

“Let’s Prevent” - A Diabetes Prevention Study

A randomised Controlled Study for the Prevention of Diabetes using Structured Education and Continuous Support Programme for those with Pre-diabetes in a multi-ethnic population

**Principal Investigators: Professor Melanie Davies
 Professor Kamlesh Khunti**

Can a 6 hour group session that is interactive and enjoyable help prevent people at high risk from developing Type 2 diabetes?

This is the question our study is looking to answer. But we can't do this alone. We need the support of GPs and practice nurses, and even more, we need people at risk of developing diabetes who are also interested in finding the answer to this question to join us. In fact, we need over 800 people - just like you !

If your GP or practice nurse has given you a copy of this leaflet, it means you are eligible to join the study, and this is our invitation to you.

Because joining any research study is an important decision, we have put together some information to explain why the research is being done and what being involved will mean. Feel free to take your time to read this leaflet. You can talk it over with your family or friends, and if anything is not clear, or you would like to know more, we have put a name and contact number at the end of the leaflet so you can talk directly to us.

So, why is it important to look at ways of preventing Type 2 diabetes?

Even a few years ago, you might not have been aware of diabetes at all, unless you knew someone with this serious condition. But, now, it's hard for a

week to go by without some mention of diabetes on the news or in newspapers and magazines. This is because so many people currently have the condition or are at risk of developing it in the future. There are about 2.3 million people in the UK with diabetes, and it's predicted to rise over the next few years.

But what is Type 2 diabetes?

In a healthy person without diabetes, a part of our body called the pancreas produces insulin. This substance enables the glucose energy in the food we eat to be used by our body for energy. In people with Type 2 diabetes, the pancreas does not work as well and cannot produce enough insulin to do this. As a result, no energy gets into the muscles, and sugar levels in the blood become high. People with Type 2 diabetes may have unpleasant symptoms, no symptoms at all, or just feel a bit under the weather. But whatever the symptoms, the most important thing to know is that this situation puts people at much higher risk of heart disease, stroke, kidney failure, and major problems with nerve damage in the eyes and feet. Because diabetes is what's called a 'progressive' disease, once you have it, it doesn't go away, and becomes more serious over time.

Does everyone have the same risk of getting diabetes?

The fact is that some people are more at risk than others. This is because certain factors such as being overweight, having a family history of diabetes or heart disease, having a previous history of raised blood sugar measurement or diabetes during pregnancy increase the risk of developing diabetes later in life. People who eat a high fat diet or have high blood pressure or who smoke are also at high risk.

That sounds like bad news! Is there something we can do to stop people developing diabetes?

Yes there is! The good news is that everyone at risk of diabetes can do things to keep healthy and slow down or even stop the development of this serious disease. Even better, recent studies have shown that lifestyle changes, such as being more active and changing your diet, could be more effective than medicines in helping to stop people developing Type 2 diabetes. But because we don't yet know which of these ways of treating people is best, we need to compare them.

Why have you invited me?

Some of the information held by your GP shows that you are one of many people in the practice who may be at high risk of developing diabetes, or a related condition we call 'pre-diabetes'.

What is Pre-diabetes – I've never heard of that before?

When someone's blood glucose levels are higher than normal but NOT high enough for a diagnosis of diabetes, we say they have Pre-diabetes. You may also hear it called Impaired Glucose Tolerance or Impaired Fasting Glucose (IGT/IFG), depending on which test was used to detect it. Pre-diabetes is a better way of explaining what it means to have higher than normal blood glucose levels. It means you are more likely to develop diabetes and may already be experiencing some health problems because of it. Just like someone with diabetes, if you have Pre-diabetes, you are at higher risk of heart disease and/or stroke. And if you are overweight, eating a high fat diet or are not very active, you could be increasing your risks. Some people who have diabetes in their family have an added risk factor. But, as we said earlier, the good news is that there are things you can do to help yourself, and our study is about helping us find out which of these are best.

Do I have to take part?

No! Taking part is entirely up to you, although of course we hope that enough people will come forward to help us run the study. Even if you decide to take part now, and change your mind later, you can stop whenever you wish. And whatever decision you make, either now or during the trial (if you decide to take part), will not affect the quality of the health care you receive.

If I decide to take part, what happens then?

Firstly, you will be invited to visit the diabetes research team at a local venue and this visit will take around 3 hours. We will ask you to come to this visit fasting, however this does not mean that when you arrive you are obliged to take part. When you arrive for this first appointment you will have the chance to meet our team and to ask any questions you might have before signing our consent form. This means you are now able to have an oral glucose tolerance test (OGTT) and participate in the study.

What is an Oral Glucose Tolerance Test (OGTT)?

An Oral Glucose Tolerance Test (OGTT) involves drinking a sugary drink (Lucozade). You will need to fast from midnight before your test and then have your blood sugar levels measured to see how well your body is dealing with the sugar intake. Before you drink the Lucozade we will take blood samples from you to check the levels of sugar in your blood. Two hours after you have had the Lucozade we will take another blood sample. Whilst we are taking blood samples for your glucose levels we will also take some blood to check the amount of fat (cholesterol) in your blood and the health of your kidneys and liver. We would also like to take some extra blood samples to look at genes and molecules in your blood that may show whether you are at higher risk of diabetes.

What are the extra blood tests for?

In the last few years research has shown that certain molecules in the blood are linked to lifestyle and the risk of developing diabetes. We will measure this before, during and after the study to see how amounts of these molecules change during the course of the study. We would also like to look at some important genes in your blood; however we understand this is a sensitive issue and we need to stress that these tests are optional and we have to ask for your consent separately for this. We will store the samples in our secure freezers for up to 10 years, after which time the samples will be sent to a national officially recognised 'tissue bank' for future research if they have not

already been used. Before we undertake any genetic testing we will anonymise the sample which means that the results will not be linked to you nor will you be able to receive the results of any such tests. This will not affect anything personal to you in the future, such as life assurance. You will not own the samples and, when you donate the samples, you are 'gifting' them to us. However, at any time you can request for them to be destroyed if they have not been used. If you are happy for us to take and store these extra samples then you will have to tick a box on the consent form.

We will ask you to provide a sample of urine so that we can look at the levels of molecules (called free radicals) which are linked to diabetes and fruit and vegetable intake. We will take a sample of urine at each appointment and monitor these levels throughout the study.

Other tests

In between the two blood tests one of our team will ask you to complete a questionnaire about your health, physical activity, eating habits and overall well-being. It should take about 30 minutes to complete. We will also measure your height, weight, hips, waist and take your blood pressure. At this visit we will also give you a step counter (pedometer or accelerometer) to record how much walking activity you are doing. We will ask you to wear this during waking hours for 7 days and then return the device to us in a pre paid envelope.

Depending on which clinic you attend you may also be offered the option of having a non-invasive investigation to measure your risk of diabetes.

eZscan: This device involves placing six electrodes on different parts of the body to assess changes to your metabolic health. You will need to stand barefoot on two electrodes and place your hands palms down on two electrodes. By applying a very small electric charge to the electrodes (less than 4 volts), the system is able to measure changes in the sweat glands under your skin, which are related to your metabolic health. The test takes about 3 minutes and is completely painless, although you may feel a slight

tingling sensation. This device has got a CE mark, which means it has been cleared for routine use within the UK. The results from the eZscan test will be used in conjunction with other tests to monitor your general health during the trial.

If this investigation is offered to you, it is important to realise that you are under no obligation to undergo either investigation with the eZscan device. This decision will not effect your participation in the study or any future patient care

What will my results show?

After this first visit your results will be analysed. Your results will show one of the following:

Your results are normal and you do not have diabetes or pre-diabetes

Your results show you have diabetes

Your results show that you have pre-diabetes

What if my results are normal?

If your results are normal then you and your GP will receive a copy of the results of all your tests within 2 weeks of your appointment. At this point your participation in the study comes to an end.

What if my results show I have diabetes?

To diagnose diabetes we need two results on two separate occasions so this means that if your blood glucose levels are in the diabetes range we will call you back to have a second oral glucose tolerance test (OGTT). If this second OGTT shows a diabetes results then you will be referred to your GP for appropriate treatment. Because you have diabetes you will not be able to participate in this study from this point onwards.

What if my results show I have pre-diabetes?

Depending on which GP surgery you attend, you will be entered into one of our two study groups. The groups have been randomly selected by computer (a bit like tossing a coin), so you cannot choose which group you are in.

Group 1 is what we call the 'control' group. If you are in this group, you will receive the usual excellent care for pre-diabetes provided by your GP practice and some useful leaflets from us.

Group 2 is the 'intensive' group and will receive education sessions and continuous support to help you address your risks of developing diabetes. During your first visit we will arrange an appointment for a diabetes risk education session. At the next visit you and several others like you will be seen by two diabetes educators who will deliver an education programme to inform you about pre-diabetes and changes you could make to your lifestyle to help stop you getting diabetes in the future, such as setting objectives for increasing physical activity and varying the food you eat. These will consist of either a full day of 6 hours or 2 sessions of 3 hours over two days. You will also be informed about the continuous support structure that the research team is providing to help you meet these targets. This will include a dedicated phone line to speak to a diabetes healthcare professional, the study website, a regular newsletter full of supportive information. During the next 3 years you will be in regular contact with a diabetes healthcare professional with a wide range of resources to help you.

During the study you may be asked to attend a semi-structured interview with a trained researcher to find out your feelings of being at risk of diabetes and how you felt during the study. The interviews would take place as a group or as a one to one for about an hour, in a private location and would be recorded onto audiotape for further analysis.

Regardless of which group you are in, once a year for the next 3 years, we will ask you to visit us for an Oral Glucose Tolerance Test (OGTT). This will help us keep an eye on your pre-diabetes and your general well-being. During these visits we will also take a blood sample from your arm for testing

glucose and cholesterol levels in your blood and to monitor your progress. In total we would like to collect 49ml of blood at each visit, this is the same as 10 teaspoons. We will also measure your:

Height

Weight

Hip and Waist Measurements

Blood Pressure

and ask you to complete a questionnaire at each visit, just as you did when you joined the study, and to provide a sample of urine.

What are the side effects of any treatment received when taking part?

You will not be given any medication for this study. You may suffer slight discomfort while the blood samples are being taken from your arm and some people do experience bruising after blood samples have been taken.

Will my GP be informed of my results?

Yes, your family doctor will be informed of all the results of the tests taken at the hospitals.

What do I have to do if I want to take part in this study?

If you decide to take part in the study you will be asked to sign a consent form when you come for your first visit to the hospital. You will be given a copy of the patient information sheet and a copy of the signed consent form to keep for your own records. If you need an interpreter to help you when you attend for visits at the hospital we can arrange this for you.

What are the possible benefits of taking part?

We hope that all people in the study will avoid progressing to diabetes. The information we get from this study may help us to prevent future people with pre-diabetes or at a high risk from developing the diabetes.

Will I get travelling expenses?

Parking charges and travelling expenses up to £10 can be reimbursed.

What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are 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.

Will my taking part in this study be kept confidential?

Absolutely! All information that is collected about you during the course of the research will be kept strictly confidential. All your research data will be sent to the co-ordinating centre at the University Hospitals of Leicester NHS Trust and any information which leaves the co-ordinating centre will have your name and address removed so that you cannot be recognised from it.

What will happen to the results of the research study?

The results of the study may be published in a professional journal, but you will not be identified by name in any publications. You will be informed about the results of the study when it has finished.

Who is organising and funding the research?

The funding is coming directly from the National Institute for Health Research (NIHR). This is part of the governments funding for health research. The study is coordinated by the University Hospitals of Leicester and it is being in run in several other counties.

Who has reviewed the study?

All research that involves NHS patients or staff, information from NHS medical records or uses NHS premises or facilities must be approved by an NHS

Research Ethics Committee before it goes ahead. Approval does not guarantee that you will not come to any harm if you take part. However, approval means that the committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits and that you have been given sufficient information on which to make an informed decision

If you would like more information about the study, you can contact the Let's Prevent Team on [REDACTED] or you can contact us by e mail on

[REDACTED]

Thank you for taking the time to read this patient information sheet.