ISRCTN72571312 https://doi.org/10.1186/ISRCTN72571312

A placebo controlled pilot study to explore the affects of GABA tea on children with autistic spectrum conditions

Submission date
14/11/2017

Recruitment status
No longer recruiting

Registration date
21/11/2017

Overall study status
Completed

Last Edited
08/05/2019

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Autism is a common neurodevelopmental disorder, affecting 1% of the population. There is a lack of evidence-based treatments for commonly experienced difficulties with sleep, sensory processing, and movement in autism. The impact and significance of finding a natural 'treatment' that could alleviate these symptoms and improve quality of life would be wide-reaching and welcome to families. Gamma-aminobutyric acid (GABA: an inhibitory neurotransmitter) is significantly reduced in individuals with autism and has been implicated in difficulties with sleep, anxiety, sensory and motor skills in autism. However, no studies have yet investigated how increasing GABA may positively impact sleep, anxiety, sensory and motor skills. A previous study showed that an oolong tea supplement increased GABA in rats, alongside increasing sensory and motor skills. This novel study uses an oolong tea supplement to increase GABA in children with autism. This was expected to lead to increases in melatonin, decreases in cortisol and associated improvements in sleep, anxiety, sensory and motor skills.

Who can participate?
Children younger than 14 who have a diagnosis of autism.

What does the study involve?
Participants attended Coventry University four times in total, with each visit three weeks apart. The first visit involves a one-hour observation of the child in order to confirm ASC diagnosis. This is followed by tests of non-verbal and verbal reasoning, and language understanding. The second part of the study consisted of the introduction of the following three tea conditions in a random order GABA, L-Theanine or the placebo. Participants are asked to drink a cup of tea four times per day, with each main meal and an hour before bed. Parents are provided with the tea and advised on dosage and brewing time. Following seven days of tea, the child wears an actiwatch for seven days. At the end of the second week of drinking the given tea, the parent collects and freezes the saliva samples from their child. Parents and children then return to the University with their saliva samples, actiwatch and sleep diary. After having each type of tea, participants return to the university where they are assessed for their autism severity, sensory sensitivity and movement.

What are the possible benefits and risks of participating?
The benefits of taking part in the study included a £10 Love2Shop voucher (£40 in total) each time they visited the University. There were no known risks for taking part in this study as GABA in such small quantities is not considered to have any side effects.

Where is the study run from?
Coventry University (UK)

When is the study starting and how long is it expected to run for?
September 2015 to September 2017

Who is funding the study?
Coventry University (UK)

Who is the main contact?
Ms Penny Hannant

Contact information

Type(s)
Public

Contact name
Ms Penny Hannant

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Additional identifiers

Protocol serial number
P25753

Study information

Scientific Title
A double-blind, placebo-controlled, crossover-designed GABA tea pilot study in children diagnosed with Autism Spectrum Conditions

Study objectives

This novel study uses an oolong tea supplement to increase GABA in children with autism. This is expected to lead to increases in melatonin, decreases in cortisol and associated improvements in sleep, anxiety, sensory and motor skills

Ethics approval required
Old ethics approval format

Ethics approval(s)
Coventry University Ethics Committee, 14/03/2016, ref: P25753

Study design
Randomised cross over double-blind study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Autism Spectrum Conditions

Interventions
Nine children aged 6-14 years with a diagnosis of autism participatein the study. This was a repeated measures design with all children participating in three conditions: oolong tea high in GABA, oolong tea high in L-Theanine and oolong tea with as low GABA as possible (control condition). A double-blind procedure ensured the rigour of the methodology, whereby neither the researchers nor the participants will know which order they are participating in each condition, so eliminating researcher bias and participant expectancy effects.

After parental consent to take part in the study is obtained, the parent and child are invited to an assessment session at the University. During this session trained researchers carry out the following assessments: ADOS-II, BPVS III and WASI-II non-verbal subsets.

The three teas are:
1. GABA Oolong (GABA 279mg/100g, L-Theanine 104.48mg/100g);
2. Placebo Jiao Gu Lan (GABA 157mg/100g, L-Theanine 0mg/100g);
3. L-Theanine Gyokuro Green (GABA 156mg/100g, L-Theanine 1340mg/100g).
Counter balanced by randomly assigning order of teas 1 to 3. Children 1,2 and 3 were given tea in the order A,B,C; children 4,5,6 were given tea in the order B,C,A and children 7,8,9 were given tea in the order C,B,A. Participants are asked to drink a cup of tea four times per day, with each main meal and an hour before bed. The tea could be brewed and cooled then added to the child' s favourite fruit squash if preferred.

Following this the parent is given the first tea, saliva collection devices and tubes, an actiwatch, sleep diary, and full written instructions. The first week of each condition allows for the tea supplementation to take effect. For the second week, the parent put an actiwatch (a movement monitor) on their child's wrist to measure their sleep quality and duration. On the final night the parents collect three saliva samples form their child: one in the afternoon, one just before bed,

and one as soon as the child woke in the morning. This is done by dribbling into a tube, which are provided. These are analysed for melatonin (a sleep hormone) and cortisol (a stress hormone) to see whether the tea affects sleep or stress.

Following each tea condition, the participant returns to Coventry University, where they are tested to see whether there is any difference after drinking different kinds of tea. These visits took around 30 minutes each.

The participant's parent completes the SP and ASRS based on their child's behaviour during the previous 2 weeks alone, whilst the child completed the MABC2 with the examiner. They are then provided with the next tea, saliva collection devices and tubes, another actiwatch, sleep diary, and written instructions. This process is followed by a washout week before starting again with the second and third teas. Thus, the process lasts eight weeks. At the end of the eighth week the parent is also asked to write down which tea they felt was most beneficial and which tea was not. This is not shown to the examiner and is sealed in a folder until the end of the study.

Intervention Type
Other

Primary outcome(s)
Autism severity (including social communication, unusual behaviours, anxiety and rigidity) are measured using the ASRS (6-18 Years, Parent form) at the end of the second week of each tea condition

Key secondary outcome(s))
1. Sensory responsivity is measured using Sensory Profile 2 at the end of the second week of each tea condition
2. Coordination (manual dexterity, aiming and catching and balance) is measured using The Movement Assessment Battery for Children at the end of the second week of each tea condition
3. Sleep quality, duration and timing measured using Actigraphy sleep monitoring for the duration of the last week of each tea condition
4. Melatonin and cortisol levels are measured using hormone assaying at the end of the second week of each tea condition using saliva samples form the last afternoon, evening and following morning

Completion date
01/09/2017

Eligibility

Key inclusion criteria
1. Diagnosis of ASC
2. No known co-occurring ADHD, genetic or medical conditions
3. No current medication
4. A willingness to drink tea
5. The ability to wear a watch without tactile sensitivity
6. Younger than 14 (due to a large increase in testosterone levels after this point (Mayo Foundation for Medical Education and Research website, 1995-2017))
7. Both parent and child commitment to four university visits and precise tea making and drinking requirements

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Upper age limit
14 years

Sex
All

Total final enrolment
9

Key exclusion criteria
1. No diagnosis of ASC
2. Known co-occurring ADHD
3. Genetic or medical conditions
4. Current medication
5. An unwillingness to drink tea
6. Difficulty in wearing a watch due to tactile sensitivity
7. Older than 14 (due to a large increase in testosterone levels after this point (Mayo Foundation for Medical Education and Research website, 1995-2017))
8. Both parent and child uncommited to four university visits and precise tea making and drinking requirements

Date of first enrolment
01/09/2016

Date of final enrolment
01/04/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Coventry University
Coventry
United Kingdom
CV1 5RW

Sponsor information

Organisation
Coventry University

ROR
https://ror.org/01tgmhj36

Funder(s)

Funder type
University/education

Funder Name
Coventry University

Alternative Name(s)
CU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Penelope Hannant, Centre for Innovative Research Across the Life Course Coventry University at ab7758@coventry.ac.uk. Data will be in SPSS format. Data will be available 1 week after request and will need to destroyed within three months from receipt. Data will only be available to those with written request on academic headed note paper, providing a brief summary for application of data set. It should be considered that this study was very robust with a small number of children and as such an large amount of confidential information is included in the data.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2021	08/05/2019	Yes	No
Participant information sheet	version V4	15/11/2017	22/11/2017	No	Yes
Participant information sheet	version V4	15/11/2017	22/11/2017	No	Yes