

Stress & Health Study
Eighth Medical Examination (Phase 13)
Information Leaflet
For Clinic Visits



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Thank you for your continued participation, it is greatly valued.

We are inviting you to attend the eighth medical examination, Phase 13, of the Stress & Health Study.

Please take time to read the information contained in this leaflet as it describes the tests and procedures that will be carried out when you attend the clinic and also what will happen to the information we collect.

What is the purpose of the study?

The Stress & Health study, also known as the Whitehall II study, was established to investigate the importance of social class for health. Looking towards the future, the study seeks to answer questions about how previous and current circumstances affect health and quality of life in an ageing cohort. Older people form the largest - and growing - age group in the UK, and the more we can find out from you and other study participants, the better health policy, prevention and provision can be informed.

As usual, you will receive results for some of the measures, and if there are any abnormal results you might want to discuss them with your GP. At this phase we will ask for your consent to post a copy of your results directly to your GP. Should you consent to this please ensure your GP details are correct and up to date. Your GP can interpret the results in the light of your medical history. Should you not give consent for us to post a copy of your results to your GP, we will send you the copy to take to your GP.

How will information about me be kept confidential?

All data collected from questionnaires, clinical samples and electronic health related records are held securely and confidentially in accordance with the provisions of the General Data Protection Regulation (GDPR) 2018, the Data Protection Act (DPA) 2018 and also the NHS Information Governance requirements.

Your personal data are only used to invite you to future data collections or send you your clinical results or any other correspondence such as newsletters. In addition, we supply some of these identifiable fields to NHS Digital to perform the linkage with external health records needed for research purposes. All your data are stored under secure conditions to which only the Stress and Health administrative staff has access. By the time they reach the hands of our researchers, your data have been pseudonymised by the data management team and therefore cannot be linked to you as a named individual. This information is used exclusively for health-related research purposes.

The blood samples you provide will be stored and used in accordance with

1. The UK Human Tissue Act 2004 and
2. The Codes of Practice laid down by the Human Tissue Authority (HTA), who regulate amongst other things, the storage and use of human tissues or cells for research.

No individual can be identified in the reports published from our studies.

What do I need to do **BEFORE** the appointment?

1. Read through this information leaflet to familiarise yourself with all the tests and procedures we will ask you to complete on the day of your appointment.
2. Please complete the Health Survey Questionnaire that is included with this leaflet and bring it along with you to your appointment. If at any point you feel that you are unable to complete some or all of the questions, somebody else, such as a relative or a carer could help you.
3. Please check and complete the **Update of details form** included in the pack to ensure that we have your correct details. These details enable us to maintain contact with you. Please remember to sign where applicable.
4. Remember to read the **pre-examination instructions** at least 2 days before your appointment.

5. On the morning of your appointment please remember to drink a minimum of 1 glass of water. Drinking water will make for a smoother blood draw. The more water you drink, the plumper your veins become and the easier it is for the phlebotomist to locate your veins and take the blood.
6. Please do not eat anything 2 hours before your appointment. If you have diabetes or are on treatment for diabetes, please do not fast, follow your normal diet.
7. Take your medication as usual.

What happens DURING the clinic screening?

Your appointment will last between 2½ - 3 hours. Please remember to bring your reading glasses to the appointment.

Where indicated by an *, you will be asked to change into a gown for part of the screening.

The following tests and procedures will be performed on the day of your clinic appointment:

1. Consent:

You will be asked to sign a consent form consenting to take part in this phase of the Stress & Health Study. You will be given the opportunity to ask questions, relating to any of these tests and procedures, before signing the consent form. By signing the consent form, you will confirm your willingness to take part. Therefore please read the explanation of the tests below that will be performed on you on the day.

Please note that your participation is voluntary and that you can stop or decline any part of the examinations or measures at any time during the clinic screening.

2. Blood Pressure Measurement:

You will be seated with your right arm resting on a table, palm facing upward with legs uncrossed. A blood pressure cuff will be wrapped around your upper arm and you will be asked to relax alone for 5 minutes. A total of 3 blood pressure measurements will then be recorded, with a minute between each reading. Blood pressure is a useful indicator of risk of future cardiovascular disease.

3. Blood Test:

You will be asked to roll up both sleeves to expose your arms. The phlebotomist will decide which arm is to be used and will then rest that arm on a support and apply a tourniquet. The skin surface will be cleaned and a sample of blood will be taken for analysis. The blood taken will be processed and analysed off site by The Doctors Laboratory (TDL) for blood sugar, cholesterol levels and kidney function (estimated glomerular filtration rate/eGFR), for which you will get the results within 12 weeks of your appointment date. The remaining blood sample will be added to our freezer store, to which there is restricted access. The samples are stored and used in accordance with UK Human Tissue Act 2004 and the Codes of Practice laid down by the Human Tissue Authority (HTA), who regulate the storage and use of human tissues or cells for research, amongst other things. The remaining blood samples and the blood results from the laboratory, we use to look at changes over time, studying the causes of heart and circulatory disease and possible ways of preventing it.

4. Liver Function Scan (Fibroscan):

A fibroscan is a non-invasive, ultrasound-based scan of your liver. It will measure how elastic or how stiff your liver is.

You will be asked to lie on an examination couch and place your right arm above your head. The nurse/technician will feel your abdomen to find the right place to perform the scan. He/she will then place a probe on your abdomen and trigger the probe to start. The sound waves will be sent out from the probe in pulses, which will pass through your skin to your liver and bounce back. This will feel like a gentle flick against the side of your skin – it should

not hurt. The scanner measures the time it takes for the sound wave to bounce back. We will repeat this at least 10 times to make sure we get an accurate result.

5. Refreshments: You will be invited to help yourself to refreshments.

6. General Knowledge Questionnaire:

You will be asked to put on headphones and follow instructions from pre-recording. This measurement will take approximately 30 minutes. This assesses memory, numerical and verbal skills.

7. MemScreen:

The MemScreen is a memory test which is performed on a computer. You will answer the questions yourself but a member of staff will be on hand to explain and assist if needed.

8. * Height/Weight and Body Mass Index (BMI):

Your height and weight will be measured as at previous phases. These may indicate early signs of heart disease and diabetes.

9. * Pulse Wave Velocity (PWV):

This measure will be performed after your height and weight have been taken. Three ECG electrodes will be attached to your chest, your blood pressure will be measured while you are lying down. The nurse will locate the pulses in your neck and groin area and mark these. Then using an ultrasound device, two readings of the pulses in your neck and groin area will be taken. This is a non-invasive measure that looks at the elasticity of your arteries and is entirely painless.

10. Lung Function:

You will be shown how to blow into a small Spirometer. You will then be asked to follow the nurse's instructions a minimum of three times and a maximum of five times. This test measures your lung capacity.

11. Walking Test:

You will be asked to walk, at your normal pace, along an 8 foot measured area. The nurse will show you how they want you to do this and will record the time it takes you to complete the measure. This test measures your lower limb mobility.

12. Hand Grip Strength:

You will be asked to squeeze a machine for two or three seconds, as hard as you can. You will be asked to repeat this three times. The reading from the machine will be recorded. This test measures your upper body strength and is generally a good marker of muscle strength.

13. Short Interview (MMSE):

If necessary, you will be asked to clarify missing information from your Health Survey Questionnaire. Following this, a short interview (MMSE) will be conducted for approximately ten minutes to assess your mental well-being and alertness.

14. Trail Making Test:

You will be asked to 'connect-the-dots' using a pencil and paper. The 'dots' will consist of a series of numbers and letters that you need to connect up in consecutive order. This test provides us with information about cognitive skills such as visual attention and task switching.

New Tests this phase

The new tests that are added to the screening this phase are the MemScreen, the liver function scan (fibrosan) and taking a blood sample for DNA epigenetics (e.g. DNA methylation). The MemScreen is a memory test which is performed on a computer. You will answer the questions yourself but a member of staff will be on hand to explain and assist if needed.

The liver function scan (fibrosan) is a non-invasive, ultrasound-based scan of your liver. It will measure how elastic or how stiff your liver is.

DNA epigenetics: we will take an extra blood sample of 4mls/1 tube from you when we are taking your other blood samples.

DNA Testing

We will only be collecting a blood sample for DNA testing from you if we do not already have a sample in storage from a previous phase or the sample we have in storage is running low.

When you provide us with a DNA sample, it is stored and used for the study of genetic influences which may be relevant to diabetes, heart disease, stroke and cognitive function. We will continue to use any DNA samples provided previously for the study of genetic influences. Should you no longer wish us to do so, please inform us in writing and these samples will be destroyed.

DNA Epigenetics

Should you consent to having the sample taken for DNA Epigenetics, an extra 4 mls of blood (1 tube) will be taken from you at the same time as we are taking your bloods for the other tests. This blood sample will be used only for testing for epigenetic modifications of DNA, such as DNA methylation.

What is Epigenetics?

Our 'genetic code' is our DNA sequence, and you have had that tested previously. Epigenetics is the study of minor changes to DNA, that don't affect the genetic code but 'fine tune' which parts of the genetic code are 'active'. Not all parts of the body's DNA are necessarily active at any given time. In fact, the body has ways to regulate which parts of the genetic code are active or inactive i.e. which genes are turned 'on' and 'off'. We know that the genetic code is important for determining risk for some diseases such as heart disease and diabetes, but whether these genes are 'on' or 'off' is also an important part of that risk. Epigenetic change is a regular and natural occurrence but can also be influenced by several factors including age, the environment/lifestyle, and disease

DNA methylation is one of the epigenetic ways in which gene activity is regulated. There are others, such as DNA acetylation. These are essentially modifications of how 'accessible' the DNA is, but don't have any impact on the actual genetic code. By seeing which parts of the DNA have been methylated or acetylated, we can see which genes have been turned 'on' or 'off' over time. We can then work out how environmental factors (such as cigarette smoking, alcohol etc) contribute to this. It is hoped that the results from this research will help us to identify links between general health and DNA methylation which turns genes 'on' and 'off'.

Why do you need an extra DNA blood sample?

For 'DNA methylation', we need to assess changes in the methylation pattern of DNA over the life course. It is for this reason that we need to collect an extra blood sample that will enable us to compare your blood samples from 2 different time points, i.e. one sample from a previous phase

and one sample from this phase. Using these, we can assess which genes have been 'turned on' or 'turned off' by environmental exposures over time.

Why am I not told the results of the genetic tests on my samples?

At present, we do not know how significant genetic results are to your health. To the best of our knowledge, the health risks associated with genetic markers are very small in comparison to the risk associated with family history of coronary heart disease, smoking and raised serum cholesterol.

The genetic tests we undertake are carried out on groups of people for research purposes only. The clinical importance of the findings for individuals is not clear at this time. The research tests are not screening tests.

Are there any risks involved?

Participation involves a minimal risk. It is possible that you may be slightly uncomfortable with some of the questions asked, or measurements made, during the screening. You can stop or decline any part of the examinations or measures at any time during the screening.

You may feel some discomfort when you have blood taken, although all our staff are specially trained to reduce this risk.

What happens AFTER the clinic screening?

Results:

Approximately twelve weeks after your health screening we will send you the results of your:

- Blood sugar levels
- Cholesterol
- Weight
- Body mass index (BMI)
- Blood pressure (BP)
- Kidney functioning (eGFR)
- Liver Function Scan (Fibroscan)

As at the previous phase we will ask for your consent to post a copy of your results directly to your GP. Should you consent to this please ensure your GP details are correct and up to date. Your GP can then interpret the results in the light of your medical history.

Should you not give consent for us to post a copy of your results to your GP, we will send you the copy to take to your GP who can then interpret the results in the light of your medical history.

Blood samples:

The remaining blood sample/s will be added to our UCL secure freezer store, to which there is restricted access, and may be used in future research. The samples are stored and used in accordance with UK Human Tissue Act 2004 and the Codes of Practice laid down by the Human Tissue Authority (HTA), who regulate the storage and use of human tissues or cells for research, amongst other things.

Using the remaining blood samples and the blood results from the laboratory, we look at changes over time, studying the causes of heart and circulatory disease and possible ways of preventing it.

Data:

All of the information we have collected from you is processed to generate analysable research data. Any personal identifiers (such as your name, contact details, detailed health diagnosis and dates, etc) are removed. We have implemented a data sharing policy to make data as widely and freely available to scientists from the UK, other EU countries and overseas as possible while protecting confidentiality, and making sure that we maintain the reputation of the study, funders and participants. Each participant is simply identified with a numeric ID. The resulting research data are analysed at group level for health-related research purposes only.

In addition to the collection of questionnaire and clinical data, a crucial aspect of this study is the identification and verification of illnesses and health status, even after incapacity or death. This is achieved by securely linking with electronic health data such as cancer and death registrations, hospital records and mental health data. The linkage has been approved by the Health and Social Care Information Centre (HSCIC) which changed its name to NHS Digital in July 2016. The HSCIC, now NHS Digital, is the national provider of information, data and IT systems for commissioners, analysts and clinicians in health and social care. NHS Digital have established a robust system for provision of health data for research purposes. This system involves a very strict application process, secure data linkage procedures and data release. For more information about NHS Digital please visit their website at <https://digital.nhs.uk/about-nhs-digital>

If you **DO NOT** want the electronic health records held by NHS Digital to be shared with us, you need to register a type 2 opt-out with your GP practice. If you have already chosen to opt-out with your GP practice we will not receive your data. Further information can be found at <http://content.digital.nhs.uk/yourinfo>

Further information on how patient data is used and why, what the safeguards are and how decisions are made can be found at: <https://understandingpatientdata.org.uk/what-you-need-know>

What happens if I withdraw from the study?

As a volunteer you have the right to withdraw completely from the study at any stage. If you withdraw, we will not contact you to participate at any future phases. Information you supplied voluntarily at previous study phases will be retained in a pseudonymised (that is without your personal identifiers) form. This enables us to continue our research into stress and health and about how previous and current circumstances affect health and quality of life in an ageing cohort.

If you wish to withdraw from the study please contact us on the number or e-mail below.

General Information

Our measures and procedures have been approved by the London-Harrow Research Ethics Committee (REC) and we aim for the best possible clinical and professional practice.

REC Ref: 85/0938

IRAS Project ID: 142374

This approval and our compliance with the NHS Information Governance allow us to obtain information held by the NHS and records maintained by the Health and Social Care Information Centre (NHS Digital).

An up to date list of our publications can be found on our website, <http://www.ucl.ac.uk/whitehall11>, or you can contact us on the Freephone number below.

If you have any concerns, complaints, questions or would like further information regarding any aspect of the Stress and Health Study, you are welcome to contact us on:

Freephone: 0800 068 1562

Email: shstudy@ucl.ac.uk