T1D-DAB

The Diversity of Type 1 Diabetes Across Bristol

Participant Information Sheet

Your invitation to take part.

As a person with Type 1 Diabetes, we would like to invite you to join our study. It is called The Diversity of Type 1 Diabetes Across Bristol (T1D-DAB). This study is run by the Diabetes and Metabolism group at the University of Bristol. Before you decide if you do or do not want to take part, we want to tell you why this research is being done and what it will involve. Please take the time to read this information sheet; you can discuss it with others if you wish.

Please contact us if you have any questions or if anything is unclear. We are happy to answer any questions you may have.

Thank you for reading this information sheet.

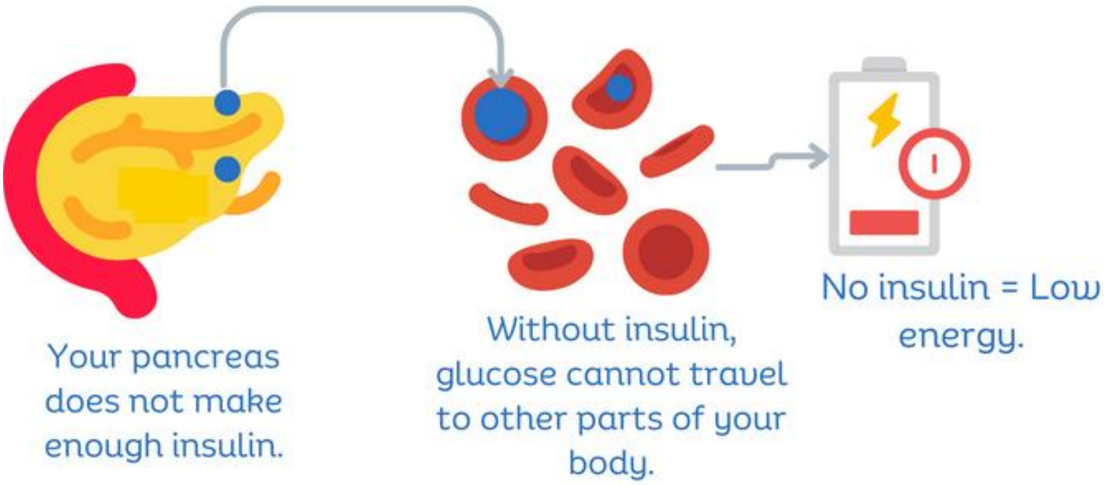
What is Type 1 Diabetes?

The pancreas in our body digests (breaks down) the food we eat and produces a hormone called insulin. We need insulin to help change the glucose (sugar) in our food into energy.

In Type 1 Diabetes, our pancreas does not make enough insulin. This makes us feel exhausted and unwell because we have less energy.

People with Type 1 Diabetes are treated with insulin injections to help them have more energy. Anyone can develop Type 1 Diabetes, even babies, and it is not their fault.

The picture below shows what happens in our body when we do not have enough insulin.



Alt text picture caption: There is a picture which has three images linked to one another. The first image displays a pancreas and how not enough insulin is produced. The second image displays how due to the lack of insulin, glucose is not able to travel in the red blood cells to other parts of the body. The final image shows a low battery to explain how low insulin is linked to lower levels of energy.

When someone has Type 1 Diabetes, their immune system becomes confused. It mistakenly thinks that the cells that make insulin are harmful. Their immune system attacks the insulin-producing cells in the pancreas. Proteins called antibodies show this attack is happening.

These antibodies can be found in your blood years before you develop Type 1 Diabetes, even from when you were a child.

Why is the T1D-DAB Study Important?

We have a good understanding of Type 1 Diabetes in White children. However, we know little about Type 1 Diabetes in adults and people from other heritages.

We want to find out if age and ethnicity affect the development of Type 1 Diabetes. This information could help everyone with Type 1 Diabetes, no matter their age or ethnicity.

Why have I been invited?

Your doctor has told you that you have Type 1 Diabetes.

You also live and attend Diabetes clinics in Bristol (BS Postcodes only).

We aim to recruit 1100 people with Type 1 Diabetes into T1D-DAB.

Your help can make a difference in our understanding of Type 1 Diabetes.

Who can join T1D-DAB?

We are asking people aged over 3 years who have Type 1 Diabetes and live in Bristol to take part in our study.

Who is not eligible to take part in T1D-DAB?

- Your doctor thinks it's unsafe for you to take part in T1D-DAB.
- Anyone currently taking part in a clinical trial and taking a clinical trial product. This may affect your participation.

What will T1D-DAB involve?

This study will be split into two parts:

1. The first part will look at 1000 people who have had Type 1 Diabetes for a long time.
2. The second part will focus on 100 people whose doctor has told them in the last year that they have Type 1 Diabetes.

For people who have been recently told (within the last year) they have Type 1 Diabetes:

This is for people whose doctor has told them in the last year that they have Type 1 Diabetes. We will ask you to do two extra steps in addition to Steps 1 and 2 below.

A. When your doctors first thought you might have Type 1 Diabetes, they did some tests to confirm this. We are asking for permission to use any left-over samples from this blood test.

If you agree to take part in the T1D-DAB study, this leftover sample can be used for research (otherwise, it will be thrown away). This will not change your medical treatment.

B. Our research team wants to understand your thoughts about taking part in T1D-DAB, including what you enjoyed and disliked. We will ask you to complete an optional online participation feedback survey on REDCap. Researchers use this web-based tool to manage and collect clinical data.

Please contact our study team if you prefer to receive the participation feedback survey by post. This survey will help us improve the T1D-DAB study and the design of our future research studies. This survey is entirely voluntary, so you do not need to complete it if you do not want to.

You will also be given the option to complete this participation feedback survey even if you decide not to take part in the rest of the study.

For all consented participants (including those who have recently been told they have Type 1 Diabetes):

If you decide to take part in our study, you will need to follow these steps:

Step-1: Collect (one-off) samples at home:

We will post sample collection kits to your home. These collection kits will include instructions. They will explain how to collect the urine, mouthswab, finger-prick blood, and saliva samples.

We also have sample collection instruction videos on our study website here: https://tinyurl.com/T1D-DAB-sample-collection

After collecting your samples, you will be asked to complete a form with the dates and times you collected them. The sample collection kits will also include freepost packaging for returning samples to our research team using any standard Royal Mail post box. This packaging will be labelled with our return address.

Step 2: Complete Questionnaires at home

We will ask you to answer questions about:

- Your age and ethnicity
- When were you told you had Type 1 Diabetes
- How you feel about having Type 1 Diabetes

You can complete the questionnaires online on REDCap. Researchers use this web-based tool to manage and collect clinical data.

Please contact our study team if you prefer to receive the questionnaires by post.

The questionnaires will be completed at home, but please contact our research team if you need any help. We are happy to help.

With your consent, we will also collect information about your diabetes care from your medical records.

What will happen to my biological sample(s)?

Antibody testing:

We will test your finger-prick blood and saliva samples for antibodies. These antibodies will help us to see if there have been any changes to your immune system.

We know these antibodies can be found in your blood, but we are also interested in seeing if they are in your saliva.

Our research team at the University of Bristol will perform the antibody testing.

Genetic testing:

Your mouthswab samples will be processed and examined for DNA (Deoxyribonucleic acid).

We are interested in learning how genes can cause Type 1 Diabetes. We will only look at the genes in your DNA related to Type 1 Diabetes.

Our research team at the University of Bristol will perform the genetic testing.

C-peptide testing:

We will assess your urine samples for a substance called C-peptide, which is made at the same time as insulin. A C-peptide test will help us to see how well your pancreas makes insulin.

The urine samples will be analysed for C-peptide by the University Exeter.

We may send some samples to national and international laboratories for further study. These samples will be coded and anonymised. This code will be used for all communication and results. We will also strictly follow the data protection guidelines.

A PhD student at the University of Bristol will perform the laboratory work. The results will support their PhD project.

The samples may also be used for future research in the same area. If you agree, we will keep your sample (s) to use again if we have new methods or questions to study. However, if you prefer that we do not use your samples for future approved studies, we will respect your decision and destroy them after the T1D-DAB study ends.

How long will I need to be involved in the T1D-DAB study?

The T1D-DAB study only requires one data collection point and a one-off collection of each biological sample type. All your data will be collected at home. You will not need to attend any study visits at our research centre.

The table below shows how long each study activity will take on average.

Study activity	Average time needed	Where will it take place
Completing a consent form	10 minutes maximum	At your home-online on REDCap or written
Completing study questionnaires	1-hour maximum	At your home-online on REDCap or written
Collecting a Finger-prick sample	10 minutes	At your home
Collecting a urine sample	10 minutes	At your home
Collecting a mouthswab sample	5 minutes	At your home
Collecting a saliva sample	5 minutes	At your home

What are the possible benefits of taking part?

You will not personally benefit from taking part in T1D-DAB.

We hope this study and others will help make new tests to find out if someone has Type 1 Diabetes before they get symptoms. Our study will collect samples to see if your age and ethnicity affect Type 1 Diabetes.

We cannot offer any payments or expenses for taking part in the T1D-DAB study. However, we are very thankful to all those who take part and give their time to support our study.

What are the possible disadvantages and risks of taking part?

You may experience some discomfort and soreness at the site of the finger-prick test.

The questionnaires may include sensitive topics such as your mental well-being. We know it can be challenging to talk about having an illness. If at any point you feel that your distress about your diabetes is too much, please contact us. The T1D-DAB study team will contact your GP to support you.

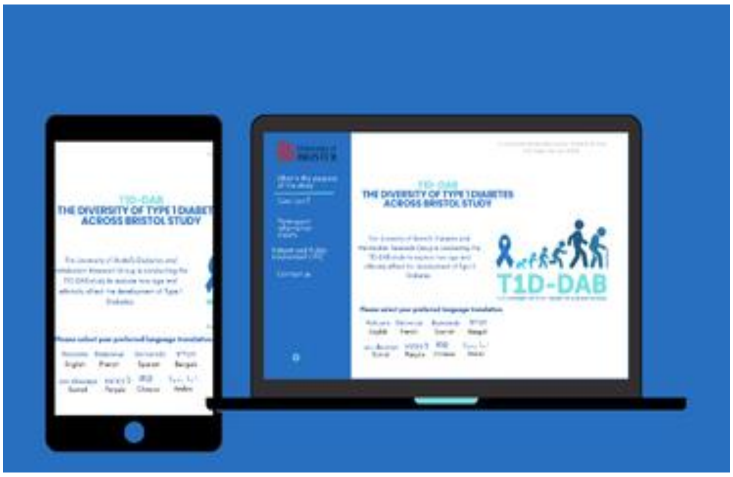
How can I take part?

If you want to participate in the T1D-DAB study, you must read and sign a consent form stating that you are happy to do so.

You can do this online on REDCap.

Please get in touch with us if you want a consent form sent to you by post.

You will also receive a record of your signed consent form.



Alt text picture caption: There is a picture of a tablet and a laptop with the research study's logo and website on them.

Do I have to take part?

No, taking part in T1D-DAB is entirely voluntary. You do not have to take part in T1D-DAB if you do not want to.

What happens if I change my mind about taking part?

If you join the study and change your mind, you can stop anytime. You do not need to explain why. Your choice will not affect your medical care.

If you wish to stop taking part, we will keep the study information (data) we have collected about you for our research.

If you wish to withdraw from the study at any time, please contact Dr Anna Long, who leads our study. Their contact details are at the end of the information sheet.

What happens if I lose capacity during T1D-DAB?

In some cases, you might experience mild to moderate confusion because of a sudden health problem during the study. This would mean you have a loss of capacity.

If this happens, you will be withdrawn from the study, and we will keep any information we have collected about you for our research.

What Personal information will you collect in T1D-DAB?

We will ask to collect the following personal information from you:

- Your contact details.
- Your name, age, ethnicity, and sex at birth.
- Your family medical history
- Your date of birth
- Your GP and diabetes doctor's contact details. We would like to inform them of your participation in the T1D-DAB study.

We will use this information to help us understand the study's results. This information will also be checked to ensure the research is done correctly. All your personal data will be analysed and processed using codes instead of your personal details.

Once we have finished the study, we will keep some of your personal data to check the results. However, all scientific reports and publications will not include any information that can be used to identify you. This is to ensure nobody knows you took part in the T1D-DAB study.

How will my information be kept confidential?

We are committed to protecting your privacy and promise to keep all the information collected about you safe.

We will follow strict guidelines to protect your personal information, such as the General Data Protection Regulation (GDPR) and the Confidentiality Act. We will ensure that any information that leaves our research centre will not include your name or any other information that can be used to identify you.

You can find out more about how we will take care of your data here:
http://www.bristol.ac.uk/secretary/data-protection/policy/research-participant-fair-processing-notice/

General Data Protection Regulation (GDPR) Information:

How will we use your information?

This study is sponsored by The University of Bristol, which is based in Bristol, United Kingdom. We will use your information to undertake this study and act as the data controller for this study.

This means we are responsible for protecting and using your information correctly. The University of Bristol will keep your identifiable information for 5 years after the study ends.

The only people at the University of Bristol with access to your personal information will be staff who need to contact you to provide study updates or to audit the data collection. The researchers who analyse the study information will not be able to identify you or be aware of your name or contact details.

What are your choices about how your information is used?

Your rights to access, change, or move your information are limited, as we need to manage it in specific ways for the research to be reliable and accurate.

If you decide to withdraw from the study, we will respect your decision and protect your rights. We will only keep the information we have already

collected about you and use as little of your personal information as necessary.

Where can you learn more about how your information is used?

You can learn more about how we will use your information under the GDPR statement here:

http://www.bristol.ac.uk/secretary/data-protection/policy/research-participant-fair-processing-notice/

Will my General practitioner/Family Doctor (GP) be told I'm taking part in T1D-DAB?

Yes. We will notify your GP in writing that you are taking part in the T1D-DAB study. We will do this to let them know you are in the study. Also, if we find anything that could affect your health, we will contact your GP and diabetes doctor. They will provide you with more support and medical care if necessary.

What will happen to the results of the research study?

We will not give the results to the study participants. However, we will update our study website with a plain English summary of the results.

The coded study results will be written up in scientific journals for other researchers to read and learn from.

We will also share the results at conferences to educate other healthcare staff and researchers.

What if there is a problem?

No special compensation is available if you are harmed by taking part in this research project. However, if you are injured due to someone's negligence, you may have the right to take legal action, but you may have to pay your legal costs.

If you want to complain about how you were treated in T1D-DAB, please contact the University of Bristol's Research Governance Team. Their contact details are at the end of the information sheet.

If you have medical concerns, please contact the Patient Advice and Liaison Service (PALS). The PALS and Complaints Teams are responsible for addressing complaints, queries, or questions that patients, their families, or members of the public raise about the Trust.

The contact details for the PALS teams of the NHS Trusts involved in T1D-DAB are listed in the table below.

T1D-DAB involves the University Hospitals and Weston NHS Trust Foundation (UHBW- Bristol Royal Infirmary, St Michaels Hospital and Weston General Hospital) and the North Bristol NHS Trust (NBT- Southmead Hospital, Frenchay Hospital and Cossham Hospital).

NHS Trust	PALS
UHBW	Telephone number: 0117 342 1050 Email: PALSandComplaints@uhbw.nhs.uk For St Michaels Hospital and Weston Trust: PALSWeston@uhbw.nhs.uk
NBT	Telephone number: 01174 414 4569 Email: pals@nbt.nhs.uk

You can also raise a complaint or concern online using an electronic form:

For University Hospitals and Weston NHS Trust Foundation (UHWB), please visit:

UHBW NHS - UHBW NHS

For further information on UHBW's PALS and complaints process: Patient Advice and Liaison Service (PALS) and Complaints Team | University Hospitals Bristol NHS Foundation Trust (uhbristol.nhs.uk)

For North Bristol Trust (NBT), please visit: Raise a Concern/Complaint | North Bristol NHS Trust (nbt.nhs.uk)

For more information on NBT's PALS and complaint process: How to Raise a Concern or a Complaint | North Bristol NHS Trust (nbt.nhs.uk)

Who is organising and funding this study?

The University of Bristol internally funds this study. The study data will support future targeted funding applications.

Who has reviewed the study?

To protect your interests, an independent group called the Research Ethics Committee (REC) reviews all research conducted in the NHS.

The study received a favourable ethical opinion from Southeast Scotland REC 02.

Who should I talk to if I have any questions?

If you have any questions, feel free to contact our research team using the contact information below. You can also visit our study website here: https://tinyurl.com/T1D-DABStudyHomepage

We are happy to answer any questions you may have.

Contact us:

T1D-DAB Study Address: Diabetes and Metabolism Level 2, Learning and Research Southmead Hospital Bristol BS10 5NB	T1D-DAB Study E-Mail: diabetes-study@bristol.ac.uk Telephone: 0117414 7915

Chief Investigator: Dr Anna Long

Email: Anna.long@bristol.ac.uk

The University of Bristol's Research Governance Team

Email: Red-Office@bris.ac.uk

Thank you for taking the time to read this!