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Multimodal longitudinal and machine learning-based predictive modelling to understand the development of eating disorders (ESTRA-BED) study

Participant Information Sheet

We would like to invite you to take part in the ESTRA-BED research study. The overall aim of this study is to understand the biological and social causes of eating disorders. This will allow us to work towards developing better treatments for people with eating disorders, and making recommendations relating to lifestyle, diet and behaviour.

In this study you will be asked to complete some computer-based tasks, questionnaires, answer some questions from a member of our study team, have an MRI scan and give some blood. All these parts of the study are explained in more detail on the second page of this information sheet.

What is the purpose of this research?

Eating disorders (EDs) are serious mental illnesses that affect up to 15% of young women and 3% of young men in high income countries. The causes of EDs are complicated and involve many biological, psychological, and social factors. We are interested in understanding the connections between a range of factors/behaviours such as negative emotions, difficulties with attention, substance use, and disordered eating. In this project we will investigate the causes of eating disorders. We hope that the results of this study will be useful in developing better treatments for people who have eating disorders.

Can I take part in the study?

This study involves participants who are between the ages of 18-30, sufficient in English. We will need to ask you a few questions over the telephone to ensure that you are eligible for the study.

Do I have to take part?

No. It is up to you to decide whether or not you would like to take part. You are given as long as you need to decide if you want to take part and are free to ask any questions about the study. If you agree to take part, you are free to withdraw at any time, without giving a reason.

What does taking part involve?

The study is made up of 3 parts. In the first part you will fill in some online questionnaires about yourself and your lifestyle, and this will last about 1.5 hours. In the second part one of our research team members will schedule a video call with you (via MS teams), where you will be asked to answer some questions relating to your thoughts, feelings and behaviours. This call will take around 1 hour. The third part requires a visit to our research centre in Denmark Hill. The visit will last around 4 hours in total and will involve additional questionnaires and tasks,

collection of blood and urine samples, and an MRI scan. Prior to each testing session we will ask you to consent that you do not drink alcohol or use drugs including caffeine (unless prescribed) within 24 hours of the session because this will invalidate your performance on the psychological tests and compromise the quality of the MRI data. These procedures are explained below. All medical information will be used in an anonymous form for scientific analysis.

Research Visit

1. Psychological assessment

You will be asked to complete a number of questionnaires with one of our researchers. These questions are about your emotions, behaviours, lifestyle and personality. In addition, we will ask you to perform some tasks that are bit like puzzles or games. These tasks help us to understand how you would respond to different kinds of information/situations.

2. Biological Samples

You will be asked to provide a blood sample of no more than 30 ml (approximately 2 tablespoons) during the study. In all cases, we would like to take a blood sample as this is important for the analyses we would like to carry out. You will also be asked to provide a urine sample so that we can test for any drugs that may affect the results of our research or and pregnancy (for your safety in the scanner). The information from these tests will be kept completely confidential.

3. MRI Scan

An MRI (Magnetic Resonance Imaging) scanner is shown in the picture. During the scan you will have to lie as still as possible in the machine and you will be asked to complete a number of tasks that require pressing buttons when a signal is presented on a screen in front of you. You will be given clear instructions before the start of each task. You will hear loud banging noises during the scan and we will provide earplugs and headphones to avoid any discomfort. You will be helped into the scanner by MRI technicians. The MRI scan takes place at the Centre for Neuroimaging Sciences, Denmark Hill (SE5 8AF), and will last about 1.5 hours.

Compensation

Upon your completion of the study tasks, we will give you **£100** as a form of compensation for your time and travel costs. Please be advised that this subject payment is taxable and it is your responsibility to declare this as a form of income.

Do I have to take part in all parts of the study?

All parts of the study are very important and help link together the different types of data collected to better understand mental health (MRI scan data, biological samples and psychological assessment). For this reason, we ask you to take part in the whole study.

What are the possible benefits of taking part?

It is unlikely there will be a direct benefit in taking part but many people find taking part in research a rewarding experience. Your participation may contribute to the development of medical knowledge that may benefit other people in the future. Upon your completion of the study tasks, we will email you a picture of your brain.

What are the possible disadvantages and risks of taking part?

Psychological assessment:

The psychological assessment involves answering questions that are personal, which some people may find distressing. All parts of the questionnaires are very important and the information you provide will be very useful to the outcome of the study. However, if you are uncomfortable answering any questions, you are not obliged to do so.

MRI scans:
MRI scans use magnetic fields to produce pictures of your brain. This does not involve ionising radiation, and is painless and safe. As MRIs involve magnetic fields, they can interfere with magnetic body implants. Therefore, people with such implants will not be allowed to participate in this part of the study. This interference can also occur with large tattoos (which contain iron particles) or dental bridges. A radiographer will carefully investigate if you will be allowed to enter the MRI scanner and ensure that no harm will be done. Furthermore they will remind you not to carry any electronic devices which can be damaged by the magnetic fields. To date, the effect of MRI scanners on an unborn child is unknown. In order to eliminate any potential risks, if you state that you are or might be pregnant you will be excluded from the study. In order to take part in this study, we will ensure that you are eligible to be MRI scanned including checking for claustrophobia (see below).

Claustrophobia:
Some people undergoing an MRI scan may feel confined, closed-in, or frightened. If you do suffer from claustrophobia we do recommend that you do not take part in this study. However, we do make sure that you have continuous contact with the person conducting the scan, so that you can be removed from the MRI scanner in less than 2 minutes if you feel you cannot continue with the scan.

Blood taking:
Some people feel mild discomfort when giving a blood sample. Sometimes there is mild bruising afterwards, but the risks are the same as for any routine blood sample.

What happens if you find something unexpected?
This study is for research and not a medical screening/ test. However, your brain images will also be read by a competent radiographer. The radiographer will not perform a full diagnostic scan and we cannot guarantee that an existing abnormality will be identified in the images. However, in the unlikely event that we detect a serious brain abnormality, we will report this to your GP who will contact you. Findings from blood and urine testing will not be disclosed to you nor shared with your GP.

Will my data be handled confidentially?
There are limits to our confidentiality. If we have significant concerns about your or someone else's safety, we may deem it necessary to share information with your GP or the relevant authorities or seek advice from the study psychiatrist.

All personal data, e.g. name and address, will be kept strictly separate from the questionnaires, brain imaging data and the blood/urine tests. All information will be used in an anonymous form for scientific analysis. Personal data will not be disclosed to the scientists carrying out the statistical analyses. Your consent form will contain some personal data, and will be stored securely in the office of the study team. Your data will be stored on the Psytools platform (www.delosis.com) and a secure database with a company called 'Neurospin'. Delosis Psytools is the survey provider. It will not be possible to link any of your responses to questionnaires to your personal details due to a strict pseudonymisation procedure being in place for the data.

In order to achieve the goal of the study, we must collaborate internationally with scientists and also make anonymised data available to other scientific research groups. Sharing data improves scientific research by encouraging new ideas and the development of new research methods, and increasing the likelihood of scientific discoveries.

The anonymity of your data will be protected. Data will be stored and analysed for as long a time as they prove beneficial for the identification of biological/environmental factors associated with mental health. Storage and work on data will always be in accordance with the current ethical guidelines, and the conditions of the informed consent obtained from you. Please refer to final page of this information sheet for more information concerning compliance with Genderal Data Protection Regulation (GDPR).

In the event of a loss of capacity, we will retain tissue and personal data collected and continue to use it confidentially to meet the aims of the study (which could include further research after the current project has ended). Personal data will be kept for 25 years to invite you to potential follow-up studies in the future. Pseudonymised research data will be stored for 25 years.

What will happen to the biological samples (blood, urine) I give?

Analysis of the biological samples is not being carried out for this study. Samples will be stored anonymously in a biobank for potential future analyses. You can still take part in the study without agreeing to your samples being stored in a biobank for future use in research.

In future research, we will potenially use the blood samples to identify biological markers that might be associated with mental health. Your results and that of other study participants will be analysed together with the results from the psychological tests and the imaging scans. We expect that this research may help us determine whether certain genes and other biological markers, either alone or in combination with factors from your life experiences and surroundings, are associated with certain behavioral and imaging results. Furthermore, we hope that the results of this study will prove useful in improving current treatments for mental health patients, to increase treatment effectiveness and reduce treatment side-effects.

In future research, we will potentially use the urine sample to test for drugs. As previously mentioned this information will be kept confidential and not shared with your GP.

The biological samples will be stored at the UK Biobank or other dedicated storage facilities. The anonymised samples and data will be shared with our colleagues for storage and analysis. These facilities have strict confidentiality procedures and restricted access. The samples will be stored without any identifiable information on them (e.g. your name). We ask your permission for these samples to be kept for future projects, and that the data (without any personal details) can be shared with those working in biomedical and healthcare research, that may include commericial companies, to investigate the genetic basis of disease and traits. We also ask for permission to contact you again if we need to.

How will my data be used?

Your data will be collected by the research team members including research staff and students. Your data will be used in an anonymous form for scientific analysis. The anonymised data from this study will be combined together with those from the STRATIFY study (IRAS project ID: 218030) and STRATIFY-ESTRA study (IRAS project ID: 272117) that involved participants with other subtypes of eating disorders and healthy controls, and the IMAGEN study

(REC reference: PNM/10/11-126) that involved participants who were assessed several times from adolescence to young adulthood. These data will be analysed together to identify neural-behavioural markers that are shared and distinct across different subtypes of eating disorders, and risk predictors of disease development from adolescence to young adulthood. Findings from these analyses will help us better understand the mechanisms underlying eating disorders, and may inform better treatment and prevention strategies.

What will happen to the results of the research?
The results of this study will be published in scientific journals and presented at conferences. You will not be identified personally in any report or publication.

Who has reviewed this study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the North West – Greater Manchester (GM) South Ethics Committee (study reference: 23/NW/0232).

Arranging appointments
If you are interested to take part please contact the research team via email at estra@kcl.ac.uk. We will try to arrange the appointments at times that are convenient for you. If for any reason you need to cancel an appointment, we ask that you contact a member of the research team as soon as possible so that this can be rescheduled.

How will we use information about you?

We will need to use information from you for this research project. This information will include your name, date of birth, and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. We will keep all information about you safe and secure. Some of your information will be sent to data servers at Neurospin, France. They must follow our rules about keeping your information safe. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?
You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research (KCL) or https://www.slam.nhs.uk/about-us/privacy-and-gdpr (SLaM)
- by asking one of the research team

- by sending an email to info-compliance@kcl.ac.uk (KCL) or dataprotectionoffice@slam.nhs.uk (SLaM)

Further Questions and/or Complaints?

If you have further questions or complaints, please do not hesitate to contact the research team via email at estra@kcl.ac.uk We are happy to answer all the questions you may have concerning this study.

What happens if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [Zuo Zhang, zuo.zhang@kcl.ac.uk]. If you remain unhappy and wish to complain formally, you can do this through the SLaM Patient Advice and Liaison Service (PALS) on 0800 731 2864, pals@slam.nhs.uk. In the event that something does go wrong, and you are harmed during the research, you may have grounds for legal action for compensation against King's College London and/or SLaM NHS Foundation Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

How your personal data will be used in compliance with General Data Protection Regulation (GDPR)

King's College London (KCL) is the lead sponsor for this study. 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. KCL will keep identifiable information about you for 25 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. There will also be students involved in the data collection.

You can find out more about how we use your information by contacting the Chief Investigator (Dr Zuo Zhang, zuo.zhang@kcl.ac.uk) or visiting the KCL website: https://www.kcl.ac.uk/research/support/rgei/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research.

King's College London 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 King's College London and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The only people in King's College London who will have access to information that identifies you will be people who need to contact you to organise assessments 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.

KCL will keep identifiable information about you from this study for 25 years after the study has finished.