

**SUPPORT COVID19 Healthcare
Workers Study: Stress-reduction Using
Probiotics to Promote Ongoing Resilience
Throughout (SUPPORT) Study**

Lead investigator: Dr Rebecca Slykerman

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You are invited to take part in a study about stress. 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.

This study is being run during the COVID19 pandemic in New Zealand, it does not require any in person contact to participate.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to see if taking probiotics (good bacteria like the ones found in some foods like yogurt) can help with feelings of stress and also immunity to common symptoms of colds and flu during the stressful COVID19 pandemic.

Studies that have been done before both here and overseas have found that taking a supplement of good bacteria called probiotics might help people with feelings of stress and also immunity to common colds and flu. But this has not been studied in healthcare workers and it has not been studied in an unusually stressful time such as during this COVID19 pandemic. Because stress can lead to other problems we want to see if taking this supplement of probiotics could help healthcare workers.

WHO ARE WE?

Dr Rebecca Slykerman is a researcher from the University of Auckland who is interested in stress and ways of improving psychological wellbeing.

WHAT ARE PROBIOTICS?

Probiotics are good bacteria like the ones we have in our gut. They occur naturally in some foods but can also be taken as a capsule like the ones in this study.

The probiotic used in this study is called *Lactobacillus rhamnosus* HN001. It has been safely used in studies with pregnant women and babies in New Zealand.

All the capsules used in this study are:

- Lactose/dairy free
- Gluten free
- Contain no animal products and are vegan

Capsules can be swallowed with a drink.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

The study involves four parts:

Part 1: Online questionnaire

We want to ask you some questions about yourself, stress levels and how you are feeling. This will take about 5-10 minutes and can be done on your phone, computer or tablet.

Part 2: Taking capsules

You will be sent capsules which contain either a placebo or the probiotic and asked to take one capsule every day for 12 weeks.

This study is called a double-blind study, this means that neither you nor the researcher will know which type of capsules you receive (probiotic or placebo). Participants will be randomly assigned to either the probiotic or placebo group. After the study has finished the researcher can let you know what type of capsule you were taking if you would like this information.

Part 3: Weekly text

Once a week for the 12 weeks you will receive a text asking you how many days in the past week you had cold or flu symptoms. You will be asked to text back the number of days 0-7

Part 4: Post-intervention online questionnaire

After 12 weeks we would like you to complete the same questions about stress anxiety and wellbeing. This should take about 5-8 minutes and can be done on your phone, computer or tablet.

You will not need to come to any appointments for this study. Capsules will be couriered to your address and all the data you provide will be through a secure online database.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

It is possible that you might feel very stressed during the COVID19 pandemic. We will provide every participant with a list of sources of support including full contact details of support agencies.

The probiotic we are using in this study *Lactobacillus rhamnosus* HN001 has been safely used in pregnant women and babies in our previous New Zealand studies. The probiotic can be bought in health food stores, pharmacies and through online supplement shops. While we do not anticipate any adverse effects from taking the capsules in this study you can contact the lead researcher Rebecca Slykerman on r.slykerman@auckland.ac.nz if you have any questions or concerns. If you were injured as a result of 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.

Each participant will receive a koha of a gift voucher to thank them for taking time to answer the questions and take part in the research trial. Participants will receive a \$10 petrol voucher after answering the online questions at the beginning of the trial. A second petrol voucher of \$10 will be given to you when you answer the questions again at the end of the study.

WHO PAYS FOR THE STUDY?

It does not cost any money to take part in this study. We will give you the capsules for the study.

The capsules for this study and funding to cover research costs have been provided by Fonterra Cooperative New Zealand. None of the investigators are being paid by Fonterra.

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.

Any information you provide as part of this study will be kept completely confidential to the research team. Information will be stored securely and confidentially and only the researchers will be able to access it.

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 20 October 2020. Data will be stored securely for six years.

WHO YOU CAN CONTACT FOR MORE INFORMATION

If you have any questions about the study you can contact the investigators:
Rebecca Slykerman r.slykerman@auckland.ac.nz or
Roger Booth rj.booth@auckland.ac.nz

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

Contact details for Māori cultural support or to lodge a complaint:
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.
If you have any questions or complaints about the study, you may contact the Auckland and Waitemātā District Health Boards Māori Research Committee or Māori Research Advisor by phoning 09 486 8920 ext 3204.

AHREC Chair contact details:

For concerns of an ethical nature, you can contact the Chair of the Auckland Health Research Ethics Committee at ahrec@auckland.ac.nz or at 373 7599 ext 83711, or at Auckland Health Research Ethics Committee, The University of Auckland, Private Bag 92019, Auckland 1142.

TO TAKE PART

To take part in the study **CLICK HERE** www.supportstudy.nz