

HREC Project Number:	20495		
Short Name of Project:	Cognitive Training in ADHD		
Full Name of Project:	Cognitive Training in Children with Attention-Deficit/Hyperactivity Disorder: A Randomised Control Trial		
Principal Researcher:	Dr Hannah Kirk, Monash University		
Version Number:	7	Version Date:	21 st July 2021

Thank you for taking the time to read this **Parent/Guardian Information Statement and Consent Form**. We would like to invite your child to take part in a research project that is explained in this form.

This form is 7 pages long. Please make sure you have all the pages.

What is an Information Statement and Consent Form?

An Information Statement and Consent Form tells you about the research project. It explains exactly what the research project will involve. This information is to help you decide whether or not you would like your child to take part in the research. Please read it carefully.

Before you decide if you want your child to take part or not, you can ask us any questions you have about the project. You may want to talk about the project with your family, friends or health care worker.

Taking part in the research project is up to you

It is your choice whether or not your child takes part in the research project. You do not have to agree if you do not want to.

Signing the form

If you want your child to take part in the research, please sign the consent form at the end of this document. By signing the form you are telling us that you:

- understand what you have read
- had a chance to ask questions and received satisfactory answers
- consent to your child taking part in the project.

We will give you a copy of this form to keep.

1. What is the research project about?

Attention problems have a significant impact on cognitive development and educational achievement. We know that developing and strengthening the attention and concentration skills of young children improves their learning capacity and academic outcomes. Long term attention problems are a common complaint among children with attention-deficit/hyperactivity disorder.

Cognitive training has been identified as a potential new treatment approach for children with ADHD. Cognitive training has been shown to improve aspects of attention in young children (4 to 8 years) with severe attention difficulties resulting from an intellectual disability. These improvements also translated into improved numeracy skills in children who used cognitive training.

The aim of the current project is to examine the effectiveness of a computerised cognitive training program in improving attention, broader cognitive skills (e.g. memory) and social skills in children with attention-deficit/hyperactivity disorder.

2. Who is running the project?

This project will be run through Monash University, for children who live in Melbourne and surrounding areas. The research team for this study includes researchers and psychologists from Monash University. The protocol for the study was written by the research team. This study is being funded by a Medical Research Future Fund (MRFF) grant.

Dr Hannah Kirk and Professor Kim Cornish are co-inventors of the intervention program. The intervention program is owned by a commercial company. None of the researchers are associated with this company and have no personal or financial interests in the outcomes of this project. Professor Mark Bellgrove, Dr Sally Richmond, Dr Beth Johnson, Ms Tori Gaunson and Ms Meg Bennett are independent researchers and as such do not have any personal or financial interests in the intervention program.

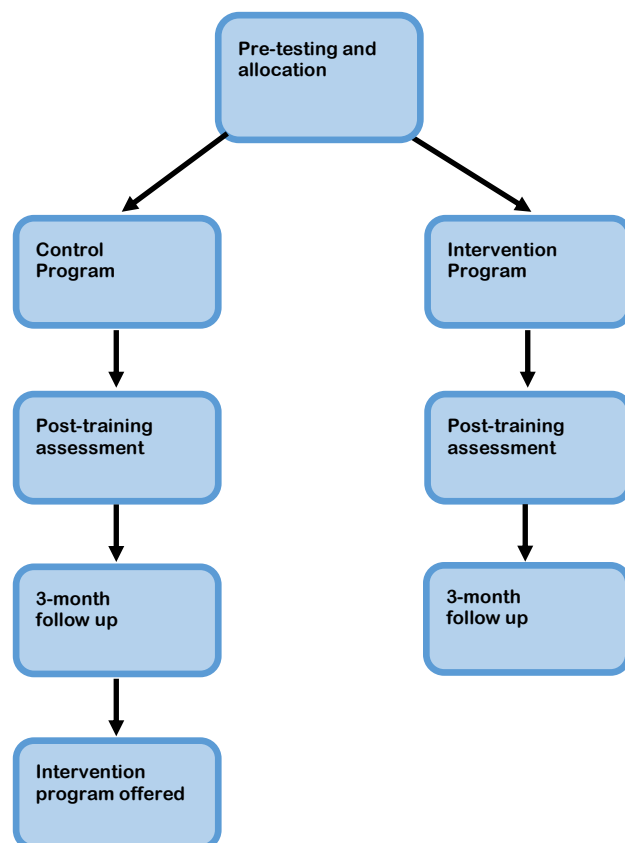
3. Why is my child being asked to take part?

We are inviting you and your child to participate in this project because your child is aged between 5 and 8 years and has been diagnosed with attention-deficit/hyperactivity disorder (ADHD).

4. What do my child and I need to do in this project?

You will be asked to complete a few short questionnaires to determine your child's eligibility. If your child meets the eligibility criteria they will have an individual attention, social and learning assessment either within the family home or at Monash University. We will ask your child to do computer and pencil and paper tasks to look at your child's thinking, learning and attention skills. We will also ask you to complete several questionnaires about you and your child. We are asking these questions because your child's sleep habits or your wellbeing, for example, might influence the results of the training program. The assessment will be carried out by a trained researcher and is expected to take no more than two hours to complete.

Your child will then be randomly allocated to one of two cognitive training programs a) the intervention program; or



b) a control program. This will be done by chance, similar to tossing a coin, so your child has an equal chance of being in either group. This is a double blinded study which means neither you, your child, nor the researchers conducting the assessment, will know whether your child is completing the intervention program or the active control task. This is done to ensure that results are accurate and not influenced by bias.

After completing the first assessment session, a researcher will provide you with a tablet to take home and use and set you up with your allocated program. All children will then complete their allocated program in the home under the supervision of a parent/guardian 5 days a week for 5 weeks. The programs both last for 20 minutes and run on computerised tablets (e.g. iPad). You will be provided with a tablet to use for the study. A researcher from the study will be contactable throughout the study to answer any questions you may have and address any concerns that may arise. You will be asked to keep any pharmacological or psychological treatments for the purpose of treating your child's inattention stable throughout this 5 week intervention phase. If changes to your child's treatment do occur, we ask that you inform the research team so that any modifications can be recorded.

After completing the program, you and your child will then attend assessment sessions 5 weeks after the start of the project and 3 months after the start of the project. You will be asked to complete some questionnaires about your child and yourself while they have an assessment. These questionnaires are designed to assess your child's attention and social communication and aspects of the family environment that might influence the results of the program. Each assessment session is expected to take no more than 2 hours to complete. It is important that neither you nor your child talk to the researcher conducting the assessments about the program your child has completed so that the study blind is maintained. Over the course of the study we may provide you with an additional form asking your permission for a student intern to observe your child's assessment sessions.

As children in the control group will be unable to experience the training program during the course of the study, children in this group will be sent a code to allow them access to the intervention program at the completion of the study should they be interested. This will enable them free access to 5 weeks of the training program to be used as desired on their own personal device.

5. Can my child stop taking part in the project?

Your child can stop taking part in the project at any time. You just need to tell us so. You do not need to tell us the reason why. If your child leaves the project we will use any information already collected unless you tell us not to.

6. What are the possible benefits for my child and other people in the future?

This project will help us assess whether cognitive training is feasible for use with children with attention-deficit/hyperactivity disorder and if it promotes improvements in attention and other cognitive skills in these children. It will also give families the opportunity to use a commercial and scientifically validated product at no cost. Whilst researchers hope to see improvements in attention following completion of the cognitive training program, it is possible that these improvements will not be seen and there will be no benefit.

7. What are the possible risks, side-effects, discomforts and/or inconveniences?

We do not anticipate any risks or side-effects from participation in this project. Participants may find the assessment sessions to be tiring, but we will give your child small breaks when needed. Participants will be encouraged to do their best and positive feedback will be given for effort.

We do not expect the questionnaires to cause any distress, however you and your child can skip any questions you don't want to answer. You are also welcome to look at the questions we plan to ask your child before we

ask them. Some of the questions for parents will ask about the safety of your child. We need to ask these questions because such experiences might influence the development of cognitive skills like attention. Please note that we are legally required to report suspected cases of child abuse. Please take time to consider this before deciding to answer these questions or take part in this research project.

If researchers notice a decline in the child's and/or parent's/caregiver's wellbeing during weekly check-ins, or during follow up assessment, they are able to provide a referral to an appropriate service for support. Alternatively, permission may be sought to notify your child's treating clinician to ensure that you and your child are being supported. Researchers may also consult with the Principal Investigators to determine whether it is in the child's best interests to be withdrawn from the study. Families can withdraw from the study at any time.

8. What will be done to make sure my child's information is confidential?

We respect your privacy; any information obtained in connection with this project will remain confidential. Only the researchers involved with this project can have access to this information. We can disclose the information only with your permission, except as required by law. In accordance with relevant Australian privacy and other relevant laws, you have the right to access and correct the information we collect and store about your child. Please contact us if you would like to access this information. The study information will be re-identifiable. This means that we will remove your child's name and give the information a special code number. Only the research team can match your child's name to their code number, if it is necessary to do so. When we write or talk about the results of this project (e.g. at a conference or a paper), we will report information about the whole group of participants only. This means that no one will be able to identify your child. Aggregate de-identified data from the study may be used as part of future research projects only where ethics approval has been granted.

All study information will be stored securely in a locked filing cabinet in the School of Psychological Sciences at Monash University. Your child's information and family contact details will also be stored on a restricted access, password-protected computer database. All paper-based participant and parent data will be disposed of in a confidential manner 15 years after the youngest participant turns 18 years old, as per Monash policy. De-identified electronic data collected both directly and derived from the paper-based information will be kept indefinitely for future analyses where consent from participants has been obtained.

9. Will we be informed of the results when the research project is finished?

You will receive a 6 monthly email newsletter that will update you on how the study is going and future research direction. At the conclusion of the study, a summary of your child's results will be provided to you if requested. The overall results of the trial will be included in a final email newsletter.

The research findings will be published in journal articles and conference proceedings. All data used for this purpose will be de-identified to protect the privacy of participants. If external researchers request data to verify our results, relevant de-identified participant level data will be available from the time of trial outcome submission for up to 20 years.

10. Will I be reimbursed for participating?

At the end of each assessment session, you will be reimbursed with a \$30 Coles-Myer voucher. An additional \$20 voucher will be provided to cover transport and parking costs per assessment visit where travel is required.

11. What if I have concerns and require support during the study?

If you have any concerns during the course of the study, please contact the research team and we will discuss access to appropriate support services. If you wish to access support independent of this research, below are the details of some general services that specialise in the area of childhood development.

Kids Help Line

www.kidshelp.com.au

1800 55 1800

Beyond Blue

www.beyondblue.org.au

1300 22 4636

SANE Australia Helpline

<https://www.sane.org/get-help>

1800 18 7263

ADHD Australia

www.adhdaustralia.org.au

12. Who should I contact for more information?

If you would like more information about the project, please contact:

Name: Tori Gaunson or Meg Bennett

Contact telephone: (03) 9905 5507

Email: Med.atica@monash.edu

Should you have any concerns or complaints about the conduct of the project, you are welcome to contact the Executive Officer, Monash University Human Research Ethics Committee (MUHREC):

Executive Officer
Monash University Human Research Ethics Committee (MUHREC)
Room 111, Chancellery Building D,
26 Sports Walk, Clayton Campus
Research Office
Monash University VIC 3800

Tel: (03) 9905 2052

Email: muhrec@monash.edu

Fax: (03) 9905 3831

CONSENT FORM

HREC Project Number: 20495

Short Name of Project: Cognitive Training in ADHD

Version Number: 2 **Version Date:** 30th November 2020

- I have read this information statement and I understand its contents.
- I understand what my child and I have to do to be involved in this project.
- I understand the risks my child could face because of their involvement in this project.
- I voluntarily consent for my child to take part in this research project.
- I have had an opportunity to ask questions about the project and I am satisfied with the answers I have received.
- I understand that this project has been approved by the Monash University Human Research Ethics Committee (MUHRC). I understand that the project and any updates will be carried out in line with the National Statement on Ethical Conduct in Human Research (2007).
- I understand I will receive a copy of this Information Statement and Consent Form.

OPTIONAL CONSENT

<input type="checkbox"/> I do	<input type="checkbox"/> I do not	consent for my child's de-identified data to be used in other related studies by Monash University
<input type="checkbox"/> I do	<input type="checkbox"/> I do not	consent to be contacted about future research projects related to attention-deficit/hyperactivity disorder

Child's Name

Child's Birthdate

Parent/Guardian's Title
(Ms/Mrs/Mr/Dr)

Parent/Guardian Name

Relationship
to child

Parent/Guardian Signature

Date

Telephone Number

Email

Home Address – Street Name and Number

Suburb

State

Postcode

Declaration by researcher: I have explained the project to the parent/guardian who has signed above. I believe that they understand the purpose, extent and possible risks of their child's involvement in this project.

Research Team Member Name

Research Team Member Signature

Date

Note: All parties signing the consent form must date their own signature.