|  |  |  |
| --- | --- | --- |
| *Study Title: Use of Probiotics as an additional treatment of Major Depression Disorder* |  | |
| Locality: Auckland Ethics Committee approval number:  Sponsor: Oakley Mental health research foundation |  |  | |
| Lead investigator: Dr. Venkat S K Naga  Contact phone number: |  |  | |

You are invited to take part in a study on 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 would 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.

This document is 9 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

## What is the purpose of the study?

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 significant studies done in NZ to study this effect of probiotics.

Several human and animal studies have demonstrated altered gut microbiota as a significant 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.

This is a feasibility study to explore the possibility of using probiotics as an additional treatment in the management of mild to moderate Major Depressive Disorder, if this study shows feasibility, we will conduct a larger study to see whether taking probiotics as an additional treatment will be beneficial for individuals who suffer from mild to moderate Major Depressive Disorder.

## What will my participation in the study involve?

*Time commitment:* This study will take approximately 11 hours of your time and includes eight visits to our research Centre over two months.

*Suitability:* To take part in the study, you must be over 18 years old and under 65, have had depression for at least four weeks, and you have received an antidepressant for at least four weeks. Unfortunately, you will not be eligible to take part if you are planning significant changes to your medications or already taking probiotics/prebiotics or any other similar gut health supplements. In addition, anyone suffering from serious medical conditions like Traumatic brain injury, Neurological disorder, auto-immune disorders or take medications that can cause the above or suffer from another serious mental illness like Schizophrenia, Schizoaffective disorders will not be eligible to participate in the study.

Location: The research will take place at the University of Auckland; individuals will be assessed for suitability to participate in the study.

*Blood withdrawal:* In this research, we will need to withdrawblood twice***.*** Blood material will be used to check the levels of inflammatory marker's interleukin 6 and 1b in your body. Blood taken will be stored in Auckland Regional Biobank. In the last leg of the study, all the samples will be processed in a university lab, for measuring the above inflammatory markers. Blood will not be used for any other purpose. Blood withdrawal, storage, and processing will be made with the utmost respect and any remaining tissue will be discarded. You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with storing your tissue will be discussed with your family/ whānau as appropriate. There are a range of views held by Māori around these issues; some iwis disagree with storage of samples citing whakapapa and advise their people to consult before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose.

*Screening:* 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 meeting, 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 demographic’s information and a psychiatric questionnaire to quantify and assess your level of depression.

*Study:* After screening assessment, if eligible, we will also do the screening questionnaire for eating habits and exercise and withdraw blood. On the same day, we will give you seven packs of probiotics or placebo sachet powder. We will instruct you about the way it needs to be ingested.

*Probiotics*, we are planning to provide to you is Winclove Probiotics, this comes in powder form and it needs to be stored at room temperature usually. It does not have any taste. Placebo powder, we will use is maltodextrin powder and it is bland and tasteless as well. Probiotics contain number of live bacteria which can be beneficial for health.

 We will call you in two days to clarify any side effects, if any from taking either of the powder.

Every week, an hour will be spent on doing questionnaires covering the above topics of depression, eating habits, 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 eight weeks after you join our study.****?***

At the end of the eighth week, when we meet, we will get another blood test done for measuring the same inflammatory markers after being on probiotics during the study.

Throughout the study, we want you to continue with your usual treatment for your depression, including antidepressants. 

You will visit our Centre 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, as mentioned above.

## What are the possible benefits and risks of this study?

* You may not get any benefit from participating in the study.
* There is minimal risk involved in taking probiotics. Probiotics could often cause abdominal bloating sensation in healthy individuals.
* Probiotics powder, if not stored and used properly, can disseminate in the air and contaminate edible materials. Any individual who is immunocompromised due to a medical condition living in the household can get infection from the bacteria’s, if the above contamination occurs.
* Probiotics can get inactive, if not stored in room temperature
* Probiotics can possibly help with depression and also for your gut health.
* There are some studies to state that it can improve overall health of individuals including your cardiovascular health.

## Who pays for the study?

* Oakley Mental health research foundation is an NGO organization, which funds mental health research projects in New Zealand. This foundation has kindly agreed to sponsor the pilot study.
* Participant will not incur any costs
* Once participants complete the study, they will be provided 50$ gift voucher, in recognition of participation.

## What if something goes wrong?

* If you were injured in this study, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. 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.
* If there is deterioration in your mental health during the study, we will inform you treatment provider /GP about it. In rare cases, if there is a risk to your self or others, we might have to inform the local District Health Board, crisis team based on your residential address.

## What are my rights?

* Participants are free to decline to participate, or to withdraw from the research at any practicable time, without experiencing any disadvantage
* participants have the right to access information about them collected as part of the study
* Participants will be told of any new information about adverse or beneficial effects related to the probiotics that becomes available during the study that may have an impact on their health.
* Participants information will be kept in confidential electronic files in the University of Auckland’s secure cloud servers for at least 10 years.

## What happens after the study or if I change my mind?

* After the end of study or if you leave the study, above mentioned probiotics is not available in New Zealand retail market at this point of time but many other probiotics can be obtained as a health supplement from retail pharmacy however, it will not be sponsored by the funding agency for the study.
* Study data will be stored for 10 years, in a secure University of Auckland’s cloud storage.
* Blood specimens collected during the research will be destroyed at its conclusion
* Study findings will be communicated on completion of the study, through an email.

## What will happen to my information?

During this study the study researchers and other site staff will record information about you and your study participation. This includes the results of any study assessments. If needed, information from your hospital records and your GP may also be collected. You cannot take part in this study if you do not consent to the collection of this information.

## Identifiable information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). Only researchers will have access to your identifiable information. However, the following groups may have access to your identifiable information:

* Your usual doctor/GP, if a study test gives an unexpected result that could be important for your health. This allows appropriate follow-up to be arranged.
* Rarely, it may be necessary for Study Doctor to share your information with other people – for example, if there is a serious threat to public health or safety, or to the life or health of you or another person.
* University of Auckland regional biobank staff, to process and store your blood material.

## De-identified (coded) information

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the researcher AND/OR any study information sent to the sponsor. Instead, you will be identified by a code. The researcher will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

The following groups may have access to your coded information

* The sponsor, for the purposes of this study.
* Regulatory or other governmental agencies worldwide.

## Future research using your information

If you agree, your coded information may be used for future research related to probiotics in Major Depressive Disorder.

## Security and storage of your information

Your identifiable information is held at University of Auckland’s Cloud storage during the study. After the study it is transferred to a secure archiving site and stored for at least 10 years, then destroyed. Your coded information will be entered into electronic case report forms and sent through a secure server to the sponsor. Coded study information will be kept by the sponsor in secure, cloud-based storage indefinitely. All storage will comply with local and/or international data security guidelines.

## Risks

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

This research includes basic information such as your ethnic group, geographic region, age range, and sex. It is possible that this research could one day help people in the same groups as you. However, it is also possible that research findings could be used inappropriately to support negative stereotypes, stigmatize, or discriminate against members of the same groups as you.

In case there is data breach of the study information, we will inform you as soon as possible and do our best to stop further breach from occurring. We will also update you on the steps our team will be taking to stop further breaches. We will also notify the Health and Disability Ethics Committee of the breach, if there is a significant breach.

## Rights to access your information and results

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

You can request a letter telling you about the study results. The letter will be sent to you once the final study report is available (this can take 1 – 2 years).

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

Please ask if you would like to access the results of your screening and safety tests during the study. You may access other study-specific information before the study is over, but this could result in you being withdrawn from the study to protect the study’s scientific integrity.

If you have any questions about the collection and use of information about you, you should ask Study doctor.

## Rights to withdraw information

You may withdraw your consent for the collection and use of your information at any time, by informing your Study Doctor.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

If you agree, information collected up until your withdrawal from the study will continue to be used and included in the study. However, you may ask for it to be deleted when you withdraw, unless you withdraw after the study analyses have been undertaken.

## Who do I contact for more information or if I have concerns?

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

*Dr.Fredrick Sundram*

*Principal Investigator*

*Consultant Psychiatrist and Senior Lecturer at*

Department of psychological medicine,

The University of Auckland

*Telephone number*

*Email*

If you want to talk to someone who isn’t involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050  
Fax: 0800 2 SUPPORT (0800 2787 7678)  
Email: [advocacy@advocacy.org.nz](mailto:advocacy@advocacy.org.nz)

Website: https://www.advocacy.org.nz/

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHIC

Email: [hdecs@health.govt.nz](mailto:hdecs@health.govt.nz)

If you require Māori cultural support please contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext 42324

**Consent form:**

**Please tick to indicate you consent to the following** *:*

|  |  |  |
| --- | --- | --- |
| I have read, or have had read to me in my first language, and I understand the Participant Information Sheet. |  |  |
| I have been given sufficient time to consider whether or not to participate in this study. |  |  |
| I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study. |  |  |
| I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet. |  |  |
| I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care. |  |  |
| I consent to the research staff collecting and processing my information, including information about my health. |  |  |
| If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed. | Yes 🞏 | No 🞏 |
| I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study. | Yes 🞏 | No 🞏 |
| I understand that there may be minimal risks involved in taking part in the study |  |  |
| I agree for the study doctor to withdraw blood for the study. I am aware that it will stored and processed within the university. I understand that these samples will be disposed of using established guidelines for discarding biohazard waste. |  |  |
| I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study. |  |  |
| I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study. |  |  |
| I understand the compensation provisions in case of injury during the study. |  |  |
| I know who to contact if I have any questions about the study in general. |  |  |
| I understand my responsibilities as a study participant. |  |  |
| I wish to receive a summary of the results from the study. | Yes 🞏 | No 🞏 |

**Declaration by participant:**

I hereby consent to take part in this study.

|  |  |
| --- | --- |
| Participant’s name: | |
| Signature: | Date: |

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant, and have answered the participant’s questions about it.

I believe that the participant understands the study and has given informed consent to participate.

|  |  |
| --- | --- |
| Researcher’s name: | |
| Signature: | Date: |