



Probiotic intervention for constipation and gut symptoms in children and young people with Down's Syndrome

We are seeking to recruit children and young people with Down's Syndrome (DS) to participate in this research project. They should only participate if you wish them to. Before you decide whether you would like your child or young person to take part, it is important for you to understand why the research is being done and what their participation will involve. **Please take the time to read the following information carefully** and discuss it with us (our contact details are given below) or others if you wish.

What is the purpose of the study?

The study aims to understand the effect of consuming probiotics on constipation and gut symptoms (such as abdominal pain and bloating) in children or young people with DS. It is well established that children or young people with DS commonly report chronic constipation, in addition to other gut symptoms, but there is very little research exploring therapeutic options beyond medications such as laxatives. Probiotics are live bacteria that have been shown to influence the gut and gut microbiome (the trillions of microbes found mostly in the large intestine which are crucial for health and wellbeing). We believe the results of this study could be important for the future management of constipation and gut symptoms in children and young people with DS.

Who are we recruiting?

We are looking for children and young people (anyone aged under 18 on 1 Jan 2022) with DS. To be eligible, participants will have diagnosed constipation with or without other gut symptoms.

How many participants are we recruiting?

We would like to recruit around 500 participants. If significantly more participants sign up we may select who we enrol based on a number of eligibility criteria.

Does your child or young person have to take part?

No. Your child or young person's participation in this study is voluntary and it is entirely up to you whether they take part. Even if you do decide they will take part, you can change your mind at any time and they can withdraw from the study without giving a reason. Any decision not to be involved in the study at any time will not affect the standard of care they receive now or in the future. If you agree for your child or young person to take part you will be asked whether you are happy for them to be contacted about participation in future studies. Their participation in this study will not be affected should you choose not to be re-contacted.

What will happen if your child or young person does take part?

The study will involve your child or young person taking a liquid probiotic (70 mL) every day for 12 weeks, first thing in the morning on an empty stomach. The probiotic that will be provided is from a trusted and well-known probiotic manufacturer. The probiotic will be supplied free of charge and delivered direct to your door. You will be asked to rate your child or young person's stool frequency and consistency at the start of the trial, and at 4 weeks, 8 weeks and 12 weeks, using a standardised scoring system that we will provide.

You will also be asked to complete an additional questionnaire at the start and the end of the trial period (these should take no more than 5 mins to complete). An optional component of the study is for your child or young person to provide a small stool sample at the start of the trial, midway through the trial (approx. 6 weeks) and at the end of the trial (12 weeks) so we can determine the exact proportion of microbes in your child or young person's gut microbiome. We have the capacity to measure stool samples from 40 participants so if you would like us to consider your child or young person for inclusion in this part of the study, please indicate so on the enrolment form (see below).

What are the possible benefits of taking part?

The results of this study may help to answer scientific questions about the effects of probiotics on constipation and gut symptoms in children and young people with DS. This may therefore help your child or young person and other people in the future, as the probiotic supplement may help improve these symptoms and reduce or avoid drug treatments or medications that may have unpleasant or adverse side effects. We also believe that improving gut function in children and young people with DS will help with long-term health.

What if my child or young person is on medication?

Your child or young person should continue to take all medication(s) (including laxatives) as prescribed by their doctor, although you may adjust the dose of laxatives (up or down) as the study progresses if you feel it is appropriate to do so. We will ask you to record the medications your child or young person is taking at the start and end of the trial. If you have any concerns about medications, side-effects and/or any other aspect of this study you should speak to the project lead (contact details below).

Will my child or young person's participation be kept confidential?

Your child or young person's participation in the study will be completely confidential. We will ask you for your name and address details, so that we can contact you during the study and send you the probiotic. You will also be assigned an identification number and only this number, NOT your name, will label your completed questionnaires, and other paperwork. Your data will be kept confidentially in line with the General Data Protection Regulation (GDPR) requirement and your personal details will not appear anywhere in any publication or description of our findings. Personal data and unidentifiable research data will be kept for 10 years on a research database and when you consent to this study, you will be asked if we may contact you in the future about follow up studies to this project or ethically approved research studies of a similar nature.

What will happen if I don't want my child or young person to continue with the study?

Taking part in this study is entirely voluntary and your decision will in no way affect your child or young person's current or future care. You will not lose any of your legal or ethical rights. You may withdraw from the study at any time without affecting your child or young person's routine clinical care and you are not obliged to give reasons. However, if you withdraw because of a side effect please inform the research team. You may be withdrawn from the study if it is considered in your best interests. If you withdraw from the study, we will need to use the data collected up to your withdrawal.

If I opt my child or young person in to stool analysis, what will happen to their stool samples?

The stool samples will have no personal details on them, so your child or young person's identity will not be recognisable; your child or young person will be identifiable only by a code, which only the researchers will have access to. Only members of the research team will have access to your samples. Stool samples may be stored in a secure freezer for up to 2 years, as they may be valuable for future research. If we wish to use these remaining samples in future research studies, we will contact you to ask for your consent to do so. After they have been used, or after 2 years, your samples will be destroyed.

What will happen to the results of the research study?

UCL has partnered with Down Syndrome UK, Positive About Down Syndrome, Down's Syndrome Research Foundation UK and 21Together to help us reach out to the Down's syndrome community. We will publish

the results of the study in an international research journal and will disseminate results to the Down's syndrome community through the media and our charity partners. Your child will not be identified in any publication.

Who is organising and funding the research?

The team from University College London (UCL), led by Prof Simon Gaisford, is working in collaboration with a well-known and trusted probiotic manufacturer for this research. The UCL team will run the project.

Do you have further information about the trial?

Prof Gaisford has prepared a short video that explains the research project in more detail which can be viewed on YouTube using the following link;

<https://youtu.be/QTxpwmUt2nY>

If you have any further questions, then please write to Prof Gaisford at the email address below.

I'd like my child or young person to participate, what should I do?

Participation in the research is entirely voluntary and it is up to you to decide whether or not to allow your child or young person to take part. If you decide for your child or young person to take part you will be asked to give your consent. **Remember, if you do decide for your child or young person to take part you are still free to withdraw them at any time and without giving a reason.** You may also withdraw any data or information you have already provided up until it is transcribed for use in the final publication. You can request this by writing to the project lead.

If you are interested in your child or young person taking part, then you can enrol them online by filling in the form available here;

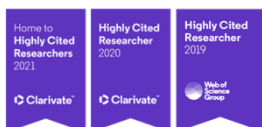
<https://forms.office.com/r/7XjuBT1x7B>

Team contact details

The project will be led by Professor Simon Gaisford (University College London) who can be contacted at any time should you require further details about the study. Once enrolled, you will be assigned a project coordinator, who will keep in regular contact.

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Thank you for taking the time to read this information.