

# Participant Information Sheet

Study title: Effectiveness of Probiotics as an adjuvant treatment in Major Depressive Disorder (MDD)

Locality:  
University of Auckland

Principal investigator: Dr. Fredrick Sundaram  
Lead Investigator: Dr. Venkat Krishnamurthy Naga

Contact number: 0276543295  
Email: [vkri010@aucklanduni.ac.nz](mailto:vkri010@aucklanduni.ac.nz)

You are invited to take part in a study on the antidepressant effects of probiotics. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

You are invited to take part in a study on the antidepressant effects of probiotics. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what will happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide, you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

- In this study, we are investigating the potential antidepressant properties of Probiotics. There is evidence that probiotics can reduce the symptoms of depression or improve the effectiveness of antidepressants in patients. Currently, probiotics have been studied for the above reasons in many countries, including the USA, Australia, and Europe; however, there are no major studies done in NZ to study this effect of probiotics.
- Our Gut (mainly large intestine) has a large number of bacteria of a wide variety; they remain stable throughout adult life. However, during disease conditions or when we fail to eat healthy foods, they can end up with certain bacteria with the potential to cause inflammation within the Gut.
- There are several international human and animal studies that have demonstrated the effectiveness of such dysbiosis as a major contributor to several illnesses, including Major Depressive disorder through complex interactions between them and the host.
- In this study, we are going to see whether taking probiotics as an adjuvant treatment in the management of Mild to moderate Major Depressive disorder will be beneficial in improving the effectiveness of the treatment as usual.
- Treatment takes place at the University of Auckland; individuals will be assessed for suitability to participate in the study. Once we confirm your eligibility, we will get you through

a series of questionnaires that will identify the severity of your depression and also help us quantify your Eating habits and activities. We will be repeating some of these questionnaires every week. Together it will take an hour to two hours to complete them. Once we complete the questionnaire, we will give you a pack of probiotics or a placebo based on the randomization, of which even the provider will be blinded. Each pack will contain small packs of probiotics/placebo powder in a sachet. We will ask you to take it once a day. We will supply seven of them each week when we meet you. The study will go for eight weeks. Prior to this, we will ask you to do a few screening questionnaires to check for the severity of depression and assess your normal eating and exercising behaviors for the preceding week.

- You are reading this sheet because your care provider thought that you might be eligible, and you have contacted us. This study will take approximately 11 hours of your time and includes eight visits to our research center over a period of two months.
- On the first day you come to our center, we will confirm your eligibility to take part in the study. This session will take approximately three hours. In the session, we will ask you questions about your physical and mental health as well as alcohol and recreational drug use history to confirm whether you are eligible to take part. You will also be asked to fill out your demographics information and a psychiatric questionnaire to quantify and assess your level of depression.
- To take part in the study, you must be over 18 years old, have had depression for at least four weeks, and you were taking an antidepressant for at least four weeks. Unfortunately, you will not be eligible to take part if you are planning major changes to your medications.
- During this session, we will also do the screening questionnaire for eating habits and exercise. We will also get a sample of your blood to check the levels of inflammatory marker's interferon  $\gamma$  and  $1\beta$  in your body. This blood test will be undertaken only twice during the whole study once before we start the study and again after the end of the study.
- After the above screening on the same day, we will give you seven packs of probiotics or placebo sachet powder.

We will instruct you with regard to the way it needs to be ingested, and you will have the powder in the session.

We will call you in two days' time to clarify regarding any side effects from them.

If you are tolerating the powder, we will meet you again in a week's time.

Every week, an hour will be spent on doing questionnaire covering the above topics of depression, eating habit and exercise. After the questionnaires are completed, we will give you the sachet packs for the next week.

We will meet you every week for 8 weeks after you join our study.

Once the eight weeks are completed after we finish the final questionnaire, we will get another blood test, as mentioned above. This will be the final one.

Throughout the study, we want you to continue with your usual treatment for your depression, including taking medications to help you with depression-like antidepressants.

Each session after the first week will take around an hour of your time once a week for eight weeks.

- There are no restrictions on driving throughout the study, and you are free to drive yourself to and from the sessions.

*Timeline of the study.* You will visit our center nine times, and it will take around 8-9 weeks for the completion of the study with you visiting us every week, it will take an hour each week. Initial screening day might last up to three hours, and the last session might be slightly prolonged due to the need to have blood taken for measurement in the previous night.

- After the initial session, one of the researchers will give you a follow-up phone call to address any queries or concerns that you may have.

- Risk of probiotics :

If the patient is at risk individual suffering from the immunocompromised state, then probiotics can cause infection, rarely septicemia. Otherwise, the most common side effect on probiotics is a bloating sensation for participants.

This study is funded by the Oakley Mental Health Research Foundation ([www.oakleymentalhealth.co.nz/](http://www.oakleymentalhealth.co.nz/))

If you were injured in this study, which is unlikely, you may be eligible for compensation from ACC just as you would be if you were injured in an accident at work or home. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

- Your participation in this study is entirely voluntary. It is up to you to decide whether to take part or not. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you don't want to take part, you don't have to give a reason. If you decide to take part, you are still free to withdraw at any time and without providing a reason.
- If you take part in the study, you have the right to access any information about you collected during the study after your completion or withdrawal from the study.
- If we learn anything about your health status during the study that affects your health, you will be informed of this.
- Any information you give us about yourself will remain private and confidential and can only be seen by members of the research team.

- **The treatment that you receive during the study will not be available to you after your participation in the study.**

- At the conclusion of the study, your identifiable personal data (such as contact details, medical history, and questionnaire answers) will be kept in locked cabinets in secure rooms at the University of Auckland and kept for ten years. They will be shredded after this time. All electronic data files will be held in a de-identified format such that there is no risk that you could be identified from these data. Your data will be identified by a unique trial-specific number in any database. Your name and any other identifying details will not be included in any trial data electronic file.
- Following open-data guidelines, your de-identified data may be uploaded into publicly accessible databases.
- Only members of the study team and appropriate regulatory bodies will be able to access your personal data and health information.
- It can take quite a long time for us to analyse data from these kinds of studies. We hope to be able to tell you the final results one to two years after completion of the study. We plan to publish

the results in specialized academic journals. We can send you a plain-language summary of the results.

If you have any questions, concerns, or complaints about the study at any stage, you can contact:

Dr.Fredrick Sundram,  
Principal Investigator,  
Senior lecturer,  
Department of psychological medicine,  
The University of Auckland