propels
The PRomotion Of Physical activity through structured Education with differing Levels of ongoing Support for those with prediabetes (PROPELS): *randomised controlled trial in a diverse multi-ethnic community*

MRC Epidemiology Unit

UNIVERSITY OF CAMBRIDGE

PARTICIPANT INFORMATION SHEET

The PRomotion Of Physical activity through structured Education with differing Levels of ongoing Support for those with pre-diabetes (PROPELS)

A randomised controlled trial in a diverse multi-ethnic community

Principal Investigator: Professor Kamlesh Khunti – University of Leicester

Co-Investigators: Professor Melanie Davies – University Hospitals of Leicester, Leicester Diabetes Centre; Dr Tom Yates, Dr Helen Eborall, Dr Laura Gray – University of Leicester; Professor Simon Griffin, Dr Rebecca Simmons – Medical Research Council (MRC) Epidemiology Unit, University of Cambridge; Dr Wendy Hardeman, Professor Stephen Sutton – University of Cambridge.

You are being invited to take part in a research study. Before you decide if you wish to take part, it is important for you to understand why the research is being done and what it will involve for you. This information sheet is designed to help you decide whether you would like to participate in this study. Please take time to read the following information carefully and discuss it with friends, relatives and your GP if you wish. Please ask us if there is anything that is not clear or if you would like more information.

What is the purpose of this study?

Type 2 diabetes is a disease where glucose levels (sugar) in the blood become higher than usual. The number of people who have Type 2 diabetes is increasing worldwide. By the time that many people find out that they have Type 2 diabetes, they often have a complication caused by their diabetes such as eye or kidney disease or heart problems.

Many years before getting Type 2 diabetes, people often have higher than normal blood glucose (sugar) levels. When someone's blood glucose level is higher than normal but NOT high enough to be diagnosed as having diabetes, it is called Impaired Glucose Regulation (IGR). You may have heard this also called Pre diabetes, or Impaired Fasting Glucose (IFG) or Impaired Glucose tolerance (IGT). Having these higher than normal blood glucose levels increases the chance that someone will develop Type 2 diabetes or heart disease or have a stroke in the future.

However, the good news is that studies show that if people with higher than normal blood glucose levels make changes to their lifestyles (food and activity), they may

slow down or even stop themselves getting Type 2 diabetes. Recent studies show that these lifestyle changes can be even more effective than taking medicine.

This study aims to find out how we can help people at high risk of developing Type 2 diabetes to walk more. We hope that this will reduce their risk of getting diabetes and health problems in the future.

Why have I been chosen? Can anyone take part?

You have been chosen because information held by your GP shows that you may be someone who has a high risk of developing Type 2 diabetes. We are inviting people to take part in the study if they have one or more risk factor for developing Type 2 diabetes. It could be that you have previously had a blood test that showed you had a higher blood glucose level than normal, you may have a family history of Type 2 diabetes, you may have high blood pressure or blood fat levels, you may be overweight or a smoker or it may be another risk factor.

You may also have been chosen because you previously took part in a study with our Diabetes Research Team and consented to being contacted about any future research studies that you might be eligible for.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part you are still free to withdraw at any time without giving a reason. A decision to take part or not take part will not affect the standard of care you receive.

What will happen if I decide to take part?

By receiving this information sheet, the study team are aware you are interested in taking part in the study and have sent you an appointment for your first study visit. If this appointment is not convenient and you would like to rearrange, or to cancel this visit, please contact the study team to let us know. Please note, unfortunately, we are unable to provide interpreters or translated documents for this research study and only participants with a basic understanding of verbal and written English are eligible to take part.

This first study visit will take around 2hours. At this appointment you will have the chance to meet our team and to ask any questions you might have before signing a consent form. If after asking questions you decide that you do not want to take part in this study, you do not have to.

If you decide that you would like to take part in this study and sign a consent form, you will then have blood tests to see if you are eligible to join the study and answer some health questions. For your blood test we will measure something called ‘glycosylated haemoglobin’, also known ‘HbA1c’, which can be used to estimate the average amount of glucose you have had in your blood over the last 3 months. We can check how much fat (cholesterol) is in your blood and check how healthy your kidneys and liver are. In total we will take roughly 6 teaspoons of blood from you.

One of our team will ask you to fill in a questionnaire about your health, your physical activity level, your eating habits and overall well-being. The questionnaire should take about 30 minutes to complete. Your height, weight, body fat percentage, waist circumference, arm and leg length and blood pressure will be measured. We will also 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.

At this visit we will give you an activity monitor called an accelerometer (step counter) to wear around your waist, and an optional device to wear called a 'ActivPal' which is attached to the thigh using a water proof dressing. We will demonstrate how to wear the devices and provide written instructions. We would like you to wear these monitors for the next 7 days after the study visit. These devices measure how active you are and your posture changes. Once the 7 days is over you will return the device to us in a pre-paid envelope.

Extra blood tests (Optional)

We would also like to take an extra blood sample during the study to look at how some important genes affect the risk of diabetes. This sample will be taken ONLY once during the study. This sample is optional and we will ask for your consent separately for this. If you do not want this sample to be taken that is ok and it will not stop you taking part in the rest of the study.

Before we analyse your sample, we will take your name off the sample so that the results will not be linked to you. Because these samples will be analysed anonymously, you will not get the results of this test and they will not affect anything personal to you in the future, such as life insurance.

This extra sample will be stored in our secure freezers for up to 10 years. After this time, if your samples have not been used, and if you agree (consent), these samples will be sent to a national officially recognised 'tissue bank' for future research. If you do not wish us to use these samples they will be destroyed. You will not own the samples and, when you donate the samples, you are 'gifting' them to us. At any time you can request for these blood sample to be destroyed if they have not been used. If you are happy for us to take and store this extra sample for genetic research, and further transfer them after 10 years, then you will have to initial a further box on the consent form to show you agree.

Other optional tests

You may be given the option of having the muscle and fat content of your body assessed by something called a dual energy X-ray absorptiometry (DEXA) scan. These tests show us where your body fat is stored. You need to lie still for up to 10 minutes during the scan.

The DEXA scan does involve you being exposed to a very small amount of radiation but this amount is similar to the amount you would get if you were on a 2 hour intercontinental flight. Having certain medical conditions may mean that you can not have this scan done.

This scan is optional and will not affect your involvement in the main study. If you have this scan done at the start of the study, we would like to repeat them after your

12 month visit and again at the end of the study. The results of these tests will be analysed fully at the end of the study.

How will I know what my blood glucose levels are?

After the first visit your blood results will be analysed in the hospital laboratories. Your results could show one of the following:

- Your results are normal and within the recommended range. You do not have diabetes
- Your results show that you have blood glucose levels above the target range but NOT high enough to have diabetes.
- Your blood glucose results are high enough to show you have diabetes.

What if my results show I have blood glucose levels above the target range?

If you are confirmed as having blood glucose levels above the target range you are eligible to continue to take part in the study. You and your GP will receive a copy of the results of your tests. You will then be contacted by a member of the research team to let you know which study group you have been assigned to (see page 5).

What if my results are normal?

If your results are normal **BUT** your GP has recorded a blood glucose level above the target range over the last 5 years, then you are still eligible to take part in the study. We will inform you if this is the case. You and your GP will receive a copy of the results of your tests. You will then be contacted by a member of the research team to let you know which study group you have been assigned to (see page 5).

However, if your results are normal **AND** you have had no previous recording of a blood glucose level above the target range, your participation in the study comes to an end. You will receive a notification of this outcome and you and your GP will receive a copy of the results of your tests.

What if my results show I have diabetes?

If these results show a result in the diabetes range, you will be referred to your GP to look after you. If you have a result in the diabetes range at this first visit, you can not continue being part of this study.

If I am eligible to participate further in study, what happens next?

You will be placed into one of these groups designed to look at different ways of providing you with the knowledge you need to reduce your risk of Type 2 diabetes in the future. Which group you are in will be decided randomly by a computer (a bit like tossing a coin), so you cannot choose which group you are in. At the end of the study these groups will be compared to each other to look for any differences between groups.

Group 1:
You will be given a detailed information leaflet about how to reduce the risk of developing Type 2 diabetes in the future. If you are in this group, you will receive the usual care currently provided by your GP or practice nurse for someone who has been identified as being at risk of diabetes.

Group 2:
If you are in this group you will receive the same information leaflet as group 1 and will also be invited to come to an educational programme designed to provide you with the knowledge and tools you need to become healthier and reduce your risk of Type 2 diabetes. The education sessions will be delivered in groups of between be five to ten people. Every year you will be invited to another group session which means four sessions in total. Each session will last about 4 hours and is run by two diabetes educators. Coming to these groups will not be like being at school, it will be very interactive. Together we will discuss what being at risk of diabetes means and what can be done to prevent Type 2 diabetes in the future. Important lifestyle changes, such as increasing activity levels, will be discussed in a fun interactive way. Everyone will be provided with a pedometer (step counter) and will be encouraged to become more active by increasing the number of steps they take by 2,000 - 3,000 per day (this will be achieved gradually). This is the same as about 20 - 30 minutes of walking per day.

Group 3:
If you are in this group, you will receive the same information leaflet as group 1 and the same education programme as group 2. You will also be offered additional on-going support throughout the study in the form of additional telephone contact and text message resources. Therefore, we would ask that individuals entering the study have access to a mobile phone and are willing to receive information via their phone.

Regardless of which group you are in, you will be invited to attend a clinic visit at 1 year and again at 4 years after your first visit. Your overall health and well being will be checked and the same blood tests and measurements will be taken as on your first visit.

During the study you may also be asked to attend an interview with a trained researcher to find out your feelings of having a higher than normal risk of Type 2 diabetes and your experiences of taking part in the study. The interviews would take place either as a group or on your own, with a researcher. They would take about an hour and would be arranged in a private location. The interviews would be recorded onto a tape and then typed up. The tape would then be destroyed. This part of the study is optional.

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

Taking part involves minimal risk for you because you will not be given any medical treatment on this study. You may feel slight discomfort while the blood samples are being taken from your arm. Some people do experience bruising after blood samples have been taken. However, only staff trained to take blood will do so to minimise any discomfort.

Will my GP be informed of my results?

Yes, your family doctor will be informed of all the results of the tests taken during your clinic visits. The only exception to this is the questionnaire data, which will not be available to your GP.

What are the possible benefits of taking part?

You will receive information and support to reduce your risk of developing Type 2 diabetes. You will receive thorough health checks through out the study and the results will be made available to you and your GP.

You will also help to improve the treatment of other people at a high risk of developing Type 2 diabetes.

Will I get travelling expenses?

Parking charges and travelling expenses up to £10 can be reimbursed for each clinic visit only when a valid receipt is provided. One of the requirements of this study is to have access to a mobile phone and be willing to receive (and send) a small number of text messages. Those in group 3 only will be eligible to claim these costs back at the end of the study as either a £5 voucher for your mobile phone or £5 expenses claim.

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?

Yes. All information that is collected about you during the course of the research will be kept strictly confidential. Any information about you, which leaves the hospital/ surgery, will have your name and address removed so that you cannot be recognised from it. Any tapes will be destroyed after the information is transcribed.

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 findings of the study through annual newsletters.

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 government's funding for health research. This study is being organised and co-ordinated by the University of Leicester in collaboration with the University Hospitals of Leicester Diabetes Research Group, the MRC Epidemiology Unit, and the University of Cambridge.

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 PROPELS Team on free phone **0800 085 6183** or by email on propels@mrc-epid.cam.ac.uk

Thank you for taking the time to read this participant information sheet