**INFORMATION TO PARTICIPANTS INVOLVED IN RESEARCH**

**You are invited to participate**

Your child is invited to participate in a research project entitled **‘The Effect of Diet and Nutritional Supplementation on Behaviour, Brain Activity and Attention/Thinking in Attention Deficit Hyperactivity Disorder (ADHD)’.**

This project is being conducted by student researcher/PhD candidate Jordan Hince under the supervision of Dr Michelle Ball and Professor Dorothy Bruck from the College of Arts (Psychology) at Victoria University, Dr Jacques Duff (Behavioural Neurotherapy Clinic) and Dr Henry Butt (Bioscreen Medical).

**Project explanation**

The aim of this study is to assess whether changes in diet together with nutritional supplements improve symptoms in ADHD. We will be testing children who have a diagnosis of ADHD both before and after a six month intervention to see whether any improvements can be observed in their thinking (including attention), sleep, brain activity, and behaviour. We will also be looking to see if changes in the diet causes differences in the composition of different bacteria within the large bowel that may indicate an improvement in gut health (as measured through faecal analysis).

Details about the dietary intervention and the nutritional supplements have been attached to this information form. This includes specific details about each supplement and the diet itself. A sheet outlining the risks associated with the nutrients has also been attached, although the nutrients being used in this study are generally considered to be safe and any serious adverse effects are unlikely.

**What will I be asked to do?**

If you are interested, participation in this study will involve a 6 month commitment for you and your child. First we will undertake some screening to confirm your child’s diagnosis with ADHD. Once this is confirmed we will be asking you to take part in a treatment and testing program that will take place at the Behavioural Neurotherapy Clinic in Doncaster. Please note that you are free to decide to have your child treated at the Behavioural Neurotherapy Clinic independent of this study, and that if you decide not to take part your child will not be disadvantaged in any way. If you do decide you would like your child to take part then throughout a six month period we will be asking you to come to the Clinic at least six times. The six visits will include the following:

*Visit 1*

This will be your first appointment where your child will meet for the first time with Dr Jacques Duff. He will explain the dietary and nutritional supplementation requirements of the study to you and answer any questions you may have about the treatment protocol. Dr Duff is a Registered Psychologist and also Neuroscientist and Nutritionist. We will ask you not to start your child on the diet and supplements until after your next visit. He will also provide you with a kit and instructions on how to collect a faecal sample from your child that will be sent by courier to Bioscreen Medical for analysis. We would like this to be done on the day before your next visit.

*Visit 2*

This should preferably take place on a Friday within 14 days of your first visit. At this visit you will meet Jordan Hince who is the student researcher on this project, which will form the basis of his PhD. Jordan will conduct some attention and thinking tests with your child. He will also measure your child’s brain activity using something called a QEEG. This requires your child to have an electrode cap fitted to their head that will measure the electrical activity within their brain while they are resting. We will ask you to make sure that your child’s hair is washed thoroughly without using conditioner on the morning of this visit to minimise the possibility of interference. Altogether the testing with your child (both thinking and QEEG) should take no more than two hours. While this is happening we will also be asking you to fill out two questionnaires about different aspects of your child’s behaviour.

Jordan will also be supplying you with an actiwatch at this visit. This is a device to be worn by your child on their wrist when they go to sleep at night (but can be taken off during the day if preferred). It will provide information about how much they move in bed, which can be used to inform us about the quality of their sleep. We will ask your child to wear this device for seven consecutive nights from the day of this visit. Jordan will supply you with an Express Post envelope to return the actiwatch to Victoria University (VU) after the 7 nights are completed.

*Visits 3-5*

Your child will have an appointment with Dr Duff every two months after the first visit to monitor how well things are going with the diet and nutritional supplements. You should feel free to discuss any problems you or your child is having with the treatment protocol or their behaviour at these visits. On visit 5 Dr Duff will provide you with another kit to collect a faecal sample from your child before your next visit.

*Visit 6*

You will see Jordan again on your sixth visit. He will repeat the same tests as at your first visit including the thinking and attention tests, QEEG, and behavioural questionnaires. He will once again give you an actiwatch to collect 7 days of sleep activity from your child and an Express Post envelope to return the device to VU.

You will also be asked to complete a simple diet compliance diary each month which will give you the opportunity to monitor your child’s diet and take note of any particular issues or challenges you may face. For ease of completion, this diary will be made available to you online.

**What will I gain from participating?**

Although we can promise no direct benefit to you or your child, it is hoped that results of this study will contribute to the understanding of the relationship between diet, nutrition, the gut and ADHD related behaviours. In this way you will be helping to advance the knowledge of the proposed connection between them. In particular it is hoped that results will provide knowledge about whether something as manageable as a dietary intervention could lead to improved outcomes for children with this diagnosis.

**How will the information I give be used?**

The information provided will be used for research publications, conferences presentations and contribute towards Jordan’s PhD thesis. Your child will be assigned an ID number at the beginning of the recruitment stage which will be used to identify them throughout all tests and analyses. Only group data will be published so no individual child will be identified.

**How will the study be conducted?**

This study aims to make scientific observations of your child both before and after a six month dietary and nutritional supplementation intervention as outlined above. If you have any questions about any aspect of this study, please do not hesitate to contact us via the details provided below.

**What are the potential risks of participating in this project?**

There are some minor risks associated with your child’s participation in this study.

* Although unpleasant, if you carefully follow the instructions for collecting the faecal sample from your child the risk of contamination is negligible
* There is a small risk that your child’s scalp may be irritated by the placement of the electrode cap. In the unlikely event that this becomes painful or persistent we will ask you to consult with your pharmacist or GP.
* There is also a small risk that your child’s skin may be irritated by the actiwatch. This is very rare, but should it occur we will not expect your child to continue wearing the watch meaning that we will not collect information about their sleep.
* There is also a small risk that your child may become irritated during the testing procedures with Jordan on Visits 2 and 6. Please be assured that all of these tests are commonly used in children with ADHD without major problems. However should your child become upset we will of course give them time to calm down. We will also ask that you remain present during testing so you can provide comfort to your child if necessary.
* The nutrients provided for the study also have some negligible risks associated with there use, an attached to this form outlines the warnings provided on each products label.

**Eligibility criteria .**

In order to be eligible for participation in this study your child must be aged between 6 years and 13 years of age. When you call to register your interest in the study we will conduct a short screening questionnaire about ADHD to confirm your child’s eligibility. Children diagnosed with other significant disorders will not be included.

**Who is conducting the study?**

The study is being conducted by Dr Michelle Ball, Professor Dorothy Bruck and PhD candidate Jordan Hince from the College of Arts (Psychology) at Victoria University, together with Dr Jacues Duff from the Behavioural Neurotherapy Clinic and Dr Henry Butt from Bioscreen Medical. Contact details for these people appear below.

**If you are interested in your child participating in this study please contact Jordan Hince on 0433 641 687 prior to your first visit to the Behvaioural Neurotherapy Clinic to register your interest and confirm their eligibility.**

Dr Michelle Ball Prof Dorothy Bruck Jordan Hince

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Dr Jacques Duff Dr Henry Butt

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Any queries about your participation in this project may be directed to the Chief Investigator listed above.

If you have any queries or complaints about the way you have been treated, you may contact the Ethics Secretary, Victoria University Human Research Ethics Committee, Office for Research, Victoria University, PO Box 14428, Melbourne, VIC, 8001, email researchethics@vu.edu.au or phone (03) 9919 4781 or 4461.