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Digital behaviour change and type 2 diabetes remission

Submission date
19/03/2021

Recruitment status
No longer recruiting

Registration date
01/06/2021

Overall study status
Completed

Last Edited
12/05/2023

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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.
The number of people living with type 2 diabetes in the UK is growing rapidly. The majority of people will require medications to manage their type 2 diabetes, and can also have other health problems such as high blood pressure, pain or depression. Often these conditions are treated with further medications. This can be upsetting, as people can feel their health is out of control, and they can have issues such as the hassle of organising daily medications. The cost of treating type 2 diabetes for the NHS is very high.

Recently a big study showed that weight loss delivered with intensive one-to-one support can help people with type 2 diabetes come off their medications for blood pressure and blood sugar. Participants also achieved healthy blood sugar levels. Such benefits are wonderful for patients and save significant NHS resources.vUnfortunately intensive programmes like this are expensive.

Oviva™ has developed “Diabetes 800” which can be delivered remotely, instead of face-to-face, and is already delivered in the UK. Not only is this lower cost, it also offers more flexibility to the individual patient.

In this project we plan to study the effect of Diabetes 800 on weight loss, blood sugar control and medication use in 250 people with type 2 diabetes.

We then plan to use the information we get from this project to work out exactly how much money Diabetes 800 could save the NHS if it were rolled out across the country. We hope that this work will provide people with type 2 diabetes more options to manage and improve their health.

Who can participate?
People with type 2 diabetes not on insulin will be invited to participate in the study via their GP practice.

What does the study involve?
Diabetes-800 is a behaviour change intervention delivered via an app. The programme is 12 months in duration inclusive of a 12 week low-calorie diet (approximately 800 calories per day), a four week food reintroduction phase and nine months of behaviour change support from a registered dietitian, with additional support from a diabetes specialist nurse where required. At baseline, the patient's glucose (HbA1c), lipids, blood pressure, medications, physical activity and a measure of quality of life will be collected. These outcomes will then be collected at 12 months and 24 months to see whether Diabetes-800 can improve weight, blood sugar, blood pressure, cholesterol, reduce the number of diabetes medications and improve physical activity and quality of life. An additional HbA1c measurement will be taken at six months.

What are the possible benefits and risks of participating?
The benefits for the participant are access to the Diabetes 800 programme, the Oviva app, and you will also be given a device which measures your steps (a Fitbit), and electronic scales for free. We do not consider there to be any serious disadvantage if you take part in this study. The only disadvantage would be the time it takes (5 to 10 minutes) to complete a short questionnaire about your experiences with the Diabetes-800 programme.

Where is the study run from?
University of Westminster (UK)

When is the study starting and how long is it expected to run for?
January 2019 to April 2023

Who is funding the study?
Innovate UK

Who is the main contact?
Dr Nicola Guess, nicola.guess@kcl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Nicola Guess

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
The ‘DR-EAM’ study – (Type 2) Diabetes weight Reduction - Evaluation of App coaching Model

Acronym
DREAM

Study objectives
We aim to evaluate the clinical outcome benefits and NHS return on investment of an existing Digital Behaviour Change Intervention based on the published literature of Low Calorie Diets in T2DM called Oviva Diabetes 800 compared to usual NHS care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/12/2020, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (St Luke's Hospital, Extension Block, Little Horton Lane, Bradford, BD5 0NA, UK; +44 (0)207 104 8109; bradfordleeds.rec@hra.nhs.uk), ref: 20/YH/0296

Study design
Interventional non-randomized single-arm real-world evaluation with a matched control group

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Diabetes-800 is a digital, remote behaviour change intervention, which provides personal 1 to 1 support and expert advice delivered either over the phone or via the Oviva App. . The programme is 12 months in duration inclusive of a 12 week low-calorie diet (approximately 800 calories per day), a four week food reintroduction phase and nine months of behaviour change support from a registered dietitian, with additional support from a diabetes specialist nurse where required.
During the low-calorie diet, participants will be following a TDR or Total Diet Replacement; they will consume four meal replacement products per day and no food or calorie-containing drinks.

In the food reintroduction phase, participants will move back onto food consumption, but will increase their calorie intake each week as directed by their dietitian. In the maintenance phase you will be supported to maintain weight loss or achieve further weight loss if goal weight has not been reached.
As part of the programme, participants will be given access to the Oviva app where they can log their meals, thoughts, feelings, activity levels and they will be able to communicate with their dietitian through the app. If participants cannot or do not want to access the app, they will be supported with regular phone calls from the dietitian.
This study will evaluate the effectiveness of this intervention combined with IoT GSM-connected BodyTrace weight scale and Bluetooth-connect Fitbit Inspire physical activity tracker with added linked patient-engagement ML-algorithms and will compare to a matched dataset for those subject to usual care, with data collected at 6, 12 and 24 months. The clinical outcomes will be evaluated using simple statistical tests such as paired t-tests as this is a simple within-group non-randomised design.
The study will also involve an economic evaluation of the Diabetes-800 programme compared to the matched control group accessing usual care. The impact of Diabetes-800 on NHS costs will be estimated, and extrapolated over a 5-year time period, relative to usual care. Biomedical variables and prescribing data for the intervention group during the 2-year study period will be analysed, and compared with equivalent data from a control dataset of non-participating patients with type 2 diabetes in South London. This control dataset will be used to represent usual care.
Trajectories for prescribing and for biomedical variables such as HbA1c, weight, blood pressure and cholesterol for years 3-5 will be estimated for the intervention group and for usual care based on evidence from the clinical literature.

Intervention Type
Behavioural

Primary outcome(s)
Measured at baseline and 24 months:
1. Weight (measured by BodyTrace weight scale)
2. HbA1c (by venous sample collected at GP practice)

Key secondary outcome(s))
1. Weight (measured by BodyTrace weight scale) and HbA1c (by venous sample collected at GP practice) at baseline and 12 months
2. Blood pressure (measured at GP practice) at baseline, 12 and 24 months
3. Cholesterol (measured at GP practice) at baseline, 12 and 24 months
4. Physical activity (measured using a Fitbit) at baseline, 12 and 24 months
5. Quality of life (measured by EQ-5D) at baseline, 12 and 24 months
6. Participant experience surveys at baseline, 12 and 24 months
7. Diabetes medications (type and dose) at baseline, 12 and 24 months
8. Blood pressure medications (type and dose) at baseline, 12 and 24 months
9. We will also assess the participant experience by using the NHS Friends & Family Test by standardised survey, and ask participants why they agreed or declined to take part in the initial assessment and discussion of the programme
10. The study will also involve an economic evaluation of the Diabetes-800 programme compared to the matched control group accessing usual care. The impact of Diabetes-800 on NHS costs will be estimated, and extrapolated over a 5-year time period, relative to usual care. Biomedical variables and prescribing data for the intervention group during the 2-year study period will be analysed, and compared with equivalent data from a control dataset of non-

participating patients with type 2 diabetes in South London. This control dataset will be used to represent usual care
Trajectories for prescribing and for biomedical variables such as HbA1c, weight, blood pressure and cholesterol for years 3-5 will be estimated for the intervention group and for usual care based on evidence from the clinical literature

Completion date
30/04/2023

Eligibility

Key inclusion criteria
1. Minimum age of 18 years
2. Maximum age of 65 years
3. Male or female
4. Minimum BMI of 27kg/m² (adjusted to 25kg/m² in people of South Asian or Chinese origin) BMI <45kg/m²
5. T2DM diagnosed at any time
6. HbA1c eligibility, most recent value, which must be within 12 months:
6.1. HbA1c ≥ 43 mmol/mol if on oral diabetes medication or GLP-1
6.2. HBA1c <108 mmol/mol - If HbA1c 90-108 mmol/mol, the value must be within 3 months of referral
7. On, or about to start, a second-line diabetes-related oral medication or GLP-1 (metformin is first-line)
8. Access to blood glucose monitoring equipment if on a sulphonylurea prior to referral
9. Ability to speak, read and receive care in English
10. Access to and willing to use an iOS or Android smartphone for the duration of the intervention

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. T2DM either diet-controlled alone, or on metformin alone
2. Current insulin use
3. Pregnant or breastfeeding or considering pregnancy during next 6 months
4. Significant physical comorbidities:
4.1. Active cancer

4.2. Myocardial infarction or stroke within previous 6 months
4.3. Severe heart failure defined as equivalent to the New York Heart Association grade 3 (NYHA)
4.4. Recent eGFR <30 mls/min/1.73 m²
4.5. Active live disease (except for NAFLD), or a history of hepatoma, or <6 months of onset of acute hepatitis
4.6. Severe angina, cardiac arrhythmia including atrial fibrillation or prolonged QT syndrome
5. Active substance use disorder/eating disorder
6. Porphyria
7. Weight loss >5% body weight within last 6 months or on current weight management programme or had/awaiting bariatric surgery (unless willing to come off waiting list)
8. Health professional assessment that the person is unable to understand or meet the demands of the treatment programme and/or monitoring requirements, which may include Learning disabilities
9. Taking monoamine-oxidase inhibitor medication
10. Taking warfarin
11. Taking varenicline (smoking cessation medication)
12. Unstable retinopathy or lack of retinal screening in the last year
13. Active/investigation for gastric or duodenal ulcers
14. People currently participating in another clinical trial

Date of first enrolment
26/02/2021

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
South West London CCG
120 The Broadway
London
United Kingdom
SW19 1RH

Study participating centre
NHS Buckinghamshire Clinical Commissioning Group
Study Centre
New County Offices
Walton St

Ayelsbury
United Kingdom
HP20 1UX

Sponsor information

Organisation
University of Westminster

ROR
https://ror.org/04ycpbx82

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	version v4	30/11/2020	01/06/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version v2	30/11/2020	01/06/2021	No	No