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# Enhancing type 2 diabetes treatment through digital plans of care

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 28/01/2020 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 30/01/2020 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 06/07/2022 | Nutritional, Metabolic, Endocrine | [ ] Record updated in last year |

**Plain English summary of protocol**

Background and study aims
Type 2 diabetes is a common condition that causes the level of sugar (glucose) in the blood to become too high. It's caused by problems with a chemical in the body (hormone) called insulin. It's often linked to being overweight or inactive, or having a family history of type 2 diabetes. This trial will evaluate how effective a mobile app is at helping people with type 2 diabetes to learn about their condition and manage it and whether the desired result has a positive affect on their health.

Who can participate?
People aged over 18 years with type 2 diabetes, without a history of neuropathy who owns a smartphone.

What does the study involve?
Clincians will use Healum software to deliver content to a patient facing mobile app. Patients will use the app to navigate their care including patient education, local services, goal setting, vieiwing their test results.

What are the possible benefits and risks of participating?
Benefits: Extra help and support from the mobile app
Risks: Only risk is becoming too over-reliant on the technology

Where is the study run from?
Waters Green health centre (UK)

When is the study starting and how long is it expected to run for?
April 2020 to December 2022

Who is funding the study?
Innovate UK

Who is the main contact?
Jonathan Abraham
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# Contact information

### Type(s)
Public

### Contact name
Mr Jonathan Abraham

### Contact details
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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
272569

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
H001, IRAS 272569

# Study information

### Scientific Title
A randomised controlled pilot study to explore the impact and efficacy of the Healum collaborative care planning software and app on condition management in the type 2 diabetes mellitus population in NHS primary care

### Study objectives
Providing Type 2 Diabetes patients with a mobile app designed to deliver integrated plans of care and support and content from primary care health professionals, has a positive impact on health outcomes.

### Ethics approval required

Old ethics approval format

## Ethics approval(s)
Approved 14/12/2021, North West – Greater Manchester West REC (3rd Floor Barlow House, 4 Minshull Street, Manchester M1 3DZ; +44 (0)2071048384; gmwest.rec@hra.nhs.uk), ref: 20/NW /0203

## Study design
Multi-centre interventional randomized controlled trial

## Primary study design
Interventional

## Study type(s)
Treatment

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

## Interventions
Clincians will use healum software to deliver content to a patient facing mobile app. Patients will use the app to navigate their care including patient education, local services, goal setting, vieiwing their test results.

A randomised controlled trial with active variable groups and control groups will be undertaken with the intention of gathering preliminary data on the intervention that will inform a longer RCT with a higher power calculation. We will have an anonymised control group and data will be consented and pulled from Practice records. We will use the following framework:

Intervention group (variable group):
Patients will have access to the Healum app and will receive content from a HCP once per week through the app.
Variable group will have visits and be checked for the same measures at 0 and 6 months with a nurse or GP.

Control group:
Patients with Type 2 Diabetes that receive usual standard of care. Anonymized data will be pulled from the data held by the surgery

Multi Disciplinary Teams
In order to measure the operational efficiency, resource and cost savings to a primary care organisation, we will be comparing the time and resources required for each practice to complete certain tasks while using the software with the time and resources that were required for them to complete certain tasks previously when they did not use the software. We will conduct interviews with all the staff members using the software to assess usability and understand the specific problems that the care planning software helped to solve in providing patients with the most consistent and comprehensive plan of care and support to match their goals.

Consenting
Participants identified suitable for the variable group will be contacted and asked if they are

keen to participate in the study. This recruitment can be done opportunistically through direct contact with the patient at the surgery or through a mailout for those patients who are coming for their regular review in the coming months. Ahead of their review, the participant will be provided a Participant Information Sheet, and Consent Form, which they will read, have the opportunity to ask questions about and sign either physically or digitally. This allows us to run the study and gather learnings with as much of the burden resting on digital tools as possible, instead of on human resource, ultimately improving the scalability of the digital platform and reducing the burden on NHS resources.

Demographic Data
Upon beginning of the study a practice nurse or healthcare assistant will launch the Healum software inside of the EMIS portal. This is possible owing to the Healum software being integrated with EMIS, allowing a clinician to create patient profile inside of Healum. Key details from the patient record are then pulled into the Healum software such as name and demographic data. The clinician then sends the patient the app via SMS from the Healum software. Participants download the app and further consent to share the data captured in their app back with the GP practice. Participants can provide additional demographic and preference data via their app. This demographic data will be coded to unique participant IDs and patient direct identifiable information will be removed (name, phone number, email, month and day of birth, and address; first three characters of postcode will remain in order to allow us to use the Index of Multiple Deprivation). All information that would link unique IDs to patient identifiable information will be held securely by Healum in compliance with GDPR and guidance set out by the MRA on research data (as outlined in the IRAS form).

Software and App Set-up and Training
Software and app set up and training will be done by Healum with practice staff and participants. This will be done with face-to-face training, support videos and FAQs, local experts and Healum floor walkers.

Recruitment procedure
Patients who meet our inclusion and exclusion criteria will be identified through the practice's EHR. We will then approach those whose 6-month bi-annual review is approaching as to not interrupt standard of care. We will contact these patients when the are contacted to come in for their review using the mechanism the surgery has in place (email, text, post, phone call). We will also place a web link on the practice's website and place leaflets in the surgery. We will provide clinicians with leaflets so that they can pass them to patients that might be eligible and approaching their review.
Simple randomisation will be used at a practice level. Each practice will submit participant numbers into the secure randomization software that will use a random number generator to assign patients into control and exposed groups. Whilst each practice will have to recruit between 35-40 patients in total and there does exist some risk of imbalance / statistical power at a practice level; there are 11 practices each going through the same exercise which mitigates that risk at an aggregate level for the study.
As patients are identified, they will be entered into a locally, securely held database that will record their name, age, gender, review date, if they agree to participate or the reason if they decline.

Qualitative patient & staff data
In the last 2 weeks and 2 weeks following the study, participants will be invited to join a focus group led by a third party interviewer. Four focus groups will take place with groups of 4-5 patients. Focus group discussions will be an additional option for participants and reimbursement will be made for travel and subsistence. Focus group discussions will be

recorded. For all feedback received, we attempt to cover a sampling framework that provides representation from various age, gender, and SES.

### Intervention Type
Behavioural

### Primary outcome(s)
At baseline and 6-months:
1. HBA1C measured using blood test
2. Weight (kg)
3. Blood pressure (mmHg)
4. Quality of life measured using the E5D-QoL

### Key secondary outcome(s))
1. Patient's engagement levels measured by their capability, opportunity and/or motivation to change their behaviour measured using in-app analytics
2. Mutli-disciplinary team working across the Type 2 Diabetes care pathway in primary care to save time and improve the consistency of the delivery of care plans, information and behaviour change interventions measured using a focus group

### Completion date
30/12/2022

## Eligibility

### Key inclusion criteria
1. Capable of reading the PIS and giving informed consent themselves
2. Over 18 years old
3. Diagnosis of type 2 diabetes mellitus
4. Have a smartphone and are able to use 3 apps that are not categorised as Utilities (ie. clock, calculator, phone, etc)
5. HbA1c of over 65 mmol/mol

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria

Current exclusion criteria as of 06/07/2020:
1. Have a history of peripheral or optic neuropathy
2. Pregnant
3. Cannot read or understand English

Previous exclusion criteria:
1. Have a history of peripheral or optic neuropathy
2. Pregnant

### Date of first enrolment
01/08/2020

### Date of final enrolment
31/08/2022

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Vernova CIC**
Waters Green Medical Centre
23 Sunderland St
Macclesfield
United Kingdom
SK11 6JL

## Sponsor information

### Organisation
Healum Ltd

## Funder(s)

### Funder type
Government

### Funder Name
Innovate UK

### Alternative Name(s)
UK Research and Innovation Innovate UK, innovateuk

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

### IPD sharing plan summary
Other

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |