MEDICAL AND HEALTH SCIENCES

The Department of Psychological Medicine,
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The FLASH Study:
Function of Lactic Acid-bacteria to Support Health

Lead investigator: Dr Rebecca Slykerman r.slykerman@auckland.ac.nz
Co-investigator: Dr Naomi Davies naomi.davies@auckland.ac.nz
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You are invited to take part in a study about probiotics, stress, and gut health. 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. 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 participation involves, what the benefits and risks to you might be, and what would happen after the study ends. You can ask any questions about the study. You may want to talk about the study with other people, such as family, whānau, or friends.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to see if taking probiotics as a daily supplement can help improve stress and psychological wellbeing, and improve gut health in adults.

WHAT ARE PROBIOTICS?

Probiotics are 'good bacteria' that are also found in some foods or they can be taken as a supplement. Studies that have been done before both here and overseas have found that taking a probiotic supplement might help people with feelings of stress. There are many different types of probiotics available for infants, children and adults today, but we need to research which probiotics might help with different things. The lactic acid bacteria family of probiotics used in this study have been safely used in studies in New Zealand.

All the ingredients and capsules used in this study

- Contain no lactose or dairy*
- Contain no Gluten*
- Contain no animal products and are vegan

*Capsules are manufactured in a plant that processes dairy products, soy, sesame seeds, peanuts, Tree nuts (almond, cashew, hazelnut, macadamia, pecan, pistachio, walnut), Lupin, fish and shellfish, eggs, mustard, celery, wheat and oats.

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WHO ARE WE?

Dr Rebecca Slykerman is a Clinical Neuropsychologist and researcher from the University of Auckland who is interested in ways of improving psychological wellbeing and health. Dr Naomi Davies is a researcher from the University of Auckland who is interested in improving gastrointestinal and psychological health.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You can take part in this study from anywhere in New Zealand and there are no visits to a clinic or office involved in this study.

Participating in this study involves:

1. Answering questionnaires at the beginning, middle and end of the study.
2. Providing samples at the beginning and end of the study
3. Taking a capsule daily for 8 weeks
4. Letting us know about any health concerns you have during the study

Some participants will also be randomly selected to participate in and end of study interview (via Zoom).

The information and samples we will ask you to provide are outlined in more detail below

1. QUESTIONNAIRES and SAMPLES

Questionnaires

Using your phone, tablet, or computer we will ask you to answer some questions about yourself and provide your contact details so we can send you capsules and a study pack. We will also ask you to complete questionnaires about your stress and mood, sleep, and gut health. This takes about 15-20 minutes at the beginning of the study and again after 4 weeks (middle of the study) and 8 weeks (end of the study).

Samples

We will ask you to self-collect a saliva sample at home. We send you a kit and it takes 10 minutes to drool into a small tube. Then you send this back to us in a postage bag we provide for you. We ask you to do this once at the beginning of the study and once at the end of the study (2 samples in total). Saliva samples will be sent to Los Angeles, USA for analysis. They will contain only your participant ID and no information that could identify you will be included.

We also ask you to self-collect a fecal (poo) sample at home and send it back to us in a special bag we provide to you. It is quite easy to do this at home. We provide you with

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gloves and a flushable sheet to put in the toilet, a small brush that you scrape some faeces onto and then screw into a tube. We ask you to provide one sample at the beginning of the study and one at the end (2 samples in total).

We will send you a referral form to have a blood test at a community lab that is convenient for you once at the beginning of the study and once at the end of the study (2 blood tests in total). This is just like having a blood test for any other reason and is done by people who are trained in doing blood tests.

All biological samples you provide (saliva, fecal and blood) will be used in full for analysis, and so there is no option for karakia or to have any of the sample returned to you.

2. TAKING CAPSULES

We ask you to take one capsule every day within 1 hour of a meal, for 8 weeks. The capsule will contain either a probiotic or a placebo (an inactive substance that looks like the probiotics being tested) called maltodextrin (soluble fibre). You will be assigned to one of four different probiotic groups or to the placebo group.

This study is called a double-blind study, this means that neither you nor us as the researchers will know which group you are in. This is so we cannot accidentally bias the results of the study. After the study has finished we can let you know which group you were in if you want to know.

3. FORTNIGHTLY EMAIL

We will send you an email every two weeks to remind you to tell us about any health concerns you may have regardless of whether you think these are related to the capsules or not. This email will contain details of the different ways you can contact us (email, SMS, messaging).

4. END OF STUDY INTERVIEW

We will randomly select 1 out of 5 participants to take part in an end of study interview. These will take 20-30 minutes over zoom and will ask about your experience of taking part in the study and any changes you noticed in your physical or psychological health.

GIFT VOUCHERS TO RECOGNISE YOUR CONTRIBUTION TO THIS STUDY

To recognize your contribution to this study each participant will receive:

- $20 voucher when you complete registration and baseline questionnaires (online)

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- $20 voucher when you have returned your first faecal sample
- $20 voucher when you have returned your first saliva sample
- $60 voucher when you have had your first blood test
- $40 voucher when you complete your mid-point questionnaires (online)
- $20 voucher when you complete the online questionnaires again at the end of the study (8 weeks)
- $20 voucher when you have returned your second faecal sample
- $20 voucher when you have returned your second saliva sample
- $60 voucher when you have had your second blood test at the end of the study

This means if you complete all parts of the study you will receive a maximum of $300 in gift vouchers. Gift vouchers will be either MTA or Pak'N'Save gift cards.

If you are selected for an end of study interview and you complete the interview we will send you an additional $20 voucher

AM I ELIGIBLE TO TAKE PART IN THIS STUDY?

You are eligible to take part in this study if:

- You are aged between 25-65 years old
- You live in New Zealand and intend to be in New Zealand for the next 8 weeks
- You have not taken antibiotics in the last 4 weeks
- You have not regularly taken a probiotic supplement in the last two weeks
- You have not been diagnosed by a doctor with coeliac disease, inflammatory bowel disease (e.g. Crohn's disease or Ulcerative Colitis), or Irritable Bowel Syndrome
- You are not taking medication for depression or anxiety that has been prescribed by a doctor
- You are not pregnant or breastfeeding
- You are not currently taking immunosuppressant medicine (e.g. chemotherapy), or you are not currently immunosuppressed

To find out if you are eligible to take part in the study you can use the link at the end of this information sheet using your phone or computer. We will ask you some questions about yourself, and your recent stress levels. This will take about 5 minutes and can be done on your phone, computer or tablet. If you meet the eligibility criteria, you will be directed to give your consent to take part and then register for the study by answering questionnaires.

ARE THERE RISKS TO TAKING PART IN THIS STUDY?

Probiotics have been safely used in previous studies in children and adults both in New Zealand and overseas.

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While we do not expect any adverse effects from taking the probiotics, some people can experience bloating, additional gas, and in some cases nausea vomiting or diarrhea.
During the study we will ask you to tell us about any health concerns you have (whether you think they might be related to the capsules or not) and you can contact us by email, phone, or messaging.

We will be asking you about your stress levels and wellbeing during this study. It is possible that thinking about this may make you feel worried or more stressed. We will provide you with a list of support services in the community that you can access if you want help for feelings of stress.

Because this research study is for the principal benefit of its commercial sponsor Fonterra Ltd., if you are injured as a result of taking part in this study you **won't** be eligible for compensation from ACC.

However, Fonterra Ltd. has satisfied the Southern Health and Disability Ethics Committee that approved this study that it has up-to-date insurance for providing participants with compensation if they are injured as a result of taking part in this study.

New Zealand ethical standards require compensation for injury to be at least ACC equivalent. Compensation should be appropriate to the nature, severity and persistence of your injury and should be no less than what would be awarded for similar injuries by New Zealand's ACC scheme.

Some sponsors voluntarily commit to providing compensation in accordance with guidelines that they have agreed between themselves, called the Medicines New Zealand Guidelines (Industry Guidelines). These are often referred to for information on compensation for commercial clinical trials. There are some important points to know about the Industry Guidelines:

- On their own they are not legally enforceable and may not provide ACC equivalent compensation.
- There are limitations on when compensation is available, for example compensation may be available for more serious, enduring injuries, and not for temporary pain or discomfort or less serious or curable complaints.
- Unlike ACC, the guidelines do not provide compensation on a no-fault basis:
- The Sponsor may not accept the compensation claim if:
- Your injury was caused by the investigators, or;
- There was a deviation from the proposed research plan, or;
- Your injury was caused solely by you.

An initial decision whether to compensate you would be made by the sponsor and/or its insurers.

If they decide not to compensate you, you may be able to take action through the Courts for compensation, but it could be expensive and lengthy, and you might require legal

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representation. You would need to be able to show that your injury was caused by participation in the trial.

You are strongly advised to read the Industry Guidelines and ask questions if you are unsure about what they mean for you.

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.

WHO PAYS FOR THE STUDY?

It does not cost any money to take part in this study. We will provide the capsules, sample kits, return courier bags and blood referral forms to you.

This study is funded by Fonterra Limited including funding for the researchers' time and research costs. Fonterra Limited provide the probiotic and placebo capsules for this study for the intervention period. If you decide you want to take probiotics after the study ends you would need to purchase these yourself.

WHAT HAPPENS TO THE DATA I PROVIDE?

During this study we will record information about you and your study participation. This includes your name, address (to send the study pack to), demographic information and the answers to the study questionnaires. You cannot take part in this study if you do not consent to the collection of this information. We have processes in place to protect your privacy and keep the information you provide to us private. The details of this are outlined below.

Neither your employer, co-workers or any other people will know whether or not you have participated in this study and they will not have access to any of the information you provide as part of this research project.

If you decide to take part but change your mind you can withdraw from the study without giving a reason by contacting Rebecca Slykerman on r.slykerman@auckland.ac.nz. You can withdraw the data you have provided to the study up until 31st December 2024.

Identifiable Information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). Only the researchers will have access to your identifiable information. No other researchers or people outside of the research team will be able to access your identifiable information.

De-identified (Coded) Information

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To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the researchers. Instead, you will be identified by a study code. Only the primary researcher will keep a list linking your study code with your name. We will only link your name with your study code if we need to for example to provide you personally with information you have asked for.

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you and will not include your name, address or date of birth.

All study materials, sample kits, and blood test referral forms use your study ID number rather than your name to protect your privacy during the study.

After the Study & Future Research Using Your Information.

Once the study has finished the de-identified data from the study will be stored securely at the University of Auckland and at Fonterra Limited. This data will not contain any information that could identify you. In the future this de-identified data could be used in analysis, for example in combination with data from other studies to learn more about probiotics and health outcomes. We will not be able to provide you with reports or other information about any additional research that is done using your de-identified data because we will no longer be able to link the data you have provided with your name or contact details.

Security and Storage of Your Information

Your identifiable information is held on the secure study database during the study, only the researchers will have access to this securely stored information while the study is running. After the study has finished your name and address, and study code will be stored separately from the rest of the information you provided as part of the research. This separate file will be securely stored at the University of Auckland for 10 years before it is deleted. All storage will comply with local data security guidelines. At no point during the study or after the study will any third parties receive your identifiable information.

Risks

Although every effort 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.

Rights to Access Your Information.

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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. If you would like to receive a copy of the summary results of the research analysis we will send these to you when the study and all data analysis has finished.

If you have any questions about the collection and use of information about you, you should contact the primary researcher (Dr. Rebecca Slykerman) r.slykerman@auckland.ac.nz

Rights to Withdraw Your Information.

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

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. You may ask for it to be deleted when you withdraw, unless you withdraw after the study analyses have been undertaken.

WHO YOU CAN CONTACT FOR MORE INFORMATION

If you have any questions about the study you can contact the investigators:
Dr Rebecca Slykerman: r.slykerman@auckland.ac.nz or
Dr Naomi Davies: naomi.davies@auckland.ac.nz
Study email: flashstudy@auckland.ac.nz

If you have concerns about the study you can contact the Head of Department of Psychological Medicine: Professor Trecia Wouldes r.ram@auckland.ac.nz

Contact details for Māori cultural support:
If you require Māori cultural support, talk to your whānau in the first instance.

Alternatively, you may contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext 2324.

TO TAKE PART

To take part in the study CLICK HERE: www.flashstudy.co.nz

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