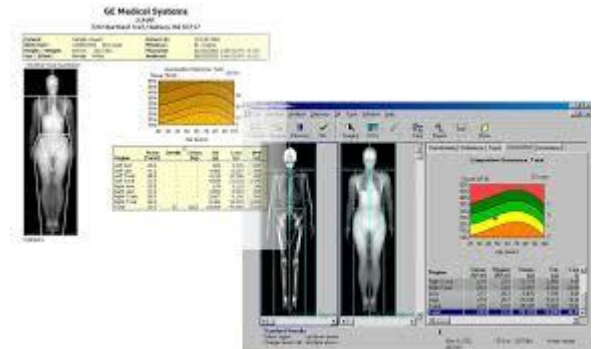




## Participant information leaflet

Study Title: Southall And Brent REvisited – Visit 3 (SABRE V3)

Chief Investigator: Professor Nish Chaturvedi



You are being invited to take part in the third stage of the Southall and Brent Revisited (SABRE) research study. The purpose of SABRE is to understand the reasons why some people are more at risk of becoming unwell, while others stay healthy in older age. The study is particularly focussed on diseases of the heart and circulation, and diabetes. The research may help to prevent illnesses occurring or to detect them early, as well as helping in the development of better treatments when problems do arise.

This information booklet gives you more detailed information about the SABRE study. Before you decide whether you want to take part, 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.

If you need any further information or have any questions or concerns about any aspect of the SABRE study, please call 0207 679 9471

or email us at [sabre@ucl.ac.uk](mailto:sabre@ucl.ac.uk)

or you can write to us at

The SABRE Study, UCL Institute of Cardiovascular Sciences

Third floor, Bloomsbury Centre for Clinical Phenotyping  
The Roger Williams Building  
69-75 Chenies Mews  
London  
WC1E 6HX

or you can visit our website at [www.sabrestudy.org](http://www.sabrestudy.org).



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## **What is the purpose of the SABRE study?**

During the past 20 years, you or your partner helped in a study of heart disease, blood pressure and diabetes. The study involved people of European, South Asian and African Caribbean origins who were living or working in west and north-west London between 1988 and 1991. At that time you or your partner completed a questionnaire and attended for a health check (some blood tests and other measurements). You or your partner may have taken part in SABRE again between 2008 and 2011- perhaps you/they completed a questionnaire or attended our clinic at St Mary's Hospital in Paddington.

This new study is being carried out to see how your health is now. We want to find out whether you are in good health or whether you have any disorders of the heart and circulation, diabetes or other disorders which affect your wellbeing or whether you have early signs or any risk factors for these disorders.

The study will help us to understand the causes of diabetes and disorders of the heart and circulation and other disorders which affect people as they get older. The study will also help us to understand what sort of treatments and preventive measures are best for people of different ethnicities.

If you would like to read more about the results of SABRE so far you can visit our website: [www.sabrestudy.org](http://www.sabrestudy.org)

## **Why have I been invited?**

You have been invited for one of two reasons. Either you were one of the nearly 5000 people who took part in the first (baseline) SABRE study between 1988 and 1991 or you are the partner of someone who took part.

## **How can I take part?**

You may choose to help in any or all of the following ways (or none at all):

- Included in this pack is a questionnaire. If you are happy to do so, you can complete the questionnaire and return it to us via the prepaid reply envelope. If you do not wish to complete the questionnaire, you can choose not to and you can also choose not to answer certain questions if you wish.

- We would like to access information from your medical and health-related records. We would need to share some of your details with the organisations that hold records for them to identify the relevant records to share them with us. Data would be shared in a secure way. We don't need you to do anything to enable us to do this. Further information about this aspect of study is shown on pages, 8, 10 and 11. However, if you do not want us to do this, you can opt out by answering question 1.6 of the questionnaire.
- We also offer a health check at our research clinic at University College London. If you are interested in hearing more about the health check, then please tick the box on the attached consent form so that we may get in touch with you.

More details on each of these ways that you can take part in the SABRE study are given on pages.....

## **Do I have to take part and can I withdraw from the study if I change my mind?**

It is up to you to decide if you want to take part. You may choose to help in some parts of the study but not in others. If you choose to take part, you are free to withdraw at any time without giving a reason. If you want to withdraw from the study you can contact the study team either by phone, letter or by email. You can inform us if you no longer want to participate and/or if you would like us to withdraw any identifiable data or samples held for long term storage.

## **Expenses and payments**

We will arrange transport to and from our clinic or will reimburse reasonable travel expenses. If you attend our clinic we will provide a £30 gift voucher as a gesture of appreciation for your help (you will have a choice of vouchers). We will also provide a £5 gift voucher if you complete the study questionnaire. We will provide refreshments after the tests are finished.

## **Who is running the research study?**

Researchers from the Institute for Cardiovascular Sciences based at University College London, are running this study. Please note that the team has moved back to University College from Imperial College London (where the second stage of SABRE took place).

The head of the study is Professor Nish Chaturvedi who worked on the earlier studies you or your partner/spouse took part in. The research team consists of doctors, nurses, technicians and experienced researchers.

## **Who is paying for this research?**

SABRE has been funded by the UK Medical Research Council, Diabetes UK, the Wellcome Trust and the British Heart Foundation. The British Heart Foundation is paying for this latest follow-up.

## **Who has reviewed this research?**

The SABRE study plans have been reviewed by independent experts in clinical research on behalf of the British Heart Foundation. In addition, the study plans have been reviewed and approved by a local research ethics committee (London-Fulham Research Ethics Committee).

## **Will I find out my own test results?**

With your permission, we will send you and your GP the results of the routine tests.

The routine test results are:

- routine blood tests (blood sugar, cholesterol and other fat levels and blood creatinine)
- urine tests
- blood pressure

For all the other tests, such as the ECG, ultrasound, DEXA and MRI scans, you will not receive results, but we will tell you and your GP if there are any findings which need further investigation.

If we do find something which needs further investigation, one of our doctors will advise and help you to receive appropriate specialist advice in consultation with your GP, if that is what you would like.

## **What are the risks (including radiation) from taking part in this study?**

We do not expect any ill effects after having the health check. However, during the health check you should be aware that:

The MRI scan of the brain involves lying still for several minutes in a fairly narrow space.

People who have a DEXA scan will receive a very small dose of radiation (30uSv or less) which is equivalent radiation dose to that of about four days of natural background radiation.



## **What are the benefits of taking part in this study?**

We do not expect the study itself to benefit you directly, but the information that we get from this research will be used to help improve treatment and preventive measures for diabetes and disorders of the heart and circulation.

You will receive the results of the health check and will be advised if further investigations are needed. Please note that results from genetic tests on blood samples cannot be made available.

## **Will I find out the results of the research study?**

If you would like to hear the results of the research study we will send you a summary and we will invite you to come to a meeting to hear some short presentations by members of the research team. The results will not be ready until the end of 2017. Some results from the earlier stages of SABRE are available on the study website: [www.sabrestudy.org.uk](http://www.sabrestudy.org.uk) and we will shortly arrange some get-togethers where we can share more results with you.

## **Will my taking part in this study be kept confidential?**

All information which is collected about you during the course of the research will be treated with the utmost care and attention to confidentiality. If you would like to know more about how we store the information or samples that you give us, please go to page X.... 'How do we store your information and samples?' We will ask your permission to tell your GP that you are taking part in the study and we will send your routine test results to your GP if you give us permission.

## **Who else may look at my data?**

We may be required to allow authorised individuals from the university (University College London), or from regulatory bodies including the NHS to have access to the study data in order to monitor the quality of the research.

We would also need to share some of your details, specifically your name, sex, date of birth, address and NHS number (if we know this) , with NHS Digital the organisation that holds medical and health-related records, in order for them to share the relevant records with us. You can opt out of this aspect of the study by answering question 6 in the attached questionnaire.

So that the most benefit may come from your valued participation in the SABRE

study, we may share SABRE study data with other research groups in the future, in order to carry out new analyses which could contribute to our research study aims. We will only release SABRE study data that is fully anonymised to other groups, meaning that a new study number will be generated for each person and identifiable information, such as date of birth or dates of events such as illness, will be removed and replaced with year of birth or year of event. Your name and address will never be released to any other research group.

## **What happens if something goes wrong during the study or I want to make a complaint?**

University 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 University 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 Nish Chaturvedi, Tel: 0207 679 9471). The normal National Health Service complaint mechanisms are also available to you. If you are still not satisfied with the response, you may contact the University College Joint Research Office (Tel: 0203 447 5557). NHS Indemnity does not offer no-fault compensation i.e. for non-negligent harm, and NHS bodies are unable to agree in advance to pay compensation for non-negligent harm.

## **Taking part in the SABRE Study**

There are many ways you can participate in the SABRE Programme of research and in particular, this research study.

- ***Questionnaire***

The questionnaire takes between 10-15 minutes to complete. This questionnaire asks about your ethnicity and health.

You can complete the questionnaire at home or we can help you to complete it during your visit to our clinic or by telephone. If you do not speak English, we can give you a questionnaire which is translated into Punjabi or we can provide an interpreter to help you.

We will ask your permission to send you 2 further questionnaires which will ask

about your health, lifestyle, background and family history. Because research has shown that health can be affected by personal, financial and social circumstances, there are some questions on these matters.

You do not have to answer any questions if you prefer not to.

- ***Your medical and health-related records***
- We would like to receive details about your hospital usage. The organisation providing this information is now called 'NHS Digital', but it used to be called the 'Health and Social Care Information Centre' (HSCIC). The information we will obtain, for people who take part in SABRE, relates to hospitalisations for any reason and includes the number of hospital visits or admissions, reason for admissions, length of stays and treatments received. NHS Digital, on behalf of Public Health England, will also provide us with information about study participants who develop cancer or (on behalf of the Office for National Statistics) who may have passed away since the start of our study- such information includes dates, type of cancer or cause of death. The data we obtain will be stored securely at UCL, and used only for the purposes of the study by researchers employed by UCL.
- We can access all of this by securely sharing some of your personal details, specifically your name, sex, date of birth, address and NHS number (if we know this), with NHS Digital who then provide us with the information described above. Importantly, no other information that might identify participants will be shared with the SABRE team and no identifiable patient data will be used in any publication or presentation. If you would like to discuss this or have any questions, please contact us. We intend to share your data with NHS Digital in late 2017 in the first instance.

If you prefer us not to access your information in this way you can opt-out of this by answering question 6 of the attached 'Questionnaire 1a'. Alternatively, you can call us or email us to inform us. Our contact details are on the front page of this booklet.

We use the information about your hospital usage to help us understand how many people have developed certain types of disorders during the course of the study, for example heart attacks, strokes or cancer. We can analyse the measurements that we have made in our clinics and the information that you have given us when you fill in our questionnaires to see which measurements

or lifestyle factors are associated with the hospital events – this is part of the research and may help towards understanding not only the causes of certain types of ill-health in different groups of people, but also why some people enjoy good health into older age.

When we receive linked data from NHS Digital, we remove all identifiers except for year of birth, year of death and your 5 or 6 digit study id number. All subsequent analyses use only subsets of the de-identified data. The data will be held only at the Institute of Cardiovascular Science at UCL. No data is released or shared in any form that would enable individual participants to be identified.

You may wonder why we are asking you to complete a questionnaire when we are going to gather similar information from your medical records. This is because other research studies have shown that the most accurate way to find out about a person’s medical history is to ask the person themselves as well as obtaining information from medical records. It is also not possible to get all the information which we need from your medical records.

- **Health check**



If you agree to have a health check, we will ask you to come to our research clinic at University College Hospital London W1, on a weekday morning at about 8.30 a.m. You may eat a light breakfast beforehand. If you have to travel a long distance we will try to arrange for you to come in later in the morning.

The main health check takes approximately 4-5 hours. Ideally the tests will be completed in one visit but if you would prefer to do two shorter visits this can be arranged. If there are some tests you do not think you can complete then you do not have to do them. We would still like you to attend to complete as many tests as you feel able to.

A small number of people who are unable to come to our clinic at University College Hospital and who live in the north-west London area may be able to undergo the height, weight and blood pressure measurements and urine and blood tests at home.

One of our research nurses will explain the tests that you will have and will answer any questions. They will ask you to consent to these tests in writing and you may choose not to have some of the tests if you prefer.

Apart from the blood tests, all the tests are painless, and do not require needles. A full list of tests is provided in the next few pages.

### **5. Future research studies**

We will ask you if we may contact you in the future about other research studies which are connected to the SABRE study, or to follow-up your health.

**We will ask you to decide whether you would like to take part in some, all, or no aspects of the study and complete a consent form accordingly.**

### **Details of the health check**

The tests and measurements are as follows:

### ***Urine and saliva test***

We will ask you to bring in a small sample of urine. We will send you a small container for this. Your urine sample helps us to assess how well the small blood vessels in your kidneys are working. We will also take a saliva sample to test your body's stress hormone levels.

### ***Blood tests***



About 2 tablespoons (30ml) of blood will be taken from a vein (usually in the arm). Blood will be tested for sugar, insulin and fats and some substances which may indicate how well the heart, kidneys and liver are functioning.

We would like to use any blood, urine and saliva samples which we have stored during the course of the SABRE study for future research into biological or genetic factors which might affect the risk of developing diabetes or cardiovascular diseases. We do not expect these future tests to have any implications for you personally. We do not plan to give the results of future tests from stored blood samples to you or your GP - as yet we do not know what tests may be considered appropriate or may become available in the future.

If you do not want us to store any of your samples of blood, urine or saliva please inform the clinic staff on the day of your appointment.



### ***Skin imaging***

We will take a 'photograph' of the skin on your forearm which will tell us about the health of your blood vessels. In people with diabetes this also gives a clue about the effect of diabetes on your arteries and heart.

## **Body measurements**

Your height and weight and the measurement around your waist, hips and thighs. We will also ask you to stand on a machine which is like a set of weighing scales to assess the amount of fat you have in your body.

## **Blood pressure**

We will measure your blood pressure using a cuff.

## **DEXA scan**



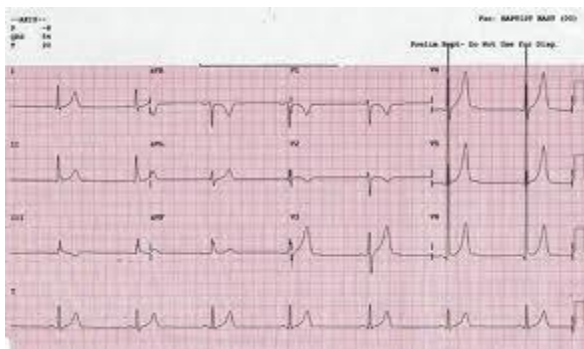
The DEXA machine scans bone density (for osteoporosis), measures calcium in the main large blood vessel (the aorta) and measures the amount of fat and lean muscle in the body. You will be asked to lie flat on a couch and stay still while the different parts of your body are scanned. The procedure is painless and takes around 20 minutes.

You will receive a small amount of radiation during the DEXA scan, but less than a normal X-ray – a DEXA scan provides the equivalent radiation dose to that of about four days of natural background radiation.

You can find some more information about DEXA scans at:  
<http://www.nhs.uk/conditions/DEXA-scan/Pages/Introduction.aspx>

**Heart measurements** will be made using 2 different devices.

## **Electrocardiogram (ECG)**



The electrocardiogram (ECG) is a tracing of the electrical activity produced by the heart while it beats. It tells us about the normal function of the heart and also gives clues about past or present heart disease.

## **Ultrasound scans**



We will perform ultrasound scans of your heart, liver and the arteries in your neck. Heart ultrasound (called echocardiography) does not use radiation (it is like a baby scan). It shows the thickness of the walls of the heart and the size of the heart chambers. It tells us how well your heart is working. The neck ultrasound looks at the health of your arteries. We'll also look at how healthy your

liver is. You can find some more information about ultrasound scans at the following websites:

<http://www.goingfora.com/radiology/ultrasound.html>

[http://www.cks.library.nhs.uk/patient\\_information\\_leaflet/ultrasound\\_scan](http://www.cks.library.nhs.uk/patient_information_leaflet/ultrasound_scan)

## **Brain MRI (magnetic resonance imaging) scan**

This scan does not use radiation. It uses magnets and radio waves to produce detailed pictures of the inside of your brain and can help to measure the health of small blood vessels in the brain.

During the scanning you will be asked to lie as still as possible for about 15 minutes. The scanner makes a loud noise during the scans. You will be given ear protection. A radiographer operates the scanner from behind a window, and will be able to see and hear you throughout the procedure. You will be given a call button to hold during the scan which you can press to get the radiographer's attention at any time.

The radiographer will ask you a series of questions about whether you have any metal inside your body. You will not be able to have the MRI scan if you have certain implanted metal devices, such as a heart pacemaker- this will be very carefully checked.

There are no known risks that could result from having an MRI scan. More information can be obtained from the following websites:

[http://www.cks.library.nhs.uk/patient\\_information\\_leaflet/mri\\_scan](http://www.cks.library.nhs.uk/patient_information_leaflet/mri_scan)

<http://www.goingfora.com/radiology/mri.html>

[http://www.brainandspine.org.uk/information/publications/brain\\_and\\_spine\\_booklets/mri\\_scan/introduction.html](http://www.brainandspine.org.uk/information/publications/brain_and_spine_booklets/mri_scan/introduction.html)

**Breathing capacity-** we will ask you to breathe in and to blow out through a tube called a spirometer.

**Memory and problem solving:** we are interested in how people's health affects



things like memory, concentration and mood. We want to find out whether blood pressure, sugar and fats in the blood may affect memory, concentration and mood and whether these effects are different in people of different ethnic origins.

We will ask you some questions about any difficulties and will carry out a few brief tests, such as remembering a list of words. We will also ask you to complete a short questionnaire about your mood.

**Walking, balance and strength tests** – we will do a simple test to assess your exercise capacity- this involves walking along a corridor for a few minutes. We will also assess your balance using a simple technique standing on a foam rubber mat and seeing whether you can hold your balance. We will do some simple strength tests of your arm and leg.

**Vision test** – we will check briefly how well your eyes can judge depth

### **Activity**



**And finally** we will give you a light lunch at the end of the tests, and we will ask you to wear a monitor (Actigraph) on your wrist the same size as a watch to measure your physical activity over the next 3 days.

### **Optional extra visit**

We will ask a small proportion of participants (if it is convenient) if they would be willing to come for a second visit in order that we may repeat some of the tests (not MRI). This is to make sure that our measurements are accurate and reliable and to ensure that our research methods are of the best possible quality.

On this optional visit we may also ask if you would be willing to have a test which allows us to take a photograph of the back of the eye (the retina). If you visited us at visit 2 you probably would have already had this test performed. Pictures of the small blood vessels at the back of the eye can tell us about the health of small blood vessels in other parts of your body.

We will put some drops into your eyes to dilate the pupil so that we can take the best pictures possible. The eye drops are normally quite safe, but if you have an eye problem such as glaucoma and have never been dilated before then they will not be used. The eye-drops cause a slight stinging sensation for a few moments. After you have the eye drops your vision will be slightly blurred for about 4 - 6 hours and you must not drive or operate any machinery until this has passed. You should not drive home after the tests. If you subsequently have further symptoms from your eyes such as redness, pain or continuing blurring – then you should contact us promptly or attend your local eye emergency department if out of hours. We will give you further advice about the procedure while it is being done.

The photographs are taken with a camera that comes close to your eye and flashes brightly. This is dazzling but does not cause any lasting effect. The procedure usually lasts less than 15 minutes.

We will provide the same travel arrangements/reimbursement and gift voucher as for the main study visit.

## Who can I contact for further information?

If you would like to ask any questions about this study you can contact a member of the research team (contact details below). You can also contact your GP for independent advice or they can call us on your behalf.

SABRE Research team

Email: [SABRE@ucl.ac.uk](mailto:SABRE@ucl.ac.uk)

Tel: 020 7679 9471

Thank you for taking the time to consider participating in this study.

## Appendix 1. Extra information

### How do we store your information and samples?

Your samples and information will be treated with the utmost care and attention to confidentiality. The information that we may hold about you may consist of the following (depending on which parts of the study that you have consented to)

- a) Your name, address, date of birth, sex and ethnicity and your GP's name and address. These are items which can identify you and we hold these in a secure database which can be accessed only by members of the SABRE study team. This database also holds information about which parts of the study you have agreed to take part in and it is stored in UCL's 'safe data haven'. This information is held separately and is not linked to any other study information which we may hold about you. This database is used to administer the study, for example, so that we can send you a questionnaire or invite you to attend our clinic.
- b) Information that you send us with regard to your health and lifestyle when you complete our study questionnaires. The questionnaires are marked with your SABRE study ID number and do not contain any information that can identify you. When we receive your questionnaires, these are scanned electronically and identified only by the study ID number. The paper copy of the questionnaire is then destroyed as confidential waste.
- c) Information recorded if you attend our study clinic, for example, blood pressure and blood test results. These results are either directly recorded electronically or they are written on paper before being entered into an electronic database. All clinical data are linked to your study ID number and never to your name, address or other information which could identify you. Paper records from the clinic are stored in a secure restricted-access room and do not contain any information which could identify you.
- d) Information recorded from your medical or health-related records.. Once we have received this information, it will be recorded electronically and linked only to your study ID number and never to your name, address or other information which could identify you. Any paper records relating to information from your medical or health-related records will be stored in a secure restricted-access room and do not contain any information which could identify you.

We will use your blood, urine and saliva samples for future research. If you have given us consent to use your blood, urine or saliva samples for future research, then these samples will be stored appropriately (usually frozen at minus 80<sup>0</sup> Celsius ) and in a secure restricted- access room. Samples are labelled only with your study ID number and never contain any information which could be used to identify you.

Your information will be kept for 25 years after the end of the SABRE study.