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**Participant Information Sheet**

**iMAGine: Motivational Abnormalities Guiding self-harm and binge-purge behaviour (Part One)**

*Understanding the cognitive processes driving repetitive self-harm and binge eating/purging behaviour*

REC Number: 19/SC/0275

Chief Investigator: Dr Martina Di Simplicio

You are being invited to take part in a research study, but before you decide whether to take part you need to understand why the research is being done 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 anything is unclear or if you would like more information.

Self-harm and binge/purge behaviour affect a lot of young people yet we don’t know much about the behaviour. Some people self-harm and/or binge-purge only one or twice while others continue over time, which can be linked to worse health and wellbeing. In this project we are investigating what makes some people more susceptible to continuing to self-harm and binge/purge.

1. **Who can take part?**

We are looking for fluent English speakers aged between 16 and 25 who have:

* Experience of self-harm within the past year or binge eating/purging within the past month

You are **NOT** eligible to take part if:

* You are currently experiencing severe symptoms of psychosis (such as hallucinations) that prevent you from completing the study
* You have a severe learning disability
* You have a severe neurological impairment
1. **What is the purpose of the study?**

We want to find out whether certain unconscious psychological processes make some people more vulnerable to repeating self-harm and/or binge-purging. For example, we will investigate whether objects and mental images (related to self-harm and/or binge-purging) trigger people to self-harm and/or binge-purge, and whether differences in learning (e.g. how people make associations between things) contribute to how frequently and how long people self-harm and/or binge-purge for. We hope that findings from this study can be used to develop psychological interventions that help people reduce or stop self-harming and/or binge-purging, by tapping into some of these unconscious psychological processes.

1. **Will I receive any remuneration?**

If you decide to take part, you will be given a £50 voucher usable in most online retailers to cover your time and travel expenses. You will also be given up to £10 depending on how you perform in one of the tasks.

1. **What will I be asked to do?**

The first step involves filling out some questions online so we can assess your suitability for the study. This online form should take about 15 minutes to complete and you can find a link to it on the study website (**www.imaginestudy.org**). If you are eligible, we will then phone you to give you more details and book a time for the testing session.

The testing session will take place either at Imperial College London in Hammersmith Hospital or online (following social distancing restrictions following the COVID-19 pandemic) and will last for approximately 3 hours. If the testing is in person, when you come into Imperial College London we will go over all the study details again and ask you sign a consent form. Then you will answer some more questionnaires and complete four tasks on the computer. After testing we will complete a debrief with you to make sure you are feeling OK before you go home.

If the testing is online this will be carried out via a video call on Microsoft Teams. During the call we will go over all the study details again and ask you sign a consent form online. After this you will answer the questionnaires and complete the four computer tasks. After testing, we will have a debrief with you to make sure you are feeling OK before we end the call. We will stay on the video call throughout the whole testing session.

In the questionnaires you will be asked questions about:

* Contact details and demographics such as date of birth
* Your mental health and substance use
* Personality traits
* Your experience of self-harm and/or binge-purging
* Experiences in your childhood

The four computer-based tasks will include:

* Two tasks showing pictures that may remind you of self-harm and/or binge-purging
* A learning task where you learn from rewards (e.g. clapping/winning points) and punishments (e.g. booing/losing points)
* An imagery task where you imagine things that make you feel good
1. **Will I need to talk about my experience of self-harm and/or binge-purging?**

To participate you need to be willing to speak about your personal experiences of self-harm and/or binge-purging with the researcher. We will ask you questions such as how often you do it, when the last time was, methods you use to self-harm and/or binge-purge and feelings around self-harm and/or binge-purging.

1. **Will the answers I give be confidential?**

All the answers you give and your performance in the tasks will be **strictly confidential** and will not be shared with anyone, unless it is judged that you or someone else is at current risk of serious harm, or you need urgent care in which case the relevant parties will be informed. We will discuss this with you first although your permission may not be required.

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

No, your involvement in this study is completely voluntary and you do not have to take part. If you decide to take part, you are still free to withdraw at any time without giving us a reason. You are also free to withdraw your data at any time for up to 10 years after taking part, unless this has been already published.

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

Participating will give you the chance to help people by contributing to research that is important for understanding what motivates young people to self-harm and/or binge-purge, so that better interventions can be developed to help people stop.

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

We will ask you some questions about your experience of self-harm and/or binge-purging, and some tasks will also involve showing you images that might remind you of self-harm and/or binge-purging. There is the possibility you may feel uncomfortable answering some of these questions or find some of the questions and images personal or upsetting. You do not have to answer any questions you do not want to, and if you find the tasks upsetting you can stop at any time.

To reduce the risk of you feeling upset, at the end of the testing you will complete a short task with images that have been shown to uplift people’s mood and distract them from negative feelings. You will also have the opportunity to take regular breaks throughout the testing. If you want, you will also be given access to an app called ‘Imaginator’ that supports people to deal with distress and achieve positive goals.

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

It is highly unlikely you will suffer harm by participating in this study, however Imperial College London holds insurance policies which apply to this study.  If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault.  This does not affect your legal rights to seek compensation. If you are harmed due to someone’s negligence, then you may have grounds for a legal action.

Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Chief Investigator (Martina Di Simplicio at m.di-simplicio@imperial.ac.uk).  If you are not satisfied with the response, you may contact the Imperial College Joint Research Compliance Office.  The normal National Health Service complaints mechanisms are also available to you. This includes the patient advice and liaison service at Imperial College Healthcare NHS Trust. They can be contacted on 020 3313 0088 during office hours, or alternatively via email at Imperial.PALS@nhs.net.

If you wish to raise a complaint on how we have handled your personal data, or to find out more about how we use your information, please contact Imperial College London’s Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502, and via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner’s Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.

1. **Are the answers I give anonymous?**

All information you give during this study will be **anonymous**:

* The only people in Imperial College London who will have access to information that identifies you will be people who need to contact you about the study or to 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.
* Imperial College London will use your name, date of birth and contact details to contact you about the research study and to oversee the quality of the study.
* Individuals from Imperial College London and regulatory organisations may look at your research records to check the accuracy of the research study.
1. **How will my data be used?**

When the study is complete, the data will be analysed and written up for publication in scientific journals and presented at scientific meetings or in talks at academic institutions. Results will always be presented in such a way that data from individual participants cannot be identified.

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/) (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/)**.**

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

1. **How is my data stored?**

Imperial College London is the sponsor for this study based in the United Kingdom. We will be using information from you 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. Your data will be stored in the following ways:

* Data from the online screening form will be collected using Qualtrics, a research data collection

platform (<https://www.qualtrics.com/uk/>). This data will be stored on a server owned by Qualtrics, whose data storage is compliant with OECD privacy rules and the European Union Directive on Data Protection. Once we have used this information to assess eligibility for the study it will be deleted from Qualtrics.

* Telephone screening calls will be recorded on a telephone screening form. If the eligibility criteria to participate in the testing session are not met, telephone screening forms will be disposed of in accordance with Imperial College London’s procedures for correct disposal of confidential documents. Telephone screening forms for participants who complete the testing session will be stored in a locked cabinet in Imperial College London.
* Non-identifiable data on your computer-task performance will stored on a secure server at Imperial College London.
* Non-identifiable questionnaire data will be stored in a locked filing cabinet at Imperial College London.
* Data will also be shared on the Open Science Framework (<https://osf.io/>), an online tool that supports the reproducibility of psychological research. This information will not identify you and will not be combined with other information in a way that could identify you.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally-identifiable information possible.

1. **How long is my data kept for?**

We will keep information obtained for the study for a maximum of:

* + 10 years after the study has finished in relation to data subject consent forms.
	+ 10 years after the study has completed in relation to non-identifiable research data.

If you withdraw from the study, we will keep the information about you that we have already obtained for the timings specified above unless you ask us to destroy your answers.

To find out more about how we use your information please contact the researcher, Rachel Rodrigues (r.rodrigues18@imperial.ac.uk).

1. **Legal Basis**

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research.  This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

1. **International Transfers**

There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country, which is not subject to a European Commission (**EC**) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your personal data is processed.

**To take part:**

Please complete the online screening form, a link can be found on [**www.imaginestudy.org**](http://www.imaginestudy.org).

**Or for more information please contact:**

**Rachel Rodrigues 07717829665**, imagine@imperial.ac.uk

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