



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 Rachel Brodie (Project Co-ordinator)

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 role of the microbiome, particularly in relation to some common mental and physical health conditions. We are also interested in learning about how the microbiome is related to physiological functions (such as levels of hormones and inflammation), stress, and wellbeing.

This research will compare the bacterial and physiological profiles of four different types of adults: 1) healthy adults; 2) adults with depression &/or anxiety disorders; 3) adults with irritable bowel syndrome (IBS); and, 4) adults with both depression &/or anxiety and IBS. You have been invited to participate in this research project because you have identified with one of these four groups. The selection criteria for these groups is very specific, and many women will not be eligible to take part in all phases. This does not necessarily indicate there is anything you should be concerned about. If you are ineligible, you will be invited to participate in a questionnaire-only assessment.

What would I be asked to do?

This research project is made up of four phases; an online screening questionnaire, an interview, collection of biological samples, and further online questionnaires. These phases are described below. **You may be asked to participate in all, or only some, of these phases.**

Phase 1 – Online Screening Questionnaire

A member of the research team will contact you to discuss the contents of this document to make sure you fully understand what is involved so you can decide whether or not you would like to take part. We will record your verbal consent over the telephone and ask you to sign the Consent Form. You will then be sent a link to an online screening questionnaire. You can complete this questionnaire online at a location of your choosing.

This questionnaire will ask about your demographic details, medication use, substance use, medical health, mental health, and gut health. It will take approximately 30 minutes to complete.

A researcher will review your responses and get in contact and you may then be invited to continue to Phase 2. If your responses indicate that you are not eligible to complete Phases 2 and 3, you will be invited to complete the Phase 4 questionnaires online.

Phase 2 – Interview with a Researcher

In this phase, we will invite you to complete an interview at the University of Melbourne, asking detailed questions about your mental health, mood, and behaviours. This interview can take up to 2 – 3 hours, however will be less than 2 hours for most people. Also, if the interview does take longer than 2 hours, or if you prefer, we can break this interview up and complete it over two sessions. You can complete the interview via video call (Skype or Facetime) or telephone if you are unable to attend in person. We will ask your permission to audio record the interview for reliability purposes. At the end of this interview you may then be invited to continue to Phase 3 and Phase 4. If you are not eligible to continue to the Phase 3 collection of biological samples, you will be invited to complete the Phase 4 questionnaires online.

Phase 3 – Collection of Biological Samples

This phase involves collection of biological samples over a 48-hour period. If you are invited to participate in this phase you will be sent faecal, urine, and saliva collection kits. Detailed collection and storage instructions will be provided by a researcher to make it as clean and easy as possible. If you would like to read these instructions prior to consenting to taking part, please let us know.

You will be asked to not collect the faecal, urinary and saliva samples when you are menstruating or if you are unwell. You will also be asked to begin the collection of samples after three days of eating a diet that is typical for you, that is, a diet that is representative of your normal diet with no unusual dietary inclusions or exclusions.

You will be instructed to collect the faecal sample first. The urine sample will be collected the following morning at the first urination. You will collect two saliva samples. The first will also be collected on awakening the morning after collecting the faecal sample. The second will be collected on awakening the following morning.

The faecal, urine and saliva samples will all be collected by you in private at your home, and stored in your freezer. We will provide materials to make this sterile and safe.

On the day that the faecal sample is collected you will be asked to notify the research team and a home visit will be scheduled as soon as possible to pick up the biological samples. During this home visit, a member of the research team will also ask to collect a small sample of your hair. The hair will be cut close to the scalp (an area about the size of 10 cent piece), and come from the back of your head (so that your hair covers the small patch left). We will show you before and after pictures of others who have had the collection done, to help you decide if you wish to provide this sample. If you have short hair (less than 3cm long), we will advise you against providing this sample, as it may leave a visible gap in your hair. During this home visit, we will also ask your permission to take measurements of your height, weight, and waist circumference. We will ask you to remove your shoes, hat, jumpers, items in your pockets, etc. for these measurements. Measurement of your waist circumference is ideally measured against the skin, and requires the researcher to identify the bottom of your rib cage and the top of your hip bone. However, if you are not comfortable with this, the measurement can be conducted over a layer of light clothing. All the measurements will be taken by a female researcher. If you would like more details about the well-established protocol we use to collect these measurements, please let us know.

Phase 4 – Online Questionnaires

For those participants completing all four phases of the study, Phase 4 is completed in conjunction with Phase 3. At the same time as you are sent the biological sample collection kits, you will also be sent a link to a set of online questionnaires. We will ask you to complete the questionnaires within 24 hours of the collection of the faecal sample. The questionnaires will consist of further demographic questions and ask you about your mood, stressful life events, coping strategies, quality of life, oral and physical health, and your diet. You can complete these questionnaires online at a location of your choosing.

For participants *not* completing all four phases of the study (i.e., questionnaire-only participants), the Phase 4 questionnaires will be completed in conjunction with the Phase 1 questionnaires.

For all participants, the Phase 4 questionnaires will take up to 60 minutes to complete.

What are the risks?

To our knowledge, there are some risks involved in participating in this study. Some of the questionnaires and the interview address potentially sensitive or distressing topics relating to mental health. However, our research team has lots of experience with the questionnaires and the interview used in this study. You do not have to answer any questions that you do not feel comfortable with. If you are experiencing emotional or mental health difficulties our research team is trained to identify 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 or Ms Rachel Brodie (03) 8344 1845; bb-study@unimelb.edu.au) if you wish to discuss any concerns at any time during the study, regardless of whether you participate in all or some aspects of the project.

For those completing the Phase 2 diagnostic interview, the interview will be audio-recorded with your permission. It is possible that you may feel embarrassed or uncomfortable about being recorded. Audio-recordings of interviews will be de-identified and will not be made without your consent. All audio-recordings will be stored in password-protected computer files, and will only be accessed for reliability purposes by a member of the research team.

For those completing Phase 3, the collection and storage of faecal, urine and saliva samples, and the measurement of height, weight, and waist circumference, may be uncomfortable, embarrassing or unpleasant for some people. You will collect the biological samples in private in your own home with the kits we provide. These kits include detailed instructions and materials to help you make the process quick, clean and sterile. Please let us know if you would like to look at these instructions prior to deciding if you would like to take part. With regard to the measurement of height, weight, and waist circumference, we will follow well-established protocols and the measurements can be taken while you are fully clothed. These measurements will be taken by a female researcher.

Another potential risk involved in participating in this study is the inconvenience and burden involved in completing the questionnaires, interview, and biological samples. For those completing all four phases of the study, we estimate that participation will take about 3.5 hours of your time plus the time to take the faecal, urine, saliva, and hair samples. You will be reimbursed for your time and/or travel expenses. You are also free to participate in all or some of the project, and can take breaks as needed.

For participants only completing the Phase 1 and 4 questionnaires, participation will take approximately 80-90 minutes in total, and the questionnaires can be completed at your convenience. Questionnaire-only 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.

Are there any risks with the biological samples?

For those completing Phase 3, there is a risk of contamination due to contact with the faecal sample. You will be provided with detailed verbal and written instructions on safe collection techniques, and provided with a collection kit that will include gloves, a paper device that catches the faeces for collection (and can then be flushed away), a tool to pick up the faeces and place them in the collection tube, and air- and water-tight plastic zip-lock bags. Antibacterial wipes and disinfectant spray will also be provided.

What happens if something unusual is found in the biological samples?

For those completing Phase 3, the biological samples may reveal the presence of health concerns such as bacterial infection, or metabolic, endocrine or immune anomalies. In circumstances where health concerns are indicated, results will be reviewed and, where required, you will be contacted and advised to seek medical follow up with your preferred general medical practitioner (GP). Please note that these results will not become available until the end of the study. Please speak with your GP if you have current health concerns.

What are the benefits?

We don't expect there to be any direct benefit to you. However, we hope to increase our understanding of the association of mental (anxiety and depression) and physical (irritable bowel syndrome) health conditions with the microbiome. At the conclusion of this study, we hope to apply the findings to the design of a clinical trial to test whether a dietary or probiotic intervention may offer symptom relief to these clinical groups. Given how common and disabling these mental and physical conditions are in the community, such knowledge has substantial potential benefit.

For those completing all four phases of the study, you will be asked if you wish to receive the results pertaining to the bacterial composition of your faecal and saliva samples once our study is completed. This will provide you with information pertaining to the relative abundance of different bacteria types found in your sample.

All participants will be asked if they wish to receive a free dietary analysis provided by Cancer Council Victoria based on the dietary questionnaire that is part of the Phase 4 Online Questionnaires once our study is completed. The analysis of this questionnaire provides detailed information about your 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.

Participants completing all four phase of the study will be reimbursed for their time, travel, and parking expenses incurred in participation. We estimate that participation in all four phases will take about 3.5 hours plus time taken to collect the biological samples over a 48 hour period. You will be reimbursed \$40 for the interview in Phase 2, \$50 for the collection of biological samples in Phase 3, and \$20 for completion of the online questionnaires in Phase 4.

For participants completing questionnaires only, we estimate that participation will take approximately 80-90 minutes in total. You will not be financially reimbursed for your time, but you will receive a free dietary analysis based on your responses to dietary questionnaire, as outlined above.

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.

For those completing Phase 3, the saliva, urine and faecal samples you provide will be stored and processed at the Melbourne Dental School and Department of Biochemistry and Molecular Biology at the University of Melbourne. Hair samples will be stored at Melbourne School of Psychological Sciences and Melbourne Neuropsychiatry Centre at The University of Melbourne.

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, 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 any of 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 read and sign the consent form that you will now be provided with.