

**LONDON’S GLOBAL UNIVERSITY**

**DEPARTMENT OF BEHAVIOURAL SCIENCE AND HEALTH**

**The Mood and Health Study**

**Participant Information Sheet for Adults**

UCL Research Ethics Committee Approval ID Number: [insert ID]

**Title of Study:** Commonalities in depression across multiple physical illnesses: the experience of living with mental and physical illness in community dwelling adults

**Department:** Behavioural Science and Health

**IRAS ID:** 244721

**Name and Contact Details of the Researchers:** Prof Andrew Steptoe, Dr Lydia Poole, Dr Rachael Frost, Dr Georgia Black, Ms Hannah Rowlands, UCL, London

**Name and Contact Details of the Principle Researcher:** Dr Lydia Poole, Department of Behavioural Science and Health, 1-19 Torrington Place, UCL, London, WC1E 6BT

You are being invited to take part in a research study conducted by staff at University College London (UCL). Before you decide whether or not to take part, it is important for you to understand why the research is being carried out and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information. Thank you for reading this.

1. **What is the purpose of the study?**

Depression is known to affect our health in many different ways. We know that people with depression are more likely to suffer from an illness such as heart disease, arthritis or diabetes. We are trying to understand more about how depression interacts with these types of illnesses. To do this, we want to compare people with depression by itself to people with depression alongside a physical illness to see if there are any similarities or differences in the types of symptoms people experience and whether or not they find their treatment works for them. The results of this study will help advance our knowledge of the links between the mind and the body and may help to develop new methods of improving patient care.

1. **Who is organising and funding the research?**

The research is a project funded by the Economic and Social Research Council (ESRC) as part of a research grant awarded to Dr Lydia Poole at the Department of Behavioural Science and Health at UCL. The research team who will carry out the work are Dr Lydia Poole and Ms Hannah Rowlands.

1. **Why have I been invited?**

We are interested in depression by itself or depression alongside a physical illness. The physical illnesses we are looking at are:

* Coronary heart disease such as a heart attack, angina or heart failure.
* Arthritis (osteoarthritis or rheumatoid arthritis).
* Type 2 diabetes.

You have been invited because your medical history indicates that you have been diagnosed by a doctor as having:

|  |  |
| --- | --- |
| Depression and coronary heart disease (e.g. heart attack, angina or heart failure) |  |
| Depression and arthritis (osteoarthritis or rheumatoid arthritis) |  |
| Depression and type 2 diabetes |  |
| Depression |  |

1. **Do I have to take part?**

No. It is up to you to decide whether or not to take part. A decision not to take part or withdraw will not affect your medical care in any way. If you give your consent and later withdraw, we would ask to be able to use all data collected up to the point of your withdrawal, which would be kept subject to confidentiality procedures.

1. **What do I have to do if I take part?**

If you do wish to take part please complete your contact details using the enclosed form and return to us using the FREEPOST envelope we have provided. We will then call you to arrange the next steps. Or if you prefer you can contact Ms Hannah Rowlands directly on 020 7679 1805 or h.rowlands@ucl.ac.uk. Please contact us within 2 weeks if you are interested in taking part or if you have any further questions about the study. If you change your mind, you are still free to withdraw at any time and without giving a reason. One of the research team will then visit you to conduct a face-to-face interview. The interview will be held at a time convenient to you and at a place you find convenient to get to (often at your own home). In our experience, most interviews last approximately 1 hour, though you will be free to talk for as you feel willing/able to. You will only take part in one interview. We will ask you to complete a short questionnaire about your personal details (such as age, religion, ethnic group) at the end of the interview; this will take about 15 minutes. With your consent, we will notify your GP that you are participating in this study. All participants will receive a £10 retail voucher as a token of our thanks.

1. **What else do I have to do?**

There are no other requirements and you should carry on as normal.

**7. Will I be recorded and how will the recorded media be used?**

With your consent, the interview will be audio-recorded using a handheld device. The audio-tapes from the interviews will be listened to by an external typist (TP Transcriptions Ltd.), who will write down what has been said. They will not know your identity and will keep everything confidential. The written transcripts will be checked by a member of the research team to make sure they are correct. We will keep the audio-recordings for a maximum of 12-months to allow these checks to be made, prior to being deleted. The audio recordings of your interview made during this research will be used only for analysis for research articles and in conference presentations and lectures. No other use will be made of them without your written permission, and no one outside the project will be allowed access to the original recordings.

1. **What are any possible disadvantages and risks of taking part?**

It will take time out of your day, but every effort will be made to minimise inconvenience and to ensure your comfort in the interview process. Any travel costs up to a maximum of £20 will be reimbursed; you will need to provide us with your receipt. Many people value the opportunity to talk about their experiences, but it will be possible to take a break or stop at any point during the interview. If, at the end of the interview, it has brought up issues you wish to discuss further, we will refer you to more expert sources of support, such as charities and helplines. If any problems become apparent that require support from a medical doctor we will advise you to contact your GP so that you can seek medical treatment as early as possible. If you tell us something that suggests that you, or someone you know, is at risk of serious harm, we are obliged to inform your GP. This is so that you can be referred for more support.

1. **What are the possible benefits of taking part?**

Although this research is unlikely to be of direct benefit to you, it will give you the opportunity to talk about your experiences and express your opinion on a variety of subjects to an interested, non-judgemental listener who is not involved in your medical care. The results of this study may help advance our knowledge of the links between the mind and the body and may help to develop new methods of improving patient care. All participants will receive a £10 retail voucher as a token of our thanks.

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

We want to emphasise that all results obtained will be strictly confidential and will only be used for research purposes. All personal information will be kept separately to your name and address so that you cannot be recognised from it. All paper questionnaires will be kept in locked filing cabinets, in locked offices, accessible only to members of the research team. Audio recordings will be accessible only by the research team and an external typist who will write down what you have said; this external typist will not know who you are and will keep everything confidential. In compliance with UCL regulations all non-identifiable research data will be stored for up to 20 years before being destroyed. Every step will be taken to ensure your anonymity in publications arising from this research.

1. **Limits to confidentiality**

Confidentiality will be respected unless there are compelling and legitimate reasons for this to be breached such as concerns for your personal wellbeing. If there is indication of risk of harm to yourself or others your confidentiality will be broken.

1. **What will happen if I don’t want to carry on with the study?**

If you agree to be interviewed, you can withdraw at any time during the interview or any time after the interview, without giving a reason. If you become sick or unwell and decide not to continue, you are free to withdraw at any time, without giving a reason. However, with your consent we would ask to be able to use all data collected up to the point of your withdrawal, which would be kept subject to confidentiality procedures.

1. **What if there is a problem?**

We do not expect you to suffer any adverse effects from this study and every care will be taken to ensure your wellbeing and safety is not compromised during the course of the study. If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff you may have experienced due to your participation in the research, National Health Service or UCL complaints mechanisms are available to you. Your local Patient Advice and Liaison Service is available to you. They offer confidential advice, support and information on health-related matters. Please ask a member of the research team if you would like more information on this. In the unlikely event that you are harmed by taking part in this study, compensation may be available. If you suspect that the harm is the result of the Sponsor’s (UCL) or your GP’s negligence then you may be able to claim compensation. After discussing with a member of the research team, please make the claim in writing to Dr Lydia Poole who is the Chief Investigator for the research and is based at UCL. The Chief Investigator will then pass the claim to the Sponsor’s Insurers, via the Sponsor’s office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

1. **What will happen to the data?**

The results will be analysed and findings subsequently published in scientific journals. We may use anonymous quotes from your interview in publications, but you will not be identifiable in any publication. The transcripts from the interviews will be fully anonymised and uploaded online to the UK Data Service once this study is complete. We wish to reassure you that your data will be completely anonymous and it will not be possible to identify you in anyway. This means any references to any names of people and places will be removed to ensure you cannot be personally identified. This study will be conducted in accordance with the General Data Protection Regulation 2018.

1. **Data Privacy Notice**

UCL is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. UCL will keep identifiable information about you for 2 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information

[www.ucl.ac.uk/legal-services/privacy/participants-health-and-care-research-privacy-notice](http://www.ucl.ac.uk/legal-services/privacy/participants-health-and-care-research-privacy-notice)

UCL will use your name, and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from UCL and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Your GP will pass these details to UCL along with the information collected from you. The only people in UCL who will have access to information that identifies you will be people who need to contact you to perform the interview or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, or contact details. UCL will keep identifiable information about you from this study for 2 years after the study has finished.

The data controller for this project will be University College London (UCL). The UCL Data Protection Office provides oversight of UCL activities involving the processing of personal data, and can be contacted at [data-protection@ucl.ac.uk](mailto:data-protection@ucl.ac.uk). UCL’s Data Protection Officer can also be contacted at [data-protection@ucl.ac.uk](mailto:data-protection@ucl.ac.uk).

Your personal data will be used for the purposes outlined in this notice. The categories of personal data used will be as follows: name, address, month and year of birth, ethnicity, religious affiliation, educational attainment, marital status, medical diagnoses history, medication history, date and reason for hospital admissions.

The legal basis that would be used to process your personal data will be performance of a task in the public interest. The legal basis used to process special category personal data will be for scientific and historical research.

Your identifiable data (name, address, phone number, email) will be processed so long as it is required for the research project and stored for up to 2 years following your participation prior to being deleted; this is so we can contact you with the findings of the study once the study has been completed. If we are able to anonymise or pseudonymise the personal data you provide we will undertake this, and will endeavour to minimise the processing of personal data wherever possible.

If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at [data-protection@ucl.ac.uk](mailto:data-protection@ucl.ac.uk).

If you remain unsatisfied, you may wish to contact the ICO. Contact details, and further details of data subject rights, are available on the ICO website at: <https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/individuals-rights/>

1. **Who has reviewed the study?**

London Fulham National Research Ethics Committee.

**Thank you for reading this information sheet.**

**If you would like to take part please complete and return the enclosed form so we can contact you to arrange the next steps.**

**Contact for further information**

If you have any questions or concerns, please contact the research team (Ms Hannah Rowlands) at the Department of Behavioural Science and Health, University College London, 1-19 Torrington Place, London, WC1E 6BT. Telephone: 020 7679 1805. Email: h.rowlands@ucl.ac.uk