



ELSA 1 (Early Surveillance for Auto-immune diabetes) - an interview study.

Adult's information leaflet

Invitation

We are inviting you to take part in the ELSA 1 study.

This leaflet will give you more information about the ELSA 1 study. You can also visit our study website for more information: www.elsadiabetes.nhs.uk

ELSA 1 Summary

The ELSA 1 study is holding interviews with individuals aged over 18 years to understand their thoughts on screening for type 1 diabetes.

We are exploring screening preferences in three different ways:

1. Individual interviews
2. Focus groups with other participants

The individual interviews last about 1 hour and can be done online, by video call, phone or face-to-face if you prefer.

Focus groups will take place in-person or by video call, and last 30-60 minutes.

Your perspectives will help us go on to explore the importance of a type 1 diabetes screening programme for adults in the UK.

Please read the next section to find out more about the ELSA 1 study.

What is type 1 diabetes?

Type 1 diabetes is a condition that affects how the body uses the food that you eat. In young people with type 1 diabetes, not enough insulin is made in their body. Insulin is like the key needed to unlock nutrition from our food.

Not having enough insulin, can make children feel very poorly. Children who have diabetes, will need to take replacement insulin for the rest of their lives.



Why is the ELSA 1 study important?

ELSA 1 wants to understand people's thoughts on screening children to find out their risk of developing type 1 diabetes. We want to understand the barriers to screening and explore how these could be addressed.

The ELSA 1 study will help us to design and deliver the ELSA 2 study, which will be testing children to find out their risk of developing type 1 diabetes. You can choose to be part of ELSA 1, or ELSA 2, or both, but ELSA 2 will open for recruitment later in 2022.

What does the ELSA 1 study involve?

In the ELSA 1 study, we want to hear your thoughts on screening adults for type 1 diabetes in a study interview setting. You can choose to do this as a one-to-one interview with the researcher or a focus group with other study participants. These will be held by the ELSA research team from the University of Birmingham.

The **one-to-one interview** 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 **focus group** will be held in-person or by Zoom. The interviews will last about an hour and can be arranged at a convenient time for you. With your consent the interviews will be audio recorded only.

After the interview:

We will send you a postcard with a few questions about the study and your thoughts on a type 1 diabetes screening programme to respond anonymously. You can choose not to complete the postcard information.

What will I be asked in the interview?

We will ask you how you feel about adults being screened for type 1 diabetes. We will also ask you about any barriers you can think of to screening adults for type 1 diabetes.

There are no right or wrong answers, we simply want to understand your thoughts and ideas. 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. We may also ask you if you could suggest anyone else we could approach for the ELSA interviews.



What are the benefits of being part of the ELSA 1 study?

- Being part of this study, you will help us understand the importance of screening adults for type 1 diabetes.
- This study is Covid friendly. It does not put you at any additional risk because you can complete the study online or by phone. Current government safety guidelines in relation to COVID will be adhered to at all times.

What are the risks of taking part?

The risks in this study are minimal. The interview team are highly sensitive and will ask questions and respond to your answers empathetically to reduce any distress caused. If you are asked a difficult question or a question you do not know the answer to, the interviewer will simply move on and you can choose to stop the interview or withdraw from the study at any time.

Who can take part in the ELSA 1 study?

Any adult living in the UK can take part in the ELSA 1 study. If you have a child with or family history of type 1 diabetes, you can still be part of this study.



How can I take part?

Taking part is a three-step process and you can complete these 3 forms online, in-person or by post:

1. Fill in the online eligibility form
2. Fill in the consent form.
3. Fill in the personal details form

The online consent process is via REDCap forms. If you would prefer in-person or postal, please contact the study team by email: elsa@contacts.bham.ac.uk or phone: 0121 414 7814.

What if there is a problem?

- If you have any concerns about the study, please contact the study team: 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

Data management

Your data will be stored confidentially in line with the Data Protection Act 2018 and General Data Protection Regulations (GDPR). We will keep all information about you safe. Your personal details will be stored securely in the REDCap database. Postal consent forms will be filed in a secure and locked office. Your personal detail will not be shared with third parties.

How we will use information about you?

We will need to use information from you for this research project, including:

- Name, ethnicity, age, gender, occupation and your contact details
- Where you heard about the study e.g. social media or text message

We will use this information to do the research or to check your data to make sure the research is being done properly. You will be assigned a code once you have consented to take part in the ELSA 1 study. The study team will process and analyse data from the study using these codes rather than you/your child's personal details. Study team members who do not need to know who you are will not be able to see your name or contact details. 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. 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 anonymised data will be published at international scientific meetings/journals, but this will all be anonymised.

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. This is because 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.

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

- On our website: <https://elsa-interviews.digitrial.com/>.
- Email: elsa@contacts.bham.ac.uk
- Email: University of Birmingham's Data Protection Officer at dataprotection@contacts.bham.ac.uk

Frequently Asked Questions:

- **Who is leading and funding the study?** The ELSA 1 study is being led by the University of Birmingham, and funded by the National Institute for Health Research. The Study's Principal Investigators are Professor Parth Narendran and Professor Timothy Barrett.
- **How have patients and the public been involved in this study?** We have worked with parents to inform the design of our study.
- **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.
- **Are there any financial costs to me for taking part, and are there any rewards or payments for taking part in this study?** We will reimburse any reasonable travel expenses you incur for this study, once we have received evidence of your travel. 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. We are very grateful to the individuals who take part in this study and we can offer a gift voucher of £20 for a completed interview as a thank you for your time.



What happens next if you want to take part in the ELSA 1 study?

1. Complete the 3-step online consent process here: URL or contact us for postal or in-person options, by email: elsa@contacts.bham.ac.uk or by phone: 0121 414 7814
2. Visit our study website: www.elsadiabetes.nhs.uk for more information

Thank you for your interest in the ELSA 1 study

