



Participant information 2

*International Centre for Circulatory Health
59-61 North Wharf Road
London W2 1LA*

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

Claire Tuson (020 7594 5947)

or email us at sabre@imperial.ac.uk

or you can visit our website at www.sabrestudy.org.uk

Some ways in which you could take part in the SABRE study



1. Questionnaire



The questionnaire is about your health and lifestyle and takes between 20 minutes and 1 hour to complete

See page 10 for more details

2. Allow a research nurse or your GP to collect information from your GP medical records



The information required from your records concerns diabetes and disorders of the heart and circulation only. All information will be treated in strict confidence.

See page 10 for more details

3. Health check



- Urine
- Height and weight
- Blood pressure
- Blood tests (2 tablespoons)
- ECG
- Ultrasound of heart and large arteries
- CT scan of heart, stomach area and thigh
- MRI scan of brain
- Photographs of the lens and back of the eye
- A short interview about memory and problem solving

Apart from the blood tests, these tests are painless and do not involve needles. They will take one morning. You will need to have fasted overnight.

If you do not have diabetes we will ask if you are willing to have one more test which takes about 2 hours. You can either have this test on the same day or come back on a different day.

See pages 10 - 12 for more details about the health check

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

Contents

What is the purpose of the SABRE study?	5
Who else will take part in this study?	5
Who is running the research study?	6
Who is paying for this research?	6
What will happen to me if I decide to take part?	6
Will I find out my own test results?	7
What are the risks from taking part in this study?	7
What are the benefits of taking part in this study?	7
Will I find out the results of the research study?	8
Will my taking part in this study be kept confidential?	8
Do I have to take part?	8
What happens if something goes wrong during the study or I want to make a complaint?	8
Taking part in the SABRE Study	10
1. <u>Questionnaire</u>	10
2. <u>Your GP medical records</u>	10
3. <u>Health check</u>	11
1. <u>Stored blood samples</u>	17
2. <u>Ultrasound scans</u>	17
3. <u>CT scans</u>	18
4. <u>MRI scans</u>	19
<u>THE FIRST BRENT AND SOUTHALL STUDIES</u>	20
What did we find out from the studies carried out between 1989 and 1991?	20

What is the purpose of the SABRE study?

You may remember that about 17 years ago, you helped in a study of heart disease, blood pressure and diabetes. The study involved people from West London who were of European, South Asian and African Caribbean origins. You completed a questionnaire and attended for a health check (some blood tests and other measurements). Your help was much appreciated and the study has been extremely helpful in working out why some people get illnesses and others do not.

This new study is being carried out to see whether your health is the same or whether it has changed. We want to find out whether you are in good health or whether you have heart disease, high blood pressure or other disorders of the circulation, or diabetes or whether you have early signs or any risk factors for these disorders. We would also like to find out whether you would be willing to come back for another health check at St Mary's Hospital and to ask you whether a research nurse may look at your medical records at your doctor's surgery with regard to circulatory diseases and diabetes and medications which you may be receiving for these disorders.

Our findings will help us to understand the causes of diabetes and disorders of the heart and circulation. 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 the first study which you took part in, please go to page 20 in this booklet, or you can visit our website: www.sabrestudy.org.uk.

Who else will take part in this study?

We hope that nearly 4,000 men and women of South Asian, European and African Caribbean origins who took part in the first study between 1989 and 1991 will take part in the SABRE study.

It is very important that as many people take part as possible to ensure that the study results are reliable and useful

Who is running the research study?

Researchers from the International Centre for Circulatory Health at Imperial College London, based at St Mary's Hospital, are running this study.

The head of the study is Professor Nish Chaturvedi who worked on the first study you took part in. The research team consists of doctors, nurses, technicians and experienced researchers.

The local research ethics committee has approved this continuing study.



Some members of the Sabre Study team

Who is paying for this research?

Two charities, the Wellcome Trust and the British Heart Foundation are paying for the research.

What will happen to me if I decide to take part?

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

1. Complete a **questionnaire** about your health and lifestyle
2. Your **GP medical records** – with your permission, a research nurse or your GP could collect some information about your health since the first study.
3. **Health check** at our clinic at St Mary's Hospital, Paddington
4. **Contact in future**- with your permission, we would like to be able to contact you in the future about your health or about other research studies connected with the SABRE Study.

You can read some more details about each of these from page 10.

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, CT and MRI scans and retinal photographs, you will not receive results, but we will tell you 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 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:

- People who have eye drops given will not be able to drive or operate machinery for 4-6 hours afterwards.
- The MRI scan of the brain involves lying still for several minutes in a fairly narrow space.
- People who have a CT scan of their heart, stomach and thigh will receive a small dose of radiation (3 mSv or less). This is about the same as the natural background radiation that we experience in the UK over a period of 12-17 months.

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.

We will arrange transport to and from our clinic or will reimburse reasonable travel expenses. We will provide refreshments after the tests are finished.

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 2012.

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 kept strictly confidential and will be stored securely and in accordance with best ethical and legal practice

We will ask your permission to tell your GP that you are taking part in the study and we will send your test results to your GP if you give us permission.

We will not give your information to anyone outside the research team (apart from your GP if you give us permission). The information that you provide will not be linked with your name

Do I have to take part?

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. Whether or not you choose to take part will not affect any health care which you receive. If you choose to take part, you are free to withdraw at any time without giving a reason.

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

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 Investigator (*Professor Nish Chaturvedi, Tel: 020 7594 3381*). The normal National Health Service complaint complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College Clinical Research Office (*Tel: 020 7594 1898*).

Taking part in the SABRE Study

1. Questionnaire

The questionnaire takes between 20 minutes and one hour to complete.

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.

The questions ask about your health in general and about diabetes and disorders of your heart and circulation, including high blood pressure and strokes.

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.

2. Your GP medical records

If you live within the Greater London area, we will ask for your permission and your GP's permission to collect some information for the research study from your GP medical records. If you live outside the Greater London area, we will ask your permission for your GP to record the same information for us.

This information concerns diabetes and disorders of your heart or circulation which you may have suffered since you took part in the first study 17-20 years ago. We will also gather information about any treatments or medications which you have received for these disorders.

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 their doctor. It is also not possible to get all the information which we need from your medical records.

Your information will be treated in strict confidence in accordance with best ethical and legal practice. Your details will not be given to

anyone outside our research team and, with your permission, your own doctor (GP).

3. Health check

The main health check takes a morning.

If you agree to have a health check, we will ask you to come to our research clinic at St Mary's Hospital in Paddington, London W2, on a weekday morning at about 8.30 a.m. If you have to travel a long distance we will try to arrange for you to come in later in the morning.

A small number of people who choose not to come to our clinic at St Mary's and who live in the London area may be able to undergo the height, weight and blood pressure measurements and urine and blood tests at home.

We will ask you not to eat or drink anything, except plain water after your evening meal on the day before the tests. We will prefer you not to take any medications on that morning until after the tests are finished. We will ask you to bring your usual medications with you, so that we may document them and you can take them after most of the tests are finished.

One of our research nurses will explain the tests that you will have and will answer any questions. She 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.

The tests and measurements are as follows:

- **Urine 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.
- **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** will be measured three times while you are sitting down.



- **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.

With your permission, we will **store a small amount of blood** which can be analysed at a later date for research purposes within the SABRE Study only. We will also keep some DNA (genetic material) from your blood. The stored blood will be marked only with a study code number and your name will not be associated with the stored samples.

- Some more information about the stored blood samples can be found on page 17.
- **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.

We will also ask you if you are willing to allow us to talk to a close friend or relative about your memory and problem solving (you do not have to agree to this).

The remaining tests described from here are only done in the clinic at St Mary's.

- **ECG** (an electrical tracing of your heart).
- **Doppler ultrasound scans of your heart and the arteries in your neck and legs.** The probe used is similar to that used during pregnancy to check the development of the baby. The ultrasound measurements show how well your heart is working and the thickness of the walls of the heart and blood vessels. Some measurements show the stiffness of the arteries.



Having an ultrasound scan of the heart

Please see page 17 if you would like more information about Doppler ultrasound scans.

- **CT scan of your heart, stomach and thigh.** This is a form of X-ray that can detect calcium in the blood vessels and the amount of fat in the area around your stomach and in and around the large muscles in your thighs. Calcium in the blood vessels can tell us about the health of the heart. We are also interested to find out how fat is stored in different parts of the body and how this may affect health. The CT scan involves a small dose of radiation (3.0 mSv or less). This is about the same as the natural

background radiation that we experience in the UK over a period of 12-17 months.



Having a CT scan

Please see page 18 if you would like more information about CT scans

- **MRI scan** (magnetic resonance imaging) of your brain. This scan 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, this is very important for obtaining good quality scans. The scan lasts 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.

Before you have your brain scanned you will be asked some questions to make sure that is appropriate for you to be scanned.

There are no known risks that could result from having an MRI scan.

Please see page 19 if you would like more information about MRI scans

- **Photographs of the lens and back of your eyes** (the retina). 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 take several pictures of each eye to allow us to see them in as much detail as possible.

We will also take photographs of the front of your eyes to see if there is any clouding or cataract in the lens.



Having
photographs
of the retina

We will put some drops into your eyes 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 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. 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.

- And finally at the end of the morning we will fit a small light-weight monitor to your arm to measure your **blood pressure over the next 24 hours**. This gives us a picture of how your blood pressure may vary at different times of the day or night.

Our driver can collect the monitor from your home the next day or you can return it to us if you prefer.

- If you do not have diabetes, we will ask you if you are willing to have one extra test to look at how well your body deals with sugar and whether you are at risk of diabetes.

The extra test takes two hours and you will be given a sugary drink (like Lucozade). You will have 2 small separate blood tests (about half a teaspoon each), one before and one 2 hours after the drink.

This can be done on the same day as the main tests or you can come back on a different day- it is up to you to decide which is more convenient.

We will give you a light lunch at the end of the tests. We will arrange transport to and from the clinic or reimburse reasonable travel expenses, and we will do our best to minimise any inconvenience to you.

4. 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.

More detailed information about the SABRE Study tests can be found in the following pages

1. Stored blood samples

The stored blood samples will be used 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 expect to give results of 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. We will use a special way of double coding results from these blood samples so that your results can never be directly linked with your name. Your results or details will never be given to anyone outside the research study team.

Stored blood samples will only be tested after approval by a research ethics committee and no tests of known value for diagnosing or predicting disease, which could be linked to you personally, will be done without your consent.

2. Ultrasound scans

An ultrasound scan, is a procedure that uses high frequency sound waves to create an image of an organ in the body.

As sound waves are used, rather than radiation, the procedure is thought to be completely safe. The procedure is completely painless.

Ultrasound is very high frequency sound that cannot be heard by the human ear, but can be detected using a machine called an ultrasound scanner.

High frequency sound waves, directed at your body, are able to pass through liquid and soft tissues, but not solid objects. When the ultrasound hits a dense or solid object, such as bile or a heart valve, it bounces back as an echo. Echoes of different strengths are reflected depending on the density of the object. A computer is used to translate the reflected ultrasound into an image.

Ultrasound is often used as a means of determining the size, shape, and structure of different organs of the body. In the SABRE study, ultrasound will be used to study your heart and the arteries in your neck and groin.

A hand-held device called a probe which looks like a thick, blunt pen is placed on to your skin, over the part of the body (chest, neck and groin) that is to be examined.

A lubricating gel is put on to your skin, so that the probe is able to move smoothly, and to ensure that there is continuous contact. The probe is connected to a computer and a monitor. Pulses of ultrasound are sent from the probe, through your skin and into your body. Ultrasound waves are bounced back from the structures of the body, and are displayed, as an image, on the monitor. As well as producing still pictures, an ultrasound scan shows movement that can be recorded on to video.

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

http://www.cks.library.nhs.uk/patient_information_leaflet/ultrasound_scan

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

3. CT scans

CT scans are sometimes called CAT scans. CT stands for computed tomography.

A CT scan uses X-rays and is a painless procedure. A series of X-rays are taken of your body at slightly different angles and these are used to make very detailed pictures of the insides of your body (in the SABRE study, the pictures will be of your heart and stomach area).

The CT scanner takes pictures while you lie on a couch, the couch will move slightly after each X-ray is taken. You will be asked to lie very still, but to breathe normally while the pictures are taken. The procedure takes about 10 minutes.

The radiographer (who operates the scanner) will leave the room during the scan, but will be able to talk to you through an intercom.

You can find some more information about CT scans at the following websites:

http://www.cks.library.nhs.uk/patient_information_leaflet/ct_scan

http://www.goingfora.com/radiology/ct_room.html

http://www.brainandspine.org.uk/information/publications/brain_and_spine_booklets/ct_scan/introduction.html

4. MRI scans

MRI stands for magnetic resonance imaging. This scan uses strong magnets and radio waves to produce detailed pictures of the insides of your body. In the SABRE study the scan will be 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, this is very important for obtaining good quality scans. The scan lasts about 10 minutes. The scanner makes a loud knocking or buzzing 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.

MRI scanning is considered to be a very safe procedure and unlike X-rays, can provide very clear pictures of soft tissues such as the brain

You can find some more information about MRI scans at the following websites:

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

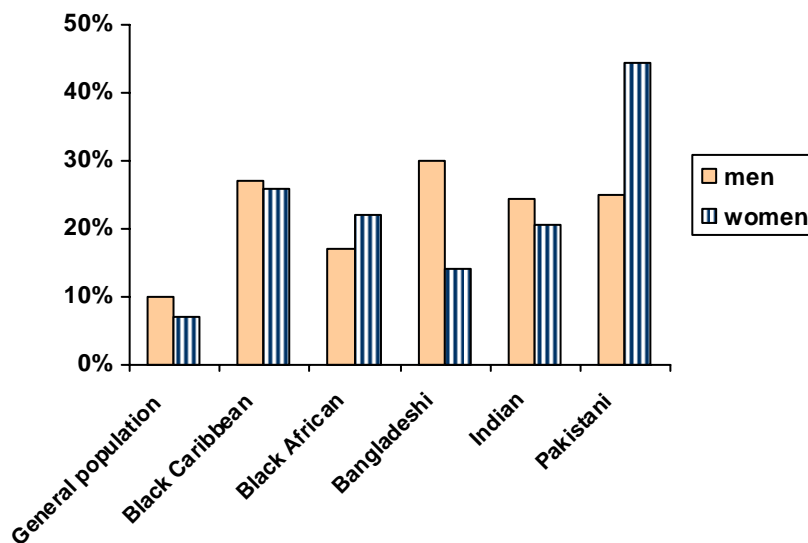
THE FIRST BRENT AND SOUTHALL STUDIES

What did we find out from the studies carried out between 1989 and 1991?

People who took part in the study were living in West London and were mainly of European, South Asian or African- Caribbean origin.

We found that people in these three groups experience different levels of diabetes, some sorts of heart disease, strokes and some other important illnesses.

Percentages of people aged over 55 living in England who have diabetes, by ethnicity *



People who are of South Asian or African-Caribbean origin are more likely to have diabetes than people from Europe. Coronary heart disease and strokes are more common in South Asians than in Europeans. African-Caribbean people are less likely to suffer from coronary heart disease than Europeans, but they are more likely to suffer from strokes, kidney and eye problems. It seems from this study and from other research, that for South Asians, coronary heart disease and strokes may be linked with body shape and the levels of sugar, fats and insulin in the blood.

People of African-Caribbean origin may gain some protection from coronary heart disease because they have lower levels of 'harmful' fats and higher levels of 'good' fats in their blood. The higher blood pressure levels that occur in some African-Caribbeans may be linked with strokes, especially in women, although there are likely to be some other factors linked with strokes in African-Caribbean men.

More research is needed to confirm these findings and to further explain why there are differences between people of different ethnic origins

PTO

* Data from Health Survey for England, 2004. (Office for National Statistics, The Information Centre, 2006)

What do we hope to learn from continuing the study?

By following up the people who took part in the first study between 1989 and 1991, we will be able to find out whether the measurements that were taken at that time can help to explain illnesses (or good health) now.

We want to continue to study the differences in illnesses that occur in people from different ethnic origins. The study will build on the findings from 1989 - 1991 and help us to find out whether and, if so, why some groups of people are more at risk of diabetes, heart disease, strokes and other serious illnesses.

We hope that the study will help us to learn how we can most effectively prevent and treat some of these illnesses occurring in our local communities.

This is why your help has already been so valuable and why we need your continued support.

Thank you