ELSA-1 (EarLy Surveillance for Auto-immune diabetes) - a family interview study.

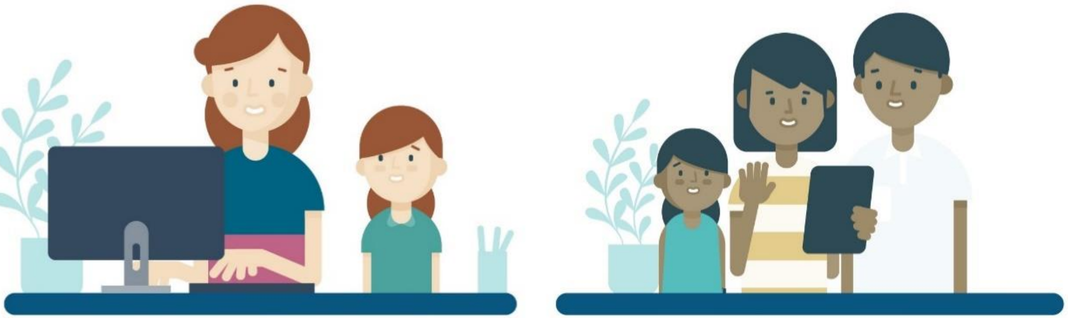
Parents’ and Carers’ information leaflet

1) Invitation

As a parent or carer of a young person in the West Midlands region, you are invited to take part in the ELSA-1 study. Joining the study is your choice. Before you decide, we would like to tell you about why we are doing the ELSA-1 study and what it would involve for you. Please read through this leaflet and you can find out more details on our website. Please feel free to talk to us and ask us any questions.

2) ELSA-1 Summary

What?	•In this study, we want to understand whether you would or would not want to know if your child was at risk of getting type 1 diabetes in the future, and if you would consider your child being part of a type 1 diabetes monitoring programme.
Why?	•We simply want to explore the reasons behind your thinking. •Talking to you about this will help us decide if a monitoring programme for type 1 diabetes is okay for children and their families. We will not be testing your child for diabetes in the ELSA-1 study.
Who?	•Families and their children, aged 5-13 years, from across the West Midlands can take part in ELSA-1
Where, How & When?	•This study is COVID friendly so that you can do it from your own home (online or by phone), but also in person if you wish. •Interviews will be held from May to December 2021.



3) What is type 1 diabetes and why is it important?

- Type 1 diabetes (T1D) is a life long illness, that often starts in childhood.
- It is caused by the body’s own immune system harming the pancreas (auto-immune), the organ in the body that makes insulin.
- This may be due to genes and other factors, such as viruses. This means any child could get T1D.
- This is not the same as type 2 diabetes, which is caused by genetic and lifestyle factors, and often occurs later in life.
- Children with T1D do not make enough insulin. Insulin is the key that the body uses to take the energy from the food we eat.
- Children with T1D, become very unwell at first, and need to see the doctor, to be started on insulin treatment straight away. This is for the rest of their lives.
- As people live longer with T1D, they are at risk of other health problems, such as heart and kidney disease.

Around the world, research studies are finding children who are at high risk, so that we can offer treatment to help delay T1D.

4) Why are we doing the ELSA-1 study?

If we find children who are very likely to get T1D in the future, we can observe them more closely in a monitoring programme. This means we can stop them from getting too sick. Also, these children could go into other research trials, to test treatments to delay the start of T1D.

ELSA-1 will also help us design ELSA-2. The ELSA-2 study will be testing children for T1D to see what their chances are of getting this when they are older. The test is a simple blood sample. Children who are found to be very likely to get T1D when they are older, can then be monitored over time. This will stop children who develop T1D from getting too sick, and means treatment can be started sooner as well.

You can choose to be part of ELSA-1, or ELSA-2, or both, but ELSA-2 will not open until 2022.

5) What does the ELSA-1 study involve?

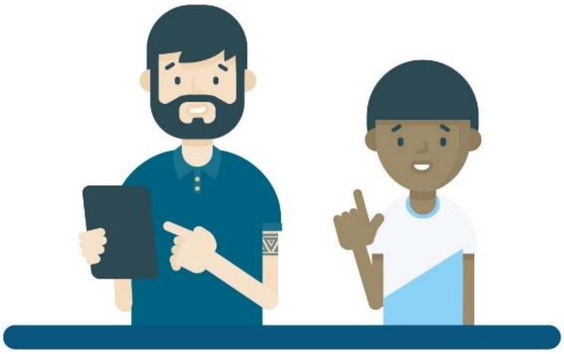
As part of the ELSA-1 study, you will have an interview with the research team. You will be interviewed in one of two ways, either by a family interview or as a group discussion, and the study team will advise you of which method you have been assigned to.

Both interview styles will be held by video call using Zoom, but you can also choose to do a phone call or an in person interview if you would prefer this. The video interviews will be from your own home and will last about an hour. The interviews will be held at a good time for you. With your consent the interviews will be audio recorded only.

The family interview can be held with up to 2 parents/guardians, and up to 3 children aged 5-13 years. This is to give us enough time to understand the opinions of all family members attending.

The group discussions will be held with other parents who have consented to be part of the ELSA-1 study. The aim of this interview is to explore potential barriers to a T1D monitoring programme. This will help us to better understand how these barriers could be reduced. You can let the study team know if you would rather not take part in a group discussion.

After the interview, you will be sent a postcard with a few questions about the study and your thoughts on a type 1 diabetes testing and monitoring programme. Parents / carers can choose not to complete the postcard information.



5a) What will I be asked in the interviews?

- We will ask you questions about whether you would or would not want to know if your child may get T1D in the future.
- We will ask you how knowing your child's risk would make you feel and the good and bad things about knowing.
- We will then ask you if you would want your child to go into a T1D monitoring programme.

- We will also ask you about the barriers you see to the implementation of a T1D testing and monitoring programme.

There are no right or wrong answers, we just want to know your thoughts and ideas and we may ask you to expand on your answers. Your answers will not be judged or challenged.

The interviews are designed to make you feel as comfortable as possible. You can stop the interview at any time and take breaks when you need to.

5b) What are the benefits of being part of this study?

By taking part in this study, you will help us to understand what it would mean to families to know if their child is at risk of T1D. These thoughts and ideas will help us go on to design and modify the testing and monitoring programme in ELSA-2.

This study has been made Covid friendly. It does not put you or your family at any additional risk because there is the option for everything to be done online or by phone. But you have the option to do in person if you want to. Current government safety guidelines in relation to COVID-19 will be adhered to in all instances.

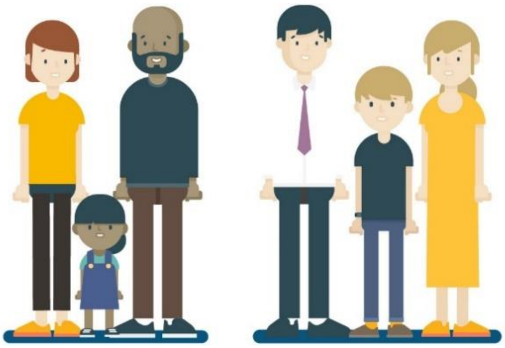
5c) What needs to be considered and what are the risks of taking part?

The interviews will ask families to reflect on difficult questions, such as how you would feel if your child were found to be at high risk of T1D. However, the interview team are highly sensitive and will ask questions and respond to your answers empathically to reduce any distress caused.

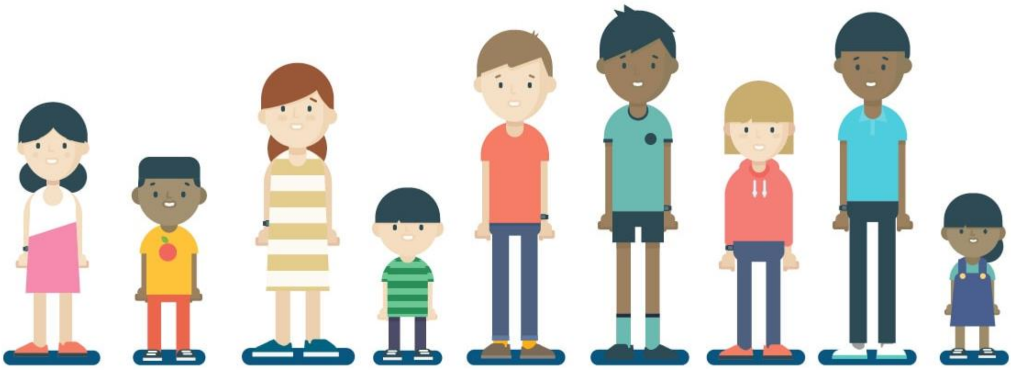
You can choose to stop the interview or withdraw from the study at any time.

6) Who can take part in this research?

This research study is open to all parents and carers in the West Midlands region. Parents / carers who do or do not have T1D in the family (type 1 or type 2 diabetes) can be part of this study. Also, parents / carers of children with T1D can also be part of this study.



As the parent or carer, you can decide if you would like to invite your child to be a part of the ELSA-1 study. Children aged 5-13 years can take part in the interviews. If you would like your child to be included in the ELSA-1 study, your child (children) will need to read the child's information leaflet or online tool, and sign the child's assent form (parents / carers can sign on their child's behalf).



7) What if there's a problem?

If you have any concerns about the study, you can speak to a member of the research team in the first instance at elsa@contacts.bham.ac.uk

If you are unhappy with their response or wish to make a complaint, you can contact the Sponsor's independent representative Dr Birgit Whitman on researchgovernance@contacts.bham.ac.uk

If you have any concerns about your data or wish to make a complaint about the way your data was handled, you can contact the University of Birmingham's Data Protection Officer on Dataprotection@contacts.bham.ac.uk

Important information

8) What will happen to the data from this study and will my data be kept confidential?

You and your child's data will be stored confidentially in line with the Data Protection Act 2018 and General Data Protection Regulations (GDPR).

The audio transcripts from the study interviews, will be transcribed by an external provider, with whom the University of Birmingham has a contractual and data processing agreement in place. Transcripts will be coded after checking the transcription for accuracy. Data analysis will only be performed on coded data, which can only be linked back to your personal data by the study administrator. Only the coded data will be shared with experts in the study team. The data will be published at international scientific meetings and in international scientific journals, but this will all be anonymised.

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We are using a web design company, Morph, to develop the ELSA study website with whom we have a contractual agreement in place. All data will be handled confidentially and no identifiable data will be shared with the company.

Online consent will be stored on REDCap, which is a secure web application used by the University to collect data electronically. Postal consent forms will be filed in a secure and locked office.

8.1) How we will use information about you?

We will need to use information from you and your child for this research project.

This information will include:

- Name of parent / carer enrolled on the study
- Name of your child(children) enrolled on the study
- Your contact details (email, phone number, and/or address)
- Ethnicity of parent / care and child (children)
- Age (years) of parent / carer and child (children
- Occupation of parent / carer
- Legal guardian status

We will use this information to do the research or to check your data to make sure the research 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.

We will keep all information about you safe and secure.

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.

8.2) What are your choices about how we will use your information?

You can stop being a part of the study at any time, without giving reason, but we will keep information about you that we already have.

We need to manage your data in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

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.

8.3) Where can you find out more about how your information is used?

You can find out more about how we use your information:

- On our website: www.elsadiabetes.nhs.uk

- By asking a member of the research team
- By sending an email to the University of Birmingham's Data Protection Officer at dataprotection@contacts.bham.ac.uk
- By calling us on 0121 371 4407

9) Who is leading and funding the study?

The ELSA-1 study is being led and funded by the University of Birmingham. The Principal Investigators for the study are Dr Parth Narendran and Prof Tim Barrett.

10) How have patients and the public been involved in this study?

Parents and young people are co-applicants on the ELSA-1 research protocol and have also been influential in the design of the study.

11) Who has reviewed this study?

This study is sponsored and insured by the University of Birmingham and has been reviewed and approved by a local and national ethics committee.

12) Are there any financial costs to me of taking part?

No, because the paperwork for this study will all be online and the interviews will be held online or by phone (from the comfort of your own home), there will be no cost burden for you. We will also arrange the interviews at a good time for you when you are not working.

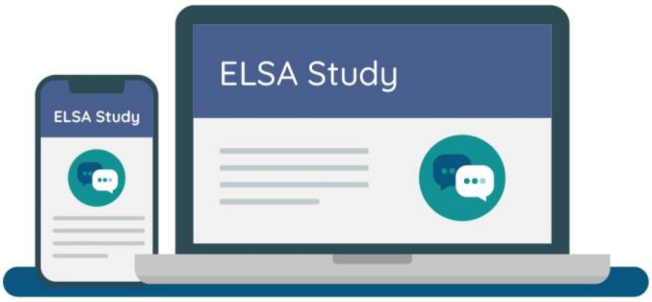
If you prefer to receive and complete the physical paperwork, we will send you the forms and provide pre-paid envelopes for you to return them to us. If you prefer to see us in person for the interviews, we will pay reasonable travel expenses, after your interview and once we have received evidence of your travel.

13) Are there any rewards or payments for taking part in this study?

No, there will be no payments or rewards for being part of this study because there is no cost burden. We are very grateful to the families who take part in this study and give their time to support our research.

14) Further information and contact details:

Please visit our website for more details about the study: www.elsadiabetes.nhs.uk. Please see our Frequently Asked Questions section of the website as well. Please feel free to contact the study team on: elsa@contacts.bham.ac.uk



15) Consent process options

You can choose to complete the online consent process or the postal consent process.

For either process, you will first need to complete the online eligibility and expression of interest form. The study team can arrange a phone call to help you with this, or complete this on your behalf, with your agreement.

15a) Online consent process:

a. If you wish to complete the online consent process, you will need to complete the following online forms in sequence, which the study team will send to you in rotation:
    i. Eligibility and expression of interest form [online]
    ii. Parent / carers online consent form [online]
    iii. +/- online children's assent form(s) [online]
    iv. Personal details form [online]
b. The study team will then be in touch with you to organise your interview

15b) Postal consent process:

c. Complete the eligibility and expression of interest form [online]. You can also send your postal address to the elsa@contacts.bham.ac.uk.
d. We will send you out the consent form with prepaid envelopes for return.
    i. We will ask you to provide your email and phone number on this form so that we can contact you.
e. You will then need to complete the online personal details forms, or you can arrange a phone call with the study team and we can complete these on your behalf.
f. The study team will then be in touch with you to organise your interview

16) What happens next if you are willing to take part in the ELSA-1 study?

1. If you would like to find out more about the ELSA-1 study, please email us on elsa@contacts.bham.ac.uk and visit our website: www.elsadiabetes.nhs.uk

2. Please let the study team know if you have any further questions on elsa@contacts.bham.ac.uk
3. If you are happy to proceed, you will be able to complete either the online or postal consent forms
4. Then the study team will be in touch with you to arrange your interview.

Thank you for taking the time to read this information leaflet.