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Exploring engagement and implementation of a digital self-management programme designed for people living with early-onset type 2 diabetes

Submission date 30/07/2025	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 04/08/2025	**Overall study status** Ongoing	
Last Edited 04/08/2025	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims

Type 2 diabetes is becoming more common, and adults are getting it at younger ages. This is called ‘early-onset adult type 2 diabetes’ (EOT2). This is worrying because heart, kidney and other problems related to diabetes can happen at an earlier age. People might also find it more difficult to do everyday activities that are important to them, feel more anxious or depressed, and may need to use healthcare services more often.

Digital self-management education programmes help people with diabetes understand and manage their condition. However, no digital self-management education programmes have been designed specifically for young adults living with type 2 diabetes. To address this, we developed a digital self-management education programme (EOT2D MyDESMOND) to meet the needs of young adults living with type 2 diabetes. We did this by working with people who have lived experience of early-onset adult type 2 diabetes. The programme includes:

Information about:

1. Diabetes stigma
2. Loneliness and mental health
3. Managing your relationships, social life and family life alongside diabetes
4. Managing work, university, or college alongside diabetes
5. Women’s health and type 2 diabetes
6. Men’s health and type 2 diabetes
7. Educational animations
8. Podcasts of young adults with type 2 diabetes talking about their experiences
9. A private chat forum which participants will have access to

The EOT2D MyDESMOND also has functions which allow individuals to monitor their activity levels, blood sugar levels, and mental health and well-being. You can also ask healthcare professionals any questions you may have about your diabetes and any aspect of managing it. Overall, EOT2D MyDESMOND aims to help people living with 2 diabetes better understand and manage their condition, and improve their overall health and quality of life.

Who can participate?
Adults aged between 18 - 45 years who were diagnosed with type 2 diabetes before their 40th birthday, who have not used a MyDESMOND digital programme within the last 6 months.

What does the study involve?
Once participants have completed the registration process and accessed the EOT2D MyDESMOND programme, they can begin to use the programme as much as they like over 12 months. The study involves no in-person visits. Instead, participants will be asked to provide health-related information at different time points over the 12 months via a secure website. After the 12 months, participants will also have an opportunity to take part in an interview to explore how they found using the EOT2D programme. We also want to speak to people who did not use the programme to better understand how we can make the experience better for people in the future. We will also speak to a range of healthcare professionals and stakeholders involved in providing care for people with EOT2D to explore how the bespoke EOT2D MyDESMOND programme can best be implemented within care pathways for people with EOT2D.

What are the possible benefits and risks of participating?
Taking part in this research study could potentially benefit other people with early-onset type 2 diabetes by providing information on how a digital programme can improve the health and well-being of people living with the condition. What we learn from testing our self-management programme will also help us explore the best ways to make it available for more people living with EOT2D, for example, through providing it through the NHS. MyDESMOND could also potentially lead to improved mental wellbeing and reduced blood sugar levels. There are no anticipated risks involved.

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

When is the study starting and how long is it expected to run for?
January 2025 to March 2026

Who is funding the study?
Diabetes UK

Who is the main contact?
Lisa Moyes, lisa.moyes@uhl-tr.nhs.uk

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
356827

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 66202; Grant Code: 24/0006709

Study information

Scientific Title
To explore engagement and implementation of a Digital package for eArly-oNset type 2 diAbetes: a mixed-methods study (the DANA study)

Acronym
DANA

Study objectives
1. To assess the rates of engagement and retention, and test the impact of a tailored digital-based self-management education programme for people with early-onset type 2 diabetes (EOT2D MyDESMOND).
2. To interview users and non-users of our EOT2D digital-based self-management education programme, and key stakeholders, to help develop a clear implementation strategy to support the integration of the programme in the 'real-world' setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/07/2025, South Central - Hampshire A Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)207 104 8120, +44 (0)207 104 8210, +44 (0)2071048135; hampshirea.rec@hra.nhs.uk), ref: 25/SC/0220

Study design
Both; Design type: Cohort study

Primary study design
Interventional

Secondary study design
Mixed methods evaluation

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See study outputs table

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

Interventions
This is a single-centre study comprising an observational study (WP1) and a qualitative interview study (WP2).

WP1: Observational Study
We will invite individuals with EOT2D to register on and use a novel, digital self-management programme tailored to the needs of people with EOT2D (EOT2D MyDESMOND) to see how often they use the programme, and whether the programme can improve their health and well-being.

Various engagement strategies will be used to promote the EOT2D MyDESMOND programme to eligible participants. With input from a Patient and Public Involvement group, participants will be recruited from diverse settings (primary and secondary care, local Research Development Networks, social media, advertisements and word of mouth). This includes, but is not limited to, text messages sent from participants' General Practices informing them study and how to register, study posters in General Practices (GP), community centres and faith centres, and posts about the study on social media. These promotional avenues will direct participants to a study-specific website where they can access a Participant Information Sheet (PIS) which provides them with more detail about the study. We aim to recruit 900 participants for the observational study.

The PIS will outline that the study does not involve any in-person visits. Participants provide all their data remotely via a secure website. This approach was taken to not overburden young persons who may have multiple priorities (e.g. work commitments, family responsibilities). Self-reported data includes blood sugar levels, anthropometric measurements (body weight, waist circumference) and measures of well-being, for example, if they feel distressed by their diabetes. They are asked to provide this information when they sign up for the programme, and at 3, 6 and 12 months, to test whether EOT2D may have impacted any of these outcomes.

If participants are still interested in taking part in the study after reading the PIS, they will follow the instructions on the study website to complete an eligibility check, provide their contact details, and provide consent to participate in the observational study. Participants can also consent to being contacted about the qualitative interview study, described in more detail below.

Once participants have provided their consent to participate in the observational study, they will be sent an automated email which provides them with a unique identification code and a link to the University of Leicester hosted database (REDCap). The REDCap database will be used by participants to provide their baseline self-reported data (participants are required to provide their unique identifier when inputting their data to ensure data collected is pseudonymised), and self-reported data thereafter, at 3, 6 and 12 months.

Upon providing consent to participate in WP1, participants are also sent a registration code via text message or email which grants them access to EOT2D MyDESMOND. Once registered, participants will have the opportunity to use the programme at their own pace and in their own time. Email reminders will be sent across the 12-month observational period to encourage engagement with programme, and to remind participants to input their self-reported data. Back-end website data on the extent of user engagement (e.g. length of time for which individual pages were viewed and the number of occasions etc) with the EOT2D MyDESMOND programme, and user retention data, will be collected. Due to the nature of observational studies, this study is not randomised or blinded. However, for the purpose of analysis, data is pseudonymised to reduce potential bias.

WP2: Qualitative Interview Study
Following their participation in the 12-month observational study, WP1 participants are invited via email or telephone call to take part in a qualitative interview study. Only those who consented to being contacted about the interview within the WP1 consent form will be approached to participate. The interviews will explore participants' thoughts and feelings around EOT2D MyDESMOND (e.g., what parts they found useful or not useful), and any reasons why they used, or did not use, the programme.

The interviews will be one-off, lasting around 30-60 minutes, and will be semi-structured, conducted by an experienced qualitative researcher, and will take place remotely (telephone or video call, depending on each participant's preference) to reduce the burden of an in-person visit. We will aim for an equal representation of EOT2D MyDESMOND users (n = 15) (defined as those registered on and actively engaged with EOT2D MyDESMOND) and non-users (n = 15) (defined as those who requested access to EOT2D MyDESMOND, but did not complete registration, and those who completed registration but did not access the programme) to be interviewed. A purposive sampling
approach will be utilised to encourage maximum variation in participants' sociodemographic characteristics (e.g., geographical location, gender, age, ethnicity) and usage of EOT2D MyDESMOND. We will ask for this information via a reply form sent via email.

In addition to interviewing participants from WP1, we aim to interview 15 key stakeholders (e.g. home nations commissioners, primary/secondary care staff, policy makers, charity leads) in order to explore any barriers and facilitators to rolling out the EOT2D MyDESMOND programme within a ‘real-world’ setting. Stakeholders will be recruited from charities and communities, and via existing links and relationships within the Leicester Diabetes Centre and Centre for Ethnic Health Research. A purposive sampling approach will be utilised to ensure there is a range of professions and areas of expertise. This will enable us to capture any distinct differences in implementation facilitators and barriers from a variety of perspectives. Interviews will be semi-

structured and will last around 30-40 minutes. They will be conducted by an experienced qualitative researcher. The aim of the qualitative interview study is to develop a clear implementation strategy to support the integration of the EOT2D MyDESMOND programme within care pathways for people with EOT2D.

The end of the study is the date when all data from WP1 and WP2 has been collected and analysed, and the final report has been submitted to DUK.

Intervention Type
Behavioural

Primary outcome measure
1. Retention, defined as the duration between the day a user registered for EOT2D MyDESMOND and the last day they accessed it during the 12-month study period.
2. Engagement, defined as the total number of logins per user during the 12 months following registration. Other user engagement outcomes per user during the 12 months include:
2.1. Total time spent using the programme
2.2. Estimated time spent per log-in (total time spent in the programme divided by total number of logins)
2.3. Logins per week (total number of log-ins divided by number of weeks spent using the programme)

Other outcomes include:
1. Conversion rates, defined as the number of individuals who are sent an EOT2D MyDESMOND registration code who go on to register
2. Self-reported outcomes, as detailed below, which are all measured at baseline, 3, 6 and 12 months. Please note, self-reported data is not mandatory for participants to provide.
2.1. HbA1c (mmol or %)
2.2. Anthropometric variables (body weight kg, waist circumference cm)
2.3. Diabetes self-efficacy is measured using the Diabetes Management Self-Efficacy Scale (DMSES)
2.4. Diabetes distress is measured using the Problems Areas In Diabetes Scale (PAID-5)
2.5. Self-compassion is measured using the Self-Compassion Scale (SSC)
2.6. Diabetes stigma is measured using the Type 2 Diabetes Stigma Assessment Scale (DSAS-2)
2.7. Illness perceptions measured using the Brief Illness Perception Questionnaire (B-IPQ)

Secondary outcome measures
The secondary outcome for this study is a ‘fit-for-purpose’ implementation strategy for the EOT2D digital self-management programme developed with input from people with EOT2D, PPI and stakeholders (including healthcare professionals, commissioners, charity leads).

Overall study start date
02/01/2025

Completion date
02/03/2026

Eligibility

Key inclusion criteria

Work Package 1: Observational Study
1. Diagnosis of T2DM before the age of 40 years (inclusive)
2. Aged >=18 and <=45 years at time of recruitment (inclusive)
3. Access to information technology to access EOT2D MyDESMOND
4. Capacity and willingness to provide informed consent to participate in the study
5. Sufficient written and verbal English communication skills to understand the Participant Information Sheet (PIS) and Informed Consent Form (ICF)

Work Package 2: Qualitative Interview Study
Participants taking part in the observational study will be invited to a one-off interview. Inclusion criteria as above; access to information technology required to participate in remote interviews.

Inclusion criteria for stakeholders:
1. An understanding of the care pathway for people with EOT2D
2. Those involved in the delivery or commissioning of care for people with EOT2D
3. Individuals involved in the provision of MyDESMOND or other digital diabetes education within an NHS setting
4. Sufficient written and verbal English communication skills to understand the PIS and ICF
5. Capacity and willingness to provide informed consent to participate in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Both

Target number of participants
Planned Sample Size: 945; UK Sample Size: 945

Key exclusion criteria
Work Package 1: Observational Study
1. Diagnosed with other forms of diabetes (e.g. type 1 diabetes, gestational diabetes)
2. Has been an active MyDESMOND user in the last 6 months
3. No access to an electronic device to support the use of EOT2D MyDESMOND
4. Unwilling or unable to give informed consent to participate in the study

Work Package 2: Qualitative Interview Study
1. Unwilling or unable to give informed consent to participate in the study
2. If required to participate in remote interviews, no access to information technology

Date of first enrolment

01/09/2025

Date of final enrolment
02/03/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals of Leicester NHS Trust
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Sponsor type
University/education

Website
https://le.ac.uk

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Charity

Funder Name
Diabetes UK

Alternative Name(s)
DIABETES UK LIMITED, British Diabetic Association

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request in writing to the Chief Investigator: Dr Michelle Hadjiconstantinou (mh333@leicester.ac.uk)

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.0	20/05/2025	01/08/2025	No	Yes