



PARTICIPANT INFORMATION SHEET – SCREENING

What is research?

Our research question is to see if a medicine can stop type 1 diabetes developing in children who have a higher risk of developing the condition.

This study involves a screening phase to identify children and young adults at risk of developing type 1 diabetes, followed by three treatment stages for those who are.

You are being invited to take part in the first part of this study called the screening phase.

Why is this research project being done?

At present, there is no treatment that can prevent type 1 diabetes. We know that more children each year are developing the disorder, and want to find a way to stop this trend. In this research project we want to find out if we can prevent children at high risk of developing type 1 diabetes from needing insulin, by treating them with a medicine called metformin. We think metformin will help children at risk of developing type 1 diabetes because it will stop their insulin cells from working too hard, which could then protect them from the damage that would eventually lead to the children needing to inject insulin.

In the screening phase of the study we will be able to tell from a small blood test if a person is at a higher risk of developing type 1 diabetes.

In the follow up treatment phase of adAPT we want to find out if metformin will prevent children developing diabetes.

Nineteen out of every 20 children (95%) will not have diabetes antibodies which means they have a low risk of developing diabetes in the future.

The remaining one out of 20 will have diabetes antibodies, this does not mean they will definitely develop diabetes, but it means they have a higher risk.

The next stage of the study will be available to those who have the antibodies and they will be invited to take part in in the prevention trial.

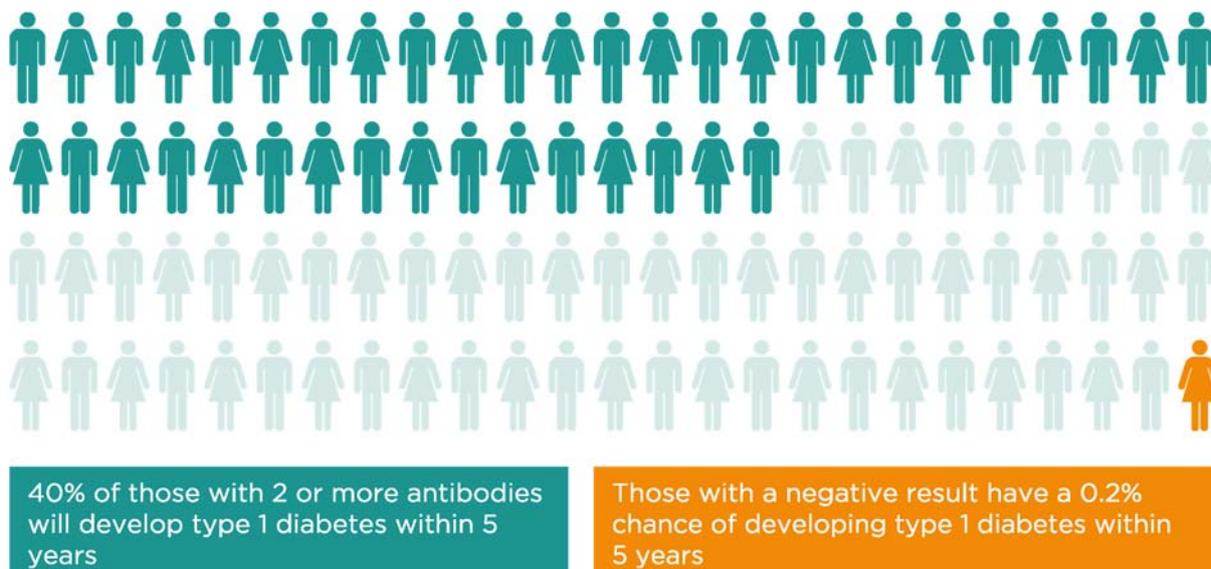
Chart 1 below shows the chances of developing diabetes based on antibody test results.

Why am I being asked to take part?

We think this study might be of interest to you because you are aged between 5 and 16 and you have a brother, sister or parent who was diagnosed with diabetes before they were 25y.

We hope to screen approximately 3500 children and young adults just like you from Scotland and England.

Chart 1. Chances of developing diabetes based on antibody blood test.



Do I have to take part?

No. It is up to you.

- Your study doctor or nurse will ask you to take part.
- Your parents/guardian will be asked if they also agree.
- You can stop at any time without giving a reason.

What will happen to me if I take part in the research?

We will invite you to attend a visit with the research team at a suitable location.

This visit will take about an hour.

During the visit we will discuss the study in detail and answer any questions you have. We will make sure the study is suitable for you.

We will ask you and your parent/guardian to sign consent forms to show that you are happy to take part (you will be given a copy to take home.)

We will take a small blood sample (3.5mls, less than a teaspoon) from your arm. We will numb your skin before we take the sample.

We will send your blood sample to one of our laboratories and will give you the test results within 8 weeks.

We will either send you a letter or give your parent a call with your result.

If the test is positive, the study doctor will contact you and your parent(s) by telephone, initially to talk over the result and to make an appointment to discuss it further. After this call, and you agree, we will send you information for the next stage of the study.



Even if you do not wish to take part in the next stage you are encouraged to discuss your results with the study doctor.

Are there any discomforts or risks?

There are no risks to taking part in this part of the study. The blood sample may be slightly uncomfortable but we will offer you a numbing spray or cream so that you will only feel a small scratch or slight pressure.

Will joining in the project help me?

We cannot promise the study will help you but if the medicine works in the treatment phase of the study it may delay or stop children from going onto develop diabetes. Whatever the result of the study the information we get will help other children and young people who are at risk of developing diabetes in the future.

Further Contact

We will ask you and your parents' permission to contact you with information about any future studies that may be of interest to you. You do not have to take part in these additional studies.

We will also ask for permission to be informed if you develop diabetes for up to 10 years after you have taken part in the study. This information is gathered from electronic hospital records using a code. We do not have to see you to find this out. This information will help us assess how good our screening techniques are in predicting diabetes.

Did anyone else check the study is OK to do?

Before any research is allowed to happen, it is checked by a group of people called an Ethics Committee. They make sure that the research is appropriate to do. This project has been checked by the East of Scotland Research Ethics Committee 1.

Will I be told about the results of the research?

The adAPT study will last for over 5 years. When adAPT finishes the results will be posted on the study website and in scientific magazines.

What if something goes wrong during the project?

Your study doctor or nurse will discuss any problems with you and your parent/guardian to decide what to do next.

Keeping you safe and well will always be the most important thing for the study doctor and nurse.

Will anyone else know I'm doing this?

Your study doctors and nurses will know you are taking part. If you and your parents agree we will also let your GP know. The University responsible for the research need to make sure the research is done properly. This means that specially trained people may look at your study and hospital notes, but all your information is kept private.



How will my information be stored?

All the information which we collect about you during the study will be private. We will only use your name and address when we write to you. All your study information will be saved under your study number.

All information will be stored securely and only the research team will have access.

What if I do not want to do the research anymore?

If at any time you don't want to take part just tell your parents, doctor or nurse. They will not be cross with you.

If you do decide to drop out of the study we will ask if it is okay to keep any information we have already collected to use for the study results.

Will I receive payment for taking part?

No, you will not receive money for taking part but we will pay for you and a member of your family travel to the hospital for your study visits.

Further Information

You can also find out more information about this study on the website www.adaptdiabetes.org

Chief Investigator: Professor Terry Wilkin
Contact Number: 07712 184547

Trial Manager: Dr Roberta Littleford
Contact Details: 01382 383991

Thank you for taking the time to read this information sheet, and for thinking about taking part.

