ISRCTN12014792 https://doi.org/10.1186/ISRCTN12014792

Diabetes My Way: your home for online diabetes support

Submission date	Recruitment status	[X] Prospectively registered
17/06/2019	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/07/2019	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
15/10/2025	Nutritional, Metabolic, Endocrine	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Type 2 diabetes (T2D) affects about 7% of the UK population. Sub-optimal management of T2D leads to serious complications such as heart attacks, kidney failure and blindness. Poor patient knowledge about T2D contributes to sub-optimal levels of glucose and cardiovascular risk factors. There is major variation in the level of knowledge that patients have about diabetes; major variation in the quality of diabetes care across general practices in Greater Manchester (GM); practical and financial challenges for delivering behavioral interventions supporting healthier lifestyles; major blocks in clinical care because of diabetes-related psychological distress - all compounded by low attendance rates in clinics and structured education in some patient groups. The aim of this study is to assess whether digital interventions improve T2D self-management across Greater Manchester.

Who can participate?
Patients with type 2 diabetes, registered with a GP who can provide the DMW support, and who own a digital device.

What does the study involve?
Digital interventions are offered to all patients with T2D across Greater Manchester including access to educational resources, their medical records, personalised care planning, goal-setting tools, personalised care quality reporting against Care Standards and glucose monitoring displays through DiabetesMyWay (DMW). Sub-groups of patients also have access to online behavioural interventions (Oviva; Changing Health), cognitive intervention (MyCognition); targeted incentives to improve clinic attendance rates (BillawayHealth) and more flexible clinic interactions with patients (Smart Care Videoconferencing). Clinicians have access to patient data including information on the impact of the intervention, enabling personalised treatment plans.

What are the possible benefits and risks of participating?
If the Intervention is found to support self-care and clinical care in T2D across GM then this evidence could justify rollout of these interventions across the NHS in England.

Where is the study run from?
NIHR CRN: Greater Manchester (UK)

When is the study starting and how long is it expected to run for?
October 2018 to March 2026

Who is funding the study?
Innovate UK

Who is the main contact?
Mr Ewan Jones
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Contact information

Type(s)
Public

Contact name
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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
261268

Protocol serial number
42204

Study information

Scientific Title
Improving care and self-management in type 2 diabetes through digital interventions

Acronym
DMW

Study objectives
To assess whether digital interventions improve self-management of type 2 diabetes across Greater Manchester.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/06/2019, Greater Manchester South Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, HRA NRES Centre Manchester, M1 3DZ, UK; Tel: +44 (0)207 104 8345; +44 (0)207 104 8063; Email: nrescommittee.northwest-gmsouth@nhs.net), ref: 19/NW/0365

Study design
Non-randomised; Interventional; Design type: Treatment, Process of Care, Education or Self-Management, Psychological & Behavioural, Other

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
A. Design
This will be a prospective cohort study. The effectiveness of interventions will be assessed within patients by comparing before and after intervention levels of risk factors such as glucose control as assessed by HbA1c levels. Within the short time frame made available by the funders, a randomised control trial is not possible.

In a future substantial amendment to this application, the researchers plan to compare, when appropriate, changes in risk factor levels in those receiving interventions with control groups of people choosing to not take up the offer of interventions matched for age, sex, ethnicity, deprivation (defined by GP postcode) and diabetes type.

B. Overview of methodology
B1: Identification of participants

In this study, the digital interventions will be offered as an adjunct to current diabetes care to all people with a diagnosis of T2D within GM (~150K patients across 10 CCGs and 450+ Practices). Enrolment to the study will be entirely voluntary. Selection criteria are described in Section 6.1 of the protocol. Based on current DMW usage (10% of the Scottish diabetes population), we anticipate that there will be ~7000-14,000 active users at the end of the intervention period (31 /03/2020). It is anticipated that the service will go live during Spring 2019.

Once live, DMW and the associated digital interventions will be promoted locally via primary and secondary care health care professionals and by the GM Diabetes Clinical Research Network team. Identification of potential participants will take place primarily through searches of primary care practice databases to identify patients with T2D. Practice searches will be facilitated by GCP-trained staff of the Greater Manchester Diabetes Clinical Research Network whenever possible. The researchers anticipate that letters from the practice will, in most cases, make initial contact with potential study participants. In some cases a text message from the practice to the patient or an email message sent from the practice to the patient will be used. The researchers are also planning to publicise the study through local diabetes networks, pharmacies, opticians, external media and through 3rd party organisations including Diabetes UK.

B: Registration
B1: Registration with online Patient Services: If participants are interested to take part after reading the introductory letter, email, text and patient information sheet (see submitted documents), then they will be invited to register for online Patient Services with their GP practice staff. Patients will probably be invited to fill in a paper form in order to do this (will depend on the system in place at each practice). Patient registers their basic information with Patient Services and unique codes provided by Patient Services enable signup to the system (https://www.patientservices.co.uk/login) and on-going communications with their primary care provider.

B2. Registration with DiabetesMyWay: When participants are accepted for online Patient Services they will be able to register online with DiabetesMyWay (patients are provided web address via the patient information sheet), which will give participants access to the system. Patients will be given access to terms and conditions and privacy notices.
Patients will be invited to confirm that they have T2D and are 18 years of age or older. Potential participants will have as much time as they need to decide to take part. Consent will be implied through reading the patient information sheet, conditions and notices and will be captured on first system access.

C: What will be provided to each participant
All participants will be offered access to DiabetesMyWay and will also be offered an assessment of their cognitive function (MyCognition)

1) DiabetesMyWay: The DiabetesMyWay interactive website and mobile app will provide participants with high-quality information about diabetes including access to the information in their medical records. Information is presented in the form of videos, interactive content and carefully worded and easily understood text. Participants will be provided with the ability to plan their care, set goals and look at their sugar and other results in a way that is easy to understand. These tools are expected to greatly support people in managing diabetes.

2) MyCognition assessment: participants will be invited to perform 5 short tests to assess which brain functions.

A selected number of participants will be invited to take part in one additional targeted digital intervention from this list:
• Behavioural interventions (Oviva or Changing Health)
• MyCognition
• BillawayHealth
SmartCareDoc video conferencing
Offers to participate in studies of targeted digital interventions will be based on selection criteria described in Section 6.3 of the protocol.

i) Oviva: The Oviva programme provides 8 weeks of one-to-one support from a diabetes specialist dietitian, along with providing high-quality information about healthy lifestyles. Participants can either use their online resources and app or choose to keep in contact with the team through phone calls, printed materials and DVD content sent to their home. The online programme can be accessed anytime and anywhere via phone or computer including dietitian coaching at a convenient time. The research will monitor changes in sugar levels (HbA1c), weight, blood pressure and cholesterol. At the end of the programme participants will be invited to complete an online questionnaire to assess the usability of the programme.

ii) Changing Health: Changing Health provides a 12-week programme starting with short videos and articles about type 2 diabetes, diet, exercise and goal setting via the app. Then, via phone, participants will meet a personal lifestyle coach who will support lifestyle changes. The Changing Health app allows participants to monitor meals, weight loss
and track goals. The research will monitor changes in sugar levels (HbA1c), weight, blood pressure and cholesterol monitored from GP records. At the end of the programme participants will be invited to complete an online questionnaire to assess the usability of the programme.

iii) MyCognition intervention: The MyCognition app involves playing a fun video game over 12 weeks. Before starting, participants will be invited to perform 5 short questionnaires to assess which of their brain functions can be improved (these questionnaires are part of the app; please see https://mycognition.com/). Participants will be invited to complete an online questionnaire assessing their current ability to cope with living with diabetes, and in particular their level of distress linked to the condition.
These brief questionnaires are followed by playing a fun video game, which is personalised to participants' test results, for 15 minutes a day with increasing challenges designed to improve memory, learning skills and concentration and decision-making skills. The app also provides tips and guidance on everything from diet to exercise and practical guidance on sleep and work habits. At the end of the programme participants will be invited to complete the brief questionnaires again looking for improvements in cognitive function and level of diabetes distress. At the end of the programme participants will be invited to complete an online questionnaire to assess the usability of the programme.

iv) BillawayHealth intervention: The study will focus primarily, but not exclusively, on research-active practices currently supported by the Diabetes Clinical Research Network. Enrolment will follow this routine:
• BillawayHealth secures rechargeable MasterCards
• The Diabetes Clinical Research Network research nurses will search the practice register to identify patients with poor clinic attendance (those in the bottom quartile for clinic attendance; such as those who have not attended for >18 months).
• These research nurses will make initial contact with participants through communication from the GP practice by letter (see participant information sheet relating to BillawayHealth), clinical contact, patient support groups and/or DMW newsletters.
• These communications will request that the patient book a diabetes clinic appointment with

the GP practice and, after reading the patient information sheet on the DMW website, to register with Patient Services (as described above) and then with DMW as a BillawayHealth user. Patients will be informed that rewards will not be given for clinic
attendances that are unrelated to diabetes such as flu vaccination appointments.
• As with the other digital interventions, BillawayHealth registration will be through the DMW website.
• At registration, patients will provide their preferred ID such as a their mobile phone number or email address which will be used by BillawayHealth to identify the patient when they attend clinic and then to authorise payment.
• If a patient fails to attend they will be offered a follow-up call only if this would be offered in routine practice. This ensures that any improvements associated with the intervention are not simply attributed to follow-up calls.
• If patients attend their diabetes clinic appointment then a member of the practice clinical staff such as the practice nurse, GP or one of the Diabetes Clinical Research Network research nurses uses the app to inform BillawayHealth that the patients has attended (using the patient ID e.g. mobile phone number or email address)
• Contacting BillawayHealth through the app initiates the mailing of the MasterCard to the patient by a secure MasterCard processor who will be provided with the patient's name and address by BillawayHealth (this will be the same process that consumers experiences when receiving a credit card).
• Contacting BillawayHealth also generates a payment authorisation code that is given or electronically sent to the patient to activate the card when it is delivered to them.
• The value on card (£10) will be available within 2-3 days to the patient. A merchant category code within the card will prevent it being used to purchase alcohol or tobacco.
• Another appointment will be made for the patient to attend clinic as clinically indicated. If this appointment falls within the timeframe of the study (ending 31 March 2020) then the patient will be eligible for another reward. A maximum of 3 rewards per patient will be permitted within the study period.
• The system described above will apply for 2nd and 3rd rewards except that the value of the reward will increase to a maximum of £25.
• At the end of the intervention period, participant will be invited to complete an online questionnaire to assess their feedback on the use of the BillawayHealth intervention (see usability questionnaire).
v) Enrolment to SmartCareDoc: The study will focus primarily, but not exclusively, on research-active practices currently supported by the Diabetes Clinical Research Network. Enrolment will follow this routine:
• The Diabetes Clinical Research Network research nurses will promote the service in research-active practices across Greater Manchester
• These research nurses or practice nurses will make initial contact with participants through communication from the GP practice by letter (see participant information sheet relating to SmartCareDoc), clinical contact, patient support groups and/or DMW newsletters.
• Interested patients will register at their practice's reception for Online Patient Services and then DiabetesMyWay so that the research team know that the patient is using this app and enable some general demographic information (age, sex, ethnicity, duration of diabetes, medication) to be collected from the primary care record.
• The participant will be invited to download the SmartCareDoc App to your tablet or phone from the App Store or Google Play.
• The participant will select their GP practice from the list and register their details on the app.
• The participant will be invited to choose appointments at times that are convenient for them.
• The participant will be advised to find somewhere appropriate to hold the personal conversation with the clinician and ensure that they have a secure and stable Internet connection.

• The participant will be advised log in to the app and check that their speakers and microphone are working and that the camera is using is facing the right way.
• The participant will then find himself or herself in a virtual waiting room. The appointment will start when the doctor or nurse is ready.
• The participant will then be invited to complete an online questionnaire to assess their feedback on the use of the video conferencing facility (see usability questionnaire).
vi) Enrolment to 1:1 Interviews and focus groups: The researchers will be inviting a small number of participants (<40) to take part in 1:1 Interviews and focus groups with a research psychologist. Details will be provided in a substantial amendment to this ethics application.

Intervention Type
Other

Primary outcome(s)
1. Average within-person changes in HbA1c in participants using Diabetes My Way (measured by either immunoassay, ion-exchange high-performance liquid chromatography, boronate affinity HPLC, or enzymatic assays in an accredited NHS biochemistry lab) at some time prior to enrolment and after 3-6 months as clinically indicated
2. Average within-person change in HbA1c in participants using the behavioural interventions (Oviva and Changing Health) (measured by either immunoassay, ion-exchange high-performance liquid chromatography, boronate affinity HPLC, or enzymatic assays in an accredited NHS biochemistry lab) at some time prior to enrolment and after 3-6 months as clinically indicated
3. Average within-person changes in diabetes distress scores in participants using MyCognition as assessed by online questionnaire (www.diabetesed.net/page/_files/diabetes-distress.pdf) prior to intervention and after 3 to 6 months
4. Within-person changes in attendance rate and estimate associated costs in participants using BillawayHealth; attendance rates assessed from practice records comparing before and after the intervention, which may last from when the study starts until October 2020

Key secondary outcome(s))
1. Average within-person changes in systolic blood pressure, cholesterol, smoking and bodyweight/BMI in participants using Diabetes My Way:
1.1. Blood pressure measured by sphygmomanometer
1.2. Cholesterol measured using conventional methods in an accredited NHS biochemistry lab
1.3. Smoking assessed from data collected from the primary care record
1.4. Bodyweight assessed using calibrated scales in primary care
1.5. BMI assessed from weight in kilograms divided by height squared (in metres)
2. Average within-person changes in systolic blood pressure, cholesterol, smoking and bodyweight/BMI in participants using the behavioural interventions (Oviva and Changing Health):
2.1. Blood pressure measured by sphygmomanometer
2.2. Cholesterol measured using conventional methods in an accredited NHS biochemistry lab
2.3. Smoking assessed from data collected from the primary care record
2.4. Bodyweight assessed using calibrated scales in primary care
2.5. BMI assessed from weight in kilograms divided by height squared (in metres)

All secondary outcomes assessed in primary care sometime prior to enrolment and after 3 to 6 months as clinically indicated

Completion date
31/03/2026

Eligibility

Key inclusion criteria
Inclusion criteria for the main intervention (DMW):
1. Age > = 18 years
2. T2D (as determined by primary or secondary care records)
3. Registered with GP in GM or other diabetes care provider e.g. hospital is linked to DMW
4. Self-certified understanding of spoken and written English or available support from family or friends
5. Able to access a digital device

Additional selection criteria for participants/practices offered other digital interventions:
MDMW will apply additional selection criteria (described under a-d below) prior to patients being offered access to targeted digital interventions. Once offered, participants will be encouraged to discuss the option of their participation with these targeted digital interventions with their regular clinical team members responsible for their diabetes care. The final decision to participate in these targeted digital interventions will rest with the patient.
1. Behavioural interventions (Oviva or Changing Health) will each be offered to 600 participants. The researchers will exclude people self-reporting current pregnancy, those treated with insulin (Changing Health only), those with no contraindication for weight loss or physical activity (Changing Health only) and those receiving diabetes care at a location other than their GP surgery.
2. MyCognition assessment will be offered to all DMW participants and the MyCognition intervention will be offered to the first 1000 participants who complete the assessment (as explained above). There will be no additional selection criteria.
3. Billaway: This intervention will be offered to up to 600 patients in the lowest quartile for diabetes clinic attendance rates. When the researchers have access to attendance rate data then this, for example, might mean offering the intervention to people who had failed to attend their previous two diabetes clinic appointments. The researchers will focus primarily, but not exclusively, on research-active practices currently supported by the Diabetes Clinical Research Network. The researchers will not invite those receiving diabetes care somewhere other than the GP surgery.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Age < 18 years
2. No T2D (as determined by primary or secondary care records)

3. Not registered with GP in GM
4. Unable to understand spoken and written English
5. Unable to access a digital device

Date of first enrolment
26/07/2019

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NIHR CRN: Greater Manchester
2nd floor, CityLabs
Nelson Street
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United Kingdom
M13 9NQ

Sponsor information

Organisation
The University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
Innovate UK; Grant Codes: 104658

Alternative Name(s)

Technology Strategy Board

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the limits of the ethics approval.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version 1.7	10/12/2021	17/08/2022	No	No