MONASH University

Explanatory Statement for Parents/Guardians of Participants

Full Title:	Early assessment and intervention of childhood attention difficulties
Short Title:	TADA Project
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1. Introduction

You and your child are invited to take part in this study. This is because your child is between the age of 5 to 7 years and is experiencing either diagnosed (e.g. ADHD) or undiagnosed attention difficulties, and you have expressed an interest in the study.

This Explanatory Statement tells you about the study. Knowing what is involved will help you decide whether or not to participate in this research. If you would like further information about any part of this project, you can contact the research team at med-tada@monash.edu.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. If you decide not to participate it will not have any consequences for you or your child. If you decide to take part and change your mind, you can withdraw from the project at any time without any consequences for you or your child. If you choose to withdraw, we will use the information previously collected from you unless you inform us in writing that you do not want us to.

If you decide you would like to take part in the research project, please sign the attached Consent Form. By signing the consent form, you are telling us that you:

- Understand what you have read
- Have had a chance to ask questions and received satisfactory answers
- Consent to your child taking part in the research project (involving completing the assessments that are described)
- Consent to be involved in the research project (involving completing the questionnaires that are described)

2. What is the purpose of this research?

Attention skills provide the foundation for cognitive development and educational achievement. We know that early detection of attention difficulties and early intervention to strengthening attention is vital to improve learning capacity and academic outcomes. Current methods to assess and support attention in childhood are limited. They often require the involvement of clinicians, interventions are typically drug-based and assessments rely on behavioural rating scales, which are costly, time-consuming and don't provide information of the underlying causes of attention difficulties.

Monash University in conjunction with Tali Health and Torus Games have developed a world first touchscreen attention screening tool, Tali Detect, and a 5-week intensive attention training program, Tali Train. These digital tools aim to revolutionise the way attention skills are assessed and supported, early in childhood. These tools have been evaluated in typically developing children and children with

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intellectual disabilities, however to date they have not been evaluated in children with elevated attention difficulties, such as those with ADHD.

The aims of the current pilot study are:

1) To assess whether the novel digital assessment tool (Tali Detect) is an accurate measure of attention
2) To assess the feasibility of children with attention difficulties using a novel digital early intervention (Tali Train) at home over a 5-week period.
3) To assess the impact of the Tali Train program on core attention skills and inattentive/hyperactive behaviours in children with attention difficulties immediately after the 5-week intervention.
4) To investigate whether certain individual characteristics (e.g. age) predict the outcomes of training.

3. What does this research involve?

After you have expressed interest in participating in this study, we will give you a call or email to ask you a few questions regarding your child's eligibility in this study. Currently, we are looking for children between the ages of 5 and 7 years, and who display high levels of inattention.
Children who will be deemed ineligible to participate in this study include those who:

- are outside the ages of 5 and 7 years
- do not have any attention difficulties as reported by you
- have a diagnosed intellectual disability (have an IQ of below 70)
- have any visual, hearing, or physical impairments that would prevent them from understanding the assessment requirements or from completing the Tali Detect and Tali Train programs.

Once we have confirmed your child's eligibility in this study, you and your child will be invited to attend a baseline assessment session. This will involve the completion of a brief assessment of general cognitive skills known as the Kaufman Brief Intelligence Test (KBIT2; 15-20 minutes), Tali Detect (20-30 minutes) and an existing computerised assessment measure of attention (Test of Everyday Attention for Children; TEA-Ch 2; 30-40 minutes). The assessment will take no longer than 1 hour and 30 minutes, and can be completed at a location that best suits you.

Tali Detect consists of 7 game-based assessment tasks which measure children's ability to: focus, switch attention, inhibit impulsive responding, filter out distractors, and locate important information. The tool is delivered via a touchscreen tablet and incorporates interactive characters and rewards so that children aren't even aware they are completing an assessment.

In order to understand more about your child's typical behaviour, we also ask that you complete the Strengths and Weaknesses of ADHD and Normal Behaviour rating scale (SWAN; approx. 10 minutes) and either the Conners Early Childhood or Conners 3 Parent Rating Scale (approx. 20-30 minutes). These questionnaires will ask about your child's attention and associated behaviours.

Following the initial pre-training session, children will be provided with a portable touchscreen tablet to allow them to complete the Tali Train program at home. Tali Train is designed to be completed 5 times a week over 5 weeks, with each training session lasting approximately 25 minutes. Tali Train consists of 4 different training exercises that each target a vital attention skill: selection, focus, inhibition, and control. The exercises adjust in difficulty depending on the child's responses, ensuring

that the program is tailored to the abilities of each child. Children are guided through training by colourful characters, and the program includes an in-built reward system for motivation.

Upon completion of the training program, we will invite you and your child to attend a post-training assessment session (identical to the pre-training assessment session) to assess if any changes occurred in your child's attention over the course of training.

4. What are the possible benefits and risks of participating in this research project?

This project will help us to assess whether a novel attention screening tool (Tali Detect) is a valid assessment of attention abilities in early childhood. If the tool is shown to be valid, it offers the potential to transform the way childhood attention difficulties are assessed. This project will also help us to investigate the benefits of the Tali Train program in children experiencing attention difficulties. If the program is shown to be effective, then it provides a novel intervention to support attention skills in children (including those with ADHD). This is important given that untreated attention difficulties in early childhood can have a devastating and long-term impact on the developing cognitive system.

Individual benefits to participants will be provided through free access to the commercial Tali Train program, access to performance scores on cognitive and behavioural measures of attention, and a movie voucher as a token of appreciation for participants time and effort.

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.

5. Will my participation be kept confidential?

We respect your privacy; any information obtained in connection with this project will remain confidential. Only the researchers involved with this project and the Monash University Ethics Committee 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, in a thesis, 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.

6. How will my data be stored?

All study information will be stored securely in a locked filing cabinet in the School of Psychological Sciences at Monash University. All research data will be collected through the questionnaires and cognitive assessments as outlined in this Explanatory Statement. This data will be disposed of in a confidential manner after 5 years. Your child's de-identified information and family contact details will be stored indefinitely on a restricted access, password-protected computer database. Only combined de-identified data will be used for other projects conducted by the current research team where ethics approval has been granted.

7. Who is organising and funding the research?

This research study is being conducted in Melbourne as part of an honours research project and will be internally funded through Monash University School of Psychological Sciences. Dr Kirk and Professor Cornish are the co-inventors of Tali Train and the newly developed Tali Detect tool. As a result, both Monash University and the co-inventers receive a small amount of pre-defined royalties from Tali Health. Neither Dr Kirk nor Professor Cornish are involved with Tali Health and have not received funding from Tali Health to conduct this project.

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8. How can I access the results of this Research Project?

All participants can request access to their individual data by contacting the research team at med-tada@monash.edu. If you have consented to the research team contacting you via email then you will be sent the final report from the project which will present the outcomes of analysis of the whole de-identified dataset.

9. What if there are unexpected findings in my child's results?

If during the course of participation in this research, potential areas of concern are identified the researchers will notify you and discuss access to appropriate support services. If you wish to access support services independent of the outcomes of this research then below are the details of some general services that support childhood development:

Kids Help Line
www.kidshelp.com.au
1800 551800

Beyond Blue
www.beyondblue.rog.au
1300 224636

ADHD Australia
www.adhdaustralia.org.au

SANE Australia Helpline
https://www.sane.org/get-help
1800 18 7263

Further Information and Contact Information

If you would like further information concerning this project or if you have any problems during your involvement in the project, please contact the principal investigator, Dr Hannah Kirk:
Hannah.kirk@monash.edu

This study was approved by the Monash University Human Research Ethics Committee (project number 20491). If you have any concerns or complaints about the conduct of the project you are welcome to contact the Monash University Human Research Ethics Committee (MUHREC):

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