London North West Healthcare NHS
NHS Trust

PARTICIPANT INFORMATION SHEET

Title: **Prevention of Type 2 Diabetes amongst South Asians with central obesity and prediabetes**
Short Title: **iHealth-T2D**
REC Ref: **XYZ. Screening - version 1. March 2016.**

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish.

Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Part 1

1. What is the purpose of the study?

Diabetes is a major medical problem in which the body loses control of blood sugar levels. As a result, people with diabetes need long-term treatment to help bring the blood sugars under control. Diabetes can also lead to complications such as heart and kidney disease.

Diabetes in particularly common amongst people of South Asian ancestry, with diabetes affecting almost one-quarter of South Asian men and women. Understanding how to prevent diabetes in South Asians is therefore of great importance.

Diabetes can be prevented or delayed by adopting a healthier lifestyle. Although this is good news, it is not clear which people benefit most from lifestyle change, or the best way to improve healthy living amongst South Asians. We will be comparing differing approaches to screening South Asian people for risk of developing diabetes (we will be comparing blood tests with measures of fatness). We will also be assessing the effectiveness of different approaches to promoting healthy living (we will be comparing extended, intensive approaches with conventional brief interventions).

2. Why have I been invited?

We are inviting South Asian men and women aged 40-70 years old to take part in the study. We are doing this in partnership with GPs, who have given us permission to contact people registered with their practices to invite them to take part. In total we expect to approach ~5,000 people to ask them to take part.

As part of this effort, we are writing to invite you to come for a screening visit to see whether you are at risk of developing diabetes. If the results of your assessment suggest that you may be at risk of developing diabetes we will then invite you to come back for healthy lifestyle advice to try to help you prevent or delay diabetes developing.

3. Do I have to take part?

Not if you don't want to. It is up to you to decide. We will describe the study and go through this information sheet, a copy of which will be yours to keep. If you agree to take part, we will ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This would not affect the medical care you receive.

4. What will happen to me if I take part?

You will be asked to attend Ealing Hospital for one visit lasting about one hour. During the visit, we will go through this information sheet and explain the study to you ourselves. We will answer any questions you may ask about the study. If you agree to take part, you will be asked to sign a consent form, a copy of which will be yours to keep.

After you have signed the consent form, we will ask you to complete a questionnaire about yourself and your health. This will ask questions about things like medical problems you may have had and medications that you may be taking. A member of the research team will be available to help you answer these questions. As part of the research we may need to review your medical notes so that we can confirm the medical details of any suspected health problems that you tell us about. We would like your permission to do this.

Next we will take some measurements from you. These will be measurements of your height, weight, blood pressure and waist size. After that we will take a small blood sample (60mls, approximately 3 tablespoons). This will be sent for measurement of blood sugar and blood fats to diagnose diabetes, and for high blood fats which are a risk factor for heart disease. Some of the blood will be stored for future testing, including tests for genetic factors that may lead to diabetes and other major medical problems. The goal of this aspect of the research is to find new ways of predicting and preventing diabetes. More information on this is given in Part 2.

After these tests have been carried out, your direct participation is complete. Once we have collated your results we will forward them to you. We shall include a copy for you to give to your GP.

After your visit is over, we would like to continue to monitor your health. This will allow us to work out who has remained well, and who has developed diabetes and related health problems in the future, and to help us improve our approaches to screening. We would therefore like your permission to use any records held by the NHS (hospital or GP) and by the General Register Office to keep in touch with you and to monitor your health status.

Your future treatment will not be affected by participating (or not participating) in this study.

5. Expenses and Payments

We are happy to reimburse your travel expenses to and from Ealing hospital.

6. What will I have to do?

We will ask you to come to Ealing Hospital for a single appointment lasting about one hour. You will need to come fasting (nothing to eat or drink except water for 8 hours prior to the appointment).

At the visit we shall ask you to do the following:

- Read this information sheet, ask us any questions you like, and sign a consent form
- Complete a questionnaire about your health and lifestyle
- Allow us to measure your height, weight and blood pressure
- Allow us to take a blood sample

7. What are the possible disadvantages and risks of taking part?

You may experience some mild discomfort from the blood test. No other risks are expected from the appointment.

There is a chance that your results will show a significant abnormality of which you were unaware. In such circumstances you will be referred to the appropriate specialist in consultation with your GP, if that is what you would like. Such detection has the benefit of starting treatment early, but in a small number of cases may have implications for future employment and insurance.

8. What are the side-effects of any treatment received when taking part

At this stage there are no treatments involved in this study. If your results show that you may be at risk of developing diabetes then we will invite you back to offer you lifestyle advice to help you prevent or delay development of diabetes.

9. Ionizing radiation

There is no radiation involved in this study.

10. Harm to the unborn child

Women of child-bearing age may participate in this study without risk, as the study does not involve treatment, invasive procedures or ionizing radiation. Women who are pregnant though should defer their research study appointment until 3 months after the baby is born, as pregnancy has a number of effects on blood pressure, blood sugar and blood fats that make the research results difficult to understand.

11. What are the possible benefits of taking part?

The tests may reveal health problems about which you were previously unaware, for example diabetes, high blood cholesterol level, high blood pressure or heart problems. Such detection has the benefit of starting treatment early, which will help you to avoid complications. We cannot promise the study will help you personally, but the information we get from this study will help improve the prevention and treatment of heart attack and stroke in the wider community, in the future.

12. What happens when the research study stops?

We plan to follow your health through NHS and General Register Office records over the long term. This may be 20 or more years. Once the research is completed the data and results will be made fully anonymous (ie all personal information removed), and available for use by other researchers. Any remaining blood samples will be destroyed.

13. 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 on this is given in Part 2.

14. Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

More detail – information you need to know if you still want to take part

1. What will happen if I don't want to carry on with the study?

You are free to withdraw from the study at any time. Please talk to any member of the research team if you wish to withdraw. The research team may ask you why you are leaving the study. Explaining why will help us to design future studies. However, you do not have to give any reasons for your withdrawal if you do not want to.

If you withdraw from the study, we will destroy all your identifiable samples, but we may need to use the data collected up to your withdrawal. For example, where samples and data have been anonymised, we will not know the identity of the person who gave any particular sample. If data has been publicly shared on scientific databases we also will not be able to retrieve it.

2. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (Professor Kooner and Professor John Chambers can both be contacted on 020 8967 5000). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

Imperial College London holds insurance policies which apply to this study. If you experience serious and enduring harm or injury as a result of taking part in this study, you may be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Professor Jaspal S Kooner, Consultant Cardiologist, Ealing Hospital, Uxbridge Road, Middx UB1 3HW). The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Compliance Office.

3. Will my taking part in this be kept confidential?

We will keep your information in confidence, and in a way that meets the security criteria set by the Data Protection Act 1988. Professor John Chambers will act as the custodian of the data.

Your research data will be anonymised (all personal information removed). Only your research doctors will have access to the key matching anonymous numbers with personal information. This means we will only tell those who have a need or a right to know (eg authorised persons such as research regulatory authorities). Wherever possible, we will only send out information that has your name and address removed.

The study duration is 5 years, however ate the end of the study we expect to preserve the data and samples for 20 years. Once the research is completed, the data and results will be made fully

anonymous (ie the key matching research data and samples to personal information will be destroyed). The fully anonymised data may be available for use by other researchers.

4. Involvement of your GP.

We would like to inform your GP that you have taken part in the study, but will only do this if you agree. We will also provide you with a copy of your key test results (such as high blood sugar levels requiring treatment) for you to give to your GP if you wish.

5. What will happen to any samples that I give?

As part of this study we wish to store small amounts of blood for future testing. The samples will be used to try to identify new ways of predicting and preventing diabetes and other major medical problems. Professor John Chambers will act as the custodian of the samples.

Your samples will be anonymised (all personal information removed). Only your research doctors will have access to the key matching the anonymous samples with personal information. This means we will only tell those who have a need or a right to know (eg authorised persons such as research regulatory authorities). Your samples will be kept in secure databases freezers. They will only be accessible to authorised researchers.

Because technology and analysis tools develop all the time, it isn't possible to give you an exact list of everything that might be done with your samples/information in the future. Our aim is always to work towards the benefit of patients and communities. In doing so, we may feel it is beneficial to work with other hospitals, universities, research institutes, pharmaceutical and bio-technology companies, including organisations in other countries. They may have expertise, technology, and resources unavailable to us, which would be helpful in driving research forward to everyone's benefit. However, we won't share your information with any other organisation unless it is anonymised ie the information can't be traced back to you.

If we find out information which has implications for your future health or healthcare, or which we believe impacts on your interests, we will feed this back to. If you would rather not know, you have the option not to be told. If however your samples/information are put into fully anonymised form, you must understand that it will then no longer be possible to feed back specific results to you and any testing/research done will not be available to you.

The role of an individual sample/set of information in any commercial project is likely to be minimal and impossible to quantify. Therefore it is not possible to trace back any benefit to individual donors and you should regard participation in the project as being for the benefit of the community at large. No financial benefits from exploiting the results of the study will come back to you.

The study duration is 5 years, however ate the end of the study we expect to preserve the data and samples for 20 years. Once the research is completed, any remaining blood samples will be destroyed.

6. Will any genetic tests be done?

Some of the research and testing on your sample may be genetic in nature as this can be the most powerful way to discover the causes of disease/defects and to treat and deal with these by developing new drugs and treatments. For example we may try to find variants in genes that protect against or increase the risk of heart attack and stroke. This may include "sequencing" the DNA samples to read all the genetic information in it.

Because technology and analysis tools develop all the time, it isn't possible to give you an exact list of everything that might be done with your samples/information in the future. We will not contact you directly about these individual genetic studies, as this would be impractical given the numbers of persons participating in the research.

As noted above, our aim is always to work towards the benefit of patients and communities. In doing so, we may feel it is beneficial to work with other hospitals, universities, research institutes, pharmaceutical and bio-technology companies, including organisations in other countries. They may have expertise, technology, and resources unavailable to us, which would be helpful in driving research forward to everyone's benefit. We will not your information with any other organisation unless it is anonymised ie the information can't be traced back to you.

There is a small chance that we may find out information from the genetic tests which has implications for your future health or healthcare or which we believe impacts on your interests. Such detection has the benefit of starting treatment early, but in a small number of cases may have implications for future employment and insurance. If you would rather not know the results of these tests, you have the option not to be told. If you would like to know the results, then we will feed them back to, and you will be referred to the appropriate specialist in consultation with your GP, if that is what you would like. If your samples/information have been put into fully anonymised form, you must understand that it will then no longer be possible to feed back specific results to you.

7. What will happen to the results of the research study?

If you wish, you will receive an individual report of medically relevant results from your tests. If you would rather not know, you have the option not to be told.

We plan to publish the overall results of the completed study in medical journals. You will not be identified in any publications. The results of the research may also be shared through open access (public) scientific databases, including internet databases (www.HapMap.org is an example of such an approach). This will enable other researchers to use the data to investigate other important research questions. The results will always be fully anonymised by removing all identifying information (eg name, address, date of birth, NHS numbers).

8. Who is organising and funding the research?

The research is organised by Professor Kooner and Professor Chambers. The research is funded by the European Union. Your doctors will not receive any payment for including you in the study.

9. Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity. This study has been reviewed and given favourable opinion by the Research Ethics Committee.

10. Sponsor

Imperial College London is the main Sponsor for this study. Delegated responsibilities will be assigned to the NHS trusts taking part in this study.

11. Further information and contact details

For general information about research, please see

MRC Clinical Trials Unit (http://www.ctu.mrc.ac.uk/TakePart.asp). This provides useful advice for potential participants in research.

For further information about this research project, or if you are unhappy with any aspect of the study, please contact:

Professor Jaspal S Kooner, Consultant Cardiologist, Ealing Hospital, Uxbridge Road, Middx UB1 3HW, telephone 020 8967 5000, fax 020 8967 5007.

Professor John Chambers, Consultant Cardiologist, Ealing Hospital, Uxbridge Road, Middx UB1 3HW, telephone 020 8967 5000, fax 020 8967 5007.