T1D-DAB

The Diversity of Type 1 Diabetes Across Bristol

Parents and Guardians’ Information Sheet

Your invitation to take part.

As a parent or guardian of a child aged 3-15 years with Type 1 Diabetes. We would like to invite your child or someone under your care to join our study, 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 your child or someone under your care to take part, we want to tell you why this research is being done and what it will involve for you and them. Please take the time to read this information sheet and discuss it with others if you wish.

Please get in touch with 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.

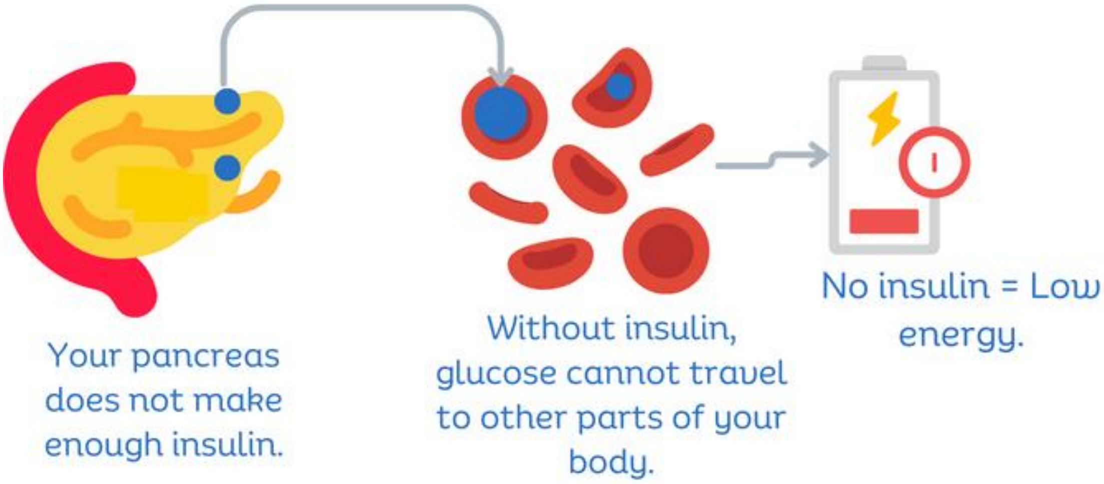
What is Type 1 Diabetes?

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 their blood years before they develop Type 1 Diabetes, even from when they were a baby.

Why is my child or someone under my care being asked to take part?

Your child or someone under your care's doctor has told them that they have Type 1 Diabetes.

Your child or someone under your care also lives and attends 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.

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 young people from other heritages.

We want to find out if age and ethnicity affect Type 1 Diabetes.

This information could help everyone with Type 1 Diabetes, no matter their age or ethnicity.

Who can join T1D-DAB?

We are asking children aged 3-15 years who have Type 1 Diabetes and live in Bristol to take part in our study.

Who is not eligible to take part in this study?

- Anyone whose doctor thinks it is unsafe for them to take part in the study.
- Anyone currently taking part in a clinical trial and taking a clinical trial product. This may affect your child or someone under your care's participation.

What will this study 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 your child or someone under your care to do two extra steps in addition to Steps 1 and 2 below.

A. When your child or someone under your care's doctors first thought they 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 and your child or someone under your care 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 child or someone under your care's medical treatment.

B. Our research team wants to understand your and your child or someone under your care's thoughts about taking part in T1D-DAB, including what you enjoyed and disliked. We will ask you and/or your child/someone under your care 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 and your child/someone under your care 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 their samples, you and/or your child/someone under your care will be asked to complete a form with the collection dates and times you collected them. The collection kits will also include freepost packaging for returning samples to us using a standard Royal Mail post box. This packaging will be labelled with our return address.

Step 2: Complete Questionnaires at home

We will ask you and/or your child/someone under your care to answer questions about the following:

- Their age and ethnicity
- When were they told they had Type 1 Diabetes
- How they feel about having Type 1 Diabetes

These questionnaires can be completed online on our study website or 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 if you need help, please contact our research team. We are happy to help.

With your consent, we will also collect information about your child or someone under your care's diabetes treatment from their medical records.

What will happen to my child or someone under my care's biological sample(s)?

Antibody testing:

We will test their finger-prick blood and saliva samples for antibodies. These antibodies will help us to see if there have been any changes in their immune system. We know these antibodies can be found in their blood, but we are also interested in seeing if they are in their saliva.

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

Genetic testing:

Their 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 their 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 their 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 their 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 child or someone under your care's sample (s) so we can use them again if we have new methods or questions to study. However, if you prefer that we do not use their samples for future approved studies, we will respect your decision and destroy them after the T1D-DAB study ends.

How long will we 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 their data will be collected at home, and they will not need to attend any study visits at our research centre.

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 an assent 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?

Your child or someone under your care will not personally benefit from taking part in T1D-DAB. However, 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 their 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?

Your child or someone under care may experience some discomfort and soreness at the site of the finger-prick test.

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

How can we take part?

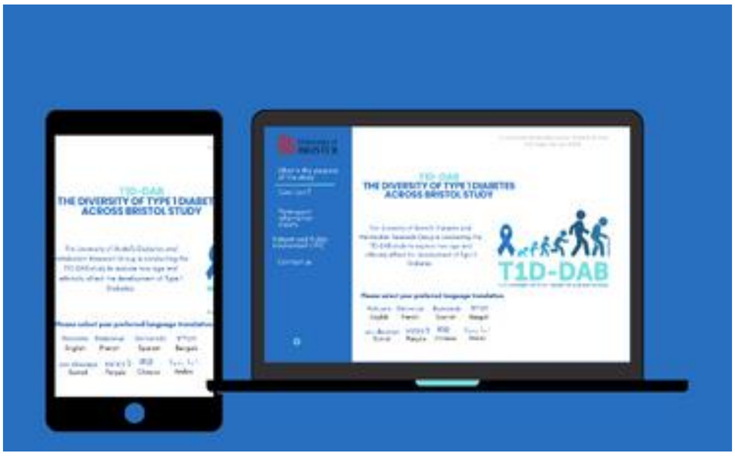
There are separate information sheets for children aged 7-11 years and 12-15 years to read. This is to ensure they understand what the study is about and what it will involve them doing.

If you want your child or someone under your care to participate in the T1D-DAB study, you must read and sign a consent form stating that you are happy for them to do so.

Children aged 7-15 years will be given a form (called an assent form) to sign to state that they agree to take part.

Both forms can be completed online on REDCap. You will also receive a record of the signed consent and assent forms.

Please contact us if you want to get these forms sent to you by post.



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 we have to take part?

No, taking part in T1D-DAB is entirely voluntary. You and your child or someone under your care do not have to take part in T1D-DAB if you do not want to.

What would happen if we changed our minds about taking part?

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

If you wish to stop taking part, we will keep the study information (data) we have collected about you and your child or someone under your care 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 Personal information will be collected in T1D-DAB?

We will collect the following personal information from you and your child or someone under your care:

- Your contact details.
- Their name, age, ethnicity, and sex at birth
- Their family medical history
- Their date of birth
- Their GP and diabetes doctor's contact details. We would like to inform them of their 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 their personal data will be analysed and processed using codes instead of your child's or someone under your care's personal details.

Once we have finished the study, we will keep some of your child's or someone under your care's data to check the results. All scientific reports and publications will not include any information that can be used to identify your child or someone under your care. This is to ensure nobody knows they took part in the T1D-DAB study.

How will my child's or someone under my care's information be kept confidential?

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

We will follow strict guidelines to protect your and their 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 their name or any other information that can be used to identify them.

You can find out more about how we will take care of all the data collected about you and your child or someone under your care 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 child or someone under care's information?

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

This means we are responsible for correctly protecting and using their study information. The University of Bristol will keep their identifiable information for 5 years after T1D-DAB ends.

The only people at the University of Bristol with access to their 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 your child or someone under your care or be aware of their name or your contact details.

What are your choices about how your child or someone under care's information is used?

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

If you and your child or someone under your care decide to withdraw from the study, we will respect that decision. We will also protect your rights and theirs. We will only keep the information we have already collected about them. We will use as little of their personal information as necessary.

Where can you learn more about how your child or someone under your care's information will be used?

You can find out more about how we will use their information under the GDPR statement here: http://www.bristol.ac.uk/secretary/data-protection/policy/research-participant-fair-processing-notice/

Will my child's general practitioner or someone under my care's Family Doctor (GP) be told they are taking part in T1D-DAB?

Yes. Your child's/some under your care's GP will be notified in writing that they are taking part in the T1D-DAB study. We will do this to let them know that your child or someone under your care is taking part in the study. Also, if we find anything that could affect the health of your child or someone under your care, we will contact their GP and diabetes doctor. They will provide your family 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 or their parents/guardians. 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 your child or someone under your care is harmed by taking part in this research project. However, if your child or someone under your care is 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, your child, or someone under your care 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 NHS 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 and their interests, an independent group called the Research Ethics Committee (REC) reviews all research conducted in the NHS.

This 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, 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!