



Education for children, young people and families living with diabetes

Information for young people age 11-16 about the research

We are asking if you would take part in a research project to find the answer to the question 'what is the better way of teaching children and young people and their parents how to live with diabetes?' Before you decide if you want to join in it's important to understand why the research is being done and what it would involve for you. So please consider this leaflet carefully. Talk about it with your family, friends, doctor or nurse if you want to.

Part one:

Why are we doing this research?

This study is testing different ways of teaching children and young people and their parents how to live with their diabetes, and how to manage diabetes together and keep it well controlled.

Why have I been invited?

You have been invited to join our study because you have diabetes. The study will involve over 250 young people.

Do I have to take part?

No, it is up to you. If you do, a researcher from the University of London will ask you to sign a form agreeing to take part. You will be given a copy of this information sheet and your signed form to keep. You are free to stop taking part at any time during the research without giving a reason. If you decide to stop, this will not affect the care you receive.

What will happen to me if I take part?

All clinics aim to teach children and young people and their parents how to look after their diabetes. This study is comparing different ways of teaching this information to families. All the ways of teaching have potential advantages and disadvantages. By doing this study we will be able to find out which approach is better.

How clinic staff provide this information to you will depend on which education programme is being used at your clinic. Some clinics will ask children/young people and parents to attend separate sessions in addition to their usual clinic appointments to be taught this information; others offer information during your usual clinic appointments. The clinics have been chosen by chance to offer the different ways of teaching information. If your clinic offers this information in separate sessions, this will mean that you and your parents will be asked to attend four separate sessions, lasting 2 to 3 hours each, as well as your usual appointments. The extra sessions are spread over three to four months. They will be attended by three or four families with young people of a similar age. If your clinic offers information in the usual clinic sessions you will continue to attend clinics as before.

All young people and parents taking part in the study, however they are taught about living with diabetes, will be asked about the clinic education programmes and how they look after and live with their diabetes. You and your parents will be given a questionnaire to complete, with the help of a researcher, when you join the study, and one year and two years later. Some young people and their parents will also be invited to attend a focus group to discuss the education programme at the clinic. The travel costs of attending the focus group will be paid by the study.

When you join the study, you will have a sample of blood taken from your vein to test your diabetes control. This happens at your clinic visits anyway, but we know that at some clinics this would normally be taken from a pin prick in your finger. The blood sample from the vein will be repeated at 12 and 24 months after you agree to take part in the study. Other blood samples will be taken using the method normally used by your clinic as part of usual care.

What are the possible benefits of taking part?

We cannot promise that the study will help you but the information we get from this study might help improve care for young people with diabetes in future.

What happens when the study stops?

The study lasts for four years. Separate education sessions shared with other families last four months during the study. Your care will not be interrupted by the end of the study

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information is given in part 2.

Contact details

If you would like to know more, please ask Carol Vigurs who can be contacted at 0207 612 6613 or c.vigurs@ioe.ac.uk

Thank you for reading so far – if you are still interested, please go to Part 2.

Part two:

What if relevant new information becomes available?

Sometimes during research, new things are found out about how to care for patients. Your doctor will tell you if this happens. What is best for you might be:

- To carry on as before with the study
- To go back to your usual care

What if there is a problem or something goes wrong?

If you are unhappy about anything, you can discuss it with the researchers or project manager Dr Vicki Strange on 0207 612 6731 or v.strange@ioe.ac.uk or with your doctor. If you wish you can complain to the hospital.

Will anyone else know I am doing this?

We shall keep your information in confidence. This means we shall only tell those who have a need or right to know. If during the research you were to tell us that you were being harmed, we might have to give this information to an appropriate person. We would talk to you about this before we told anyone else.

With your permission, we will let your GP know that you are taking part in the study.

It would also be very helpful if you would agree that your name could be registered with the NHS Central Register. This would make it easier for the study team to contact you in the future, even if you move house.

What will happen to any samples I give?

Blood taken at the beginning of the study and at 12 and 24 months will be sent to a central laboratory for testing. Samples will be identified with an anonymised code number. The results will be fed back to you by your clinical team.

What will happen to the results of the research study?

The results of the research study will be published in a report that will be available on the World Wide Web, and in journals for doctors. You will not be named in any report or publication. A short report will also be available to you and your parents through your clinic.

Who is organising and funding the research?

The NHS Research and Development programme will pay your clinic for including you and your parents in this study.

Who has reviewed this study?

Before any research goes ahead it has to be checked by a Research Ethics Committee. They make sure that the research is fair. Your study has been checked by the East Kent Research Ethics Committee.

For more information you can contact Carol Vigurs on 0207 612 6613

Thank you for reading this – please ask any questions if you need to.