

Gut Bugs in Autism FAQ

Gut issues

Question: What would be considered moderate or severe gut issues?

Answer: Moderate or severe gut issues may include a combination of moderate or severe:

- Pain in the pit of your stomach
- Burning sensation in the chest
- Discomfort due to the sensation of regurgitating sour or bitter fluid from the stomach up to the throat
- Discomfort due to feeling of sickness leading to vomiting
- Discomfort due to swelling of your stomach
- Discomfort due to reduced ability to empty your bowels
- Discomfort due to frequent emptying of your bowels
- Discomfort due to the urgent need to empty your bowels

Question: Do I need to have gut issues all the time to participate in the study?

Answer: No. However, we will recruit participants who would experience these gut issues most of the time.

Treatment

Question: Is the treatment offered in this study a treatment for autism?

Answer: No, the treatment we offer is not for autism but the associated gut issues, to improve the wellbeing of autistic individuals.

Question: What is the rationale for treating gut issues among autistic individuals?

Answer: Many autistic individuals suffer from chronic gut issues and it has been reported that up to 50% of children and adults are affected and these symptoms can adversely affect their quality of life.

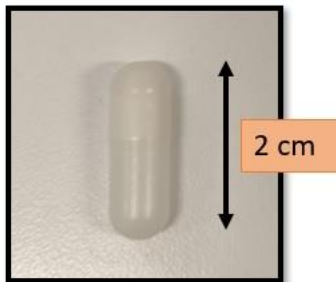
Question: What is the treatment that will be offered?

Answer: Participants will receive capsules that contain either gut microbiome from physically healthy donors or saline (salt water). The treatment will consist of 20 capsules taken over 2 consecutive days (10 capsules on Day 1 and 10 capsules on Day 2).

Question: Is this treatment safe?

Answer: Absolutely. Gut microbiome donors are extensively screened to ensure they do not carry any bacteria, viruses, or parasites that could potentially cause an infection. The strict selection criteria for donors mirror those used for blood donations in New Zealand. Only donors who pass all these screening tests are included in the study.

Question: What are the capsules like?



The capsules are:

- smooth
- cylindrical-shaped
- approximately 2 cm in length
- tasteless & odourless

Question: How do I know if I can swallow the treatment capsules?

Answer: If you are concerned about whether you can swallow the capsules and are eligible to participate in the study, we can give you some empty capsules to swallow under the supervision of our clinical research staff when you come to the clinic for your enrolment visit. If you struggle or dislike swallowing the capsules, we will not enrol you into the study.

Study participation

Question: What are the criteria that would prevent me from participating in the trial?

Answer: The exclusion criteria are:

1. Antibiotics or probiotic supplements one month before the trial
2. Regular steroid treatment
3. Require a tube to ingest food
4. Any serious medical problems that require specific treatment (excluding those related to gut issues)
5. Moderate to severe depression
6. Pregnancy
7. Allergy to macrogol (active ingredient in the bowel preparation product)

Question: What will my participation in the study involve?

Answer: Participation includes:

1. One clinic visit for the baseline assessments (2 ½ hours)
2. Two clinic visits on consecutive days to take the treatment capsules first thing in the morning before you have breakfast (1 ½ to 2 hours each)
3. Three follow-up clinic visits for assessments at 6, 12, and 26 weeks after the treatment (2 ½ hours each)
4. At least three phone calls to assess any possible side effects of treatment (10 minutes each)

Question: What if I am unable to come to the clinic for my scheduled visit?

Answer: If you cannot come to the clinic for your scheduled visit, the visit can be re-scheduled to a date and time that would suit you.

Question: What if I am unable to come to the clinic for one or more of the appointments due to sensory issues?

Answer: If you cannot come to the clinic, it may be possible to arrange home visits. Please discuss with us and we will work out how to best support you.

Question: What are the assessments that will be carried out?

Answer: The assessments include:

1. Questionnaires – we will ask questions to evaluate your well-being, sleep quality, diet, and gut health.
2. Body measurements – we will measure your height, weight, waist, and hip circumferences.
3. Body composition – we will measure your body composition (amount of muscle and fat tissue) using a dual-energy x-ray absorptiometry (DXA) machine scan which is safe and pain-free.
4. Hair samples – we will ask you to provide hair samples to measure stress hormone levels. We only need to cut a few strands of hair that will not be noticeable at all.
5. Stool samples – we will ask you to provide stool samples to study changes in your gut microbiome and gut health.
6. Urine and blood samples – we will ask you to provide a urine and optional blood sample to analyse metabolites produced by your gut microbiome. It is important to note that you will not be required to give a blood sample if you feel uncomfortable, and your study participation will not be affected.

Question: What if I start to feel overwhelmed during my clinic visit? Can I take a break?

Answer: Absolutely. We understand that coming to clinic and having to do so many assessments can be exhausting. So, please feel free to take a break whenever you want to. We will also prepare a laminated card with the words, ‘Take a Break’, and you can show us the card if you are unable to verbally communicate at that time.

Question: What if I decide to change my mind and withdraw from the study?

Answer: Participation in the study is entirely your choice. You are free to withdraw from the study at any time if you change your mind.

Question: Can I bring a support person?

Answer: Yes. You’re also welcome to bring along any calming or fidget/stim items that would help you feel more comfortable.

Benefits & compensation

Question: What are the benefits of participating in this study?

Answer: You will help us understand more about the role of the gut microbiome in the gut health and general wellbeing of autistic people. This may lead to the development of a new treatment for gut problems.

Question: Will I receive any compensation for participating in this study?

Answer: As a token of appreciation for your participation in the study, we will offer you a \$50 gift voucher after the baseline visit and after each post-treatment follow-up visit (\$200 in total).

Health Information and Samples

Question: Will my DNA be extracted and analysed in this study?

Answer: No, we are not extracting your DNA. We are only studying the DNA of the gut microbiome that is present inside you.

Question: How will my collected data be stored?

Answer: Clinical information collected will be stored on a secure electronic database. This data will be password protected on secure servers accessible only to the study investigators. Hard copies will be secured in locked filing cabinets at the Liggins Institute and only the research team will have access to this information.

Question: How will my collected stool, hair, urine and blood samples be stored?

Answer: Stool, hair, urine and blood samples from the study will be safely stored at Te Ira Kāwai, Auckland Regional Biobank. Samples will only be accessible to the study investigators for the purposes of this study. On completion of our analyses, any remaining samples will be disposed of using established guidelines for discarding human samples.

Question: How will my data be disseminated?

Analysis will be conducted on all your data and the summary of these results will be reported. These data will be used for scientific publications and presentations. No one will be identifiable from the analysis. You will be provided with a copy of your individual results at the end of the study.

Question: What happens to my data after the study has been completed?

Answer: After completion of the study, your coded and anonymised health information may be shared with researchers outside of this study for future research deemed appropriate by the Liggins data governance committee. Information about your gut microbiome may be deposited in an international sequence database where it may be used for future microbiome research outside of this study. This information includes your de-identified study code but does not include any health information. The purpose of this database is to help build the global catalogue of microbiome data to help with science reproducibility and new discoveries.

If you would like more information regarding data sharing, you can get in touch with the principal investigators of the study:

Professor Wayne Cutfield (w.cutfield@auckland.ac.nz)

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