

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



Contact details

Stress & Health Study
Department of Epidemiology and Public Health
University College London
1-19 Torrington Place
London WC1E 6BT

Freephone: 0800 068 1562
Telephone: 44 (0)20 7679 5621
Fax: 44 (0)20 7679 1831
E-mail: shstudy@ucl.ac.uk

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 have your appointment with the nurse, in your home, 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 directly 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, before the nurse visit and give it to the nurse on the day of 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, before the nurse visit, to ensure that we have your correct details. These details enable us to maintain contact with you. Please remember to sign where applicable and hand this to the nurse on the day of your appointment.
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. Take your medication as usual.

What happens DURING the appointment?

Your appointment will last between 2½ - 3 hours.

Please remember to have your reading glasses to hand for the appointment and to wear loose clothing (separates) on the day of your appointment.

In order to keep both you and the nurse safe whilst conducting the home visit, nurses will be required to wear Personal Protective Equipment (PPE). This will mean that the nurse will wear a mask and a long-sleeved gown for the duration of the visit. When they need to spin the blood samples and perform the lung function test, they will also wear a full-face visor, which will be removed once these tests have been completed. Nurses will remove their PPE on leaving your home and all PPE will be properly and safely disposed of. Please note all equipment is cleaned after each visit and before the nurse carries out her next visit.

The following tests and procedures will be performed on the day of the nurse visit:

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 be confirming 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 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 nurse 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 by The Doctors Laboratory (TDL) for blood sugar, cholesterol levels, liver and kidney function (estimated glomerular filtration rate/eGFR), for which you will get the results within 12 weeks of your appointment date. We will also be testing some of your blood for COVID-19 antibody, for which you will receive the result of. 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. Refreshments:** You will be invited to help yourself to refreshments.
- 5. General Knowledge Questionnaire:**
You will be asked to put on headphones and follow instructions from a pre-recording. This measurement will take approximately 30 minutes. This assesses memory, numerical and verbal skills.
- 6. 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.
- 7. 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.
- 8. 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.
- 9. 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.
- 10. 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.
- 11. Trail making test:** The participant is asked to 'connect-the-dots' using a pencil and paper. The 'dots' will consist of a series of numbers and letters that they 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

There are 2 new tests added at this phase:

1. The testing of blood for COVID-19 antibody (SARS-COV-2 IgG/Antibody)
No extra blood sample will need to be collected. We will use blood from the samples you are already supplying, and we will be testing for COVID19 Antibody. You will receive the results of this test. This antibody test will tell whether a person has been previously infected with coronavirus. Most patients who recover from a coronavirus infection have been found to produce antibodies, but it is not yet known if an individual with a positive result showing presence of SARS-COV-2 IgG/Antibody levels will be protected, either fully or partially from future infection, or for how long protective immunity may last. These results should be used in conjunction with information available from clinical evaluation and other diagnostic procedures and discussed with your GP.
2. COVID Questionnaire
The questionnaire includes questions about any COVID-19 symptoms you may currently have or have had in the past as well as questions about whether you have been tested for COVID-19 or waiting to be tested for COVID-19.

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. In the future we may also study other diseases such as COVID-19 as well as ageing and functioning

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.

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 nurses are specially trained to reduce this risk.

Due to the COVID 19 pandemic both nurse and participant are at risk of COVID 19 infection. All nurses are required to wear Personal Protective Equipment (PPE) and are supplied with the necessary PPE associated with this risk. All equipment is cleaned after each visit and prior to the next visit.

What happens AFTER the appointment?

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)
- COVID-19 Antibody

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 directly 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 in two ways:

1. 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>

2. Supporting details from GP and hospital records may also need to be obtained to confirm the occurrence of any events/ illnesses.

In certain cases, this might involve writing directly to the GP or visiting hospitals to gain physical access to your hospital records. In order to do this, we need your permission. There is a section on the update of details form where we ask for your consent allowing us to access your notes.

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

E-mail: shstudy@ucl.ac.uk