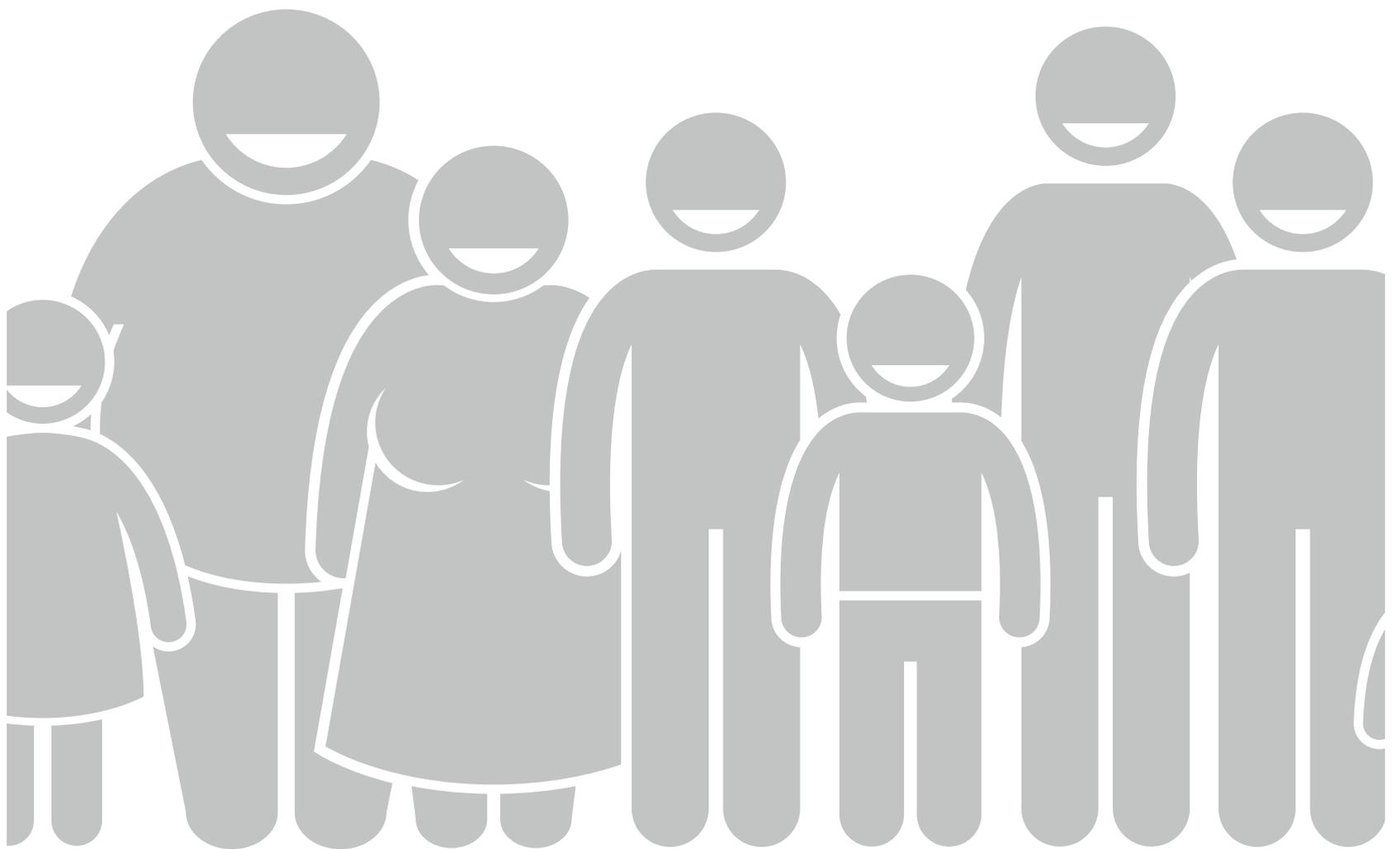




# PARENT/ GUARDIAN INFORMATION SHEET







## Prevention strategies for adolescents at risk of diabetes – Validation of a PRE\_START Tool for young people aged 12 - 14 years

Thank you for taking the time to read this information sheet. We would like to invite your child to take part in what we think is a very important research study but before you decide whether or not to take part, it is important for you to understand why the study is being done and what it will involve, so that you can make an informed decision. Please take some time to read the following information carefully.

### What is this study about?

This is an international study taking place in the UK, Spain, Portugal, Germany and Greece. The study aims to help us understand why some young people are more likely to get type 2 diabetes than others. Type 2 diabetes is a serious condition that occurs when people have too much sugar in their blood for too long. Too much sugar in the blood for long periods of time can lead to lots of health problems, including problems with the heart, kidneys, eyes and feet.

Risk is the likelihood it is that a certain thing will happen in the future. Although we cannot say for sure how much risk young people have for developing type 2 diabetes, we do know that there are a number of key behaviours and actions that begin in teenage years that will increase this risk in the future, such as not being active enough and having an unhealthy diet.

### What is the purpose of this study?

Although type 2 diabetes used to be a disease only diagnosed in adults unfortunately it is now starting to be diagnosed in young people. However type 2 diabetes doesn't just develop over-night, it takes time to develop, and the good news is that it can be prevented. We know that there are certain characteristics and lifestyle choices in adults that can make people more likely to get diabetes (such as having a family member who has diabetes, eating the wrong types of foods and not getting enough exercise) but we want to know if the same risk factors apply in young people specifically. So that is why this study came about.



We want to develop a questionnaire that can be used on young people aged 12-14, that will be able to identify those children who are most 'at risk' of developing diabetes in the future. If we can spot the ones most at risk, we can get in early to help them. Identifying these young people early in their life might help to stop or delay them from developing diabetes in the future. To do this we want to do health assessments on 100 young people in Leicestershire and from the results we will create a questionnaire that can be used on all young people worldwide to help identify young people who may be risk of developing type 2 diabetes because of certain characteristics.

### Who is doing this study?

Researchers and doctors from the University Hospitals of Leicester NHS Trust, the University of Leicester and the Leicester Diabetes Centre are working together on this study. We are also working with other research teams across Europe.

### Why has my child been chosen? Can anyone take part?

We are interested in any young person between the age of 12 and 14. Only those children who cannot speak or read English very well, or who already have type 1 or type 2 diabetes will be excluded from the study. We hope that 100 young people will take part.

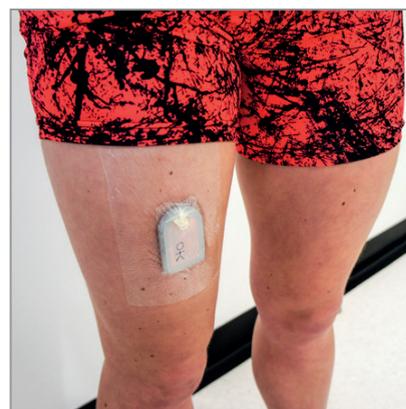
### Does my child have to take part?

No, you do not have to take part. Whilst we would really value having you on board, it is completely up to you and your child whether or not you decide to take part. We want you to be happy with whatever decision you make. If you do decide to take part in this study and you change your mind later, you can easily withdraw from the study. You don't have to give us a reason, and it won't affect your or your child's normal medical care in any way.

## What will happen if I decide I want my child to take part?

If you decide to take part, you and your child will be invited to an appointment at a local venue, which we expect will last about 90 minutes. At this appointment, we will explain the study in more detail and give you and your child the opportunity to ask any questions you might have. After this, you and your child will have some questionnaires to fill in about your family (e.g., family history of chronic disease) and lifestyle habits. The questions are not a test – there is no right or wrong answers, it just helps us get a better picture of you and your family. We will also do a health assessment on your child, including:

- Height and weight
- Waist and neck size
- Body fat percentage using scales
- Blood pressure
- Small blood sample taken from a prick to the finger
- Posture Monitor (optional): You will be given a small posture monitor to wear for 7 days (see picture). This monitor is attached directly to the skin (using transparent dressing) on the mid-thigh under your clothing. This monitor tells us when during the day you sit, stand and walk. If it is of interest to you we can provide you with some feedback from the monitor at the end of the study.



These measurements will help us investigate risk factors for type 2 diabetes in young people. We will share these results with you in a letter along with ranges that are considered healthy (green) unhealthy (amber) and very unhealthy (red). If your child has more than one value that is considered unhealthy we will suggest that you follow up with your GP. We will also have an independent doctor look at your child's results and, if they deem any of your child's values to be concerning, or are confirmed to be in the "red" range, we will send a copy to your child's results to your nominated GP.



These measurements will also be combined with data from another 400 young people from around Europe. The data will be used to refine the questionnaire that you will complete at the measurement session as this is like a 'first draft'. We will use this improved tool on your child's data to see whether, based on a number of factors, your child might be considered at higher risk for developing type 2 diabetes in the future. If this is the case, you will be informed by letter and invited to take part in a follow-on study a few months after this study is complete. However, you are under no obligation to take part in the follow-on study or any other research programme.

### Why are parents/guardian involved?

Parents must give written consent for their child to take part in this study because they are under the age of 16 and therefore not legally able to provide informed consent to a research study. We also need you to accompany your child to the study visit as we will ask you some question about your family health history and your child when they were very young that only you will know.

### What are the side effects of taking part?

Your child's safety and comfort is our number one priority, and so we hope to make the experience as comfortable as possible. Your child might experience a slight discomfort during blood pressure measurements due to the pressure of the cuff on the arm. This will only last for a few seconds while the reading is taken, and if it gets to painful we can stop at any time. Your child may also feel a slight discomfort when their finger is pricked for a blood sample, but we will use a numbing cream to try and stop it from hurting too much. All of these measures will be under taken by a fully trained healthcare professional to minimise any discomfort.

### What are the possible benefits of taking part?

We cannot guarantee there will be any benefits. Your child will receive a free health assessment and you will receive the results of this. You and your child will be contributing to health research and to the development of a questionnaire that may be used across Europe in the future to help identify young people at risk of type 2 diabetes. Your child will also receive a £5 'Love2Shop' gift voucher at the end of the visit as a small thank you for taking part.



## Who will be able to see my child's results?

Only people in the PRE-STARt team will see your child's name and results. All information that will be collected during the course of the study will be kept strictly confidential. We will not use names or addresses to identify you and your child will be given a unique code so that they cannot be recognised. As mentioned above, we will also have an independent doctor look at your child's results and, if they deem any of your child's values to be above the unhealthy range, we will send a copy to your child's results to your nominated GP

## What will happen to the results of the research study?

The results of the study will be written into a report and printed in a medical journal. We will also share these results at meetings with other researchers and doctors so that other people are able to benefit from this study. You and your child will not be identified in the results.

## Who is organising and funding the research?

The funding for this study comes from the European Commission Health and Consumers Directorate General. The study is being organised and co-ordinated by the University Hospitals of Leicester Diabetes Research Centre in collaboration with researchers from the University of Leicester and University Hospitals of Leicester, NHS trust.

## Will I get travelling expenses?

We want to make it as easy as possible for you to take part and so parking charges and travelling expenses up to £10 can be reimbursed for any visits associated with the study. Just make sure you keep hold of your receipt, as you will need this to claim the money back.

## Who has made sure that this study is safe to do?

All research studies have to be checked by a group of people called an 'Ethics Committee'. They read all the study details to make sure that it is safe and follows the rules that researchers have to work by. The Northampton Research Ethics Committee and University Hospitals of Leicester, NHS Trust has agreed that this is a safe study.



## What if something goes wrong or I am not happy with how the research was conducted?

If you or your child were unhappy or harmed by taking part in this study, there are no special compensation arrangements. If you or your child is harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you. You should ask to speak to Emer Brady on 0116 258 8959 who will do their best to answer your questions. If you remain unhappy and wish to address your concerns or complaints on a formal basis, you should contact: Patient Information & Liaison Service via email at [pils.complaints.compliments@uhl-tr.nhs.uk](mailto:pils.complaints.compliments@uhl-tr.nhs.uk), in writing to The Firs, c/o Glenfield Hospital, Groby Road, Leicester. LE3 9QP or using freephone 0808 178 8337.

## What do I do now if I want my child to take part?

We are pleased that you and your child are considering taking part in this study. For the next step, please complete the enclosed reply slip and post it to the research team using the pre-paid envelope provided. Please also remember to tick the box to confirm that your child does not have type 1 or type 2 diabetes. A member of the research team will then contact you to set up a suitable date and time for your appointment. Alternatively, please contact the research team on the number or email address below and a member of the PRE-STARt team will arrange this for you.

Just because you agree to attend the appointment, it doesn't mean you are agreeing to take part in the study. At the appointment we will answer any questions you may have, and only when you are happy with everything will we ask you to sign a consent form to say you agree to take part. This gives us a record of what was discussed and we will give you a copy of this form for your records. Remember, even after you have signed the consent form you are still free to withdraw at any time. Once again, thank you for taking the time to consider taking part in our study. We really look forward to having you on board.

If you would like more information about the study, or to book an appointment you can contact Georgie SurrIDGE on 0116 258 8929 or email [georgie.surrIDGE@uhl-tr.nhs.uk](mailto:georgie.surrIDGE@uhl-tr.nhs.uk) and we will be happy to answer any questions you might have. Thank you for taking the time to read this information sheet



## Reply Slip

I,  the parent/guardian of

am interested in participating in  
the PRE-STARt study.

- My child's age:
- My child's sex (please circle one)    M        F
- My child's height (if you don't know please give your best guess)
- My child's weight (if you don't know please give your best guess)
- I tick to confirm that my child does not currently have type 1 diabetes or type 2 diabetes

Telephone Number:

Best time to call:

Email address:







[www.pre-start.org](http://www.pre-start.org)



 @LDC\_Tweets |  [facebook.com/leicesterdiabetecentre](https://facebook.com/leicesterdiabetecentre)  
 [www.leicesterdiabetescentre.org.uk](http://www.leicesterdiabetescentre.org.uk)