Imperial College London

PARTICIPANT INFORMATION SHEET

Investigation of lifestyle, environmental, genomic and molecular factors underlying health outcomes in South Asians and Europeans – the LOLIPOP 100K study

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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?

Heart disease, diabetes and cancers are leading causes of death and disability in the UK and globally. We know some of the reasons why these chronic health problems develop - for example smoking or poor diet. However, many people develop health problems without having any clear reason.

The purpose of this study is to improve our understanding of the causes of heart disease, diabetes and cancer, as well as many other important 'chronic conditions' such as asthma, visual impairment, memory loss and obesity. We are trying to work out why some people, but not others, develop these health problems. If we are successful, the results of the study will allow us to better identify which people are at risk, enabling earlier preventative interventions. Better understanding of the causes of these chronic conditions may also lead to the development of new treatments.

2. Why have I been invited?

The study is being carried out in partnership with GPs from locations across the UK. We are inviting men and women aged 18 to 85 years old registered with one of our partner GPs to take part in the study. This invitation is not based on any prior medical information about you. We are inviting many thousands of people to take part in this study. Participation in the study is voluntary.

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, and give you an opportunity to ask questions. 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 one of our research clinics for a single visit lasting about 90 minutes.

During the visit, we will go through this information sheet with you, to explain the study to you and for you to ask any questions. You may keep a copy of this information sheet. 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, admissions into hospital, symptoms of chest or other pain, memory, lifestyle, diet 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. We will then record an ECG from you. This is a tracing of the heart that simply involves you lying still on a couch for a few minutes. We will also measure your lung function through a breathing test, and take photographs of the back of your eyes (the retina).

After that we will take a small blood sample (60mls, approximately 4 tablespoons). This will be sent for measurement of blood sugar and blood fats to diagnose diabetes and high blood fats, both risk factors for heart disease. Some of the blood will be stored for future testing, including tests for genetic factors that may lead to heart disease / stroke. We will also ask you for a urine sample. More information on this is given in Part 2.

In addition we may ask you to give a stool sample, but this is optional. The research staff will provide instructions along with appropriate appliances and containers to do this. These samples will be used to study bacteria in your gut and how they relate to health.

Finally, we may ask you to wear a physical activity monitor on your wrist for the next 7 days. The monitor is light weight (equivalent to a £2 coin) and resembles a wrist watch. You should wear it all day and night, but not in water (bath, shower, swimming). We will provide you with a prepaid jiffy bag to return the device to us after 7 days.

Certain aspects of the assessment such as the ECG, retinal imaging and the physical activity monitor may not be available at all sites due to limited resources.

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 may have developed a heart attack / stroke. We would therefore like your permission to use any records held by the NHS (hospitals or GP), by other healthcare providers (eg pharmacies, retinal screening services), by government departments responsible for health related information (eg NHS Digital and the General Register Office) and other organisations who hold health-related data, 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 reasonable travel expenses to and from the research clinic, supported by receipts where appropriate.

6. What will I have to do?

We will ask you to come to a research clinic for a single appointment lasting about 90 minutes. You will need to come fasting (nothing to eat or drink except water for 4hours prior to the appointment).

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

- Read this information sheet, ask us any questions you have, and sign a consent form
- Complete a questionnaire about your health, lifestyle and diet, and that tests your memory and thinking
- Allow us to measure your height, weight and blood pressure
- Lie still on a couch for 5 minutes so that we can record an ECG (heart tracing)*
- Complete measurements of lung function (how well you can breathe out) *
- Let us photograph the back of your eyes (retina)*
- Allow us to take a small blood sample
- Provide a urine sample
- Provide two stool samples using a stool sample swab kit*
- Wear a wrist watch physical activity monitor for one week.*

* Certain aspects of the assessment such as the ECG, retinal imaging and the physical activity monitor may not be available at all sites due to limited resources.

7. Research health report and incidental clinical findings

We will offer you a report comprising physical measurements (adiposity, blood pressure), blood results and a clinically reported 12 lead ECG. These tests are recommended by the NHS as part of routine, periodic health-check in the adult population.

We do not intend to routinely report the results of the other research tests (eg lung function, retinal imaging, cognition or diet). However, if a clinical abnormality of major significance is noticed during the course of the study visit, this will be reviewed by the study team for consideration of reporting back to you as an ‘incidental clinical finding’.

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

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

There is a small 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.

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

There are no treatments involved in this study

10. Ionizing radiation

There is no radiation involved in this study.

11. 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.

However, we ask that women who know they are pregnant 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.

12. 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.

13. What will happen next?

We may contact you again to invite you to take part in future studies. You may be asked to participate in these studies on the basis of genetic/biochemical results obtained from your sample as described above and other information given to us or obtained from your medical records. You will be provided with full information regarding each of these studies and will be free to decide whether or not to participate. We closely monitor the number of times you are approached and invited to studies and will ensure that the maximum number of invitations to studies will be 4 each year.

14. What happens when the research study stops?

We plan to follow your health through NHS and other health related 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.

15. What if something goes wrong?

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.

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 something goes wrong?

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will 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 Investigators Professor Kooner and Chambers, using the contact details provided below. The normal National Health Service mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College, Joint Research Compliance Office.

3. HOW WILL WE USE INFORMATION ABOUT YOU?

Imperial College London is the sponsor, and will act as the data controller, for this study. This means that we are responsible for looking after your information and using it properly. Imperial College London will keep your personal data for:

- At least 20 years after the study has finished in relation to data subject consent forms.
- At least 20 years after the study has completed in relation to primary research data.

We will need to use information from you, your medical records, your GP and other health related datasets for this research project. The information will include personal data such as your NHS number, name, address, telephone, email address and date of birth. It will also include data from NHS Digital, ONS, NHS Scotland and NHS Wales. We may access your medical and health-related records now and in the future, even if you can no longer make decisions for yourself, or after your death. People will use this information to do the research or to check your records to make sure that the research is being done properly. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study

The information collected from you, and your medical records, may be used for research in any aspect of health or care, and may be combined with information about you from other sources held by researchers, the NHS or government. The information will only be used for the purpose of appropriately approved health and care research, to contact you about future opportunities to participate in research, or to check your records to make sure that the research is being done properly. It will not be used to make decisions about future services available to you, such as insurance.

We will take all reasonable measures to ensure that the information collected from and about you is kept confidential and secure. We will keep your information in a way that meets the security criteria set by the General Data Protection Regulations. In order to keep your information confidential, numerous safeguards are in place. In particular, we will:

- Remove direct personal identifiers (name, date of birth, NHS number, address, phone number and other contact details) from the research data and samples, and replace your identity with a unique anonymous 'code number'
- Keep your personal identifiers separate from your research data and samples.
- Ensure that your personal identifiers, and the 'code number' that links you to the research data and samples, can only be accessed by a small number of personnel, directly authorised by the Principal Investigators. People who do not need to know who you are will not be able to see your name or contact details.
- Use stringent security measures to protect all the data collected, and to prevent unauthorized use, including: strict access controls, computer security and data encryption techniques, confidentiality agreements and staff training.

Some of your information will be sent to other countries. If we do that, the recipients must follow our rules about keeping your information safe. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

By signing the Informed Consent Form attached, you are thus authorising (i) collection, access to, use and storage of your "Personal Data", and (ii) disclosure to authorised service providers and relevant third parties.

LEGAL BASIS

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research

INTERNATIONAL TRANSFERS

There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a European Commission (**EC**) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your personal data is processed.

SHARING YOUR INFORMATION WITH OTHERS

For the purposes referred to in this privacy notice and relying on the bases for processing as set out above, we will share your personal data with certain third parties.

- Other College employees, agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.
- Research Collaborators / Partners. The information about your health and care, including your personal data, may be provided to researchers in other universities, NHS organisations or companies involved in health and care research in this country or abroad. They may have know-how or expertise that enhances the research that we do. Your information will only be used by

organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research at https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/.

WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?
You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. If you choose to stop taking part in the study, we would like to continue collecting information about your health from NHS records. If you do not want this to happen, tell us and we will stop. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED
You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to j.kooner@ic.ac.uk, or
- by ringing us on 020 8967 5000
- www.lolipopstudy.org

COMPLAINT
If you wish to raise a complaint on how we have handled your personal data, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.

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 the samples that I give?

As part of this study we wish to store small amounts of blood, stool and saliva for future testing. In addition some of the blood will be stored long term to allow us to study functional impact of genetic variants. We will keep your samples securely and in confidence. Professor JS Kooner will act as the custodian of the samples, on behalf of the study Sponsor.

Your data and samples will be "de-identified" (all personal information removed). Only your research doctors will have access to the key matching the 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 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 data and samples 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.

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 is expected to last at least 20 years, and samples will be kept for this time. 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 is likely to 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 from your blood 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.

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 share your information with any other organisation unless it is anonymised ie the information can't be traced back 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. This will enable other researchers to use the data to investigate other important research questions. The results will be deidentified by removing all traditional identifying information (eg name, address, date of birth, NHS numbers).

8. Risks of personal identification from genetic and other research data

We may generate lots of genetic information about the people whose samples are studied. This information may be put in open access scientific databases, available on the Internet to anyone who wants to look at it. Although only experts will know how to interpret this information, there is a small

chance that somebody could figure out how to connect you with the information from the study of the sample you give.

As technology advances, there may be new ways of linking information back to you that we cannot foresee now. Also, we cannot always foresee the results of research, so new risks may come up in the future that we cannot predict now. We believe that the benefits of learning more about human genetic variation and how it relates to health and disease outweigh the current and potential future risks, but this is something that you must judge for yourself.

9. Who is organising and funding the research?

The research is sponsored by the Imperial College London and organised by Professor Kooner and Professor Chambers. The research is funded by the Wellcome Trust and the National Institute for Health Research. Additionally, we hold unrestricted grants from industry. Your doctors will not receive any payment for including you in the study.

10. 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 Fulham REC.

The study has also been reviewed and approved by the Health Research Authority (HRA) and by Imperial College London as the study Sponsor.

12. Further information and contact details

For general information about research, please see

MRC Clinical Trials Unit (https://www.ctu.mrc.ac.uk/patients-public/). 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, Hammersmith Hospital, Ducane Road, Lonon W12 0HS, telephone 020 3313 1000.