After that time, participants will be encouraged to continue tracking and participating in peer support, for the remainder of the 52-week programme. Information from the modules is available for the entire 52-week period.

## Technical features of the intervention

Melon Health’s platform is built to maximise patient confidentiality and general security of the application at all levels. The system exceeds New Zealand privacy requirements and meets US HIPAA ((Health Insurance Portability and Accountability Act) security rules for health data, with regular auditing by external security specialists. Access to patient data is limited to the absolute minimum number of people required, and is isolated from data needed for development/testing.

The platform currently integrates with over 350 wearables and biometric sensors through our open API (application programing interface). The platform is accessible through a web based application or Android/iOS applications (Table 2).

Table 2: Technical features of the BetaMe application



**Data stored in the Melon Health data store**: The platform consists of:

* Web based application
* Native Android and iOS applications
* REST API utilising JSON
* Homogeneous Identity model, API and database structures
* Clinical knowledge assets or care plans are encoded in a computable form
* Include computable logic for responding to patient activity and tracking
* Identity management data - users and their roles
* Patient-generated data - unstructured natural language (posts), patient outcome data, medication adherence, symptom tracking, exercise tracking
* Human readable patient education content, e.g. articles, videos and tips

**Integration points:**

Although this will not be used in the current RCT, Melon’s platform has the ability to integrate with PMSs (practice management systems) and external CMS’s (content management systems)

# Methods

## Aims

**Our primary aim of this study is:** to evaluate the effectiveness of the BetaMe programme versus usual care among primary care populations in improving the control of 1) T2DM and 2) prediabetes, as measured by change in HbA1c and weight over a 12-month period.

**Our secondary aims of this study are:** To evaluate the effectiveness of the BetaMe programme versus usual care in a) improving the control of T2DM and prediabetes (combined) as measured by change in HbA1c for Māori and Pacific participants over 12 months; b) reducing weight over a 12-month period for Māori and Pacific participants, c) improving the management of T2DM and prediabetes, and reducing weight over a four-month period, overall and reported for Māori and Pacific participants; and d) impacting on other health-related outcomes waist circumference, blood pressure, quality of life and self-reported self-management, overall and reported for Māori and Pacific participants.

## Study Design

The study will be a two-arm randomised controlled trial for pre-diabetic and diabetic patients comparing the BetaMe programme with usual care (active control), with investigator-blinded assessment of outcomes (see Figure 1: Flowchart of RCT below).

## Setting

The study will be based in two regions of NZ, Midlands and Greater Wellington, through two PHOs (Midlands Health Network and Compass Health), and a large Māori provider (Whai Oranga o Te Iwi). These providers collectively include around 800,000 patients. Up to ten practices will be selected to provide the sampling frame for recruitment. At least two practices will have high numbers of Māori and Pacific patients. The research team will work directly with the two PHOs to identify practices that are interested in being involved in the study and able to commit to the study timeframes and process requirements. Practice recruitment will be through an opt-in process. Participating practices will be those based in these regions that are interested in being involved in the study and able to commit to the study timeframes and process requirements.

## Participants

Participants will initially be identified for the diabetes or pre-diabetes group using clinical data held by participating PHOs and practices. Those identified as having diabetes and meeting the eligibility criteria below will be included. Those with HbA1c in the 41-49 mmol/mol range in the two years prior to commencing the study with no recorded diagnosis of diabetes will be classified in the pre-diabetes group.

### Inclusion criteria

Patients will be eligible for inclusion if they meet the following inclusion criteria:

* Have a current HbA1c of 41-70 mmol/mol (either from a test within three months prior to invitation to the study, or on the basis of an HbA1c test taken by the research team at invitation to the study).
* Are not currently on insulin treatment for diabetes (because subsequent changes in HbA1c may be driven by changes in insulin dosage which are difficult to capture. as patients self-adjust).
* Adults aged between 18-75 years, enrolled in participating practices.
* Have daily internet access (on any of computer/tablet/smartphone)
* Are able to provide informed consent.

### Exclusion criteria

Patients will not be eligible for the study if they:

* Are pregnant
* Have cognitive impairment likely to be sufficient to hinder their understanding of the study or the programme, as this may negatively affect their self-management behaviour.56
* Are unable to read and write in English.
* Unable to use phone or computer due to physical disability such as poor eyesight or manual dexterity.

### Recruitment

**Eligibility screening:** The PHOs, and in some cases the practices themselves, will generate a list of current people with diabetes and prediabetes within participating practices. This will be produced through a patient query on the PHO or practice database identifying patients with an HbA1c result of 41-64 mmol/mol within the past 24 months. Individuals that are retested at baseline and return an HbA1c result of 65-70 remain eligible for the study. Practice nurses will then work systematically down this list, using clinical records and knowledge of the patients to apply the study exclusion criteria, removing patients who are currently on insulin, are pregnant, have significant cognitive impairment, are unable to read and write in English or have a physical disability that prevents them using a phone or computer.

**Participant recruitment:** The remaining eligible patients will initially be contacted by their practice nurse, who will use a script provided by the research team to outline the study (Appendix 2: Draft Practice letters and Practice Nurse Phone Script), determine eligibility based upon access to the internet and an internet capable device, and, if eligible, obtain consent for the research team to contact them directly. If practices prefer, patients may be sent a letter introducing the study prior to a phone call from the practice nurse. The practice nurse will check the clinical records for new drug treatments started within the last 3 months and the most recent HbA1c results. The practice nurse will pass this information onto the research team, if the patient consents.

A research nurse will then contact participants to explain the study and invite them to meet at their usual primary care provider, using a script provided by the research team. At this meeting the research nurse will obtain full informed consent (Appendix 3: Participant Information and Consent Form). Baseline data will be collected at this point including HbA1c (for those who do not have an HbA1c test result in preceding three months), weight, height, waist circumference and blood pressure (Appendix 4: Research nurse baseline measure guidance), along with a quality of life measure, a validated measure of chronic condition self-management; and a validated measure of diabetes-specific behaviours (e.g. frequency of blood sugar monitoring) (Appendix 5: Participant baseline and follow up questionnaire).

Participants will then be centrally randomised into the intervention or control arm, based upon their baseline HbA1c test results. This process ensures that the research nurse is blinded to which study group the patient belongs to for the first assessment. Blinding and randomisation is further described below.

### Intervention group

Those randomised to the intervention arm will begin the BetaMe programme whilst continuing to receive usual clinical care from their primary healthcare team. They will also receive resources produced and provided by Diabetes NZ.

### Control group

Participants in the control arm will receive usual care. This will vary somewhat between practices and GPs, but our interest is the extent to which the BetaMe programme may improve outcomes beyond that expected in the context of usual care. For people with diabetes, this would typically involve an annual diabetic review to monitor glycaemic control and assess the patient for the presence of any diabetic complications and a review of treatment. In addition, it could include education and advice on lifestyle factors such as diet and exercise provided by a trained practice nurse or diabetes specialist nurse. For people with prediabetes, usual care would typically include lifestyle advice and education about diet and exercise, and an annual HbA1c.

The study team will also provide participants in the control arm with standard information about T2DM and its management, from resources produced and provided by Diabetes NZ (Pamphlets entitled ‘Pre-diabetes’, ‘Diabetes and Healthy Food Choices’, and “Live Well with Diabetes’, available at http://www.diabetes.org.nz/resources\_and\_publications/printable\_pamphlets). This is to increase retention of control arm participants in the study, and to ensure that all patients have basic information on T2DM and prediabetes. Note that the individual-level randomisation of participants to intervention and control arms will reduce issues arising from variations between practices in the provision of ‘usual care’.

## Blinding

### Randomisation

Based upon their baseline HbA1c test results (prediabetes or diabetes range), participants will be randomised into the intervention or control arm (1:1 allocation) using a computer generated randomisation schedule stratified by participating practice and ethnicity. Randomisation will be completed within two working days of receiving each HbA1c result. To ensure allocation concealment, randomisation will be centrally determined from within the REDCap electronic data capture platform *after* the patient is enrolled in the study (following the first assessment with the research nurse and when full eligibility based on current HbA1c level has been determined). To ensure that equal numbers are allocated to each study arm, randomisation lists will be blocked (e.g. into sets of 8 randomised allocations, with 4 intervention and 4 control allocations per block.)

The randomisation list will not be visible to the team member(s) requesting the allocation, and these individuals will only have details on the patient ID, practice, and ethnicity when requesting allocation for any patient. The exact length of each randomisation block will be kept in a separate document held by the PI, project manager and project statistician, and this will not be available to the team member(s) responsible for determining allocation. These two steps will further reduce the potential for allocation bias.

At the time of randomisation, contact details for participants randomised to the intervention arm will be forwarded to Melon Health Ltd in excel format with password protection. A health coach will then contact the participant within 5 working days of receiving their data.

### Allocation concealment

Given the nature of the intervention, it is not possible to keep participants blind to their intervention status. Research nurses will be kept blind to the intervention status of participants to the extent possible. However, when the nurse meets with the participant at the 4 and 12 month follow-up visits, it is not possible to guarantee that the nurses remain blind to the intervention allocation of the participant. The primary outcome measures are objective (HbA1c, weight, waist circumference, blood pressure) and any resulting bias in their assessment is likely to be minimal.

The results dataset will be stored with the study arm identity blinded by code (e.g. “A” for participants in one study arm, “B” for participants in the other arm: actual key chosen at random) The key to this code will be held independent of the analysis dataset by the PI, a second member of the research team (MM), and the independent member of the data monitoring committee. Data cleaning and analysis will be conducted by a statistician who is blind to group allocation. Once analysis is complete, the results will be unblinded.



Figure 1: Flowchart of RCT

# Outcome measures

**Outcome measures** (all measured at baseline, 4 months, and 12 months)

**Primary outcomes** are changes in HbA1c and weight at 12 months. HbA1c provides the most sensitive measure of glycaemic control among those with T2DM. High levels are predictive of higher levels of complications and mortality. Weight (and waist circumference) are associated with T2DM, cardiovascular disease, several cancers and overall mortality.57-59 We will focus on weight in kilograms as this is the most common outcome in systematic60,61 and Cochrane reviews,62,63 but for completeness we will also report differences in units of BMI.

**Secondary outcomes**:

* Change in waist circumference at 12 months.
* Change in blood pressure at 12 months.High blood pressure (common amongst people with diabetes) is associated with a higher risk of cardiovascular disease and mortality, and is amenable to lifestyle interventions.64,65

**Additional self-reported outcomes:**

* Medications (regular prescription medications), and changes to medications and doses.
* Changes in self-management of chronic conditions using the Partners in Health Scale. A validated tool that of self-reported self-management of chronic conditions.66
* Diabetes-specific behaviours and outcomes will be measured using two validated instruments: the Summary of Diabetes Self-Care Activities tool, which assesses participants’ self-care activities67; and the Diabetes Distress Scale which differentiates those with high and low levels of distress.68
* Quality of life as measured by the EuroQol group’s EQ-5D-5L instrument, to calculate quality-adjusted life-years (QALYs).69

Interim outcomes: we will assess primary and secondary outcomes at 4 months. This will give an indication of the effect of the “active” part of the intervention. Research has shown that even short-term decreases in HbA1c can have a long-term effect on health outcomes, with effects tending to attenuate over time.19,20,70

Outcomes will be assessed on all participants by trained nurses at baseline and at 4 and 12 months (Table 3). At baseline, nurses will meet consenting participants at their usual primary care practice, where they will ask participants to provide key background information (demographic, comorbidity, smoking status, healthcare use), take their blood pressure, weight, height and waist measures using standard processes. Participants will be provided with an iPad to complete the self-reported outcomes on site, although paper versions will be available for those who prefer them. Participants will either have a blood sample taken by the research nurse, or will be provided with a laboratory request form for an HbA1c blood test that will be taken as per usual processes within a week of the assessment period. They will repeat this process (except basic demographic data) at 4 and 12 months after recruitment. In most cases follow up will be completed by research nurses, but occasionally trained practice nurses may do this if preferred by participants. Results from these tests will be provided to the study team and results from the HbA1c will be provided to the primary care practitioner.

Table 3 shows a summary of the primary and secondary outcome measures of this study.

Table 3: Summary of outcome measures

|  |  |  |
| --- | --- | --- |
| Outcomes | Time point\* | Measurement/ definition |
| Primary Outcome measures |
| Change in HbA1c | At 12 months  | Measured using whole blood sample collected in EDTA tube (2mls minimum) using Variant Turbo Ion Exchange HPLC |
| Change in weight | At 12 months  | Measured in kilograms using calibrated digital scales and standardised methods\*\* |
| Secondary Outcome measures |
| Change in HbA1c | At 4 months | Measured using whole blood sample collected in EDTA tube (2mls minimum) using Variant Turbo Ion Exchange HPLC |
| Change in weight | At 4 months | Measured in kilograms using calibrated digital scales and standardised methods\*\* |
| Change in waist circumference | At 4 and 12 months | Measured in millimetres using tape measure using standardised methods\*\* |
| Change in blood pressure | At 4 and 12 months | Measured using calibrated syphgmomanometer using standard approach (blood pressure taken when participant has been sitting quietly for five minutes, without eating, drinking or smoking. They will be asked to have feet flat on the floor, with their back up against the back of the chair, and their left arm straight on the table). Three measures will be taken with the lowest of the last two measures recorded. |
| Change in self-management  | At 4 and 12 months  | Measured using the Partners in Health Scale (Smith et al 2017) |
| Change of score in diabetic-specific behaviours and outcomes | At 4 and 12 months  | Measured using the Summary of Diabetes Self-Care Activities tool, which assess participants’ self-care activities (Toobert et al 2000) |
| Quality of life | At 4 and 12 months  | Measured using the EuroQol group’s EQ-5D-5L instrument (Eurocare Working Group, 1990) |
| Change in score of diabetes-specific outcomes | At 4 and 12 months | Measured using Diabetes Distress Scale (Fisher et al 2008) |
| Change in dose of insulin | At 4 months relative to baseline, and 12 months relative to 4 months. | Categorised as 1) starting insulin in current time period; 2) increasing dose of insulin in current period; 3) reducing dose of insulin in current period or 4) stopping insulin in current period. Data will be collected from patients, verified where possible from clinic records. |
| Change in dose of metformin | At 4 months relative to baseline, and 12 months relative to 4 months. | Categorised as 1) starting metformin in current time period; 2) increasing dose of metformin in current period; 3) reducing dose of metformin in current period or 4) stopping metformin in current period. Data will be collected from patients, verified where possible from clinic records. |
| Change in dose of other oral hypoglycaemic agents (not metformin) | At 4 months relative to baseline, and 12 months relative to 4 months. | Categorised as 1) starting oral hypoglycaemic agents in current time period; 2) increasing dose of oral hypoglycaemic agents in current period; 3) reducing dose of oral hypoglycaemic agents in current period or 4) stopping oral hypoglycaemic agents in current period. Data will be collected from patients, verified where possible from clinic records. |

\*All time periods are time after recruitment, and compared with baseline with exception of changes in medication dose specified above. \*\*See Appendix 4

Table 4 Summary of outcome measures included in the patient questionnaire

|  |  |  |
| --- | --- | --- |
| Measure | Details | Source |
| Baseline patient demographic questions | Name, address, date of birth, ethnicity | All questions based upon Statistics New Zealand census questions:Available from: <http://www.stats.govt.nz/methods/classifications-and-standards/classification-related-stats-standards/gender-identity.aspx> |
| Smoking question | To ascertain current, never and ex- smokers | Parts of the New Zealand Health Survey smoking panelMinistry of Health. 2015. Adult Questionnaire (Year 5) 1 July 2015 – 30 June 2016: New Zealand Health Survey. Wellington: Ministry of Health. Available from: <http://www.health.govt.nz/publication/questionnaires-and-content-guide-2014-15-new-zealand-health-survey> |
| Healthcare utilisation questions | Primary care, afterhours, ED and hospital admissions | Modified from the New Zealand health survey Ministry of Health. 2015. Adult Questionnaire (Year 5) 1 July 2015 – 30 June 2016: New Zealand Health Survey. Wellington: Ministry of Health. Available from: <http://www.health.govt.nz/publication/questionnaires-and-content-guide-2014-15-new-zealand-health-survey> |
| Co-morbid conditions questions | List of conditions. | List is a modified version of: Sanga O, Stucki G, Liang M, Fossel AH,Katz JN: The Self-Administered Comorbidity Questionnaire: a new method to assess comorbidity for clinical and health services research. *Arthritis Rheum* 2003; 49: 156-63.71  |
| Medication questions | Name, dose and frequency | Questions developed by research team. |
| Quality of life (EQ5D) | 5 level scale and overall rating | Permission granted to use paper version of EQ5D. We have requested a license to use the electronic REDCap version. Availble from : <http://www.euroqol.org/eq-5d-products/eq-5d-5l.html> |
| The summary of diabetes self-care activities | Original scale included 5 domains on self-care with additional items on what care has been recommended. | We have focused on the self-care domains only. We have kept the general categories outlined in the original scale, but have modified the questions on diet, blood sugar, foot checks, smoking and medications to be of use for our RCT.Toobert, Deborah J., Sarah E. Hampson, and Russell E. Glasgow. "The summary of diabetes self-care activities measure: results from 7 studies and a revised scale." Diabetes care 23.7 (2000): 943-950. 67Permission to use this scale is from: <http://www.ori.org/sdsca/purchase> |
| Diabetes distress scale | 17 questions on the level of distress resulting from diabetes. | Permission granted to use the scale, and modify to also include prediabetics. Available from: <http://behavioraldiabetes.org/scales-and-measures/#1448434304099-9078f27c-4106>Polonsky, W.H., Fisher, L., Esarles, J., Dudl, R.J., Lees, J., Mullan, J.T., Jackson, R. (2005). Assessing psychosocial distress in diabetes: Development of the Diabetes Distress Scale. Diabetes Care, 28, 626-631.72Fisher, L., Hessler, D.M., Polonsky, W.H., Mullan, J. (2012). When is diabetes distress clinically meaningful? Establishing cut-points for the Diabetes Distress Scale. Diabetes Care, 35, 259-264.73 |
| Partners in Health Scale | 12 questions on chronic disease self-management | Permission sought to use the scale, Feb 2017.Smith, David, et al. "Measuring chronic condition self-management in an Australian community: factor structure of the revised Partners in Health (PIH) scale." Quality of Life Research (2016): 1-11.66Petkov, John, Peter Harvey, and Malcolm Battersby. "The internal consistency and construct validity of the partners in health scale: validation of a patient rated chronic condition self-management measure." Quality of Life Research 19.7 (2010): 1079-1085.74 |

# Adverse health events

This study does not aim to change, modify or affect the management regimes of any patient. There are no obvious risks associated with participating in this study.

# Data monitoring committee

An independent data monitoring group is not required for this study because the study is low risk in terms of likelihood of life-threatening complications or serious adverse events, the study team has no professional or financial links with the company that is delivering the intervention, and it will not be necessary to instigate stopping rules because there will be no interim analyses of efficacy.75 However an internal data monitoring group will be convened at two-monthly intervals which will consist of the study PI (Diana Sarfati), the biostatistician (James Stanley) and Dr Melissa McLeod. This group will also include an independent senior researcher. This group will assess the effectiveness of study procedures, review any potential adverse events and review and approve any amendments to study protocols. Other members of the research group will provide advice and input if requested.

# Sample size and analysis

All primary analyses will be based on intention to treat. Demographic and baseline characteristics will be summarised using descriptive statistics. Both HbA1c and weight will be analysed as continuous variables. For the HbA1c primary outcome, analysis will be conducted both combined and separately for pre-diabetic and diabetic groups. For weight, the primary analysis will combine pre-diabetic and diabetic participants. Analysis will use linear mixed models, comparing mean outcome levels between intervention and control arms at the 12-month endpoint, adjusted for initial HbA1c level (accounts for baseline differences in outcome) and for other important baseline covariates, (age, gender, ethnicity, weight). The analysis will include the 4 month measurements, providing some information for those individuals subsequently lost to follow-up and hence missing final outcome data (mixed models analysis treats these final data as missing at random conditional on baseline and intermediate covariates i.e. these individuals are expected on average to have final outcomes similar to other people with the same baseline covariates and HbA1c trajectories). As the study involves repeated measures data, these models will include random effects for individuals to account for correlation between measurements from the same person at different follow-up times.

**Sample size**

The study is powered in the pre-diabetic group to detect a difference of 2.5 mmol/mol between study arms (80% power, alpha = 0.05, presuming SD = 5.5 mmol/mol76). This requires a sample size of 76 per study arm (152 total). In the pilot study, the mean reduction in HbA1c was 2.6 mmol/mol. The sample size for the diabetic group is powered to detect a minimal clinically important difference77,78 of 5.5 mmol/mol between study arms (80% power, alpha for comparison = 0.05, presuming a standard deviation of 15 mmol/mol in this group23). This requires a sample size of 117 per study arm (234 total). This gives a combined sample size of 386 people with prediabetes and people with diabetes. To account for loss of precision due to patients lost to follow-up (projected at 10%79,80), we will recruit 430 patients at baseline (note that all participants will be included in linear mixed models analysis, even if missing final endpoint data. This reduces bias in estimating effect size, but there is still loss in statistical power compared to having complete follow-up data.)

Analysis of weight differences between study arms will use the same analytical methods as for the primary outcome. For these analyses, pre-diabetic and diabetic patients will be pooled prior to analysis as the relevant intervention target weight loss is the same for these two groups. Analysis will be stratified on patient group to account for the pooled approach, and we will also report weight differences by study arm within each patient group. The comparison of weight loss in the combined patient group is powered to detect a difference between study arms of 5kg (80% power, alpha = 0.05, SD = 15kg in this group81). This requires a sample size of 142 per study arm (284 total), which is below the combined sample size for the HbA1c outcome.

We will also estimate differences in HbA1c and weight endpoints by study arm for each of the stratified randomisation ethnic groups (Māori, Pacific, other ethnicities), and will report the mean difference and 95% confidence interval for each these. Proportions of patients meeting HbA1c and weight-loss targets will also be analysed by ethnic group with logistic regression (adjusted for baseline covariates), and adjusted absolute risk differences in treatment outcomes will be computed to quantify treatment effectiveness.82 Assuming 20% of the sample will be Māori gives an anticipated margin of error on the *intervention effect* of +/- 4.5 mmol/mol for HbA1c in the diabetic group (*n* = 234 x 0.2 = 46).

Analysis of self-reported outcomes will be conducted in a similar way, with some of these results being incorporated into the process evaluation (answering questions such as the extent to which improvements in self-reported patient management are associated with reduced HbA1c).

In all study analysis and reporting we will be cognizant of the CONSORT checklist and mHealth reporting guidelines. (Appendix 6: CONSORT check list for randomised controlled trials and Appendix 7: mHealth evidence reporting and assessment (mERA) guidelines)

# Process evaluation measures

Process evaluation is an essential part of assessing complex interventions that consist of multiple interacting components.83,84 Process evaluations provide health service planners and policy makers with critical information about how an intervention might work in a given context, the likelihood of success in implementing an effective intervention, contextual factors that may impact on that success and, modifiable factors that might improve the success of the intervention.83 The process evaluation will be based upon a logic model developed specifically for the BetaMe programme (summarised in Table 4) which outlines the intervention’s inputs, hypothesised activities and intended outputs.84 The process evaluation assesses the quality of the delivery of each aspect of the intervention, the extent to which each was enacted by participants, and the impact of these factors on the outcomes of the intervention. It will also identify any unexpected outcomes, barriers or problems with the intervention. These characteristics will also be assessed for Māori and Pacific participants.

Table 5: Logic model of BetaMe programme

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Inputs** | **Process/ Actions** | **Changes to behaviour** | **Short/ medium term outcomes** | **Long term outcomes** |
| Health coaches | Appropriate goal setting, behaviour change support. | Increase physical activityHealthier dietImproved medication adherenceImproved confidence | Decrease in HbA1cDecrease in weight/ BMIDecrease in waist circumference Improved social connections and supportImproved health literacy | Decrease in morbidityDecrease in mortalityDecrease in healthcare costs |
| Evidence-based modules | Informed participants |
| Peer support | Information/support sharing, dis-inhibition due to anonymity, asynchronous communication |
| Goal tracking | Reminder of goals, progress resulting in positive reinforcement |

There will be two key aspects to the process evaluation; assessments of implementation and mechanisms of action. The implementation assessment will identify fidelity (quality), dose and reach of the intervention. Key questions will include 1) what is the overall uptake of the intervention? 2) what proportion of participants a. access their health coaches, for what purpose and with what frequency and duration; b. access module information; c. interact online with other participants and with what frequency; d. use the tracking functions regularly? 3) how do these measures vary by age, sex, ethnicity and diabetic status of participants?

The mechanisms of action will be assessed by 1) evaluating the likelihood of positive outcomes according to intervention uptake patterns (i.e. which aspect/s of the intervention are most strongly associated with positive outcomes?); 2) seeking feedback from participants about the most and least helpful aspects of the intervention, and about unforeseen consequences and barriers.

Data will be collected from three sources: 1) from the mobile/web platform to identify key usage patterns; 2) with consent from the participants, health coaches will record audio interactions with participants and will log key reasons for contact (a random subset of the first coaching sessions (n=20) will be assessed by the research team for consistency with the log); 3) participants will be invited to provide individual feedback on the acceptability and usefulness of the intervention at the end of the study period. Two focus groups will be held in each region to obtain in-depth feedback about the intervention and how participants interacted with it.

Consent for the first health coaching session to be recorded is included in the original consent form for this study (Appendix 3). In addition, Melon Health will let participants know (get verbal consent) in the first phone call that a subset of first sessions will be recorded. Melon Health will record a random sample (randomly selected by the Otago University research team) of first sessions for each coach – which they will get consent at the end of that session to be passed to Otago University research team who will then assess the content of the first sessions against a checklist of expected discussion points (which is to be jointly developed by Melon Health and the research team).

Usage will be described, and linked to outcomes using standard quantitative analytic approaches (for example, proportions accessing health coaches will be reported, with 95% confidence intervals; frequency of accessing health coaches or engaging online will be reported as median access with range/interquartile range). Focus group data will be coded thematically, with key issues identified.

# Cost-effectiveness analysis

The economic burden of LTCs in NZ is immense, and is likely to increase rapidly.1,2 For this reason, we need fundamental shifts in the way we manage LTCs. There are a number of cost-effectiveness analyses of self-management strategies for diabetes, but these evaluations are specific to particular interventions, therefore of limited external validity in the NZ setting. However, a number of evaluations that include components of patient education and increased monitoring have been found to be cost-effective or even cost-saving to the health system.85-87 As part of this project we will provide an assessment of the cost-effectiveness of the intervention allowing health service policy makers to assess the extent to which it provides value for money. It will also provide funders an indication of the likely implementation costs of this programme.

The economic evaluation will take a health system perspective with intervention, healthcare (GP, community health, and out/in-patient visits and medication), and out-of-pocket patient costs assessed. Incremental cost-effectiveness ratios (ICERs) and cost-effectiveness acceptability curves will be calculated for outcomes showing a significant between-group difference at 12-month follow-up. These may include ICERs per controlled patient, per unit reduction in weight/BMI, and per quality-adjusted life-year.

The Burden of Disease Epidemiology, Equity & Cost-Effectiveness Programme (BODE³), University of Otago, Wellington is developing a cost-effectiveness model to assess health interventions for diabetes. The BODE3 team are keen to use (collated) data from this proposed trial to further evaluate this programme using their model enabling direct cost-effectiveness comparisons with other interventions.

# Ethical considerations

This study has ethical approval from New Zealand Health and Disability Ethics Committee (HDEC).Ethics ref: 17/CEN/49 Study title: BetaMe. An Innovative management of diabetes with a comprehensive digital health programme: a randomised controlled trial. Principal Investigator: Professor Diana Sarfati.

The study is being implemented by researchers from the University of Otago. The study team have no financial relationship with Melon Health, who designed the BetaMe programme and are delivering the intervention for the study. All design, implementation, analytic and dissemination aspects of the study are the sole responsibility of the University of Otago team.

The study is a low risk intervention study. No patient data will be made available to researchers without individual consent. Data collected in the study will be kept secure on password protected computers and will be confidential to the research team (except those data released to Melon Health for the purposes of running the intervention, with the permission of participants).

There are unlikely to be any meaningful harms to participants in the study except for the inconvenience of attending appointments for baseline and follow-up measurements. Participants will be given $20 per attendance in recognition of this inconvenience and to cover any related costs (such as petrol and parking).

If there is medical concern about any participant in the study, participants will be referred back to their primary care practitioner. Results of all HbA1c tests and blood pressure measurements over the normal range will be referred back to primary care practitioners as per the consent form for the study.

# Trial registration

The trial is registered with the Australian New Zealand Clinical Trials Registry. Registration number: ACTRN: ACTRN12617000549325. See <http://www.ANZCTR.org.au/ACTRN12617000549325.aspx>

This trial’s Universal Trial Number (UTN) is U1111-1189-9094.

# References

1. Ministry of Health. Health Loss in New Zealand: A report from the New Zealand Burden of Diseases, Injuries and Risk Factors Study, 2006–2016. Wellington: Ministry of Health, 2013.

2. Ministry of Health. Living Well with Diabetes: A plan for people at high risk of or living with diabetes 2015–2020. Wellington: Ministry of Health, 2015.

3. Westbrooke I, Baxter J, Hogan J. Are Maori under-served for cardiac interventions? *N Z Med J* 2001; **114**(1143): 484-7.

4. Robson B, Harris R, editors. Hauora: Maori Standards of Health IV. A study of the years 2000-2005. Wellington: Te Ropu Rangahau Hauora a Eru Pomare; 2007.

5. Tukuitonga C, Bindman A. Ethnic and gender differences in the use of coronary artery revascularisation procedures in New Zealand. *N Z Med J* 2002; **115**: 179-82.

6. Eaton S, Roberts S, Turner B. Delivering person centred care in long term conditions. *Bmj* 2015; **350**: h181.

7. Haggerty JL. Ordering the chaos for patients with multimorbidity. *Bmj* 2012; **345**: e5915.

8. Institute of Medicine. Living well with chronic illness: A call for public health action. Washington, DC: The National Academies Press, 2012.

9. Watt G. Looking beyond "the house of care" for long term conditions. *Bmj* 2013; **347**: f6902.

10. Coppell KJ, Mann JI, Williams SM, et al. Prevalence of diagnosed and undiagnosed diabetes and prediabetes in New Zealand: findings from the 2008/09 Adult Nutrition Survey. *Journal of the New Zealand Medical Association* 2013; **126**(1370).

11. World Health Organization. Definition and diagnosis of diabetes mellitus and intermediate hyperglycemia: report of a WHO/IDF consultation. Geneva: World Health Organization, 2006.

12. Cheng YJ, Gregg EW, Geiss LS, et al. Association of A1C and fasting plasma glucose levels with diabetic retinopathy prevalence in the U.S. population: Implications for diabetes diagnostic thresholds. *Diabetes Care* 2009; **32**(11): 2027-32.

13. Diabetes Prevention Program Research G. The prevalence of retinopathy in impaired glucose tolerance and recent-onset diabetes in the Diabetes Prevention Program. *Diabet Med* 2007; **24**(2): 137-44.

14. Ford ES, Zhao G, Li C. Pre-diabetes and the risk for cardiovascular disease: a systematic review of the evidence. *J Am Coll Cardiol* 2010; **55**(13): 1310-7.

15. Ziegler D, Rathmann W, Dickhaus T, Meisinger C, Mielck A, Group KS. Prevalence of polyneuropathy in pre-diabetes and diabetes is associated with abdominal obesity and macroangiopathy: the MONICA/KORA Augsburg Surveys S2 and S3. *Diabetes Care* 2008; **31**(3): 464-9.

16. Vinik AI, Richardson DW. Implications of the diabetes control and complications trial for persons with non-insulin-dependent diabetes mellitus. *South Med J* 1997; **90**(3): 268-82.

17. Diabetes Prevention Program Research G, Knowler WC, Fowler SE, et al. 10-year follow-up of diabetes incidence and weight loss in the Diabetes Prevention Program Outcomes Study.[Erratum appears in Lancet. 2009 Dec 19;374(9707):2054]. *Lancet* 2009; **374**(9702): 1677-86.

18. Lindstrom J, Ilanne-Parikka P, Peltonen M, et al. Sustained reduction in the incidence of type 2 diabetes by lifestyle intervention: follow-up of the Finnish Diabetes Prevention Study. *Lancet* 2006; **368**(9548): 1673-9.

19. Perreault L, Pan Q, Mather KJ, et al. Effect of regression from prediabetes to normal glucose regulation on long-term reduction in diabetes risk: results from the Diabetes Prevention Program Outcomes Study. *Lancet* 2012; **379**(9833): 2243-51.

20. Knowler WC, Barrett-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med* 2002; **346**(6): 393-403.

21. Rivellese AA, Boemi M, Cavalot F, et al. Dietary habits in type II diabetes mellitus: how is adherence to dietary recommendations? *Eur J Clin Nutr* 2008; **62**(5): 660-4.

22. Ruggiero L, Glasgow R, Dryfoos JM, et al. Diabetes self-management. Self-reported recommendations and patterns in a large population. *Diabetes Care* 1997; **20**(4): 568-76.

23. Liang X, Wang Q, Yang X, et al. Effect of mobile phone intervention for diabetes on glycaemic control: a meta-analysis. *Diabet Med* 2011; **28**(4): 455-63.

24. Nundy S, Dick JJ, Chou CH, Nocon RS, Chin MH, Peek ME. Mobile phone diabetes project led to improved glycemic control and net savings for Chicago plan participants. *Health affairs (Project Hope)* 2014; **33**(2): 265-72.

25. Norris SL, Engelgau MM, Narayan KM. Effectiveness of self-management training in type 2 diabetes: a systematic review of randomized controlled trials. *Diabetes Care* 2001; **24**(3): 561-87.

26. Franklin VL, Waller A, Pagliari C, Greene SA. A randomized controlled trial of Sweet Talk, a text-messaging system to support young people with diabetes. *Diabet Med* 2006; **23**(12): 1332-8.

27. Wolever RQ, Dreusicke MH. Integrative health coaching: a behavior skills approach that improves HbA1c and pharmacy claims-derived medication adherence. *BMJ Open Diabetes Research & Care* 2016; **4**(1).

28. Sepah SC, Jiang L, Peters AL. Long-Term Outcomes of a Web-Based Diabetes Prevention Program: 2-Year Results of a Single-Arm Longitudinal Study. *Journal of Medical Internet Research* 2015; **17**(4): e92.

29. Krebs JD, Parry-Strong A, Gamble E, et al. A structured, group-based diabetes self-management education (DSME) programme for people, families and whanau with type 2 diabetes (T2DM) in New Zealand: an observational study. *Prim Care Diabetes* 2013; **7**(2): 151-8.

30. Silva M, Clinton J, Appleton S, Flanagan P. Diabetes self-management education in South Auckland, New Zealand, 2007-2008. *Preventing chronic disease* 2011; **8**(2): A42.

31. Dobson R, Whittaker R, Jiang Y, et al. Text message-based diabetes self-management support (SMS4BG): study protocol for a randomised controlled trial. *Trials* 2016; **17**: 179.

32. Holmen H, Torbjørnsen A, Wahl AK, et al. A Mobile Health Intervention for Self-Management and Lifestyle Change for Persons With Type 2 Diabetes, Part 2: One-Year Results From the Norwegian Randomized Controlled Trial RENEWING HEALTH. *JMIR mHealth and uHealth* 2014; **2**(4): e57.

33. Ristau RA, Yang J, White JR. Evaluation and evolution of diabetes mobile applications: Key factors for health care professionals seeking to guide patients. *Diabetes Spectrum* 2013; **26**(4): 211-6.

34. Abraham C, Michie S. A taxonomy of behavior change techniques used in interventions. *Health Psychol* 2008; **27**(3): 379-87.

35. Ryan P. Integrated Theory of Health Behavior Change: background and intervention development. *Clin Nurse Spec* 2009; **23**(3): 161-70; quiz 71-2.

36. MacDonald CA. Health Psychology for Everyday Life: a bio-psycho-social thinking approach. Oceanside, California: Health Psychology Center P.C. Book; 2015.

37. <http://newsnetwork.mayoclinic.org/discussion/mayo-clinic-and-techstars-to-offer-new-program-techstars-to-health-care-entrepreneurs/>.

38. Research New Zealand. A Report on a Survey of New Zealanders’ Use of Smartphones and other Mobile Communication Devices 2015. Wellington: Research New Zealand, 2015.

39. O'Carroll AD. Virtual whanaungatanga: Maori utilizing social networking sites to attain and maintain relationships. *AlterNative: An International Journal of Indigenous Peoples* 2013; **9**(3): 230.

40. Funnell MM, Brown TL, Childs BP, et al. National standards for diabetes self-management education. *Diabetes Care* 2009; **32**(Supplement 1): S87-S94.

41. Clarke DM, Baird DE, Perera DN, Hagger VL, Teede HJ. The INSPIRED study: a randomised controlled trial of the Whole Person Model of disease self-management for people with type 2 diabetes. *BMC public health* 2014; **14**(1): 1.

42. Jordan JE, Osborne RH. Chronic disease self-management education programs: challenges ahead. *The Medical journal of Australia* 2007; **186**(2): 84-7.

43. Cole-Lewis H, Kershaw T. Text messaging as a tool for behavior change in disease prevention and management. *Epidemiologic reviews* 2010; **32**: 56-69.

44. Fischer HH, Fischer IP, Pereira RI, et al. Text Message Support for Weight Loss in Patients With Prediabetes: A Randomized Clinical Trial. *Diabetes Care* 2016; **39**(8): 1364-70.

45. Yamada T, Kiuchi Y, Nemoto M, Yamashita S. Charting weight four times daily as an effective behavioural approach to obesity in patients with type 2 diabetes. *Diabetes and Vascular Disease Research* 2014; **11**(2): 118-20.

46. Glasgow RE, Funnell MM, Bonomi AE, Davis C, Beckham V, Wagner EH. Self-management aspects of the improving chronic illness care breakthrough series: implementation with diabetes and heart failure teams. *Annals of behavioral medicine : a publication of the Society of Behavioral Medicine* 2002; **24**(2): 80-7.

47. Jennings A, Powell J, Armstrong N, Sturt J, Dale J. A virtual clinic for diabetes self-management: pilot study. *Journal of medical Internet research* 2009; **11**(1): e10.

48. Thom DH, Ghorob A, Hessler D, De Vore D, Chen E, Bodenheimer TA. Impact of peer health coaching on glycemic control in low-income patients with diabetes: a randomized controlled trial. *Annals of family medicine* 2013; **11**(2): 137-44.

49. Fisher EB, Boothroyd RI, Coufal MM, et al. Peer support for self-management of diabetes improved outcomes in international settings. *Health Affairs* 2012; **31**(1): 130-9.

50. Yin J, Wong R, Au S, et al. Effects of Providing Peer Support on Diabetes Management in People With Type 2 Diabetes. *Annals of family medicine* 2015; **13 Suppl 1**: S42-9.

51. Vissenberg C, Stronks K, Nijpels G, et al. Impact of a social network-based intervention promoting diabetes self-management in socioeconomically deprived patients: a qualitative evaluation of the intervention strategies. *BMJ open* 2016; **6**(4): e010254.

52. Ministry of Health. Self-management Support for People with Long-term Conditions (2nd edn). Wellington: Ministry of Health, 2016.

53. Nobel J, Sasser e. Digital diabetes prevention and management solutions: <http://nebgh.org/wp-content/uploads/2016/03/Digital-Diabetes-Online.pdf>, 2016.

54. Ministry of Health. Eating and Activity Guidelines for New Zealand Adults. Wellington: Ministry of Health, 2015.

55. Heart Foundation of New Zealand. The Healthy Heart: A Guideline for Health Professionals. In: Zealand HFoN, editor.; 2013.

56. Tomlin A, Sinclair A. The influence of cognition on self-management of type 2 diabetes in older people. *Psychology Research and Behavior Management* 2016; **9**: 7-20.

57. Klein S, Allison DB, Heymsfield SB, et al. Waist circumference and cardiometabolic risk: a consensus statement from Shaping America's Health: Association for Weight Management and Obesity Prevention; NAASO, The Obesity Society; the American Society for Nutrition; and the American Diabetes Association. *American Journal of Clinical Nutrition*; **85**(5): 1197-202.

58. Price GM, Uauy R, Breeze E, Bulpitt CJ, Fletcher AE. Weight, shape, and mortality risk in older persons: elevated waist-hip ratio, not high body mass index, is associated with a greater risk of death. *American Journal of Clinical Nutrition*; **84**(2): 449-60.

59. Blakely T, Sarfati D, Shaw C. What proportion of cancer is due to obesity? *NZ Med J* 2009; **122**(1279): 3478.

60. Greaves CJ, Sheppard KE, Abraham C, et al. Systematic review of reviews of intervention components associated with increased effectiveness in dietary and physical activity interventions. *BMC Public Health* 2011; **11**: 119.

61. Terranova CO, Brakenridge CL, Lawler SP, Eakin EG, Reeves MM. Effectiveness of lifestyle-based weight loss interventions for adults with type 2 diabetes: a systematic review and meta-analysis. *Diabetes Obes Metab* 2015; **17**(4): 371-8.

62. Norris SL, Zhang X, Avenell A, Gregg E, Schmid CH, Lau J. Long-term non-pharmacological weight loss interventions for adults with prediabetes. *Cochrane Database Syst Rev* 2005; (2): CD005270.

63. Wieland LS, Falzon L, Sciamanna CN, et al. Interactive computer-based interventions for weight loss or weight maintenance in overweight or obese people. *Cochrane Database Syst Rev* 2012; (8): CD007675.

64. Blumenthal JA, Sherwood A, Gullette EC, et al. Exercise and weight loss reduce blood pressure in men and women with mild hypertension: effects on cardiovascular, metabolic, and hemodynamic functioning. *Arch Intern Med* 2000; **160**(13): 1947-58.

65. Maruthur NM, Wang NY, Appel LJ. Lifestyle interventions reduce coronary heart disease risk: results from the PREMIER Trial. *Circulation* 2009; **119**(15): 2026-31.

66. Smith D, Harvey P, Lawn S, Harris M, Battersby M. Measuring chronic condition self-management in an Australian community: factor structure of the revised Partners in Health (PIH) scale. *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation* 2017; **26**(1): 149-59.

67. Toobert DJ, Hampson SE, Glasgow RE. The summary of diabetes self-care activities measure: results from 7 studies and a revised scale. *Diabetes Care* 2000; **23**(7): 943-50.

68. Fisher L, Glasgow RE, Mullan JT, Skaff MM, Polonsky WH. Development of a brief diabetes distress screening instrument. *Annals of family medicine* 2008; **6**(3): 246-52.

69. Eurocare Working Group. EuroQol - a new facility for the measurement of health related quality of life. The EuroQol group. *Health Policy* 1990; **16**: 199-208.

70. Pal K, Eastwood SV, Michie S, et al. Computer-based diabetes self-management interventions for adults with type 2 diabetes mellitus. *Cochrane Database of Systematic Reviews* 2013; **3**: CD008776.

71. Sangha O, Stucki G, Liang MH, Fossel AH, Katz JN. The Self-Administered Comorbidity Questionnaire: a new method to assess comorbidity for clinical and health services research. *Arthritis and rheumatism* 2003; **49**(2): 156-63.

72. Polonsky WH, Fisher L, Earles J, et al. Assessing psychosocial distress in diabetes: development of the diabetes distress scale. *Diabetes Care* 2005; **28**(3): 626-31.

73. Fisher L, Hessler DM, Polonsky WH, Mullan J. When is diabetes distress clinically meaningful?: establishing cut points for the Diabetes Distress Scale. *Diabetes Care* 2012; **35**(2): 259-64.

74. Petkov J, Harvey P, Battersby M. The internal consistency and construct validity of the partners in health scale: validation of a patient rated chronic condition self-management measure. *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation* 2010; **19**(7): 1079-85.

75. Health Research Council. <http://www.hrc.govt.nz/ethics-and-regulatory/data-monitoring-core-committee#what-appropriate>. Accessed 16 Jan 2017.

76. Garvey WT, Ryan DH, Henry R, et al. Prevention of type 2 diabetes in subjects with prediabetes and metabolic syndrome treated with phentermine and topiramate extended release. *Diabetes Care* 2014; **37**(4): 912-21.

77. US Food and Drug Administration. Guidance for industry: Diabetes Mellitus: Developing Drugs and Therapeutic Biologics for Treatment and Prevention US Food and Drug Administration, 2008.

78. Mearns ES, Sobieraj DM, White CM, et al. Comparative efficacy and safety of antidiabetic drug regimens added to metformin monotherapy in patients with type 2 diabetes: a network meta-analysis. *PLoS One* 2015; **10**(4): e0125879.

79. Cho JH, Lee HC, Lim DJ, Kwon HS, Yoon KH. Mobile communication using a mobile phone with a glucometer for glucose control in Type 2 patients with diabetes: as effective as an Internet-based glucose monitoring system. *J Telemed Telecare* 2009; **15**(2): 77-82.

80. Quinn CC, Shardell MD, Terrin ML, Barr EA, Ballew SH, Gruber-Baldini AL. Cluster-randomized trial of a mobile phone personalized behavioral intervention for blood glucose control. *Diabetes Care* 2011; **34**(9): 1934-42.

81. Heymsfield SB, Segal KR, Hauptman J, et al. Effects of Weight Loss With Orlistat on Glucose Tolerance and Progression to Type 2 Diabetes in Obese Adults. *Arch Intern Med* 2000; **160**(9): 1321.

82. Muller CJ, MacLehose RF. Estimating predicted probabilities from logistic regression: different methods correspond to different target populations. *Int J Epidemiol* 2014; **43**(3): 962-70.

83. Moore GF, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical Research Council guidance. *Bmj* 2015; **350**: h1258.

84. Moore GF, Audrey S, Barker M, et al. UK Medical Research Guidance: Process Evaluation of Complex Interventions. Report at <https://www.mrc.ac.uk/documents/pdf/mrc-phsrn-process-evaluation-guidance-final/>, accessed Aug 2016.

85. Urbanski P, Wolf A, Herman WH. Cost-effectiveness of diabetes education. *Journal of the American Dietetic Association* 2008; **108**(4 Suppl 1): S6-11.

86. National Institute for Clinical Excellence. Guidance on the use of patient-education models for diabetes. Technology appraisal 60.: NICE, 2003.

87. Gillett M, Dallosso HM, Dixon S, et al. Delivering the diabetes education and self management for ongoing and newly diagnosed (DESMOND) programme for people with newly diagnosed type 2 diabetes: cost effectiveness analysis. *Bmj* 2010; **341**: c4093.

88. Agarwal S, LeFevre AE, Lee J, et al. Guidelines for reporting of health interventions using mobile phones: mobile health (mHealth) evidence reporting and assessment (mERA) checklist. *Bmj* 2016; **352**: i1174.

# Appendices

## Appendix 1: Coaching guidelines for first health coach session

****

**Setting Values-based Goals**

**The purpose of the personal values-based goal is the ‘why’. It’s *why* that person wants to get healthy and feel well.**

Values are usually fairly stable, yet they don't have strict limits or boundaries. As we move through life, our values may change. For example, when we start working, success may be measured by money and status. But after a family, work-life balance may be what we value more.

Helping someone identify their values can also help them find their purpose and their motivation.

Some people struggle to find identify their ‘purpose’. It’s widely believed we need three things to be happy: a sense of purpose (reason to get up in the morning), a sense of control (we know what it’s like when our relationships, finances or health is out of control and how overwhelming that can feel) and social connections (we don’t need hundreds of facebook ‘friends’ but we need social contact with other people.

In the first coach session with your client, helping them identify a goal that has *meaning to them* will help them stay motivated and on track as it will serve as a reminder of why they want to get well. The following process will help:

For some people, the following simple question is enough for them to identify a personal, values-based goal: *what’s your reason for wanting to get healthy and well?*

*I want to be healthy enough to return to work.*

 *I want to feel confident at my daughter’s wedding and not so self-conscious.*

 *I want to be able to run round with my grand kids etc.*

Other people may need a bit more of a nudge:

*What’s most important to you, what do you value the most in your life?*

Followed by, *what’s a personal goal you’d like to achieve over the next 4-6 months.*

For other people who struggle with motivation, the following process can help them identify what’s important to them and what their values are by helping them remember a time when they felt happy, confident and proud.

**Conversation starters:**

**Defining Your Values**

When you define your personal values, you discover what’s really important to you. A good way of starting is to look back on your life and remember and identify a time when you felt really good, and really confident.

1. Identify the times you were most happiest
* What were you doing?
* Were you with other people? Who?
* What other things about it made you happy?
1. Identify the times you were most proud
* Why were you proud?
* Were others proud of you? Who?
* What else about that time made you proud?
1. Identify the times you were most fulfilled/satisfied
* What need or desire do you think was filled that made you feel this way?
* What about that had meaning to you?
* What other things make you feel satisfied or fulfilled

After completing the short process above, most people are ready to set a value-based goal. Feel free to give them some nudges:

*Now that you’ve thought about some times when you were happy and proud, is there something you’d like to try or do if you had more energy?*

*Is there something coming up that you are looking forward to that you’d enjoy more if you were feeling healthier?*

*Is there a hobby or interest that you’ve wanted to take up but have been putting off?*

If they just can’t think of something, tell them it’s ok, and encourage them to think about what is most important to them and that you’ll check in with them in a few days to see if they’re ready to set a goal.

## Appendix 2: Draft Practice letters and Practice Nurse Phone Script

The following letter is a draft only, and will be modified and sent from the practices to potential participants priori to them being called.

Draft practice letter

Dear

Be part of an important diabetes research study in our Practice.

* Are you between 18-75 years
* Are you NOT currently on insulin treatment for diabetes
* Do you have internet access (either web or phone)

If you answered YES to these questions, you may be eligible to participate in our study.

You have had a blood test that showed us that you have high blood sugar and we are testing different ways to support people to improve their health and wellbeing when they have diabetes or high blood sugar. One of these ways is a new on-line self-management support programme.

If you do take part in the study we will ask you to come into the Practice 3 times over the next year at time that suits you to fill in a questionnaire and have some basic measurements taken. There will be no cost to you to be involved in the study, each time you come in for the study you will meet a research nurse from the study team and will get a $20 voucher.

Your involvement is completely up to you, and your decision will have no impact on your ongoing health care you receive from Dr XX.

If you are interested in finding out more about the study or are definitely not interested in participating, please contact one of our Practice Nurses on XX. If we don’t hear from you one of our Practice Nurses will phone you to tell you more about the study and to see if you might be interested.

>> Full contact information provided <<

Draft Practice Nurse Phone Script

The following is a draft only. Feedback will be sought from practice nurses and research nurses on this script.

Our practice has agreed to take part in a research study run by the University of Otago, on the management of diabetes and prediabetes.

You have previously had a blood test that indicated that you are diabetic/prediabetic (*for those that have a test indicating they have prediabetes, ask “were you aware that you have prediabetes”*), and so I am calling to let you know about the study and to see if you might like to be involved. This study aims to find out how we can best support people with diabetes and prediabetes to help them to improve their health and manage their conditions. We are testing whether a new online support programme called BetaMe is better than the usual care given to people with diabetes and prediabetes. Your involvement is completely up to you, and your decision will have no impact on your ongoing health care you receive from Dr………...

First, I am going to ask a few questions to see if you are eligible to be involved in this study.

To be eligible for this study you need daily access to the internet, and you need access to a computer, tablet or Smartphone. **Do you have daily access to the internet and to one the devices I just listed?**

yes- continue

no – Unfortunately you are not able to be involved in this study, but thank you for your time.

*For diabetics only:*

**Are you currently using insulin for your diabetes?**

no- continue

yes – Unfortunately you are not able to be involved in this study, but thank you for your time.

*For females under 55 years only:*

**Are you pregnant?**

no- continue

yes – Unfortunately you are not able to be involved in this study, but thank you for your time

I will now give you some really brief information about the study.

The study will run for 12 months. All study participants will meet with a research nurse three times: once at the very start, at 4 and 12 months, to have some measures taken (including a blood test), and to answer a survey. For each of these meetings, you can receive $20 to compensate for travel and time.

Half of people that sign for the study up will receive an internet -based programme to help people to self-manage their diabetes/prediabetes. Everyone in the study will continue to have their diabetes managed by their usual health provider.

**If you are interested in getting more information about the study, or potentially being involved, I will need your permission to pass your contact details on to the research team? Are you happy for me to do that?**

yes- continue

no –thank you for your time

**If yes, the research team will contact you within the next few days to explain more about the study? What is the time of day and the best number to contact you on?**

*If an HbA1c test taken within the last 3 months ask the following….*

**Do I have permission to pass on your HbA1c blood test result taken on (date) to the research team?**

## Appendix 3: Participant Information and Consent Form



|  |  |
| --- | --- |
| **Participant Information Sheet** |  |
| Study title: | ***BetaMe: Type 2 diabetes and pre-diabetes study*** |
| Locality: | **Waikato, Wellington, Wairarapa and Hutt Valley** | Ethics committee ref.: |  |
| Lead investigator: | **Professor Diana Sarfati** | Contact phone number:  | (04) 385 5541 |

Thank you for showing an interest in this study. In this study we want to test different approaches that might support you to improve your health and wellbeing when you have Type 2 Diabetes (diabetes) or prediabetes.

Whether or not you take part is your choice. If you don’t want to take part, you don’t have to give a reason, and it won’t affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time. Regardless of your choice we thank you for taking time to consider our study.

This Participant Information Sheet will help you decide if you’d like to take part. We will go through this information with you and answer any questions you may have. If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both this Information Sheet and the Consent Form to keep.

**What is this study about?**

Diabetes and prediabetes are common health conditions affecting many adults in New Zealand. Living with and managing diabetes and prediabetes may be hard for patients, whānau and health services.

This study aims to find out how we can best support people with diabetes and prediabetes to help them to improve their health and manage their conditions. We are testing whether a new online support programme called BetaMe is better than the usual care given to people with diabetes and prediabetes.

**What will I have to do?**

If you agree to be involved in the study, at the beginning, you will be asked to give us your contact details and fill out a survey. The research nurse will take some basic measurements like your blood pressure, height and weight. You will also be asked to have a blood test for HbA1c level which is a measure of how well your diabetes or prediabetes is controlled; if you have had a HbA1c taken in the last 3 months we will get your result from the GP Practice instead. We will collect this information again after 4 and 12 months. Each of these study visits will take up to 30 minutes.

A computer will randomly assign you to one of two groups. If you are assigned to the group that receives usual care only, we will be in touch with you again at 4 months and 12 months to arrange follow-up visits to re-collect the basic measurements.

If you are assigned to the group that receives the BetaMe programme, you will receive a phone call (within 10 working days of having your blood test) from a health coach who will explain the programme to you. BetaMe is a 12 month programme delivered on-line using mobile or web-based technology. It has 4 parts: health coaching, online education sessions goal tracking and online support with others who have diabetes or prediabetes. The amount of time you spend each week on the BetaMe programme is entirely up to you, and you can do it at times that suit you. We will be in touch with you again at 4 months and 12 months to arrange follow-up visits to re-collect the basic measurements

All participants in the study will continue to get their usual care from their GP/primary care practice and will receive some educational material from Diabetes NZ.

At the end of the study, we may ask you for your feedback on your experience of the study. We may also use other information to evaluate the BetaMe programme including data from the mobile/web programme and audio recordings between you and your health coach (Recording is optional and these sessions will only be recorded with your permission).

**What are the possible benefits and risks of this study?**

Possible benefits of taking part in the study include improvements in your health and well-being, reversal of prediabetes and improved management of diabetes.

Everyone who agrees to be part of the study will be offered a token of appreciation/koha of $20 when you start participating in the study and at 4 and 12 months (a total of $60).

If you are in the BetaMe programme group, you will be provided with a set of digital scales and a tape measure so you can take your own measurements and track your progress.

There are no known risks to taking part. However if you were injured in this study, which is unlikely, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

**Who pays for the study?**

The BetaMe programme is provided free of charge for participants in the BetaMe group. Participants will need to have access to the internet and a device such as a smart phone, tablet or computer. Please let the researchers know if access to internet data is a problem for you.

Normal costs apply for all study participants if you access usual care from your GP/Primary care practice.

**Who can take part?**

You will be able to be part of the study if you:

* Have an HbA1c (diabetes blood test) result that shows that you are diabetic OR if you have an HbA1c result that shows that you are pre-diabetic, and you have not previously been diagnosed with diabetes.
* Are not currently on insulin treatment for diabetes
* Are between 18-75 years
* Have internet access (either web or phone)
* Are able to provide informed consent

You will not be able to be part of the study if you:

* Are pregnant
* Have other health conditions that prevent you from being able to participate fully in this study. Our research nurse will give you some guidance on this criterion.
* Are unable to read and write in English
* Are unable to use a phone or computer

**General information**

Participation in this study is voluntary (your choice). You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

You have the right to access any information about you collected as part of this study.

This study is being led by researchers at the University of Otago, in partnership with GP/Primary care practices in the Waikato region (Midlands Health Network), Greater Wellington/Wairarapa region (Compass Health) and the Whai Oranga o Te Iwi Health Centre (Hutt Valley).

The BetaMe programme is provided by Melon Health, the company who developed the BetaMe programme.

**What happens after the study or if I change my mind?**

You may withdraw from participation in this study at any time. This will have no effect on your future health care.

At the end of this study, or if you do withdraw from the study, you may be contacted by the research team to ask you for feedback about this study.

Any blood specimens collected during the research will be destroyed at the end of the study.

The results of the study may be published or presented at conferences. The information from the study will be used collectively and will in no way identify you as an individual.

All health information (e.g. HbA1c, weight etc.) and any audio recordings will be kept on password protected computers and in locked filing cabinets for ten years, at which time they will be destroyed. If you wish, you can be given a summary of the research findings at the end of this study in 2018/19.

**Who do I contact for more information or if I have concerns?**

If you have any questions, concerns or complaints about the study at any stage, you can contact:

 Study Manager: Dr Melissa McLeod

Phone: *04 918 6711*

Email: *BetaMestudy@otago.ac.nz*

If you want to talk to someone who isn’t involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050

Fax: 0800 2 SUPPORT (0800 2787 7678)

Email: advocacy@hdc.org.nz

For Māori health support please contact:

Māori health researcher: Jeannine Stairmand,

 Phone: 04 385 5541 or 0275323492

 Email: *BetaMestudy@otago.ac.nz*

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

 Phone: 0800 4 ETHICS

 Email: hdecs@moh.govt.nz

This study is funded by the Health Research Council of New Zealand. Ethics approval for this study has been granted by the Central the health and disability ethics committee (Ref:17/CEN/49).

|  |  |
| --- | --- |
| OU Logo(trans)**Consent Form** |  |

**Please tick to indicate you consent to the following**

|  |  |
| --- | --- |
| I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.  |  |
| I have been given enough time to consider whether or not to take part in this study. |  |
| I am satisfied with the answers I have been given about the study and I have a copy of this consent form and information sheet. |  |
| I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care. |  |
| If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be used.  |  |
| I consent to the research staff collecting and processing my information, including information about my health. |  |
| I consent to the research staff giving my contact details to Melon Health if I am assigned to the group that receives the BetaMe programme.  |  |
| I consent to the research team getting my HbA1c result from the GP Practice if I have had one taken in the last 3 months. |  |
| I consent to my GP or current provider being informed about my participation in the study, of any abnormal blood pressure results obtained during the study and of my HbA1c blood test results. |  |
| I understand that if I have any concerns about my diabetes, or general health, I need to discuss these with my GP or primary care provider. |  |
| I undertake to inform the research team if I become pregnant during the study. |  |
| I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study. |  |
| I know who to contact if I have any questions about the study in general. |  |
| I understand my responsibilities as a study participant. |  |

**Please tick to indicate whether you consent to the following optional study activities, or not**

|  |  |  |
| --- | --- | --- |
| If I am in the intervention group, I consent to an audio recording being taken during my first coaching session which the research team will use solely for the purpose of checking the topics covered by the health coaches. | Yes 🞏 | No 🞏 |
| I am happy to be contacted by the study team once my involvement in the study is completed to give feedback on this study. | Yes 🞏 | No 🞏 |
| I wish to receive a summary of the results from the study. | Yes 🞏 | No 🞏 |

**Declaration by participant:**

I hereby consent to take part in this study.

|  |
| --- |
| Participant’s name: |
| Signature: | Date: |

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant, and have answered the participant’s questions about it.

I believe that the participant understands the study and has given informed consent to participate.

|  |
| --- |
| Researcher’s name: |
| Signature: | Date: |

## Appendix 4: Research nurse baseline measure guidance

Modified from: Ministry of Health. 2015. Adult Questionnaire (Year 5) 1 July 2015 – 30 June 2016: New Zealand Health Survey. Wellington: Ministry of Health. Available from: <http://www.health.govt.nz/publication/questionnaires-and-content-guide-2014-15-new-zealand-health-survey>

**1. Blood Pressure**

Now I would like to take your blood pressure. I am going to measure this three times over the course of this visit (with a minimum 5 minute interval between readings).

Before we take the blood pressure measurement you need to have been sitting quietly for five minutes. You cannot have eaten, drunk or smoked during this time. You will need to sit with your feet flat on the floor and with your back against the back of the chair, and have your left arm straight on the table.

**🛈 Select the cuff size and attach to the respondent’s arm.**

I am now going to inflate the cuff so you will feel some pressure on your arm while this is happening. You should not move or talk during the test and it is important to stay relaxed.

Do you have any questions before we begin?

**Record the first reading**

**ABP\_1A** \_\_/\_\_/\_\_ Systolic blood pressure (mmHG) (range 30-300)

**ABP\_1B** \_\_/\_\_/\_\_ Diastolic blood pressure (mmHG) (range 30-200) **Systolic1 must be > than Diastolic1**

**Record the second reading**

**ABP\_2A** \_\_/\_\_/\_\_ Systolic blood pressure (mmHG) (range 30-300)

**ABP\_2B** \_\_/\_\_/\_\_ Diastolic blood pressure (mmHG) (range 30-200)

 **🛈 Systolic2 must be > than Diastolic2**

**Record the third reading**

**ABP\_3A** \_\_/\_\_/\_\_ Systolic blood pressure (mmHG) (range 30-300)

**ABP\_3B** \_\_/\_\_/\_\_ Diastolic blood pressure (mmHG) (range 30-200)  **🛈 Systolic3 must be > than Diastolic3**

I will write your blood pressure results on a measurement card for you to keep.

|  |  |  |  |
| --- | --- | --- | --- |
| **Results** | **Systolic** |  | **Diastolic** |
| 1: Ideal  | <130 | and | <80 |
| 2: Raised | 130-169 | or | 80-99 |
| 3: Very raised | 170 or more | or | 100 or more |

**Based upon the result of the LOWEST BP reading, inform the patient:**

**1:** *“Your blood pressure is within the ideal range.”*

**2:** *“Your blood pressure is a bit high today.”* We recommend you discuss these results with your usual doctor or health professional.”

**3:** “*Your blood pressure is high today.”*

If BP is elevated over 170 systolic, or 100 diastolic, inform the practice nurse if they are around, or if the nurse is not there, tell the patient to contact the practice nurse in the next few days. If the systolic is over 200...DO NOT LET THEM LEAVE without seeing the practice nurse or a GP.

*I am now going to take three measurements from you – height, weight, and waist. I’m then going to take those measurements again, and if any of the second measures are not close enough to the first ones, I’ll measure you for a third time. While I’m setting up the equipment, could you please remove your shoes and all heavy outer clothing so we can obtain accurate measurements. Thank you.*

**2. Height**

Please stand with your back to the post. Put your feet together and move them back until your heels touch the door. Stand up straight and look straight ahead.

**🛈 If head is not in Frankfort Plane say…**

Please raise/lower your chin.

Take a deep breath and hold it. **🛈 Take measurement and say it aloud.**

That’s fine, you can breathe normally now and step away..

**Record 1st reading 000.0 (cm)**

**3. Weight**

Wait until it turns zero. Please step onto the centre of the scale with your weight on both feet. Relax [take reading]. Thank you. You can step off now.

**Record 1st reading 000.0 (kg)**

**4. Waist measure**

Notes for research nurse on how to take waist circumference. (References: Waist circumference and waist–hip ratio: report of a WHO expert consultation, Geneva, 8–11, December 2008.)

Waist circumference should be measured at the midpoint between the lower margin of the

least palpable rib and the top of the iliac crest, using a stretch‐resistant tape that provides a

constant 100 g tension.

The subject should stand with feet close together, arms at the side and body weight evenly distributed, and should wear little clothing. The subject should be relaxed, and the measurements should be taken at the end of a normal expiration. Each measurement should be repeated twice; if the measurements are within 1 cm of one another, the average should be calculated. If the difference between the two measurements exceeds 1 cm, the two measurements should be repeated.

**Record 1st reading 000.0 (cm)**

**5. Second and third readings**

I’m now going to repeat all three measures starting with height again. If there is a difference of 1cmof greater between the first and second measures of height and waist circumference, a third measure will be taken. If there I a difference of 0.3kg of greater between the first and second weight measurements, a third measure will be taken. I’m now going to take a third measure of your **[height / weight / waist]**.

## Appendix 5: Participant baseline and follow up questionnaire

**Part 1: Contact details**

\*\*First we are going to collect some information about you. These details will never be stored with your survey answers to ensure that your survey results will always be anonymous.

(Notes: taken only at entry to the study on an iPad or supplied as a written form if preferred, and completed in the presence of the research nurse. Must have a ‘declined to answer’ and ‘don’t know’ option for every question. Contact details will be rechecked at 4 and 12 months)

|  |
| --- |
| What is your full name?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Where do you usually live? Street Address\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Suburb\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_City\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_What is the best phone number to contact you on? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Alternative contact phone number\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Email\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_When were you born? \_\_ \_\_ Day/\_\_ \_\_Month/\_\_ \_\_ \_\_ \_\_YearAre you (tick box)* Male
* Female
* Gender diverse

Which ethnic group do you belong to? Mark the space or spaces which apply to you.* New Zealand European
* Māori
* Samoan
* Cook Islands Maori
* Tongan
* Niuean
* Chinese
* Indian
* Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Please state: eg Dutch, Japanese, Tokelauan (Another box opens to write in when 'Other' is clicked) |

**Part 2: Health questionnaire**

\*\*We are now going to ask you some questions about your health.

**All of the following questions are asked at entry, 4 month and 12 month reviews)**

**Smoking**

**Have you ever smoked cigarettes or tobacco at all, even just a few puffs? Please include pipes and cigars.**  If asked, this does not include marijuana/cannabis.

1 Yes

2 No [go to comorbid conditions section]

.K Don’t know [go to comorbid conditions section]

.R Refused [go to comorbid conditions section]

**Have you ever smoked a total of more than 100 cigarettes in your whole life?**

1 Yes

2 No [go to comorbid conditions]

.K Don’t know [go to comorbid conditions section]

.R Refused [go to comorbid conditions section]

**How often do you now smoke?**

 If more than one frequency given, code the highest one.

1 You don’t smoke now

2 At least once a day

3 At least once a week

4 At least once a month

5 Less often than once a month

.K Don’t know

.R Refused

**Your health and illness**

The following is a list of common health conditions. Please indicate if you have, or have ever had the health condition.

|  |
| --- |
| Tick if you have (or have ever had)the following health condition(s) |
| * Heart disease
* High blood pressure
* Stroke
* Neurological disease e.g. Multiple sclerosis, Parkinsons disease
* Lung disease e.g asthma, COPD, Emphysema
* Ulcer or stomach disease
* Kidney disease
* Liver disease
* Anaemia or blood disease
* Cancer
* Depression or anxiety
* Osteoarthritis, Rheumatoid arthritis or other forms of arthritis
* Obstructive sleep apnoea
* Chronic pain (of greater than 6 months duration)
* Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 |

**Healthcare use**

\*\*We are now going to ask you a few questions about your recent use of health services.

The next question is about seeing a general practitioner (GP) or family doctor. This can be at your usual medical centre or somewhere else.

**How many times did you see a GP in the past 12 months?**

¬¬ \_\_\_\_\_ times (range 0-99)

.K Don’t know

.R Refused

\*\*The next question is about nurses who work at GP clinics and medical centres. These nurses are sometimes called Practice Nurses or Primary Health Care Nurses. This does not include nurses that may have visited you at home, nurses you may have seen in a hospital, or midwives and dental nurses.

**How many times in the past 12 months did you see a Practice Nurse without seeing a GP at the same visit?**

¬¬ \_\_\_\_\_ times (range 0-99)

.K Don’t know

.R Refused

**In the past 12 months, how many times did you go to an after-hours medical centre about your own health? Do not include visits to an emergency department at a public hospital – we will ask about those later.**

\_\_\_\_\_ times (range 0-99)

.K Don’t know

.R Refused

\*\*The next few questions in this section are about your use of hospitals over the past 12 months. I’ll begin by asking you about public hospitals.

**In the last 12 months, have you yourself used a service at, or been admitted to, a public hospital as a patient? This could have been for a physical or a mental health condition.**

1 Yes

2 No [go prescribed medications section]

.K Don’t know [go prescribed medications section]

.R Refused [go prescribed medications section]

**In the last 12 months, at a public hospital, which of the following happened? [Multiple responses possible]**

1. You used the emergency department
	1. (If yes) \_\_\_\_\_times 1-99
2. You used an outpatients department
	1. (If yes) \_\_\_\_\_times 1-99
3. You were admitted for day treatment, but did not stay overnight
	1. (If yes) \_\_\_\_\_times 1-99
4. You were admitted as an inpatient and stayed at least one night
	1. (If yes) \_\_\_\_\_number of nights stayed in total 1-99

5 None of the above

.K Don’t know

.R Refuse

**Prescribed Medications**

Please list all of the medications that you are currently prescribed by a doctor. (Notes: the research nurse can complete this section if provided with a list of medications)

|  |  |  |
| --- | --- | --- |
| Medication name | Dose | Frequency (e.g. twice a day, or weekly) |
|  |  |  |
|  |  |  |
|  |  |  |

**Health measurements**

\*\* I am now going to measure your height, weight and blood pressure.

(Measures taken by research nurses at 0, 4 and 12 months. See Appendix 3 for details of how measures are to be taken, and the number of times to be repeated, up to a maximum of 3)

|  |  |  |  |
| --- | --- | --- | --- |
|  | Measure 1 | Measure 2 | Measure 3 |
| Blood pressure | \_\_\_systolic\_\_\_diastolic | \_\_\_systolic\_\_\_diastolic | \_\_\_systolic\_\_\_diastolic |
| Weight | \_\_\_.\_\_ kg | \_\_\_.\_\_ kg | \_\_\_.\_\_ kg |
| Height | \_\_\_ cm | \_\_\_ cm | \_\_\_ cm |
| Waist | \_\_\_ cm | \_\_\_ cm | \_\_\_ cm |
| HbA1c | Date | Result |  |

\*\*I am now going to take a blood sample (or give you a form to take to the lab) to test your diabetes control. We will forward the result of this test to your health provider.

(Notes: HbA1c lab form will be given to patient, or if able to do so, the research nurse will take a blood sample at the time. This will be at no cost to the patient. See appendix 1 for research nurse script for requesting the above measures from the patient from the New Zealand Health Survey (Ministry of Health. 2015. Adult Questionnaire (Year 5) 1 July 2015 – 30 June 2016: New Zealand Health Survey. Wellington: Ministry of Health. Available from: <http://www.health.govt.nz/publication/questionnaires-and-content-guide-2014-15-new-zealand-health-survey>)

In addition, research nurses will be trained to take the above measures in accordance with guidance provided by the World Health Organization (see Waist circumference and waist–hip ratio: report of a WHO expert consultation, Geneva, 8–11, December 2008. Available from: <http://apps.who.int/iris/bitstream/10665/44583/1/9789241501491_eng.pdf>)

|  |
| --- |
| \*\*We are now going to ask you some questions about how you are managing your own health, and how you feel it is going. Under each heading, please tick the ONE box that best describes your health TODAY. |
| MOBILITY |  |
| I have no problems in walking about | ❑ |
| I have slight problems in walking about | ❑ |
| I have moderate problems in walking about | ❑ |
| I have severe problems in walking about | ❑ |
| I am unable to walk about | ❑ |
| SELF-CARE |  |
| I have no problems washing or dressing myself | ❑ |
| I have slight problems washing or dressing myself | ❑ |
| I have moderate problems washing or dressing myself | ❑ |
| I have severe problems washing or dressing myself | ❑ |
| I am unable to wash or dress myself | ❑ |
| USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)* |
| I have no problems doing my usual activities | ❑ |
| I have slight problems doing my usual activities | ❑ |
| I have moderate problems doing my usual activities | ❑ |
| I have severe problems doing my usual activities | ❑ |
| I am unable to do my usual activities | ❑ |
| PAIN / DISCOMFORT |  |
| I have no pain or discomfort | ❑ |
| I have slight pain or discomfort | ❑ |
| I have moderate pain or discomfort | ❑ |
| I have severe pain or discomfort | ❑ |
| I have extreme pain or discomfort | ❑ |
| ANXIETY / DEPRESSION |  |
| I am not anxious or depressed | ❑ |
| I am slightly anxious or depressed | ❑ |
| I am moderately anxious or depressed | ❑ |
| I am severely anxious or depressed | ❑ |
| I am extremely anxious or depressed | ❑ |

10

0

20

30

40

50

60

80

70

90

100

5

15

25

35

45

55

75

65

85

95

|  |
| --- |
| We would like to know how good or bad your health is TODAY. |
| This scale is numbered from 0 to 100. |
| 100 means the best health you can imagine.0 means the worst health you can imagine. |
| Mark an X on the scale to indicate how your health is TODAY. |
| Now, please write the number you marked on the scale in the box below. |

The best health you can imagine

YOUR HEALTH TODAY =

The worst health you can imagine

**Looking after yourself**

Below are some statements that people sometimes make when they talk about their health. Please show how much you agree or disagree with each statement by choosing your answer. Your answers should be what is true for you and not just what you think the doctor wants you to say. This information will not be shared with your doctor, and no personally identifiable information will be shared with anyone.

**PARTNERS IN HEALTH SCALE***Please circle the number that most closely fits for you*

* + 1. **Overall, what I know about my health condition(s) is:**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Very little |  |  | Something |  |  | A lot |

* + 1. **Overall, what I know about my treatment, including medications of my health condition(s) is:**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Very little |  |  | Something |  |  | A lot |

* + 1. **I take medications or carry out the treatments asked by my doctor or health worker:**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Never |  |  | Sometimes |  |  | Always |

* + 1. **I share in decisions made about my health condition(s) with my doctor or health worker:**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Never |  |  | Sometimes |  |  | Always |

* + 1. **I am able to deal with health professionals to get the services I need that fit with my culture, values and beliefs:**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Never |  |  | Sometimes |  |  | Always |

* + 1. **I attend appointments as asked by my doctor or health worker:**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Never |  |  | Sometimes |  |  | Always |

* + 1. **I keep track of my symptoms and early warning signs (e.g. blood sugar levels, peak flow, weight, shortness of breath, pain, sleep problems, mood):**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Never |  |  | Sometimes |  |  | Always |

* + 1. **I take action when my early warning signs and symptoms get worse:**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Never |  |  | Sometimes |  |  | Always |

* + 1. **I manage the effect of my health condition(s) on my physical activity (i.e. walking, household tasks):**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Never |  |  | Sometimes |  |  | Always |

* + 1. **I manage the effect of my health condition(s) on how I feel (i.e. my emotions and spiritual wellbeing):**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Not very well |  |  | Fairly Well |  |  | Very Well |

* + 1. **I manage the effect of my health condition(s) on my social life (i.e. how I mix with other people):**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Not very well |  |  | Fairly Well |  |  | Very Well |

* + 1. **Overall, I manage to live a healthy life (e.g. no smoking, moderate alcohol, healthy food, regular physical activity, manage stress):**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Not very well |  |  | Fairly Well |  |  | Very Well |

**Self-Care Activities**

The questions below ask you about your self-care activities during the past 7 days. If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

**Diet**

On how many of the last **seven** days did you eat a healthy balanced diet?

0 1 2 3 4 5 6 7

**Exercise**

On how many of the last **seven days** did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking).

0 1 2 3 4 5 6 7

On how many of the last **seven days** did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?

0 1 2 3 4 5 6 7

**Medications**

On how many days of the last seven days did you remember to take all of your prescribed medications?

0 1 2 3 4 5 6 7

**Smoking**

Have you smoked a cigarette - even one puff - during the past seven days?

0 No

1 Yes

**If yes, how many cigarettes did you smoke on an average day?**

Number of cigarettes: \_\_\_\_\_\_\_\_\_

Have you made any quit attempts in the last (4 or 12) months?

This question is only asked at 4 and 12 months.

**Blood Sugar Testing**

Has your health provider recommended that you test your blood sugar at home?

Yes continue /No (go to foot care)

How many times per week has your health provider recommended you test your blood sugar?

Less than once a week Once a week A few times a week Daily Multiple times a day

On how many of the last seven days, did you test your blood sugar?

0 1 2 3 4 5 6 7

**Foot Care**

Has your health provider recommended that you regularly check your feet?

Yes /No (go to medications)

On how many of the last seven days, did you check your feet (to make sure they look healthy and normal)?

0 1 2 3 4 5 6 7

The diabetes distress screening scale

Living with diabetes or prediabetes can sometimes be tough. There may be some problems and hassles concerning diabetes and prediabetes and these can vary greatly in severity. Problems may range from minor life hassles to major life difficulties. Listed below are 2 potential problem areas that people with diabetes may experience. Consider the degree to which each of the 17 items may have distressed or bothered you DURING THE PAST MONTH and circle the appropriate number.

Please note we are asking you to indicate the degree to which each item may be bothering you in your life, not whether the problem is merely true for you. If you feel that a particular item is not a bother or a problem for you, you would circle “1”. If it is very bothersome to you, you might circle “6”.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  | A slight problem | A moderate problem | A somewhat serious problem | A serious problem | A very serious problem |
| 1. Feeling overwhelmed by the demands of living with diabetes or prediabetes
 | 1 | 2 | 3 | 4 | 5 | 6 |
| 1. Feeling that I am often failing with my diabetes or prediabetes routine
 | 1 | 2 | 3 | 4 | 5 | 6 |

(If participants score less than three on each of the above measures)

\*\* Thank you for completing this questionnaire.

If participants score 3 or greater for either of the above two items they go on to complete the following 17 questions.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Not a problem | A slight problem | A moderate problem | A somewhat serious problem | A serious problem | A very serious problem |
| 1. Feeling that diabetes or prediabetes is taking up too much of my mental and physical energy every day.
 | 1 | 2 | 3 | 4 | 5 | 6 |
| 1. Feeling that my doctor doesn’t know enough about my diabetes or prediabetes and its care.
 | 1 | 2 | 3 | 4 | 5 | 6 |
| 1. Feeling angry, scared, and/or depressed when I think about living with diabetes or prediabetes
 | 1 | 2 | 3 | 4 | 5 | 6 |
| 1. Feeling that my doctor doesn’t give me clear enough directions on how to manage my diabetes or prediabetes.
 | 1 | 2 | 3 | 4 | 5 | 6 |
| 1. Feeling that I am not testing my blood sugars often enough.
 | 1 | 2 | 3 | 4 | 5 | 6 |
| 1. Feeling that I an often failing with my diabetes or prediabetes routine.
 | 1 | 2 | 3 | 4 | 5 | 6 |
| 1. Feeling that friends or family are not supportive enough of my self-care efforts (e.g. planning activities that conflict with my schedule, encouraging me to eat the “wrong” foods).
 | 1 | 2 | 3 | 4 | 5 | 6 |
| 1. Feeling that diabetes or prediabetes controls my life.
 | 1 | 2 | 3 | 4 | 5 | 6 |
| 1. Feeling that my doctor doesn’t take my concerns seriously enough.
 | 1 | 2 | 3 | 4 | 5 | 6 |
| 1. Not feeling confident in my day-to-day ability to manage my diabetes or prediabetes.
 | 1 | 2 | 3 | 4 | 5 | 6 |
| 1. Feeling that I will end up with long-term complications no matter what I do.
 | 1 | 2 | 3 | 4 | 5 | 6 |
| 1. Feeling that I am not sticking closely enough to a good meal plan.
 | 1 | 2 | 3 | 4 | 5 | 6 |
| 1. Feeling that friends or family don’t appreciate how difficult living with diabetes or prediabetes can be.
 | 1 | 2 | 3 | 4 | 5 | 6 |
| 1. Feeling overwhelmed by living with the demands of living with diabetes or prediabetes.
 | 1 | 2 | 3 | 4 | 5 | 6 |
| 1. Feeling that I don’t have a doctor that I can see regularly enough about my diabetes or prediabetes.
 | 1 | 2 | 3 | 4 | 5 | 6 |
| 1. Not feeling motivated to keep up my diabetes or prediabetes self-management.
 | 1 | 2 | 3 | 4 | 5 | 6 |
| 1. Feeling that friends or family don’t give me the emotional support that I would like.
 | 1 | 2 | 3 | 4 | 5 | 6 |

\*\* Thank you for completing this questionnaire.

## Consort-Logo-Graphic-30-12-071Appendix 6: CONSORT 2010 checklist of information to include when reporting a randomised trial\*

|  |  |  |  |
| --- | --- | --- | --- |
| **Section/Topic** | **Item No** | **Checklist item** | **Reported on page No** |
| **Title and abstract** |
|  | 1a | Identification as a randomised trial in the title |  |
| 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) |  |
| **Introduction** |
| Background and objectives | 2a | Scientific background and explanation of rationale |  |
| 2b | Specific objectives or hypotheses |  |
| **Methods** |
| Trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio |  |
| 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons |  |
| Participants | 4a | Eligibility criteria for participants |  |
| 4b | Settings and locations where the data were collected |  |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered |  |
| Outcomes | 6a | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed |  |
| 6b | Any changes to trial outcomes after the trial commenced, with reasons |  |
| Sample size | 7a | How sample size was determined |  |
| 7b | When applicable, explanation of any interim analyses and stopping guidelines |  |
| Randomisation: |  |  |  |
|  Sequence generation | 8a | Method used to generate the random allocation sequence |  |
| 8b | Type of randomisation; details of any restriction (such as blocking and block size) |  |
|  Allocation concealment mechanism | 9 | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned |  |
|  Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions |  |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how |  |
| 11b | If relevant, description of the similarity of interventions |  |
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes |  |
| 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses |  |
| **Results** |
| Participant flow (a diagram is strongly recommended) | 13a | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome |  |
| 13b | For each group, losses and exclusions after randomisation, together with reasons |  |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up |  |
| 14b | Why the trial ended or was stopped |  |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group |  |
| Numbers analysed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups |  |
| Outcomes and estimation | 17a | For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) |  |
| 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended |  |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory |  |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) |  |
| **Discussion** |
| Limitations | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses |  |
| Generalisability | 21 | Generalisability (external validity, applicability) of the trial findings |  |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence |  |
| **Other information** |  |
| Registration | 23 | Registration number and name of trial registry |  |
| Protocol | 24 | Where the full trial protocol can be accessed, if available |  |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders |  |

## Appendix 7: mHealth evidence reporting and assessment (mERA) guidelines, including mHealth essential criteria88

| **Criteria** | **Item no** | **Notes** | **Page no where item is reported** |
| --- | --- | --- | --- |
| Infrastructure (population level) | 1 | Clearly presents the availability of infrastructure to support technology operations in the study location. This refers to physical infrastructure such as electricity, access to power, connectivity etc. in the local context. Reporting X% network coverage rate in the country is insufficient if the study is not being conducted at the country level |  |
| Technologyplatform | 2 | Describes and provides justification for the technology architecture. This includes a description of software and hardware and details of any modifications made to publicly available software |  |
| Interoperability/Health information systems (HIS) context | 3 | Describes how mHealth intervention can integrate into existing health information systems. Refers to whether the potential of technical and structural integration into existing HIS or programme has been described irrespective of whether such integration has been achieved by the existing system |  |
| Intervention delivery | 4 | The delivery of the mHealth intervention is clearly described. This should include frequency of mobile communication, mode of delivery of intervention (that is, SMS, face to face, interactive voice response), timing and duration over which delivery occurred |  |
| Intervention content | 5 | Details of the content of the intervention are described. Source and any modifications of the intervention content is described |  |
| Usability/content testing | 6 | Describe formative research and/or content and/or usability testing with target group(s) clearly identified, as appropriate |  |
| User feedback | 7 | Describes user feedback about the intervention or user satisfaction with the intervention. User feedback could include user opinions about content or user interface, their perceptions about usability, access, connectivity, etc |  |
| Access of individual participants | 8 | Mentions barriers or facilitators to the adoption of the intervention among study participants. Relates to individual-level structural, economic and social barriers or facilitators to access such as affordability, and other factors that may limit a user’s ability to adopt the intervention |  |
| Cost assessment | 9 | Presents basic costs assessment of the mHealth intervention from varying perspectives. This criterion broadly refers to the reporting of some cost considerations for the mHealth intervention in lieu of a full economic analysis. If a formal economic evaluation has been undertaken, it should be mentioned with appropriate references. Separate reporting criterion are available to guide economic reporting |  |
| Adoption inputs/ programme entry | 10 | Describes how people are informed about the programme including training, if relevant. Includes description of promotional activities and/or training required to implement the mHealth solution among the user population of interest |  |
| Limitations for delivery at scale | 11 | Clearly presents mHealth solution limitations for delivery at scale |  |
| Contextual adaptability | 12 | Describes the adaptation, or not, of the solution to a different language, different population or context. Any tailoring or modification of the intervention that resulted from pilot testing/usability assessment is described |  |
| Replicability | 13 | Detailed intervention to support replicability. Clearly presents the source code/screenshots/ flowcharts of the algorithms or examples of messages to support replicability of the mHealth solution in another setting |  |
| Data security | 14 | Describes the data security procedures/ confidentiality protocols |  |
| Compliance with national guidelines or regulatory statutes | 15 | Mechanism used to assure that content or other guidance/information provided by the intervention is in alignment with existing national/regulatory guidelines and is described |  |
| Fidelity of the intervention | 16 | Was the intervention delivered as planned? Describe the strategies employed to assess the fidelity of the intervention. This may include assessment of participant engagement, use of backend data to track message delivery and other technological challenges in the delivery of the intervention |  |