



Melbourne School of Psychological Sciences

Plain Language Statement

PROJECT TITLE: **Bugs and Brains: The Gut and Mental Health Study**

Dr. Julian Simmons (Responsible Researcher)

Tel: (03) 9035 8318; email: jgs@unimelb.edu.au

Ms Djamila Eliby (PhD Student)

Tel: (03) 8344 1845; email: bb-study@unimelb.edu.au

Ms Carra Simpson (PhD Student)

Tel: (03) 8344 1845; email: bb-study@unimelb.edu.au

Introduction

We would like to invite you to participate in a project called ‘Bugs and Brains: The Gut and Mental Health Study’. This research aims to better understand the relationships between gut health and mental health in the community. We are also interested in learning about how these aspects of health interact with experiences earlier in life, as well as current lifestyle, diet, stress, and wellbeing.

Please note that this study was recruiting participants to examine relationships with the gut microbiome (i.e., bacteria), however that component of the study has now been completed. In that component we were comparing the bacterial and physiological profiles of four different groups of women between 18 and 40 years old.

In this questionnaire-only component we now invite all adults 18 years of age or older to participate in this study. This will allow us to examine relationships between gut health, mental health and individual differences across the entire community.

What would I be asked to do?

This research project involves the completion of questionnaires, and can be done entirely online. No face to face contact is required at any time.

Consent Procedure

It is important that you understand what is involved in the study prior to agreeing to take part. Please read this document carefully. If you have any questions or concerns, please contact our research team at bb-study@unimelb.edu.au. If you would like to participate, please contact us via email, or via our website (<http://go.unimelb.edu.au/8se6>). We will then send you links to the online questionnaires. We ask that you express your consent to participate either by returning the signed consent form &/or indicating it at the start of the online questionnaires.

Online Questionnaires

There are two online questionnaires. One via a Qualtrics link, and another via a Dietary Health Questionnaire link. You can complete these questionnaires online at a location of your choosing.

Please start with the Qualtrics questionnaire. This questionnaire will ask about your demographic details, medication use, substance use, medical health, mental health, gut health, stressful life events, coping strategies, quality of life, oral and physical health. It will take approximately 45 minutes to complete.

The Dietary Health Questionnaire will ask a series of detailed questions about your diet. Please note that this is an American designed questionnaire, so some of the food descriptions are different to Australian foods. For example, capsicums are called ‘sweet peppers’ and tomato sauce is called ‘ketchup’. An information sheet is provided to help with these differences. It will take approximately 45 minutes to complete.

What are the risks?

To our knowledge, there are some risks involved in participating in this study. Some of the questionnaires address potentially sensitive or distressing topics relating to mental health. However, you do not have to answer any questions that you do not feel comfortable with. Our research team has lots of experience with the questionnaires used in this study. If you are experiencing emotional or mental health difficulties our research team is trained to help with this and will discuss support options with you and help provide referrals to an appropriate clinical service, with your permission. For example, you could call LifeLine (13 11 14) or make an appointment with your GP. You can also contact the research team (Dr Julian Simmons [03] 9035 8318, jgs@unimelb.edu.au; Ms Djamila Eliby or Ms Carra Simpson on [03] 8344 1845, bb-study@unimelb.edu.au) if you wish to discuss any concerns at any time during the study.

Another potential risk involved in participating in this study is the inconvenience and burden involved in completing the questionnaires. Participation generally takes approximately 90 minutes in total, however can take longer depending on how much time participants spend on each question. The questionnaires can be completed at a time and location that suits you, and you can take breaks as needed (please keep the email with the study links so you can return to the questionnaires). Participants will not receive financial reimbursement for their time, but will receive other benefits, as detailed below in the ‘What are the benefits’ section.

There may be unforeseen or unknown risks. In the very unlikely event that you suffer an injury because of participating in this project, the public health service will provide hospital care and treatment at no cost to you.

What are the benefits?

We don’t expect there to be any direct benefit to you. However, we hope to increase understanding of the association of mental (e.g., anxiety and depression) and physical (e.g., gut) health with early life, and current lifestyle and diet. At the conclusion of this study, we hope to apply the findings to the design of a clinical trial to test whether a dietary and/or probiotic intervention may offer symptom relief. Given how common and disabling these mental and physical conditions are in the community, such knowledge has substantial potential benefit.

All participants who complete the Dietary Health Questionnaire may choose to receive a free dietary analysis based on their dietary questionnaire responses. This can be downloaded immediately upon completing the questionnaire. The analysis provides detailed information about dietary intake over the past 12 months, quantifying things such as fibre, protein, fats, salts, and key nutrients. We encourage you to discuss these results with your GP and/or a dietician if you want further information.

We estimate that participation will take approximately 90 minutes in total. You will not be financially reimbursed for your time, but you can choose to receive a free dietary analysis based on your responses to the dietary questionnaire, as outlined above.

As an acknowledgement of your time contributed to the study, you can also choose to be in the draw for a \$50 gift voucher from a retailer of your choice. One participant will be selected randomly to receive a voucher from every 25 participants who enter the draw. Recipients will be contacted via email. *Please note that if you participate via the Melbourne School of Psychological Sciences Research Experience Program for course credit, you are not eligible to enter this draw.*

You will be informed of the study results via the dissemination of regular study newsletters. These newsletters will update you on study progress and key findings, including links to study publications (e.g., peer-reviewed journal articles, media coverage). The summary findings reported will be for all participants, not your individual results.

This study is funded by the Melbourne School of Psychological Sciences, University of Melbourne.

How would my confidentiality be protected?

Any information we collect for this research project will be treated as confidential. We can disclose the information only with your permission, except as required by law. We may be required to break confidentiality if we are concerned about harm to yourself or others, or where mandated by law.

All information will be stored securely in locked filing cabinets or electronically in password-protected databases in the Melbourne School of Psychological Sciences and Melbourne Neuropsychiatry Centre at The University of Melbourne. Access to computer files will be available by password only, and only named researchers will have access to these files.

All information you provide will be re-identifiable. This means that we will remove your name and other identifying details and give the information an identification number. Only the research team can match your details to the identification number, and only if it is necessary to do so.

We will keep the information until 15 years after the last publication based on the data. After this time, it will be destroyed. The information you provide will not be used again for future research.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access and correct the information we collect and store about you. Please contact us if you would like to access this information.

When we write, or talk about the results of this project, information will be provided in such a way that you cannot be identified.

What if I want to withdraw from the Research?

Participation in this research is completely voluntary. You are free to withdraw at any time and to withdraw any unprocessed data previously supplied. This would have no effect on your relationship with any member of the University of Melbourne. It would not affect any treatment that you would otherwise be eligible for.

Where can I get further information?

If you have not understood any of this information please contact the researchers listed above. You can also visit our study website:

<http://psychologicalsciences.unimelb.edu.au/research/bugs-and-brains>.

This research project has been approved by the Human Research Ethics Committee of The University of Melbourne. If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Manager, Human Research Ethics, Office for Research Ethics and Integrity, University of Melbourne, VIC 3010. Tel: +61 3 8344 2073 or Fax: +61 3 9347 6739 or Email:

HumanEthicscomplaints@unimelb.edu.au. All complaints will be treated confidentially. In any correspondence please provide the name of the research team or the name or ethics ID number of the research project.

How do I agree to participate?

If you wish to participate please contact the research team at bb-study@unimelb.edu.au or visit our website at <http://go.unimelb.edu.au/8se6> and click on the 'Contact Us' tab.

Consent form for persons participating in a research project

PROJECT TITLE: **Bugs and Brains: The Gut and Mental Health Study
Questionnaire-Only Participants**

Name of Participant: _____

Name of Responsible Researcher: **Dr. Julian Simmons**

Name of Additional Researchers: **Ms Djamila Eliby** (PhD Student), **Ms Carra Simpson** (PhD Student)

1. I consent to participate in this project. The purpose of this research is to investigate the role of the microbiome in relation to some common mental and physical health conditions.
2. I understand that this project is for research purposes only and not for treatment.
3. In this project I will be asked to complete two online questionnaires. The details of this have been explained in the Plain Language Statement, which I have been given a copy of to keep.
4. I understand that there are risks involved in participating in this research project. The details of this have been explained in the Plain Language Statement, which I have been given a copy of to keep.
5. I understand that my participation is voluntary and that I am free to withdraw from the project at any time without explanation or prejudice and to withdraw any unprocessed data I have provided. Withdrawing from the project will not affect my relationship with the Melbourne School of Psychological Sciences. Specifically, it will not affect any treatment that I would otherwise be eligible for.
7. I have been informed that the data from this research will be stored at the University of Melbourne and will be destroyed after 15 years.
8. I have been informed that the confidentiality of the information I provide will be safeguarded subject to any legal requirements; my data will be password protected and accessible only by the named researchers.
9. I understand that after I sign and return this consent form, it will be retained by the researcher.

Participant signature: _____ Date: _____