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Title of Project: The Impact of GABA and L-Theanine in Tea on Symptoms of Autism.

Principal Investigators:

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We would like to invite you and your child/person you care for to be part of our research project. You will only be included if you want to be; choosing not to be included will not disadvantage you or the person you care for in any way. Before you decide whether you want to be included, it is important for you to read the following information carefully and discuss it with others if you wish. We have also included a symbol information sheet which you may use to help the child to understand what the study involves, and to help them to decide whether they would like to take part. Please ask us if there is anything that is not clear or if you would like more information.

What is the study about?

We are exploring the impact of GABA (gamma-aminobutyric acid) and L-Theanine on the severity of Autism in children with autism spectrum conditions (ASC). The aim of this research is to explore the impact of GABA and L-Theanine (which can be found in certain teas) on sleep, anxiety levels, sensory reactivity, coordination and emotion processing in children with ASC. Increasing our understanding of GABA and any beneficial effects on Autism could inform new interventions to help children with ASC.

We need help from children with a diagnosis of ASC (or who are on the pathway for diagnosis), aged between 6 and 12 years old.

What will happen to me if I take part?

You will need to attend Coventry University four times in total, with each visit three weeks apart. The first visit involves a one-hour observation of your child in order to confirm ASC diagnosis. If you have already participated in Autism research at Coventry University previously and recently this assessment may not be necessary. This will be followed by tests of non-verbal and verbal reasoning, and language understanding. This visit should take around 1:30 hours in total.

The second part of the study consists of the introduction of the following three tea conditions in a random 'blind' order i.e. you will not be aware of which tea is used in each condition: GABA, L-Theanine or the placebo. The duration of each condition will be two weeks, where your child will be asked to drink a cup of tea four times per day, with each main meal and an hour before bed. Parents / carers will be provided with the tea and advised on dosage and brewing time. The tea may be brewed and cooled then added to the child's favourite fruit squash if preferred. The first week of each condition will allow for the tea supplementation to take effect. For the second week, you will be instructed to put an actiwatch (a movement monitor) on your child's wrist to measure their sleep quality and duration. Your child will also be asked to fill in a daily friendly Anxiety diary throughout each condition. On the final night we will ask you to collect three saliva samples: one in the afternoon, one just before bed, and one as soon as your child wakes in the morning. These will be done by dribbling into a tube, which we will provide you with. We will be analysing these for melatonin (a sleep hormone) and cortisol (a stress hormone) to see whether the tea affects sleep or stress.

Following each tea condition, you will need to return to Coventry University, where we will carry out the following tests at each visit to see whether there is any difference after drinking different kinds of tea. These visits should take around 30 minutes each.

1. An Autism severity rating scale questionnaire to be filled in by the parent / carer, consisting of 15 items to measure social communication
2. A short sensory questionnaire to be filled in by the parent / carer consisting of 38 items to measure sensory reactivity

3. A measure of movement that actively assesses balance, manual dexterity and aim, to measure coordination

In our experience, children find the tasks fun and engaging. All of the researchers are highly experienced in conducting research with children with a diagnosis of ASC, and will always judge the willingness of the child to participate, to ensure they have a great experience.

You can opt to receive a report on the outcome of the assessments if you wish. We may also need to video tape some of these assessments, to be reviewed after the session by our research team.

Will I be reimbursed?

Unfortunately we are not able to reimburse your travel costs, but for each visit your child will receive a £10 Love2Shop voucher (£40 in total) as a token of thanks for their effort and support. This can be spent at a range of high street stores including Argos, Early Learning Centre and Toys 'R' Us.

Who will have access to information about me?

All data will be collected and stored in accordance with the Data Protection Act 1998. All information about you and your family - names, contact details, and results of assessments - will be kept securely, in a locked filing cabinet within a secured, locked office, which only the people involved in the study will be able to access. Your child will be given a code which we will use instead of their name on all test results so that it will not be possible to identify which results belong to your child. Information about you will not be shared with anyone else unless you give us permission, in writing. Videos and audio recordings of assessments will only be viewed by the study research team for further review, unless you consent for these recordings to be used to help train other researchers at Coventry University.

What will happen to the study results?

Results will be presented at conferences and written up in scientific journals. Results are presented in terms of groups of individuals. This means that no one will be able to identify you or your family from reading an article, or watching a presentation about the study results.

Leaving or stopping the study

If you and the person you care for decide to be part of this research, you can request to be removed from the study at any time, even after the study has been completed, without giving a reason, and request for your data to be destroyed by contacting Penny Hannant or Dr Anna Joyce using the contact details above.

Ethical approval

This study has received ethical approval from the Psychology Research Ethics Committee of Coventry University, which means that we conform to strict UK ethical guidelines for managing the protection of participants, their confidentiality, the researchers and the University.

Questions?

If you have any questions about the study, or would like to take part, please contact Penny Hannant or Dr Anna Joyce using the contact details above.

Thank you for considering being part of this research project.

With Thanks and Best Wishes,



Penny Hannant

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