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**The UPLIFT Study:**

**U**sing **P**robiotics to **L**essen the **I**mpact of **F**atigue in **T**eens

**Participant Information Sheet – Young people aged 13-18 years**

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You are invited to take part in a study on chronic fatigue syndrome. It is your decision whether you take part. If you don’t want to, you don’t have to give a reason, and it won’t change the care you get. 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 would like to take part in this study. It tells you about what is involved in taking part. You can ask any questions about the study. You may want to talk about the study with other people, such as family, whānau, friends or health professionals.

If you are aged under 16, we will require permission from your parents for you to take part in this study.

If you are aged 16 or older, we will also send information to your parents and ask them for their permission.

We will also be asking your parent or caregiver to be a part of this study. Your parent or caregiver has a separate information sheet that explains their involvement in the study to them.

## why are we doing this study?

We want to do a study to see if taking probiotics (good bacteria like the ones found in some foods like yogurt) can help young people with chronic fatigue.

Studies that have been done in adults have found that taking a supplement of good bacteria called probiotics might help people with chronic fatigue, but this has not been studied in young people. Because Chronic Fatigue Syndrome can be difficult to treat and can get in the way of doing normal things we want to see if taking this supplement of probiotics could help young people with chronic fatigue.

## who are we?

Dr Rebecca Slykerman is a researcher from the University of Auckland who is interested in chronic fatigue in children and young people. Rebecca also works at Starship Hospital as a Clinical Psychologist.

Dr Raewyn Gavin is a Paediatrician at Starship who sees young people with chronic fatigue syndrome.

## What are probiotics?

Probiotics are good bacteria like the ones we all have in our bodies and like the ones found in foods like yogurt. You can take probiotics in a capsule.

We have given the probiotics we are using in this study to babies and adults before and they are safe. The probiotics have long names (*Lactobacillus rhamnosus* HN001 and *Bifidobacterium animalis* HN019) and they are the sort of thing you buy in a pharmacy or health food shop.

All the capsules used in this study are:

* Dairy free
* Gluten free
* Contain no animal products

The capsules can be swallowed with a drink or they can be broken in half and the powder can be sprinkled on food or mixed with a drink.

## what do I have to do if I take part in this study?

There are three parts to this study:

**Part 1: Answering questions**

You will be asked to answer some questions about feelings, symptoms of tiredness and symptoms of chronic fatigue. These questions are answered online so you can use your phone, tablet or computer to answer them. This will take about 10 minutes.

**Part 2: Taking capsules**

After you have answered the questions you will be sent some capsules and asked to take one a day for 10 weeks. Half the people in this study will get probiotic capsules and half the people will get a placebo capsule that has sugar powder in it. You and I will not know which type of capsule you get until after the study has finished. We will send the capsules by tracked mail and will check to confirm that you have received them.

**Part 3: Answering questions again**

After 10 weeks of taking the capsules we will send you a text message and email asking you to answer the same questions about feelings and symptoms of chronic fatigue. This will take about 10 minutes and once again you can do it on your phone, tablet or computer.

During the 10 weeks of the study, we will send a text message to you at week 4, week 6 and week 8 to check in with you and remind you to continue taking your capsule daily.

You will not need to come to any appointments for this study.

## What will happen to my information?

During this study the researchers will record information about you and your study participation. This includes your name, address (to send the capsules to), demographic information and the results of the study questionnaires. 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 the researchers will have access to your identifiable information.

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 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.

Future Research Using Your Information.

Your coded (de-identified) information may be used to inform future research related to interventions for CFS in New Zealand.

You will not get reports or other information about any additional research that is done using your information.

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. After the study all study data (identified and coded) will be stored for at least 10 years, then destroyed. Coded study information will be kept by the researcher in secure, electronic storage for 10 years. All storage will comply with local data security guidelines.

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.

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 questionnaires 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 contact the primary researcher (Dr. Rebecca Slykerman).

Rights to Withdraw Your Information.

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

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.

## You should also know……

If you decide to be part of this study, we will also ask your parents or caregivers to answer some questions about your chronic fatigue symptoms and also about their own feelings. If your parents or caregivers do take part in the study, they will not see any of the information you give us and we will not tell them about your information.

Your information is kept private. No-one else will see the personal information that you tell us as part of this study and we will not tell anyone about the information.

The capsules that we are using in this study have been safely given to babies and women who are expecting a baby. If you have any questions about the capsules you can contact us anytime or talk to your doctor.

It is your decision about whether you want to be part of this study. If you do take part but then change your mind that is fine.

If you do take part in this study, we think that the information we get from this study will help young people who have chronic fatigue.

If at any point during this study anything causes you to become upset, please talk to an adult you can trust, a counsellor, or call Youthline on 0800 376 633, text them on 234, or check out [www.youthline.co.nz](http://www.youthline.co.nz).

## 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 are made by Fonterra and they have given them to us to use in this study.

If you have any questions about the study you can email Rebecca Slykerman on: r.slykerman@auckland.ac.nz or call (09) 923 1132.

If you want to talk to someone who isn’t involved with the study, you can contact a consumer advocate using these contact details:

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

Website: https://www.advocacy.org.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 Waitematā District Health Boards Māori Research

Committee or Māori Research Advisor by phoning 09 486 8920 ext 3204.

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

 Phone: 0800 4 ETHICS

 Email: hdecs@moh.govt.nz

## To take part

To take part in this study click here: www.uplift.nz

You will be directed to an electronic consent form. Upon consent, you will receive an automatic emailing confirming your participation in the trial, as well as a copy of the “electronically signed” consent form for your own records.