

INFORMATION SHEET FOR PARTICIPANTS

Ethical Clearance Reference Number: HR-24/25-50916



YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of project

Can a personalised nutrition program (ZOE) improve symptoms of Obsessive Compulsive Disorder or Body Dysmorphic Disorder?

Invitation Paragraph

I would like to invite you to participate in this research project which forms part of my Bachelor of Science in Neuroscience & Psychology (BSc) research. 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 me if there is anything that is not clear or if you would like more information.

What is the purpose of the project?

The purpose of the project is to evaluate whether a personalised nutritional program, "ZOE" improves symptoms of obsessive compulsive disorder (OCD) or body dysmorphic disorder (BDD) and depression. ZOE is a personalised nutrition programme developed by scientists that aims to improve people's overall health by **increasing the diversity of microbes in the gut** - meaning you have a high number of different species that are evenly spread across your gut community of microorganisms (such as fungi, bacteria and viruses) - **and stabilising blood sugar and fat levels**. There is some evidence that improved gut bacteria diversity is linked to better mental health.

Why have I been invited to take part?

You have been invited to take part because you are an adult over the age of 18 years old who has a diagnosis of either obsessive-compulsive disorder or body dysmorphic disorder. To take part you must have never had an eating disorder, nor be on a special diet currently (e.g. for diabetes or coeliac disease).

What will happen if I take part?

If you choose to take part in the project you will be asked to sign up to ZOE program. This will be paid for by the research team. You will receive a test kit and 3 months subscription to the programme. The test kit is to determine the microbes in your gut, and you will be sent detailed instructions in the kit on how to collect a sample of your faeces. The faeces sample collection is sent to a laboratory and can be taken alone by ZOE users at home with clear step-by-step instructions from ZOE. Postage will be paid for by ZOE.

Using this information, ZOE gives you personalised nutrition advice and foods are ranked to advise on whether they should be enjoyed occasionally, in moderation, regularly, or freely. This advice is unique to your own biology and is designed to improve the diversity of "good bacteria" in the gut. Having a diverse range of these "good" bacteria has been linked to good

health, possibly including mental health. Nutritional support is also provided through the app.

You can read more about **ZOE on their website**: <https://ZOE.com> and on their FAQ page: <https://zoe.com/faqs/gb>

It is expected that the full duration of the study will take around 27 weeks. The **key stages** in this study are outlined below.

- **Stage 1:** We will give you various questionnaires to fill in rating your mental health symptoms whilst eating your usual diet. After two weeks, you will start the 'ZOE' programme. You will take their nutritional questionnaire which looks at how your diet is currently. We would ask you to fill out questionnaires that ask you how much you think ZOE could help your symptoms, and whether it is something you feel you could use.
- **Stage 2:** You will collect a stool sample and send this to the ZOE laboratory in the supplied prepaid envelope. You will start to log your food in the ZOE app and start the support programme that they provide. The gut bacteria data from the stool sample is processed by ZOE and not directly seen by the research team, unless you choose to share it with us. You will complete weekly questionnaires looking at your mental health symptoms, sent by us.
- **Stage 3:** ZOE will send you personalised scores. Based on your scores the ZOE app will recommend you foods and recipes that improve your gut bacteria and stabilise your blood sugar and fat responses. Each day, you are provided with information about healthy eating from the app. You will continue to log what you eat on the app and this will give you a daily score. You will follow the ZOE programme for 12 weeks. We will send you regular questionnaires to fill out. At the end of this period, we will ask you to complete questionnaires on your experience of using ZOE. We will ask you to repeat your stool sample.
- **Stage 4:** You will then continue to eat your personalised diet for a period of four weeks without receiving nutritional support from ZOE. We will continue to measure your mental health symptoms weekly using questionnaires during this period. You will be asked to take part in an interview at the end to discuss your experience of using ZOE. These may be audio recorded so we don't miss what you say. Examples of questions you might be asked include 'how did you find using ZOE?' or 'did you notice any differences in how you felt after 4 weeks?' Recording of the interview will only be done if you give your consent for us to do so.

Other important things you need to know

- You will need a smart phone to support the ZOE mobile phone app (an iPhone 8 or newer with iOS 15.5 or later, or Android 8.0 or later).
- **You will not have to pay for the subscription** to use ZOE, and we will provide £100 at the start of the study to support any purchasing of fresh food.

- To be eligible to participate in this study, **you should not already be on a specialised diet**, for example, for conditions such as diabetes.
- If you start another treatment (e.g. antidepressants or cognitive behaviour therapy) or change your mental health medication dosage at any point throughout the study, **then you will need to notify the researcher as you will need to be withdrawn from the ZOE programme. This will not affect any of your future treatment.**
- You will not be withdrawn from the study if you receive emergency treatment during the study.
- You will not be able to take part if you have a co-existing mental health problem such as psychosis or if you have ever had an eating disorder.

Participation for this study will take place entirely remotely via telephone, Microsoft Teams or email.

As part of participation, you will be asked to provide information about your mental health symptoms and stool sample. This is necessary to understand the impact that your biological markers have on your symptoms. Audio recording of the post-intervention interview will only be done with your consent.

Do I have to take part?

Participation is completely voluntary. You should only take part if you want to and choosing not to take part will not disadvantage you in any way. Once you have read the information sheet, please contact us if you have any questions that will help you decide about taking part. If you decide to take part, we will ask you to sign a consent form and will give you a copy of this to keep.

Incentives

We will pay for the ZOE test kit and subscription and provide £100 at the start of the study to support any purchasing of fresh food.

What are the possible risks of taking part?

Tracking what you eat daily using ZOE food tracking everyday might pose a time burden. However, the ZOE app makes this as quick as possible, including the ability to take a photo of a recipe or the food on your plate and find the ingredients for you. Some people can become preoccupied by this. If you do experience this, you can speak to one of the researchers.

Some people find taking the stool samples distressing, particularly if you have anxiety around contamination. The test-kit provides clear instructions of how to take these.

In the event that any health issues are identified through taking part in this study, a member of the research team is able to inform your GP.

What are the possible benefits of taking part?

The results of the study may increase understanding of the role of diet and its impact on anxiety disorders. However, this is the first time ZOE has been tested on people with these

mental health conditions. Whilst evidence suggests it may be possible, we cannot guarantee that ZOE will improve your symptoms of OCD or BDD.

Data handling and confidentiality

Kings College London is the Sponsor of this research and is responsible for looking after your information.

We will need to use information from you for this research project. The research team and authorised administrative staff will use this information to do the research or to check your records to make sure that the research is being done properly.

Your data will be processed in compliance with UK data protection laws, including the UK GDPR and the Data Protection Act 2018.

Categories of Personal Data	We will collect your name, date of birth, ethnicity, contact details and health data. Data from your stool samples and the food tracking questionnaires in the ZOE app will be handled according to ZOE's company policies. We as researchers at King's College London will not be given information by Zoe on your gut bacteria sample or food tracking. You can read more about how ZOE handles its users' data here: https://ZOE.com/privacy-policy#what-personal-data-we-collect If you consent to share your microbiota data and food tracking diaries with us, then we can analyse this data. This must be provided by you and does not come directly from ZOE.
Data Storage	The data collected from the questionnaires, dietary information and gut bacteria, and interviews will be securely stored on laptops and the King's College London network and/or on King's premises with appropriate access controls which will all be password protected. Interview audio recordings will be transcribed (written down) and then the recordings will be destroyed. Your data can only be accessed by the research team.
Data Sharing	Your data will not be shared with any other collaborators or companies outside of King's College London.
Data Retention	Research data will be kept for 1 year following study completion, after which it will be destroyed.
Anonymity in Research Outputs	You will be allocated an anonymized code for all research purposes to ensure confidentiality and clinical information will be kept in line with King's College London confidentiality policy.
Future Use	Where consent is granted, the anonymised data will be stored for future research use. The use of the samples taken by ZOE will be handled according to ZOE's company policies which can be accessed in the link provided above.

Further information on how King's processes research data can be found at:

<https://www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research>

Please contact the research team if you require further information on data processing or a printed version of the webpage link above.

What if I change my mind about taking part?

You are free to withdraw at any point of the project, without having to give a reason. Withdrawing from the project will not affect you in any way. You are able to withdraw your data from the project up until 31st December 2026, after which withdrawal of your data will no longer be possible as the data will have been anonymised and analysed for the final report.

If you choose to withdraw from the project, we will retain the minimum amount of data required to manage our records and complete the research project.

How is the project being funded?

This project is being funded by a personal grant to David Veale at King's College London.

What will happen to the results of the project?

We aim to publish the results of this study in an academic journal and present our findings at conferences. They will also be summarised in a thesis for the BSc in Neuroscience & Psychology. **You will not be personally identifiable** from the information presented in these publications and presentations. The anonymised data set will not be made publicly available. Research participants can obtain a hard copy of the published research paper by contacting a member of the research team.

Who should I contact for further information?

If you have Obsessive Compulsive Disorder (OCD) and have any questions or require more information about this project, please contact Michelle Blunt (BSc Neuroscience & Psychology Student) using the following contact details in the first instance:

Email: michelle.blunt@kcl.ac.uk

[Tel: 020 3228 2101](tel:02032282101) (Centre for Anxiety Disorders and Trauma)

If you have Body Dysmorphic Disorder and have any questions or require more information about this project, please contact Maximillian McFarlane (BSc Psychology Student) using the following contact details in the first instance:

Email: Max McFarlane max.mcfarlane@kcl.ac.uk

[Tel: 020 3228 2101](tel:02032282101) (Centre for Anxiety Disorders and Trauma)

What if I have further questions, or if something goes wrong?

If this project has harmed you in any way, or if you wish to make a complaint about the conduct of the project you can contact King's College London using the details below for further advice and information: Professor David Veale (Chief Investigator): david.veale@kcl.ac.uk or by post to: Centre for Anxiety Disorders and Trauma, 99 Denmark Hill, London, SE5 8AZ.

Thank you for reading this information sheet and for considering taking part in this research.