



## PARTICIPANT 10-12 INFORMATION SHEET

### **WHAT IS RESEARCH?**

Research is what scientists do to find out about things. In medical research, doctors do experiments to understand more about illnesses and to develop better treatments for children and young people in the future.

We want to find out if a medicine called metformin can stop diabetes developing children and young people.

Metformin is a medicine that has been used for many years in adult diabetes, but it has never been tested in children at risk of developing diabetes.

### **WHY ARE CONDUCTING THIS TRIAL?**

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.

### **WHY HAVE I BEEN ASKED TO TAKE PART?**

You have been asked to take part because your blood test from the first part of the study was positive for diabetes antibodies. Testing positive does not mean you will get type 1 diabetes but it means you have greater risk than if you tested negative.

We are asking all children and young people who have a positive test result to take part.

### **DO I HAVE TO TAKE PART?**

No. It is up to you.

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



## WHAT WILL HAPPEN TO ME IF I TAKE PART IN THE RESEARCH?

If you say 'yes' to taking part, we will ask you to come to the hospital to have some tests done. We might ask you come ten times over 3 years. The table below shows you when you will be asked to come to the hospital, and what will happen at each visit. All visits are virtually the same. The study is made up of three stages, and we are outlining the first two here. Stage 1 will cover the first four months, and Stage 2 up to 36 months. We will arrange the visits that are suitable to you and your family.

### TREATMENT PROGRAMME FOR STAGES 1&2

Activity	 Month 0 <sup>1</sup>	 Month 1	 Months 1 <sup>1</sup> , 2 & 3 (phone)	 Months 4, 8, 12, 18, 24, 30, 36 <sup>2</sup>	 Withdrawal Visit <sup>3</sup>
General Health & Medication Questions	X	X	X	X	X
Blood samples	X	X		X	X
Urine Pregnancy Test (if required)	X	X		X	X
Measure height, weight and waist	X			X	X
Sweet drink test (MMTT) – 5 small blood samples over 2 hours	X	X		X	X
Medicine Group Allocation	X				
Collect study medication	X	X		X	
Return all study medication bottles (use/unused)				X	X

<sup>1</sup> Telephone calls to discuss medication. Dose change instructions will be given.

<sup>2</sup> The study nurse will call you every 3 months or so to check on how you are feeling. You can call the study team at any time during the study.

<sup>3</sup> Withdrawal visit will be performed if you agree.

If you take part in adAPT, you will be assigned to take either metformin or a placebo (dummy) liquid twice a day. Which treatment you are on is decided randomly, rather like tossing a coin, but decided by a computer. You won't know which you will be taking, nor will your parents or the research nurse and doctor. This is essential so that we can know for certain whether or not the treatment really does have an effect.

The dose of medicine you will be asked to take will be calculated at each study visit by measuring your weight. Your height and waist measurements will also be taken.

At each hospital visit we will ask you to have nothing to eat from bed time the night before (from 10pm), but you can drink water. These hospital visits will be in the morning. We will give you a drink like a sweet milk shake soon after you arrive. The drink is part of the study, but we will also give something to eat before you leave.

We will ask some questions about your health and any medicines you may be taking, because we have to check that adAPT will suit you. Any changes with your health or medicines you are taking during the course of the study should be noted down. To help, we will give you a diary so that you or your parents can record any change between study visits.

We shall be taking some blood samples as part of the study. We can numb your skin with spray or cream before inserting a small flexible plastic tube using a needle (cannula) in your arm vein. When we do this, you should only feel a small scratch and light pressure.

At each visit, we will be carrying out a sugary drink test called a Mixed Meal Tolerance Test (MMTT) to measure how much insulin your body produces. You will have a sweet tasting drink then we will take five small blood samples over two hours. The blood samples will be taken using the cannula in your arm.

We should know your blood results from the hospital laboratory by the end of your first visit (Month 0). If these are normal, we will give you your first month's study medication to take home.

### **WHAT SHOULD I KNOW ABOUT THE STUDY MEDICINE?**

All medicines have a chance of making you feel unwell. These are called side effects, but by no means everyone gets side-effects. The most common last only a short time feeling sick, a sore tummy, loss of appetite or diarrhoea. If you feel unwell at all it is important you let your parent/guardian and the study team know.

To reduce the chance of side-effects, which are usually only troublesome at the start, you will be given half the normal dose for the first month so that your body can get used to it. After the first month, we will increase the medicine to the normal dose which you will continue to take during the study. We will keep a close eye on you to make sure you are feeling well and managing to take the study medicine regularly.

You and your parent(s) will be given instructions on how to take the medicine. It will be taken once a day for the first two weeks, then twice a day with food, normally at breakfast and evening meal. A dropper will be used to ensure the dose is right.

We will tell you and your parent(s) how to contact the study team if you have any questions, or if there is anything you want us to know.

It is common practice in clinical trials using a medicine to ask girls whose periods have started to take a pregnancy test before and during the study. All female participants in



adAPT who have started menstruating will have a routine urine pregnancy test done before they start study medication, and at all study visits.

### ***WILL JOINING IN THE PROJECT HELP ME?***

We cannot promise the study will help you, but if the medicine works it may protect you from diabetes. Whatever the result, the information we get from the study will help other children and young people who are at risk of developing diabetes in the future.

### ***WILL I TAKE THE MEDICINE AFTER THE STUDY FINISHES?***

You will not be given metformin by the study team after you have finished taking part, but your own doctor may wish to prescribe it if the study is successful.

### ***WILL I BE TOLD THE RESULTS OF THE STUDY?***

adAPT will take more than five years to complete. When it finishes, the results will be posted on the study website and in scientific magazines. If you agree, we will send you a summary of the study results and let you know if you were taking metformin or placebo. We will not be able to let you know this until after the last child has completed the study.

### ***WHAT IF SOMETHING GOES WRONG DURING THE PROJECT?***

Your study doctor or research nurse will discuss any problems with you and your parent/guardian, and decide what to do next. Keeping you safe and well is a priority for the study doctor and research nurse.

### ***WILL MY INFORMATION BE KEPT CONFIDENTIAL IF I TAKE PART?***

All your samples are anonymised and sent to a laboratory to be tested. There may be small amounts of blood left over after the tests have been done. We will ask you if you agree to us keeping it and using it for future research.

### ***WILL ANYONE ELSE KNOW I'M TAKING PART IN adAPT?***

Your study doctors and research nurses will know you are taking part. If you and your parent/guardian agree we will also let your GP know. The University responsible for the research want to make sure the research is done properly. This means that certain people may look at your study and hospital notes as part of their job, but all your information is kept confidential.

### ***WHAT IF I DO NOT WANT TO DO THE RESEARCH ANYMORE?***

If at any time you don't want to take part in the research anymore, just tell your parents, doctor or research nurse. They will not be annoyed with you, and you won't have to give a reason if you don't want to. If you do decide to leave 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 can pay for you and a member of your family to travel to the hospital for your study visits. We will also offer you a choice of gift vouchers during the study to say thank you for taking part they will range from £10 to £15. These can be used on-line or in high-street shops.



## ***DID ANYONE ELSE CHECK THAT THE STUDY IS OK TO DO?***

Before any research can start, it has to be checked by a group of people called an Ethics Committee. They make sure that the research is appropriate and, most importantly, safe to do. This project has been checked by the East of Scotland Research Ethics Committee 1.

### ***Further information***

You can find out more information about this study on the website [www.adaptdiabetes.org](http://www.adaptdiabetes.org)

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

