



St Mary's
University
Twickenham
London

PARTICIPANT INFORMATION SHEET

A randomised controlled trial of the effects of a probiotic drink in children with ADHD

You and your child are invited to take part in a study investigating the effects of a probiotic drink on symptoms of ADHD in children. This research is being conducted by Dr Kate Lawrence at St Mary's University Twickenham, London. The purpose of this information sheet is to tell you about the study, and what will be involved. Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

THE PURPOSE AND VALUE OF THE RESEARCH PROJECT

Research suggests dietary manipulations may be a helpful treatment option for children with ADHD, although the most effective are highly restrictive, with little known about why they might work. One theory is that they may work by altering the balance of bacteria that live within the gut. Optimising the gut bacteria in individuals with ADHD may help alleviate some of the symptoms of this condition via the gut-brain-axis. A probiotic fermented dairy drink has been associated with an increase in beneficial gut bacteria. The purpose of this study is to assess the effect of six weeks daily probiotic drink consumption on symptoms such as hyperactivity, sleep disturbance and attention which are associated with ADHD.

CAN MY CHILD PARTICIPATE IN THE RESEARCH PROJECT?

Participation in the research is voluntary and open to children aged 8 to 13 years of age with a previous **diagnosis of ADHD from a health care professional**.

Your child will not be eligible to participate in the study if any of the following apply:

- Child is currently taking ADHD medication (such as methylphenidate)
- Child is currently undergoing a course of behavioural therapy
- Child has a milk allergy or intolerance
- Child has been diagnosed with, or is suspected of suffering from, an auto-immune condition

- Child has been diagnosed with, or is suspected of suffering from, a gastrointestinal disorder such as Inflammatory Bowel Disease or Coeliac disease.
- Child has taken a course of antibiotics, probiotics, antifungals or steroids within the last four weeks.

If you are unsure whether your child is eligible to take part, please discuss this with the researcher.

You and your child are free to refuse to participate and to withdraw from the study at any time. If you do not wish to take part or would like to withdraw please inform the research team in person, or email ADHDResearch@stmarys.ac.uk

THE STUDY

- **Intervention** - If you and your child agree to participate, your child will be asked to drink either 125ml of a probiotic dairy drink every day for six weeks or 125ml of a placebo dairy drink. Allocation to the probiotic or placebo group will be at the time of enrolment and will be random. Participants and the primary researchers will be blinded to which group participants are allocated to throughout the trial. The drinks will be delivered to your home at regular time points. You will be able to mix the drink into a smoothie or sweeten with honey if your child would prefer.

The week before starting the drinks and again in the last week of having the drinks, testing will be conducted. This will involve:

- **Questionnaires** - You will be asked to complete an online survey about your child which measures your child's behaviour, sleep habits and gastrointestinal symptoms. This should take approximately 30 minutes. Your child will be asked to complete an online questionnaire about their sleep and your child's teacher will also be asked to complete a short online questionnaire (18 questions) about your child's behaviour.
- **Sleep/activity monitoring** - Your child will be provided with an activity tracker watch to wear for the first and final week of the study. This will record their activity during waking periods and sleep. We also ask for a short (paper) sleep diary to be completed by yourself and your child during these weeks.
- **Attention Task** - Your child will be assessed on a short (approximately 6-8 minutes) online measure of attention, the Go/No-Go test.
- **Stool sample** - Your child will provide a small stool sample to be sent to a lab for microbiome analysis. Full instructions and equipment will be provided and this will simply involve collecting one small sample of poo in your own home and transferring this to a small tube.

RISKS OF TAKING PART IN THE RESEARCH

Some people may experience bloating and an increase in gas when they start to consume fermented foods such as probiotic drinks, this is generally temporary and can be managed

by reducing the initial dose for a few days then increasing slowly to the full amount. The research team will be available to discuss any concerns throughout the trial and you and your child are free to withdraw at any time.

POTENTIAL BENEFITS OF TAKING PART IN THE RESEARCH

Half of the children will receive a free supply of the probiotic drink for six-weeks. The drink may potentially elicit some improvements in the symptoms of ADHD. Monitoring sleep may provide you with valuable information about any difficulties in this area.

PARTICIPANTS' RIGHTS

You have the right to have your questions about the study answered (unless answering these questions would interfere with the study's outcome). If you have any questions as a result of reading this information sheet, you should ask the researcher before the study begins. Participation is entirely optional. You have the right to refuse to answer or respond to any question. You may decide to withdraw from the research study at any time without explanation. Up until the point that the data have been analysed, you have the right to ask that any data you have supplied be withdrawn/destroyed.

CONFIDENTIALITY/ANONYMITY

Your data will be kept confidential within the research team or shared only with carefully selected bona fide researchers. All data collected will be anonymised, meaning that the data collected from you will not be stored with your personal data from which you could be easily identified such as your name, address and email. Data collected online during the two testing periods will be anonymous using a unique ID and collected on GDPR compliant systems and stored securely on the St Marys University IT systems. Once anonymised, the data may be made available to researchers via accessible data repositories and possibly used for novel purposes. Any publications resulting from this study will be done so with all participant data anonymised so that it will not be possible to identify you or your child from the report.

FEEDBACK & CONTACT

If you wish to be informed of the overall results from the study, this can be requested at the end of the study. Dr Kate Lawrence, of St Mary's University, is leading this study and will be glad to answer your questions about this study at any time. You may contact her by Email: ADHDCResearch@stmarys.ac.uk. Or text 07864063242.