IRAS 238055

"Anxiety fear and disgust conditioning in people with eating disorders"

PARTICIPANT INFORMATION SHEET

We would like to invite you to participate in an original research project. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

Background and purpose of the study

In this study, we are interested in how people learn to be anxious and disgusted by new things, and how they learn that some things that make them feel anxious and disgusting might not always be unpleasant.

People differ in how easily they become fearful, worried or disgusted about experiences and things that they encounter during their lives. Some people learn very quickly and easily that certain things make them feel anxious and disgusted whereas others appear to be less likely to experience these feelings of anxiety and disgust. For some, these feelings of anxiety and disgust reduce and disappear very quickly but for others the feelings of anxiety and disgust can be longer lasting. We hope to find out whether the different ways people think, act and feel mean they react differently when facing a potentially challenging situation.

Why have I been invited?

You and other participants aged 14 years old and above have been invited to take part as you have a past/present diagnosis of anorexia nervosa, or a present diagnosis of obesity, or a present diagnosis of a different eating disorders such as Binge Eating Disorder, Eating Disorder Not Otherwise Specified, Avoidant Restrictive Food Intake Disorder or Bulimia Nervosa.

Do I have to take part?

No. You do not have to participate. It is your decision as to whether or not you would like to participate. We will describe the study and go through this information sheet with you and also give you a copy to take away. You will then have at least 1 week to decide whether or not you would like to participate. If you agree to take part, we will then ask you to sign a consent form to show that you have agreed to take part. Remember that you are still free to withdraw at any time, without giving a reason, after you have signed the consent form.

Important: Should you decide not to take part in this study or withdraw from the study, this will not affect your present or future treatment in any way.

How long will the study last?

The study will take place over two days. On day 1, you will use your mobile phone to fill in questionnaire and complete an app-based task. This will take about an hour and 15 minutes (45 minutes for the questionnaires and 30 minutes for the app-based task). Then on day 2, you will use your mobile phone to do a similar app-based task and two computer-based tasks that will take around 45 minutes in total. Your total participation will be about 2 hours. The two parts of the study will happen within a week.

Will I benefit from taking part and when will I be reimbursed for my time?

You will be reimbursed £20 in voucher form once you have completed phase 2 of the study (on day 2).

What will happen to me if I take part?

If you decide to take part in the study, we would ask you to provide your email address and telephone number to set up your personal account on the mobile phone app. Your information on the platform is confidential to you and the research team only.

On the first day, you will be asked to fill in 10 questionnaires: these will measure how you feel and react in different situations. Some questions will ask about fears or worries or things that make you sad. You will be asked to say how often you feel these. You will also be asked some questions to find out more about the way you think and act in certain situations. There are no right or wrong answers to these questions and they are not a test.

You will be asked to take part in a fear/disgust learning app-based task: you will repeatedly look at shapes that might or might not be presented at the same time as a loud noise or disgust-eliciting sound. You will be asked to wear headphones for the duration of this task. This will give us information about how much you are expecting one of these noises to happen when you are looking at specific shapes.

On the second day, you will be asked to complete the short, second part of the fear/disgust learning app-task.

Then you will be asked to take part in a computer-based tasks: in which you are asked to write notes for 2 minutes on a past memory or on anticipated future events triggered by words that relate to fear or disgust.

What are the possible disadvantages and risks of participating in this study?

Time and effort: your participation will help in developing a better understanding of eating disorders. Currently, there is very little evidence about the fear/disgust learning in and eating disorders and so your participation is invaluable.

Sensitive content of clinical and questionnaires measures: Pilot studies have shown that there are no risks associated with the administration of the questionnaires. Nevertheless, since the questionnaires ask about various psychological factors, responding to such items may result in some distress. There are questions about your eating habits and your weight, questions about events in your past, including sensitive issues such as the possibility of personal and family history of psychiatric illness. You will be able to take breaks, as and when needed, in between answering questions.

Should you become distressed or upset by the sensitive content of the questionnaire measures, you will be able to speak to clinicians of the study team (Prof Janet Treasure: Consultant Psychiatrist), by contacting them via email or telephone (janet.treasure@kcl.ac.uk; You could also contact the local Patient Advice and Liaison Service (PALS) for support and advice (PALS Maudsley Hospital, Tel. 0800 731 2864). Should you wish to interrupt your participation in the study at any time, you would be able to do so without providing any reasons.

What happens after the study?

We will contact you by phone or email to ensure that you did not experience any significant distress during the study. If appropriate, we will provide information to relevant support services. The clinical care that is provided to you will be continued as it would if you were not taking part in this study.

What if there is a problem?

Any concern or complaint about the way you have been dealt with during the study, or any possible harm you might have suffered can be addressed to one of the researchers. If you remain unhappy and wish to complain formally, you can do this through the King's College London Complaints Procedure. Details can be obtained from the university website. In the unlikely case of you losing capacity to take part, you would be withdrawn from the study. We will retain the data collected up to that point for data analysis.
Complaints should be addressed to Dr Gill Dale (Director of Research Quality, Head of Joint Research and Development Office of South London and Maudsley NHS Foundation Trust and Institute of Psychiatry, Psychology & Neuroscience, P005, Institute of Psychiatry, Psychology & Neuroscience, King's College London, De Crespigny Park, London SE5 8AF).

Will my participation be kept confidential?

Everything you tell us will remain completely confidential within the limits of the law. If you consent to take part in this study, you will be given an ID number and any responses you give during the project will be linked only to this. In this way, all information is anonymised, the only exception being the consent form, which will contain both the ID and identification information. Any information we collect about you on paper forms (e.g. consent forms) will be stored in a locked cabinet in a locked room at the research centre. Any electronic data will be stored on an encrypted network using this ID. We will keep this data for 7 years after the study has ended and will then dispose of them. If you agree to be contacted for future studies, we will retain your contact details for up to 3 years.

Your responses remain completely confidential unless you tell us something to suggest that your health and safety is currently in danger (e.g. abuse or extreme distress). In this situation, only information necessary to an emergency would be communicated to the appropriate bodies.

Under which circumstances will confidentiality be breached by the research team?

If any disclosures are made about harming yourself or others, or if any new high risk issues related to your psychological and/or physical health come to light during the study, we would discuss this with you and inform your clinical team care. If any disclosures are made about any criminal activity, confidentiality will be breached, and the relevant authorities will have to be contacted.

Will my General Practitioner (GP) be involved?

Your GP will be contacted if you disclose a risk to harm yourself or others during your participation in the study. Your GP will also be contacted you should score above cut-off on measures assessing mood or anxiety disorders and eating behaviours.

What if new information becomes available?
If new information about the treatment that is being studied becomes available, you will be informed about this.

What if I do not want to carry on with the study?
You can withdraw from the study anytime. If you decide to withdraw from the study, we will retain the data collected up to that point for data analysis.

It is also of importance for you to know that, if you decide to withdraw from the study, this will not affect your treatment in any way.

What will happen to the results of the research study?
You will be offered the opportunity to be informed about the results once the data for all participants have been collected. No results are available until all the data from all participants is entered and the final report is available. The results of the study will be sent to a medical journal for publication. Your participation in the study will, of course, not be disclosed.

The data will be stored securely at King's College London for 7 years and then will be destroyed.

Who is organising and funding this research?
This study began as a PhD student research project where the researchers in the study were not paid for including you in this study. The study is continuing, sponsored by King's College London and South London & Maudsley NHS Trust,

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 NHS Research Ethics Committee (ethics number: 18/LO/0121).

General information about this research project can be obtained from Professor Janet Treasure (janet.treasure@kcl.ac.uk) or Dr. Valentina Cardi (valentina.cardi@kcl.ac.uk)

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 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. KCL will keep identifiable information about you for 7 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 by contacting the Chief Investigator (Valentina Cardi – valentina.cardi@kcl.ac.uk) or visiting the KCL website: https://www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research.aspx.

South London and Maudsley NHS Foundation Trust will collect information from you for this research study in accordance with our instructions.

The South London and Maudsley NHS Foundation Trust 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 South London and Maudsley NHS Foundation Trust will pass these details to King's College London along with the information collected from you. 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 for the purposes of the study 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 7 years after the study has finished.