

Participant Information Sheet



Study title: BLIS-OM: Preventing Upper Respiratory Tract Infections in Infancy

Locality: Wellington & Christchurch

Ethics Committee Ref: 16/CEN/190

Lead investigator: Prof Julian Crane

Contact phone number: 04 918 5258

What is the purpose of the study?

Ear infections are common in young children and peak when children are between 6 and 24 months of age. Over 80% of children will have had at least one ear infection by 3 years of age, and 40% will have had six or more reoccurrences by 7 years of age. Colds and flus are also very common in early childhood, and can lead to wheezing in young children. Children can have around five colds and flus by the time they are one years old. Tooth decay can also be a problem in childhood.

Probiotics are bacteria that may provide a health benefit when taken regularly. The purpose of the BLIS-OM Study is to see if giving probiotics every day to children from six months of age to two years of age will prevent them from getting ear infections, colds and tooth decay. The probiotic *Streptococcus salivarius K12* (BLIS) is produced by BLIS Technologies Ltd in Dunedin is a naturally occurring bacteria found in the mouth that has been shown to stop bacteria associated with the development of ear infections and dental decay. We want to see if giving K12 to children regularly will protect them from getting ear infections, colds and reduce dental decay.

What will my child's participation involve?

This study is voluntary; you do not have to take part. If you choose not to take part, it will not affect your child's medical care in any way. If you are interested in taking part in this study, we would like to ask you some questions to see if your child is eligible. If your child is eligible and you decide to take part, we will ask you to sign a consent form, and we'll ask some questions about your child's health, give you an information pack, and provide you with a supply of either probiotic or placebo powder for your child to take daily for 18 months. Your child has a 50% chance of being in either group, which is decided by the toss of a coin. Neither the researchers nor you can choose whether they are in the probiotic or placebo group. Each group makes an equally important contribution to the study. Neither you nor the researchers you see will know which group you are in until the end of the study.

We would like you to give your child a ¼ teaspoon of the powder every day from 6 months of age to 2 years old. The powder can be given to your child in a number of different ways – either by making it into a paste and putting onto a baby spoon, or brushing on to their gums, tongue and teeth in a silicone tooth brush that we will provide, or sprinkled on to their food – depending on how old your child is and how they prefer to take the powder. Both powders contain isomalt (a sugar-free sweetener), maltodextrin (a starch carbohydrate used to thicken foods), natural flavour (strawberry) and may contain the probiotic *Streptococcus salivarius K12* if you are in the probiotic group (at a level of 1.25 billion colony forming units (CFUs) per ¼ teaspoon dose). As part of the preparation process the powder may also have been irradiated. Irradiation is commonly used to extend the shelf life of fruits, vegetables, herbs and spices by removing any bacteria and pests. The process is used in more than 50 countries and is considered completely safe by the Food Standards Authority of New Zealand. The study powder is made at a plant that also processes soy and milk, and therefore the powder may contain traces of these substances. If your child is allergic to these substances it may be better not to take part.

If you take part in the study we will also ask you some questions about your child's health when your child is 6 months old and again at 1 year, 18 months and 2 years old. We would also ask some questions on the types of foods your child is eating when they are 1 and 2 years old. At 2 years old we'd like a dental hygienist to have a look at your child's teeth. With your permission we would also like to review your child's medical records to look at their respiratory and ear health.

We would also like to take swabs from your child's mouth at 6 months old and 2 years old. We will freeze the swabs and at the end of the study, if we find that K12 has reduced the number of ear infections, colds and flus or tooth decay in children, we will apply for funding to see if the probiotic has changed the types of bacteria in the mouth.

Frequently asked questions

Where and when will I see the researchers? You will see the researchers twice – at the beginning of the study when your child is around 6 months old and again at the end of the study when your child is around 2 years old. You can come in to see the researchers, or if this is not possible, we may be able to see you at your home. We will also contact you by text to arrange appointments and send reminders, and by phone to ask you some questions on your child's health when they are around 12 and 18 months old.

Can I choose my study group? Unfortunately no, as part of the design of the study we have to randomly assign participants to the two groups, otherwise we could accidentally introduce a bias into the study.

Can I take part in some of the study but not all? There are some things that we need everyone to do. We need you to give your child the study powder every day, answer the health questions and access your child's GP records when they are 2 years old. You do not have to have your child's teeth checked at 2 years of age or have swabs taken from your child's mouth if you do not want to.

Are there any side effects? BLIS toddler powder is commercially available off the shelf in pharmacies in New Zealand and has no known or recorded side effects. In a recent study involving school children, no adverse effects were reported. It is a naturally occurring bacteria in the human mouth.

Why do you want access to my child's GP records? When your child is two years old we would like to check details in your child's medical records. This will help us to record things like whether they have had any ear infections and had to use any antibiotics. We will ask you these questions too, but sometimes it can be tricky to remember what your child has had, which is why we also like to check the doctor's records.

What if we want to go away? This is fine. While you are away from home, we would like you to take the study powder with you and continue to give it to your child.

Can I change my mind and withdraw from the study? You can withdraw from the study at any time, although we hope that you will continue to take part.

What will be gained from the study? Your child's participation in the study will allow us to gain valuable knowledge on whether we can prevent or reduce ear infections, colds and flu and dental decay in young children.

Will I receive the results of the study? Once everyone has completed the study, we will tell you which group you were in, and when all the data analysis has been completed and a paper submitted for publication, we will contact you with the results of the study.

Who has access to my information? Only the people directly involved in this study will have access to your child's personal details. No information that can identify you or your child will be used in any reports or publications.

What if something goes wrong? We do not expect any risks or side effects from participating in this study. The study will be overseen by the Health Research Council data monitoring committee who will assess any reports of adverse reactions or events. In the unlikely event of a physical injury as a result of your child's participation in this study, cover is provided by ACC under the Injury Prevention, Rehabilitation, and Compensation Act 2001, in the same way that you would be covered if you had an accident at work or home.

Who do I contact for more information or if I have concerns? If you have any questions, concerns or complaints about this study please email Professor Julian Crane, principal investigator, University of Otago, Wellington julian.crane@otago.ac.nz or call him on **04 918 5258**. If you would like to discuss any part of the research or your child's participation in it, please phone our research staff **04 918 6856** (Wellington) or **03 364 3624** (Christchurch).

This study is funded by a Health Research Council grant and has received ethical approval from the Central Health and Disability Ethics Committee (Ref: 16/CEN/190). If you have any concerns regarding your rights as a participant in this study and 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@hdc.org.nz

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

Phone: 0800 4 ETHICS, Email: hdec@moh.govt.nz

We have consulted about the study with the Ngai Tahu Research Consultation Committee. For any questions regarding Maori cultural aspects of the study, please contact Professor Julian Crane on 04 918 5258.