# Participant Information Sheet for
# People living with early-onset adult type 2 diabetes

# To explore engagement and implementation of a Digital package for eArly-oNset type 2 diAbetes: a mixed-methods study

# MyDESMOND for eArly-oNset type 2 diAbetes (The DANA study)

**Version 1.0 20.05.2025**

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**Introduction**
You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read this information sheet carefully and discuss with others if you wish.

If there is any part of this information sheet that you do not understand, or require further information about, please contact us and we will be happy to answer any questions you have.

**What is the purpose of the research study?**
Type 2 diabetes is becoming more common, and adults are getting it at younger ages. This is called 'early-onset adult type 2 diabetes'. 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 every-day 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:
  - diabetes stigma
  - loneliness and mental health
  - managing your relationships, social life and family life alongside diabetes
  - managing work, university, or college alongside diabetes
  - women's health and type 2 diabetes
  - men's health and type 2 diabetes
- Educational animations
- Podcasts of young adults with type 2 diabetes talking about their experiences
- A private chat forum which participants will have access to

EOT2D MyDESMOND also has functions which allows 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. You can find out more about MyDESMOND programmes by clicking on the following link: MyDesmond | Prevent or Manage Type 2 Diabetes.

The main goal of this study, is to see how many people with early-onset adult type 2 diabetes register to use the EOT2D MyDESMOND programme, and explore what people think of the programme and whether it can improve their health and well-being.

**Why have I been invited to participate?**
You have been invited to take part because you are aged between 18 - 45 years (inclusive), were diagnosed with type 2 diabetes before your 40th birthday, and have not used the MyDESMOND digital programme within the last 6 months.

**Do I have to take part?**
No, taking part in this study is voluntary. If you do not wish to take part, this will not affect your ongoing or future care.

**What will happen to me if I take part?**
To take part in the study, you will need access to a smartphone, laptop, computer or tablet, and an internet connection. If you meet the study's additional inclusion criteria and provide us with your consent to join the study, you will be sent a code by text or email which you will use to complete the registration process to gain access to EOT2D MyDESMOND. The instructions on how to complete the registration will be provided in the text message or email. Only once you have provided consent will you be able to start the study and access EOT2D MyDESMOND. Once you have completed the registration and accessed EOT2D MyDESMOND, you can begin to use the programme as much as you like.

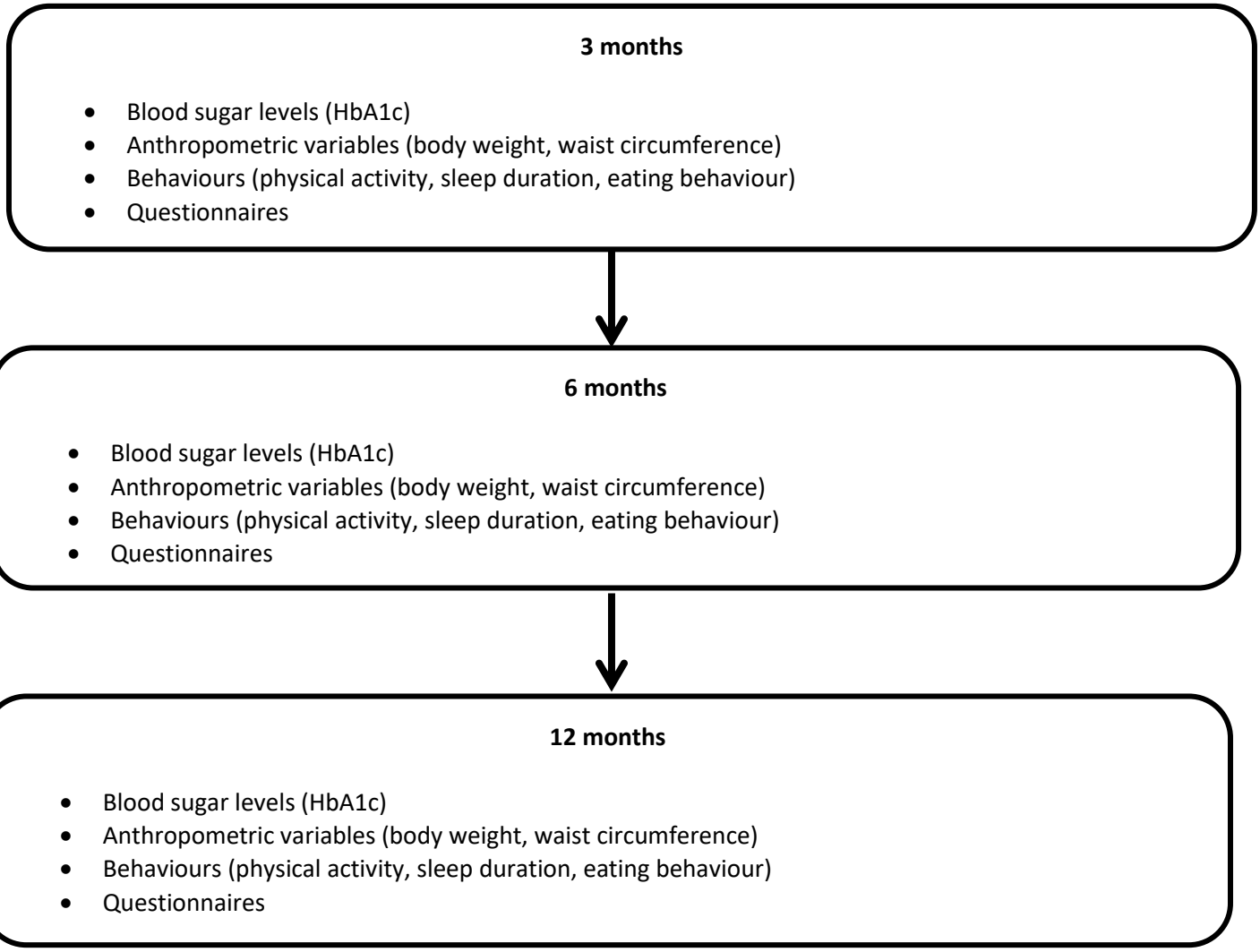
You will also be given the opportunity to consent to being contacted about an interview (explained below), but this is optional. Expressing an interest in the interview does not mean that you have committed to it and you can change your mind without this affecting your participation in the main part of the study.

***Data collection***
Taking part in this research study does not require you to attend any study visits. All the data we collect as part of the study will be provided by you online via a secure website. Once you have provided your consent to take part in the study, you will receive an email which directs you to a website where we will ask you to provide the following data:

**When you request access to the study and EOT2D MyDESMOND (Baseline)**

- Demographic information
- Blood sugar levels (HbA1c)
- Anthropometric variables (body weight, waist circumference)
- Behaviours (physical activity, sleep duration, eating behaviour)
- Questionnaires
- Consent to be contacted about an interview

We will also send you an email with a link to the same website, asking you to provide the listed data at the following time points:




The questionnaires that we will ask you to complete will help us find out the following:

- If you are distressed by your diabetes
- If you have experienced stigma as a result of your diabetes
- How confident you are in looking after your diabetes
- Your beliefs about your diabetes
- How compassionate you feel towards yourself

***Interview***

The interview will happen after the final period of data collection at 12 months. If you provide your consent to be contacted about the interview, we will contact you using the contact details provided to see if you would still like to take part. The purpose of the interview is to talk about your experiences using the MyDESMOND programme. You can decide how you would like to do the interview – it can happen by telephone or video call, using a platform such as Microsoft teams. If you wish to take part in a one-to-one interview, this will take around 40 minutes and it will be audio recorded using a recording device. The interview will be with one of our experienced qualitative researchers.

**Will I be reimbursed or receive any payment for participating?**

There is no payment for taking part.

**What are the possible benefits of taking part?**

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 early-onset type 2 diabetes, for example through providing it through the NHS. MyDESMOND could also potentially lead to improved mental wellbeing and reduced blood sugar levels.

**What are the possible disadvantages and risks of taking part?**
A possible disadvantage of the current study could be the time commitment required to complete data collection. However, all data provided is done remotely and in your own time. Therefore, you are not under any significant time pressures. There are no anticipated risks involved.

**What if something goes wrong?**
It is very unlikely that you would be harmed by taking part in this type of research study. However, if you wish to complain or have any concerns about the way you have been approached or treated in connection with the study, you can contact the team via 0116 258 4251 or uhl-tr.danastudy@nhs.net, who will do their best to answer your concerns. If you remain unhappy and wish to address your concerns or complaints on a formal basis, you should contact Patient Advice and Liaison Service (PALS) at: pals@uhl-tr.nhs or 0808 1788337. If you would like to speak to someone independent of the research team, please contact the study Sponsor via rgosponsor@le.ac.uk

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

**How will we use information about you?**
We will need to use information from you for this research study. This information will include your:

- Initials
- Name
- Date of birth
- Contact details including address, post code, email address and phone numbers
- Sex
- Ethnic Group
- Duration of type 2 diagnosis

People will use this information to do the study or to check your records to make sure that the study is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

The University of Leicester (UoL) is the Sponsor of this research, and is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- University of Leicester
- NHS Trusts
- Regulatory authorities

We will keep all information about you safe and secure by:

- Ensuring all study staff comply with the requirements of the Data Protection Act and General Data Protection Regulation (GDPR) legislation with regards to the collection, storage, processing and disclosure of personal information, and uphold the Act's core principles.
- Password protecting the data set for this study. The information will be stored electronically, password protected and encrypted on UoL and University Hospitals of Leicester (UHL) secure drives. Access to all documents will be restricted to study staff and authorised personnel from the UoL, host NHS Trust and regulatory authorities.

- Keeping all information collected in the study strictly confidential. All members of the study team undertake mandatory training in patient confidentiality and are required to follow the UK Policy Framework for Health and Social Care Research, General Data Protection Regulation (2018) and the Data Protection Act (2018).
- Neither hard copies nor electronic files containing personal information being removed from the research office. Quality control checks will be conducted by the lead site (Leicester).
- All data collected through the EOT2D MyDESMOND programme being encrypted and stored on UK servers fully compliant with the latest industry standards for security and GDPR.

The UHL or UoL will keep identifiable information about you from this study for 5 years after the study has finished. Your data will not be shared outside the UK.

**Will my taking part in this study be kept confidential?**
We take confidentiality very seriously. As we will be using information from you to undertake this study, the University of Leicester will act as the data controller for this study and is responsible for looking after your information. Access to your data will be granted to the regulatory authorities, the sponsor (University of Leicester) and the host NHS trust for monitoring and auditing purposes.

On the consent form, you can also choose to be informed about the results of the study. If you consent for this to happen, we will store your contact details securely, separately from your study data, and we will only use them for the purposes you have chosen. Your contact details will be destroyed once they have been used for the purpose that you have agreed to.

**How will we use information about you after the study ends?**
Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. The UHL or UoL will keep your study data for a maximum of 5 years. The study data will then be fully anonymised and securely archived or destroyed.

**What are your choices about how your information is used?**
- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. With your permission, we would like to retain your contact details and some basic information about you on our Leicester Diabetes Centre Research Volunteer's database for the purpose of being able to contact you in the future about our other research studies that you might be eligible for and interested in participating in. This database is held on University Hospitals of Leicester NHS Trust computer servers and can only be accessed by researchers at the Leicester Diabetes Centre and your information will not be shared with anyone else.

**Where can you find out more about how your information is used?**
You can find out more about how we use your information:
- our leaflet available from **www.hra.nhs.uk/patientdataandresearch**
- by asking one of the study team
- by sending an email to **uhl-tr.danastudy@nhs.net**
- by ringing us on **0116 258 4251**
- You can also contact the University's Data Protection Officer by email dpo@le.ac.uk

**What will happen to the data I provide?**
Your research data will be entered onto a password protected study database which is owned and maintained by UoL/UHL. A separate database containing identifiable information for the purpose of contacting participants will be held on the UoL/UHL trust servers, access will be limited to relevant members of the research team only. Paper

copies of your research data will be stored in a secure office environment at Leicester Diabetes Centre, Leicester General Hospital for the duration of the research study. At the end of the study your coded/deidentified research data will be transferred to the University of Leicester for analysis and will be stored on servers owned and maintained by the University of Leicester.

**What will happen to the results of the study?**
Once completed, the findings of this study will be published in a written report for Diabetes UK. You will be offered a copy of the results, if you would like to receive it, but this is optional and you don't need to agree to that. Findings will also be used in scientific journals and conference presentations. We will also share the results with the public through press releases, TV and radio interviews, social media, public lectures and the internet. All information about participants will be pseudonymised (given a code in place of your name) and you will not be able to be recognised from any report or publication.

**Who is organising and funding the research?**
The research is funded by Diabetes UK. The research is being coordinated by the University of Leicester and the Leicester Diabetes Centre at the Leicester General Hospital.

**Who has reviewed the study?**
All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. This study has been reviewed and has been granted a favourable opinion by South Central - Hampshire A Research Ethics Committee. Favourable Opinion means that the committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits and that you have been given sufficient information on which to make an informed decision.

**What should I do if I want to take part?**
If you are willing to take part in this study, please follow the link to the study website and complete the eligibility check and consent form **<<insert website link>>**. You can also contact us by phone or email to express your interest. Even if you are not sure if you would like to take part at this stage, we will be very pleased to answer any questions you may have.

**Contact for Further Information:**
DANA study team
Leicester Diabetes Centre
Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW
Tel: **0116 258 4251**
Email: **uhl-tr.danastudy@nhs.net**

**[insert QR code]**

**Thank you for taking the time to read this information sheet and consider taking part in the study.**