



EXPLANATORY STATEMENT

HREC Project Number: 21530
Short Name of Project: ALFI VR
Full Name of Project: ALFI VR - Training the vulnerable teen brain: Pilot study
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Version Number: 3 **Version Date:** 5 December 2019

You and your child are invited to take part in this study. Please read this explanatory statement in full before deciding whether or not to participate in this research. If you would like further information about any aspect of this project, please contact the researchers using the details listed above.

What is the research project about?

This study will investigate whether a new cognitive training program using Virtual Reality (VR) can help improve inhibitory control in teenagers who are experiencing either inattention, hyperactivity or impulsivity (e.g. behaviours associated with attention deficit hyperactivity disorder (ADHD)) or who have a diagnosis of ADHD. Inhibitory control is the ability to stop impulsive reactions, and to change your behaviour to suit a situation. This skill is incredibly important and allows us to control our emotions and behaviours, plan, and set goals. Difficulties with inhibition, which are common in children with ADHD, can affect both behaviour and thinking, and can cause a person to act impulsively or make it challenging to ignore distractions and pay attention.

In Australia, around 7% of all children and teenagers meet the diagnostic criteria for ADHD (approximately 312,000 based on 2016 population estimates). Additionally, attention difficulties are common among children without a diagnosis, with an estimated 13% of Australian children showing symptoms of ADHD (e.g. inattention, hyperactivity or impulsivity).

For 80% of children diagnosed with ADHD, symptoms will persist into their teenage years and for some, into adulthood. Symptoms such as heightened impulsivity, forgetfulness, and distractibility can have a significant impact on a teenager's learning, mental health, and social relationships. Furthermore, the intensified educational demands and social pressures associated with these years can leave a person particularly vulnerable without appropriate treatment. A recent report on ADHD found that over 800,000 Australians met the criteria for ADHD, and that each year the social and economic impacts of ADHD on Australian communities equates to approximately \$20 billion.

Many young people who have reached adolescence with attention disorders have not received suitable intervention or treatment early in their lives. Currently there is a lack of non-pharmaceutical interventions available for ADHD, with standard treatment often involving the use of stimulant medications. Although often very effective in the short term, some individuals can have unpleasant side-effects, and the long-term effectiveness is unclear.

Cognitive training is a promising alternative for individuals and families struggling with attention difficulties. Research suggests that improvements in the directly trained skill can be expected as a result of cognitive training interventions. VR-based cognitive training could be an engaging way to enable young people of all ages to reach their full potential without having to rely solely on pharmaceutical interventions.

Who is running the project?

The research team involved in this study includes researchers and psychologists from the Turner Institute for Brain and Mental Health, Monash University. This research and the development of this training program were funded by a philanthropic grant from the 5 Point Foundation. Dr Hannah Kirk, Dr James Coxon, Ms Danielle Courtney, Professor Mark Bellgrove, and Professor Kim Cornish were involved in the development of this program with an industry partner, Torus Games. Ms Erin McKay and Mrs Liz Nicolaou are independent researchers.

Why is my child being asked to take part?

We are inviting teenagers aged 13 – 18 who reside in Victoria to take part. We have approached your child's school about participating in this research, and the principal has given permission for us to distribute this information to all students and their families who might be interested in being involved.

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

Initially, parents will be asked to complete an online screening survey, which should take no longer than 50 minutes. This will include questions about your teenager's attention and behaviour, as well as general demographic information. Participants who are either (a) experiencing inattention, hyperactivity or impulsivity, or (b) have a formal diagnosis of ADHD will be invited to participate in the study.

Participation in this study will involve:

- Pre-training Cognitive Assessment: Teenagers completing a brief cognitive assessment at their school which should take no longer than 60 minutes.
- Pre-training Online Questionnaire: Parents/guardians completing some online questionnaires about your teenager's daily functioning, thoughts, behaviour, and wellbeing, estimated to take no longer than 45 minutes. Teenagers will complete similar questionnaires, estimated to take 35 minutes.
- 7 hours of VR based training or teaching as usual: On completion of these baseline assessments, your teenager will be randomly assigned to one of two groups, this is done similar to a coin toss, with a 50:50 chance of being in either group. One group will receive the training program, and one group will receive teaching as usual, and complete their normal classroom activities.
- Post-training Cognitive Assessment: Within one week of completing the training or control program, teenagers will be asked to complete a brief post-training assessment session at their school. This assessment will involve the same tasks completed at pre-training and should take approximately 60 minutes.
- Post-training Online Questionnaires: Parents and teens will also be asked to complete the same online questionnaires as at pre-training.

The overall time commitment required from participating families is estimated at 16 hours across one school term (approximately 9 weeks).

What is the training program?

The VR based program is an inhibitory control training program called ALFI-VR. The program uses virtual reality technology to deliver a game-based adaptive training experience. ALFI-VR comprises of different blocks or levels, each lasting approximately 6 minutes. As participants progress through the levels, they become more difficult. Teenagers assigned to the control condition will continue with their typical classroom activities.

During the training period, teenagers will attend two 30-minute training sessions per week, over the course of 7 weeks (total time required 7 hours). These sessions will be held at your teenager's school, and will be during school hours. Each session will be supervised by one of the research team, so your teenager will have the opportunity to discuss any concerns or questions.

Can my child stop taking part in the project?

You and your child have the right to withdraw from this pilot study at any time. Upon your withdrawal, any data which may have already been collected will be stored securely, for use in this pilot study and future analyses, unless you tell us not to do so.

How do my child and I consent to take part in the project?

If you and your child wish to take part in this research after reading this explanatory statement, please return the signed consent and assent forms. Your child can drop the completed form off at a designated box in their classroom, or you can complete a consent form online. A signed consent form must be returned to the research team before you can begin the study.

Please access the secure online consent form here: [insert link when active here]

As your child is under the age of 18, we are asking for a parent or guardian's signed consent to participate, as well as your child's signed agreement. Information has also been provided in this study information pack for your child in the form of a teen information sheet. After receiving the consent and assent forms, the researchers will contact you to confirm your interest, and provide an opportunity to ask any questions. Your child will be asked to confirm their assent in person at their initial assessment visit.

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

We cannot guarantee that you or your child will receive any benefits from this research; however, possible benefits of this intervention may include improvements in your child's inhibition or reduced impulsive behaviour, which could lead to improvements in mental health, educational outcomes and decision-making.

What are the possible risks?

There may be some risk of discomfort associated with participation in this study. Participants may become fatigued during completion of the assessment sessions, or experience 'cybersickness' while completing the VR training sessions. Potential temporary side-effects of cybersickness can include blurred vision, headaches, seizures, disorientation, drowsiness, apathy, nausea or dizziness. If cybersickness is experienced the researchers will immediately stop the training session and offer the participant the opportunity to complete the session after a short break. If required, the session might be stopped completely, and another appointment might be organised to complete the session. If symptoms of cybersickness persist across sessions, then researchers will discuss withdrawal from the study with the family.

Who can I speak with if we need support?

ADHD Support

ADHD Australia

Online: adhdaustralia.org.au

Crisis Support

Lifeline

Ph: 13 11 14

Online: lifeline.org.au

Kids Help Line

Ph: 1800 551 800

Online: kidshelp.com.au

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

Data will be collected in the form of questionnaires and cognitive assessments, which will provide the source data for this study. All data collected will be entered into password protected study database by individuals in the research team, and will be identified by a unique study identification number (created for each participant at the time of recruitment). The research findings will form part of a PhD thesis, and be

published in journal articles and conference presentations. All data will be deidentified and analysed as a group.

How will the data collected be stored and used?

Storage of the data collected will adhere to University regulations and be kept on University premises in a locked cupboard/filing cabinet, with electronic information stored on a password protected computer. Identifying information and the source data collected for this study will be kept in separate sections of the study database (with restricted access) and separate participant files in secured filing cabinets in the School of Psychological Sciences, Monash University. These research records will not be made available to any individuals who are not part of the research team unless requested by the caregiver or required by law.

In the event that a caregiver (i.e. parent or person responsible) requests certain information or summary reports of cognitive assessments to be provided to a third party (e.g. school teacher, family member, paediatrician), a Permission to Share Information form will be completed and signed by the caregiver in order for study information to be released and shared. The investigators involved in this study are trained in matters of confidentiality.

Torus Games will have access to de-identified training gameplay data, which will be stored on a secure server based at Torus Games, Melbourne. They will not have access to any identifying information or other assessment data, and the data held will only be used for research purposes. Paper-based information collected as part of this study will be retained for 5 years. After this time, this information will be destroyed (shredded and securely disposed of). Electronic data collected both directly and derived from the paper-based information will be kept indefinitely for future analyses where consent to do so has been obtained from participants. Data collected during this pilot study may be used as part of future research projects at Monash University. This data will be de-identified where ethics approval has been granted.

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

A summary of the research will be provided to all participants, and researchers will organise an information evening for parents to attend to hear about the results of the research.

Who can I contact if I have a concern or complaint?

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

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Thank you,



Dr Hannah Kirk