PROTOCOL

TALI-Train 2

Training Attention in Children with Acquired Brain Injury: A Randomised Control Trial of the TALI Attention Training Program

Protocol Version 7, 18 September 2019

Revision Chronology:

Date of change	Summary of changes
16th October 2018	- Additional details added to S.2.1 regarding potential benefits of the TALI intervention - Additional details added to s.5.3 regarding identifying potential participants through EMR audit, and contact by senior researchers - S6.2 added that access to TALI platform and weekly intervention support to families will be provided by unblinded researcher - S.10 additional detail added regarding response in the event that a decline in wellbeing is noted - S.11 Amended to clarify data storage locations - S14.7 estimated timeframe for information session added - S.15 Equipment added to protocol
7th November 2018	- Additional details added to equipment section
14th January 2019	- 1.4 Addition of Sally Richmond to Contributorship - 5.2.1 Age range reduced - 5.2.2 Modification of Exclusion Criteria - 8.3 Addition of Conners EC to Screening - 8.4-8.6 Removal of TEMA and TERA - 8.4-8.6 Addition of Child ANT, Anticipated Response task, WIAT II, and IMS (child report) and PECI, GHQ-12, CDS-P, SCAS-P, and PEERS-Q (parent report) to baseline, 6 week, 3 month, and 6 month assessments - 10. Addition of parent/caregiver to risk and adverse events assessment - 13.2 Changes to statistical analysis plan - 16.1 Change to age range
29th March 2019	- Modification to the outcome definitions in Protocol Synopsis Table, 9.1 Primary Outcome, and 13.2 Statistical Analysis Plan - Trial registration amended - 5.3 Recruitment letter (Appendix E) - 7 Randomisation and Blinding, modifications to block size and stratification - 8.4 Procedure for administering Digit Span task amended for computer-based version - 11.2 Clarified sites for data storage and retention - 13.1 Sample Size Estimation updated - All references to WISC changed to WASI - Clarified the use of REDCap - Appendix C Question added to tracing letter - Conflict of interest statement updated (including on PICF)

30th April 2019	- 5.2 Added an upper age limit to exclusion criteria, and clarified that an ABI diagnosis must be the primary diagnosis - 5.3 Updated with additional avenues of recruitment - 8.2 Schedule of assessments updated to reflect maintenance of study blind as per previous amendment - 14.5 Participant reimbursement extended - 14.6 Update to Financial Disclosure and Conflicts of Interest statement
18 September 2019	- Operationalised ABI as used in this trial - Clarified the language, sensory and motor exclusion criteria - Updated with additional avenues of recruitment (Appendix F) - Amendments to the tracing letter process and template (Appendix C) - Adjustment made to the assessment duration - Additional reimbursement offered - PICF updated in line with the above (Appendix A) - Changes to the Clinician information sheet and participant flyer reflect the above changes - Proposed changes to information recorded from EMR, and associated consent form changes (Appendix A).

Statement of Compliance

This document is a protocol for a research project. This study will be conducted in compliance with all stipulations of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

CONTENTS

PROTOCOL SYNOPSIS

TITLE	Training Attention in Children with Acquired Brain Injury: A Randomised Control Trial of the TALI Attention Training Program
OBJECTIVES	*Primary objective:* To determine the efficacy of the TALI Train Program in improving attention in children with Acquired Brain Injury *Secondary Objectives:* (a)To compare attentional deficits between children with ABI, TBI and typically developing children; (b)To identify factors which predict improvements in attention following the completion of the TALI Train program and to determine whether improvements in attention resulting from completion of the TALI program are translated into improvements in other domains including mathematics ability, working memory, and social skills
DESIGN	The study design will be a 2 (conditions; control and attention training) x 4 (time points: pre-intervention, post-intervention, 3 month follow up, 6 month follow up) design. The study will comprise a blinded, parallel group, randomised control trial. Data will be analysed using Latent Growth Curve Modelling.
OUTCOMES	*Primary outcomes:* The primary outcome will be change in cognitive attention as measured by the Test of Everyday Attention for Children second edition (selective and sustained attention) and experimental paradigms of attentional control (interference control and response inhibition) between the intervention and control group at post-training. *Secondary outcomes:* Secondary outcomes will include behavioural attention (inattention and hyperactivity), measured using the SWAN; working memory measured using the Corsi block-tapping task (visuospatial working memory) and a digit span test (auditory working memory); social skills, measured using the Paediatric Evaluation of Emotions, Relationships, and Socialization (PEERS); and mathematics ability measured using the WIAT-II.
STUDY DURATION	24 months
INTERVENTIONS	TALI Train Program (www.talihealth.com.au)
NUMBER OF PARTICIPANTS	80 participants; 40 per group (2 groups)
POPULATION	80 Victorian children aged 4-9 years, with Acquired Brain Injury, residing in Victoria (both Metropolitan and Regional Areas).

GLOSSARY OF ABBREVIATIONS

ABBREVIATION	*TERM*
ABI	*Acquired Brain Injury*
ADHD	*Attention Deficit Hyperactivity Disorder*
ANOVA	*Analysis of Variance*
CRF	*Case Report Form*
HREC	*Human Research Ethics Committee*
MCRI	*Murdoch Children's Research Institute*
NHMRC	*National Health and Medical Research Council*
PEERS	*Paediatric Evaluation of Emotion, Relationships and Socialisation*
RCH	*Royal Children's Hospital*
SWAN	*Strengths and Weaknesses of ADHD symptoms and Normal Behaviour*
TBI	*Traumatic Brain Injury*
Tea-Ch2	*Test of Everyday Attention for Children*
VPRS	*Victorian Paediatric Rehabilitation Service*
WASI	*Wechsler Abbreviated Scale of Intelligence*
WPPSI	*Wechsler Preschool and Primary Scale of Intelligence*

1. ADMINISTRATIVE INFORMATION

1.1. Trial registration

Trial has been registered with Australia New Zealand Clinical Trials Registry; http://www.anzctr.org.au/, ACTRN: ACTRN12619000511134 (UTN: U1111-1218-0881).

1.2. Sponsor

Study Sponsor	Monash University
Contact name	Professor Kim Cornish
Address	Monash University, Victoria, 3800, Australia

1.3. Expected duration of study

The study is expected to run for a period of 24 months. Rolling recruitment is expected to take place for the first 18 months of the study. The study will commence in October 2018.

The TALI train program will run for 5 weeks, with a 6 month follow up period for each individual in the study.

1.4. Contributorship

Name	Summary of contribution
Erin McKay (Monash University)	Protocol draft and finalisation
Kim Cornish (Monash University)	Revision and amendment of protocol
Hannah Kirk (Monash University	Revision and amendment of protocol
Cathy Catroppa (MCRI)	Revision and amendment of protocol
Sally Richmond (Monash University)	Revision of protocol, identification of additional measures

2. INTRODUCTION AND BACKGROUND

2.1. Background and rationale

Childhood inattention has been linked with poor academic outcomes and increased lifetime social, occupational and psychiatric morbidity. An estimated 13% of Australian children will enter school without the requisite attentional skills to facilitate their learning in the classroom, (Australian Bureau of Statistics, 2014; Graetz, Sawyer & Baghurst, 2005) with a combined cost of approximately $24 billion dollars per annum (The Royal Australian College of Physicians, 2009). Lack of focus and concentration, distractibility, poor task completion, and forgetfulness are all common manifestations of inattention and can have an insidious impact on health and education. Given that attention is considered to be the gateway to learning, a child entering school with just a few inattentive behaviours can be 'at risk' for poor developmental outcomes. Recent studies highlight the pivotal role of attention as a predictor of literacy and numeracy scores in preschool through high school (Clark, Sheffield, Wiebe & Espy, 2013), in facilitating social inclusion and peer relationships (Gomes & Livesey, 2008), and in reducing significant mental health problems such as depression and aggression (Diamond, 2013).

In Australia and the United States, ABI constitutes one of the most common causes of disability in children (Anderson, Godfrey, Rosenfeld, & Catroppa, 2012; Yeates et al., 2005). Within ABI populations, deficits in attention are extremely common (Anderson et al., 2012; Catroppa et al., 2014; Yeates et al., 2005), with these deficits being seen across both non-traumatic ABI such as those resulting from stroke, brain tumours and encephalitis and ABI resulting from traumatic brain injuries. It is estimated that as many as 20% of children with an ABI will go on to develop Secondary Attention Deficit Hyperactivity Disorder (SADHD) within six months of injury (Max et al., 2004), demonstrating both the extent and severity of attentional deficits commonly seen in this population.

Recognising the burden of attention deficits on society and the far reaching negative impacts on cognitive development, a number of interventions have been developed with the aim of improving attention in children. Whilst these interventions have demonstrated some success in regards to improvements in cognitive measures of attention (I. V. t. Hooft et al., 2005; Sjö, Spellerberg, Weidner, & Kihlgren, 2010; Treble-Barna, Sohlberg, Harn, & Wade, 2016), a common shortfall of these interventions has been the lack of transfer to other domains (Treble-Barna et al., 2016), with little to no improvements seen in academic achievement, behaviour and other behavioural measures of attention. Furthermore many of these interventions require extensive time commitments, and compliance tends to be poor (Missiuna et al., 2010; Piovesana et al., 2017).

One such training program that has yet to be trialled in ABI populations is an adaptive cognitive training program known as Training Attention and Learning Initiative (TALI). The impetus to develop this training program came from both the lack of suitable non-invasive, non-pharmacological treatments for young children with attention difficulties, and mounting evidence that targeted training can have a positive lasting impact on cognitive functions. TALI is the only evidenced-based attention training platform that applies gaming technology to an intervention for young children with attention deficits.

TALI is a series of tablet-based exercises presented to children via game modules, for use on a tablet device in home, school and clinical settings. Drawing on over 25 years of research, TALI provides a much needed scientifically driven, non-invasive, non-pharmacological method targeted at improving early attention skills and providing the foundation for successful cognitive development. To date, TALI has been shown to improve attention capacity and learning outcomes in children (4-10 years) with intellectual delay due to conditions such as autism spectrum disorder and Down syndrome (Kirk, Grey, Ellis, Taffe & Cornish, 2016) which affect an estimated 650,000 Australian children (Simpson, Colpe & Greenspan 2003). TALI is yet to be trialled in children with ABI and as such its efficacy in this group is unknown. It is also unknown whether improvements similar to those seen in children with developmental delay, will be found to occur in children with ABI who complete the TALI program. This study will therefore aim to answer the question of whether a computerised, game-based attention training program can be used to improve attention in children with Acquired Brain Injury.

The Test of Everyday Attention in Children (TEA-Ch 2) was selected as the primary outcome measure for this study due to the prevalence of its use in past research utilising similar samples, and its good psychometric properties. There are two versions of the TEA-Ch2; the TEA-Ch2 J and the TEA-Ch2 A for ages 5-7 years and 8-15 years respectively. As the sample for this study extends down to children aged 4 years old, advice was sought from TEA-Ch2 developer Professor Vicki Anderson who advised the test could be used with this age group. The TEA-Ch2 has good internal consistency across both the Junior (Cronbach's alpha .75-.88) and Adolescent (.84-.95) version subtests. Limited psychometric information is available as the TEA-Ch2 only became available in March 2018, however the original TEA-Ch was a widely used and well validated measure of attention in children.

The risk of discomfort and the time burden associated with participation in the study is justified through the provision of an evidence based intervention that has previously been found to effectively improve attentional capacity in typically developing children and children with developmental delay. The burden and potential consequences of inattention in children with ABI (as outlined above) are seen to outweigh the risks and burdens associated with participation in the study.

2.2. Aim(s)

The primary aim of this study is to assess the efficacy of the TALI Train program in children with ABI.

3 STUDY OBJECTIVES

3.1 Primary objective

The primary objective of this study is to evaluate the impact of the TALI Train program on attention in children with ABI, compared to children who complete a control task

3.2 Secondary objectives

The secondary objectives of this study are:

- to investigate whether there are differences in the types of attentional deficits found in typically developing children, when compared with children with an ABI.
- to identify factors which predict improvement in attention in children with ABI who complete the TALI attentional training program, and

- to determine whether improvements in cognitive attention transfer to improvements in other domains including mathematical ability, working memory and social functioning in children with ABI who complete the TALI Train program.

4 STUDY DESIGN

4.1 Type of Study

This is an outcome, assessor-blinded, randomised controlled trial comparing the TALI attentional training program with a parallel control, tablet based task. The trial will involve a five week intervention with a 3 and 6 month follow-up period.

4.2 Study Setting

The study will take place at the Murdoch Children's Research Institute, however some screening measures may be administered in the family home or the child's school where required.

5 PARTICIPANTS AND RECRUITMENT

5.1 Number of Participants

This study will aim to recruit 80 participants, 40 per group. Participants will comprise children with an ABI. Participants will be recruited through the Victorian Paediatric Rehabilitation Service Database and review of medical records.

5.2 Eligibility Criteria

Participants will be accepted into the trial only if they meet all of the inclusion criteria and none of the exclusion criteria.

5.2.1 Inclusion criteria

Participants must meet all of the following criteria to be enrolled in this study:

- Is between the ages of 4 years and 9 years 11 months at the time of randomisation.
- Has a primary diagnosis of an ABI.
- Has an attentional deficit as determined by the Conners EC/3 parent rating scale. Children who score above 60 (t-score: elevated range) on either of the subscales relating to inattentive behaviour (inattention: DSM Inattentive) of the Conners 3, or on the inattention/hyperactivity subscale of the Conners EC will be deemed eligible for inclusion in the trial.
- At least 6 months has passed since the time of injury, or in the case of ABI due to cancers, since the conclusion of treatment (including chemotherapy).
- Has a legally acceptable representative capable of understanding the informed consent document and providing consent on the participant's behalf.

5.2.2 Exclusion criteria

Participants meeting any of the following criteria will be excluded from the study:

- Is unable to comprehend or follow study instructions, including where sensory or physical impairments are present
- Has had a previous brain injury
- Has a diagnosed or borderline intellectual delay as defined as IQ<80 on the WASI/WPPSI
- Has a prior diagnosis of developmental delay.
- More than 6 years has passed since the time of injury, or in the case of ABI due to cancers, since the conclusion of treatment (including chemotherapy).

5.2.3 Definitions

Acquired Brain Injury

An acquired brain injury (ABI) is defined as damage to the brain that occurs from 28 days after birth. ABI can be classified as traumatic brain injury (TBI) and non-TBI dependent upon causative factors such as trauma, brain tumours, vascular insults, and infections; it does not include injuries induced by birth trauma, or degenerative or congenital brain abnormalities (Emanuelson et al., 2003)."

5.3 Recruitment and identification of potential participants

Participants will be recruited through the following sources and methods:

Victorian Paediatric Rehabilitation Service

Children who meet the inclusion criteria and whose guardians have consented to be contacted for research may be identified both by their current VPRS Clinician and through the VPRS state-wide registry. Identification of potential participants will be undertaken by VPRS. For children engaged with a VPRS clinician, an information pack relating to the study may be provided to them by their clinician. All other children who meet the inclusion criteria will be contacted by a senior member of the research team (Professor Vicki Anderson or A/Prof Cathy Catroppa), via their listed preferred contact details, and an information pack including a recruitment letter will be mailed or emailed to them.

Review of Medical Records

An audit of Electronic Medical Records (EMR) will be conducted by members of the research team with approved access to EMR, who have completed EMR training. Guardians of children identified as meeting eligibility criteria by way of an Electronic Medical Records audit, will be sent a tracing letter by a senior member of the research team (Professor Vicki Anderson or A/Prof Cathy Catroppa). However, in cases where the family has had contact with another department at RCH, the letter will be co-signed by a senior medical consultant or the head of department from the aforementioned department. Should guardians respond to this tracing letter, an information pack will be mailed or emailed to the address provided. In cases whereby no response is received, a member of the research team will attempt to make contact via phone 2 weeks after sending out the tracing letter.

Social Media and Community Outreach

Information about the trial will be disseminated via official MCRI social media channels (Facebook, Instagram, Twitter), and website. Posts will link to an information page on the MCRI website. Potential participants may then contact the study coordinator directly if they would like further information about participation. The MCRI Communications team have also approved that study flyers be displayed at the MCRI. The Turner Institute at Monash University may also share information about the trial via their social media channels (Facebook and Twitter). Additionally, information will be shared on the MCRI Intranet notice board and the Monash University Workplace page.

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Additionally, organisations which provide ABI support services and community sports organisations will be approached about supporting this research project. Researchers may offer to run a workshop or similar speaking event to engage families involved in these organisations. Researchers may also

enquire about other recruitment opportunities through these organisations' networks, such as social media, participant flyers, websites, email and newsletters. In such cases, potential participants will contact the study coordinator directly if they would like further information about participation. See Appendix F for examples of this content.

5.4 Consent

Prior to performing any study specific procedure (including screening procedures to determine eligibility), a signed consent form will be obtained for each participant. Written consent will be provided by the legal guardian, as all participants will be under 12 years of age.

All potential participants will be provided with an information pack, by mail or email, including a Plain Language Statement, a consent form, a child information sheet and a reply paid envelope (if required). The Plain Language Statement will include information detailing the purpose of the study, the procedures used, the risk, benefits, and other relevant information. Consent will be voluntary and free from coercion. Upon receipt of the signed consent form, contact will be made with the guardians of potential participants by a member of the research team to confirm interest in participating in the study, to address any questions raised from the information pack and explanatory statement, and to ensure that participants understand the purpose, extent and possible risks associated with their involvement in the study. The researcher that conducted the consent discussion will also sign the informed consent form. If a consent form has not been returned after a period of 2 weeks, researchers will contact participants to follow up. A copy of the consent form will be given to the participant or their legally acceptable representative and the fact that the participant has been consented to the study will be documented in the participant's research file.

For participants who do not meet the eligibility criteria for the study, de-identified electronic data will be retained for use in future studies, where consent has been provided by the guardian to do so. A database of ineligible participants will be maintained for the duration of the study to ensure that they are not contacted by any other member of the research team during recruitment should the child be identified through more than one method (eg. EMR audit and VPRS database).

6 INTERVENTION

6.1 Intervention arms

Intervention – TALI Attentional Training Program

Active Control Task – TALI based active control task

6.2 Intervention(s)

Intervention/TALI group

The intervention/TALI group will complete the TALI Attentional Training Program (TALI Train). TALI Train is a gamed-based computerised task, delivered on a tablet. The TALI program comprises four different activities, each lasting 4 minutes in duration. Each activity requires children to utilise a different attentional skill; selective attention, sustained attention, attentional control, and response inhibition respectively. Children may complete the four activities in any order, but must complete all activities each session. As children progress through the levels within the activity, the tasks become more difficult. TALI has been designed to be adaptive and therefore when children respond incorrectly, or fail to respond, prompts are given and levels become easier until the child again begins

to record correct responses. Children are rewarded for successful completion of an activity with a virtual toy. Each day the child recommences the activities at the level they finished on during their last session. Sessions take 20 minutes to complete. The TALI program is designed so that children are locked out until midnight following completion of a session, to ensure that only one session is completed per day. Children will be required to complete five 20 minute sessions per week for five weeks.

Following the initial assessment, children and parents will be set up on the TALI system and provided with a tablet to use for the duration of the intervention. Following this, children will be asked to continue to use TALI for the above specified timeframe. Parents are asked to supervise each training session. Sessions can be completed in the home and do not require an internet connection. Each week families will receive a phone call from the unblinded member of the research team to address any questions or concerns raised. If the family do connect to the internet during the intervention delivery, data will automatically be uploaded to the secure TALI platform to be accessed by the unblinded member of the research team. This will allow researchers to monitor compliance, and also address concerns raised by parents. The TALI train program will be used in the default mode to ensure consistent setting for all children in the trial.

Active Control Task/Control Group

In order to control for generic training effects and to maintain blindness to group allocation, an active control program was developed by Monash University. The active control program based upon the TALI program, is computerised, game-based and delivered on a tablet. The active control task utilises the same characters and rewards as the TALI program and sessions run for the same duration as the TALI program (e.g. 4 exercises each 4 minutes in duration). In this program children are required to use basic motor skills to touch, drag, move and rotate shapes around a screen. Importantly this program was designed to involve minimal attentional skills and unlike TALI Train is not adaptive. Therefore, children complete the same exercises each day with no increase in complexity. Children will be required to complete 5 sessions a week for a period of 5 weeks.

Similarly to the intervention group, families will be set up on the control task provided with a tablet on which to complete the task. The control task is then completed at home, by the child, under the supervision of a parent, for the above specified timeframe. Each week parents will receive phone calls to address any questions or concerns raised.

6.2.1 Modification

Not applicable. Once children have been allocated to either TALI Train or the active control program there will be no change in group allocation. If children or parents do not wish to continue with their allocated program they will be able to withdraw from the study.

6.2.2 Measurement of participant compliance

Accurate records will be kept regarding when questionnaires are emailed out to participants and if and when they are returned, including how complete they are. Information regarding invitations to attend testing and attendance at testing will also be recorded.

Compliance with the intervention will be monitored via the secure TALI online platform, and through weekly phone calls with participants families. Compliance with the active control tasks will be monitored through weekly phone calls with the participants families. Dates and times of all phone calls (including attempted phone calls) will be recorded.

Compliance with the programmes will be defined as completing 20 training sessions out of a possible 25.

6.2.3 Exclusion

Children will be excluded from the trial if they commence any therapy, or engage in any intervention for the specific purpose of improving attention, for the duration of the study.

Children will also be excluded if they commence medication for the purpose of addressing inattention or hyperactivity at any point during the study.

7 RANDOMISATION AND BLINDING

A statistician not directly involved in the analysis of the study results will prepare the randomisation schedule using block randomisation (ratio 1:1, blocks of 4) to maintain balance between intervention arms. The randomisation will be stratified by injury severity with three strata: mild, moderate to severe, and other (where injury severity cannot be classified). Computer-generated random numbers will be used to allocate participants.

The documentation pertaining to the randomisation will be securely stored and inaccessible to researchers undertaking recruitment and testing.

7.1 Concealment mechanism

An independent researcher will be solely responsible for the implementation of the allocation and will be the point of call for parents during the intervention period. Researchers conducting screening and assessments with participants will be unaware of group allocation for the entire duration of the trial (including data analysis). Prior to the commencement of each assessment session participants will be explicitly instructed not to discuss the contents of their assigned program with the researcher. On completion of the follow-up assessments researchers will open a sealed opaque envelope which contains details of the condition that the participant was assigned to.

7.2 Breaking of the Study Blind

7.2.1 On study

The randomisation code for an individual participant may only be unblinded in emergency situations, or for safety reporting purposes, and with permission from the Principal Investigator (PI) Kim Cornish. To break the study blind researchers must open the opaque sealed envelope containing the participant's allocation. For any participant for whom the study blind is broken, the date, time, participant ID and reason for unblinding must be documented.

7.2.2 On completion of the study

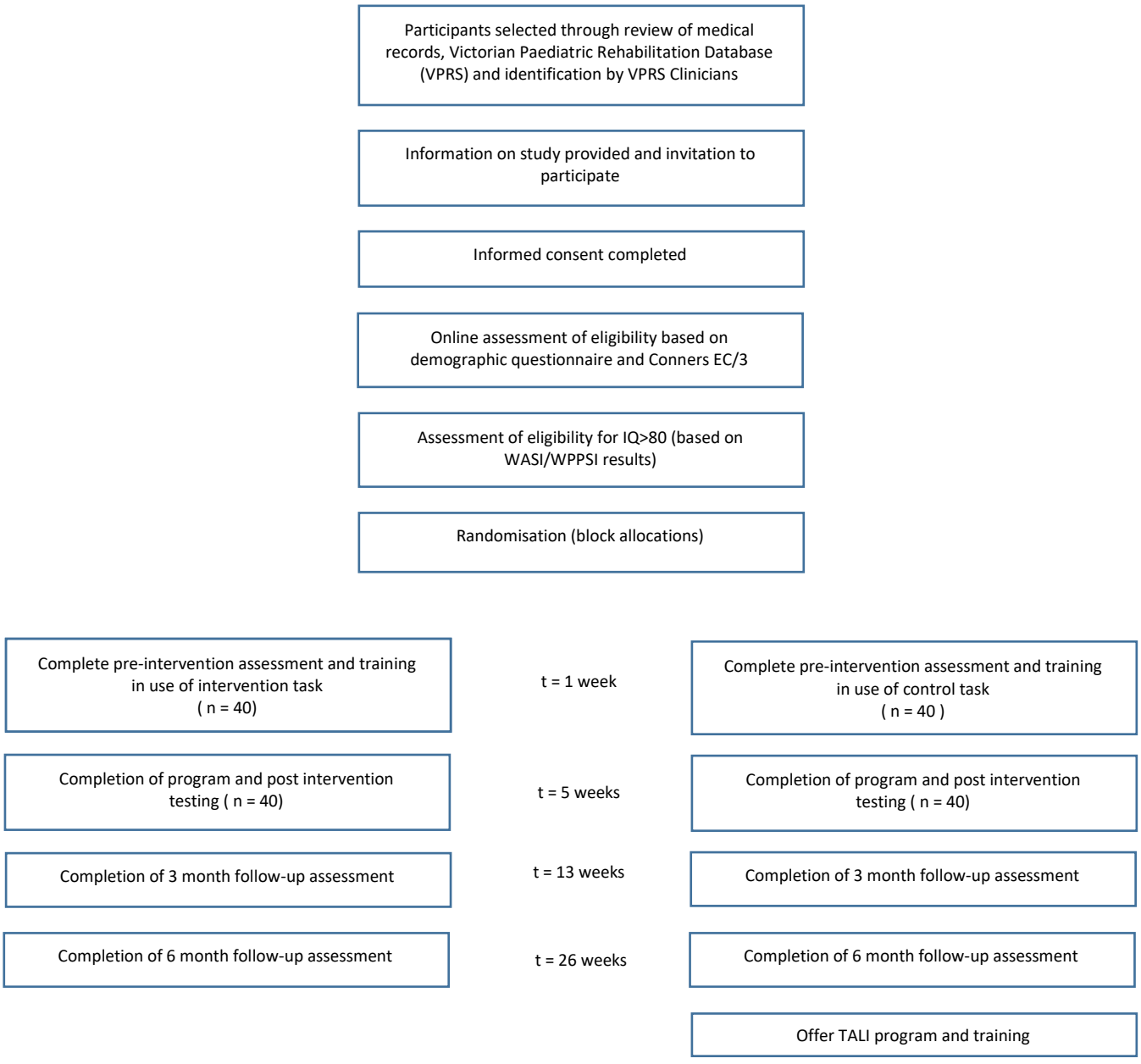
Group allocation details and randomisation codes will only be available once all data collected have been entered into the study database (Research Electronic Data Capture, REDCap) for every

participant and the database has been finalised, except in the case of an emergency, as detailed above. Once data entry has been completed, researchers will be given access to a spreadsheet linking the participant number to their individual randomisation code.

Parents and children will be surveyed on whether they thought they were in the TALI program group or the control group to ensure the blinding was effective.

8 STUDY VISITS AND PROCEDURES

8.1 Study timeline



8.2 Schedule of assessments

Time point relative to randomisation		
Screening	A	
Screening	B	
Randomisation (0 week)	Intervention	Control
Pre-intervention assessment (1 week)	C	C
Training in intervention (1 week)	D	E
Completion of intervention (1 week to 5 weeks)	F H	G H
Post-intervention assessment (5 weeks)	C	C
Post-intervention assessment (3 months)	C	C
Post-intervention assessment (6 months)	C	C
TALI offered to control group (6 months)		I
Intervention (6 months to 7 months)		F

A	Questionnaire screening for attentional deficits, and other inclusion/exclusion is emailed to families for completion.
B	Screening for IQ criteria completed for children who have not undergone IQ testing post injury, or within the past two years.
C	A face to face assessment session (2 - 2.5 hours) is held at MCRI. A researcher will administer the SSS, TEA-Ch2 selective attention and sustained attention subtests, the child ANT, the Anticipated Response Task, the Corsi Block-Tapping Test, a digit span task, the PEERS, the WIAT-II, and the IMS (pre-intervention only). Parents will be asked to complete the SWAN, the CSHQ, the PECI, the GHQ-12, the CDS-P, the SCAS-P, and the PEERS-Q.
D	Parents and children will be trained in the use of the TALI program. Researchers will provide a tablet with the intervention program and parent guidebook.
E	Parents and children will be trained in the use of the control task program. Researchers will provide a tablet with the control program and parent guidebook.
F	Children will complete TALI modules for 20 mins per day, 5 days per week for 5 weeks, under the supervision of a parent.
G	Children will complete control task modules for 20 mins per day, 5 days per week for 5 weeks, under the supervision of a parent.
H	Families will receive weekly phone contact from a researcher to offer support throughout the intervention, address any technical issues that arise, and to monitor compliance.
I	Families in the control group will be offered access to the TALI program.

8.3 Screening

Stage 1 Screening

The first stage of screening will be undertaken by researchers based on information gained from the VPRS database and audit of medical records and will be based on the inclusion criteria outlined in section 5.2.1. The parents of children who meet the inclusion criteria will be contacted via the means outlined in section 5.3. Once informed consent for participation is received by the researchers, families will be invited to participate in the second stage of screening.

Stage 2 Screening

The second stage of screening will be conducted online. Parents/guardians of participants will be sent an email inviting them to participate in the screening process. Parents will be asked to complete a demographic and medical questionnaire, and the Conners 3 or Conners EC depending on the age of the child. Both the Conners 3 and Conners EC will be administered and scored via the online Conners platform. The Conners is used to measure ADHD symptoms and in this study, will be used to determine whether children meet the criteria of an attentional deficit needed to participate in the study. An attentional deficit will be defined as a t score >60 on either of the two inattention subscales of the Conners 3, or on the inattention/hyperactivity subscale of the Conners EC.

If the screening assessments have not been completed after a period of two weeks, a member of the research team will contact participants to follow up. This will entail one documented reminder email, and one follow up Short Message Service (SMS) or phone call. If a period greater than 2 weeks has passed from the first reminder contact date then participants will be recorded as having 'incomplete' screening and they will not be contacted further.

Stage 3 Screening

Following completion of the second stage of screening, researchers will assess eligibility for the study based on the exclusion criteria listed in section 5.2.2.

In cases where children meet all other eligibility criteria, children who have not undergone IQ testing post injury and within the last two years, will be asked to complete either the WASI or the WPPSI (dependent on age). The WASI/WPPSI will be administered by a trained member of the research team at MCRI. Should the child be unable to attend MCRI, an offer will be made to conduct this assessment at the child's school or within the family home.

8.4 Baseline

Enrollment/Baseline Visit (Visit 1, Week 1)

Pre-intervention assessments will be conducted by Dr Richmond, Ms Courtney, Ms McKay or an MCRI research assistant. These assessments will take place at MCRI. Participants may find the assessment sessions to be tiring and small breaks should be provided when needed. The assessments will comprise the following tasks and are estimated to take 2 – 2.5 hours to complete:

1. Stanford Sleepiness Scale – The SSS is a single item self-report assessment of current levels of sleepiness. Children are asked to rate their current level of sleepiness on a 7 point scale ranging from 1 (very awake) to 7 (very sleepy). This measure is expected to take no more than 5 minutes to complete.
2. Test of Everyday Attention for Children (Tea-Ch2) will be used to assess attention. Children aged 4 to 7 will complete 4 subscales from junior version which are either facilitated by or wholly completed on the computer. The subtests are designed to assess selective attention (Balloon Hunt; Balloons 5) and sustained attention (Simple Reaction Time; Sustained Attention to Response Task). Children aged 8 to 9 years will complete 4 equivalent subscales from the older version (Hector Cancellation; Hector-B; Simple RT and SART). The battery should take no more than 20 minutes to complete. This measure provides both raw score and scaled scores for each of the subtests.
3. Child Attention Network Task (ANT) – a child friendly version of the flanker task which is suitable for children aged 4 years and above. The Anticipated Response task - a stop signal task that measures the ability to rapidly prevent already initiated actions. The Child ANT would enable assessment of interference control and the Anticipated Response task assessment of response inhibition, both aspects of attentional control. These measures are administered on a laptop and should take no more than 30 minutes in total to complete.
4. Corsi Block-Tapping Test (forwards and backwards) – Visuospatial working memory. Children are required to replicate a sequence by clicking the corresponding blocks on the screen. This test is administered on a laptop and should take no more than 10 minutes to complete. This measure provides a raw score of the number of sequences children have correctly replicated.
5. Digit Span task (forwards and backwards) – Auditory working memory. Children are required to replicate a sequence of digits by selecting them from a circle of digits on the screen. This task is administered on a laptop and should take no more than 5 minutes to complete. This measure provides a raw score of the number of accurately recalled digits.
6. Paediatric Evaluation of Emotions, Relationships and Sociability (PEERS) – Measures social skills. This is a game-based computerised task which is administered via a touchscreen tablet. Children will be asked to complete the Emotion Perception and Emotion Recognition subtests from the Social Cognition Domain, and the Non-verbal Gestures and Social Perception subtests from the Social Communication Domain. These domains were selected as there are the areas of social functioning thought to be most impacted in children with Acquired Brain Injuries. This task should take no more than 10 minutes to complete.
7. The Wechsler Individual Achievement Test II (WIAT II) is a standardised measure of mathematics ability. The WIAT II can be used with both children and adults. Children will complete the numerical operations and mathematical reasoning subtests to give a measure of mathematics ability. Starting points are based on the child's age and children progress until they make six consecutive errors. Completion time is expected to take no more than 30 minutes.
8. Intrinsic Motivation Scale – This is a child-specific 18 item self-report measure of motivation with regards to school and schoolwork. This measure provides a score relating to the child's overall motivation. This task should take no more than 10 minutes to complete.

Parents will be asked to complete the following, note the time to complete all measures is estimated at less than 2 hours:

1. Strengths and Weaknesses of ADHD symptoms and normal behaviour – The SWAN is an 18 item parent report questionnaire based on DSM-5 criteria for ADHD. The SWAN provides raw scores on children inattentive, and impulsive/hyperactive behaviours. Higher scores on this measure indicate greater attention difficulties.
2. Children's Sleep Habits Questionnaire – The CSHQ is a 33 item parent report sleep screening assessment tool. The CSHQ provides a total score and 8 subscale scores, assessing key domains of sleep, both medical and behavioural. Higher scores across subscales indicate greater sleep concerns.
3. The Parent's Experience of Child Illness (PECI) – The PECI is a parent-report measure of family environment designed to measure parental adjustment relating to their child's chronic illness. The PECI comprises four subscales; Guilt and Worry, Unresolved Sorrow and Anger, Long-term Uncertainty, and Emotional Resources. The PECI is widely used in paediatric ABI samples. The measures comprises 25 items, each rated on a 5-point Likert Scale.
4. The General Health Questionnaire (GHQ-12) - The GHQ-12 is a commonly used 12-item self-report instrument designed to measure mental health in adults within community settings.
5. Children's Depression Scale 3rd Ed.(CDS-P) – This measure is a 50 item, parent report measure of child depression symptoms. This measure has good reliability and validity for assessing depressive symptoms and wellbeing in children.
6. Spence Children's Anxiety Scale –Parent (SCAS-P) – This measure is a 38 item parent report questionnaire, designed to measure anxiety symptoms relating to DSM anxiety disorders including panic disorder, generalised anxiety disorder, social phobia, and separation anxiety disorder, as well as school phobia. The SCAS is appropriate for use with children with an Acquired Brain Injury.
7. Paediatric Evaluation of Emotions, Relationships and Sociability Questionnaire (PEERS-Q) – This measure is a 55 item parent report questionnaire, designed to measure social skills in daily life. The PEERS-Q is appropriate for use with children with an Acquired Brain Injury.

Following the completion of the pre-intervention assessment, children and their parent or guardian will be given their allocated intervention tablet and handbook.

8.5 Visits

Visit 2, Week 6 ± 1 week

Participants may find the assessment sessions to be tiring and small breaks should be provided when needed. Children will be asked to complete:

1. Stanford Sleepiness Scale
2. Tea-Ch2 selective and sustained attention subtests
3. Child ANT and Anticipated Response Task

   Break if needed

4. Corsi Block-Tapping Test
5. Digit Span task
6. PEERS
7. WIAT II

Parents will be asked to complete:

1. SWAN
2. CSHQ
3. PECI
4. GHQ-12
5. CDS-P
6. SCAS-P
7. PEERS-Q

Visit 3, Week 13 ± 1 week

Participants may find the assessment sessions to be tiring and small breaks should be provided when needed. Children will be asked to complete:

1. Stanford Sleepiness Scale
2. Tea-Ch2 selective attention and sustained subtests
3. Child ANT and Anticipated Response Task

   Break if needed
4. Corsi Block-Tapping Test
5. Digit Span task
6. PEERS
7. WIAT II

Parents will be asked to complete:

1. SWAN
2. CSHQ
3. PECI
4. GHQ-12
5. CDS-P
6. SCAS-P
7. PEERS-Q

8.6 Final study visit

Visit 4, Week 26 ± 1 week

Participants may find the assessment sessions to be tiring and small breaks should be provided when needed. Children will be asked to complete:

1. Stanford Sleepiness Scale
2. Tea-Ch2 selective and sustained attention subtests
3. Child ANT and Anticipated Response Task

   Break if needed
4. Corsi Block-Tapping Test
5. Digit Span task
6. PEERS
7. WIAT II

Parents will be asked to complete:

1. SWAN
2. CSHQ
3. PECI
4. GHQ-12
5. CDS-P
6. SCAS-P
7. PEERS-Q

After completing the above measures, parents and children will then be asked to complete a questionnaire, asking them to indicate whether they thought they had been allocated to the TALI program group or the control group.

Following this visit, parents of children in the control group will be contacted and offered access to the TALI train program by an unblinded member of the research team.

Parents will be advised that they will receive a 6 monthly newsletter outlining the study progress, and at the completion of the study they will receive an invitation to an information session where researchers will present the findings of the study.

8.7 Withdrawal

Given that the assessments are the same for each of the time points it is unlikely that a participant will wish to complete the assessment if they chose to withdraw or if the project ends early. All participants will be provided with results from the assessments after each timepoint, if they wish.

8.8 Unscheduled visit

Although unscheduled visits are unlikely, all contact with participants and their families will be documented by researchers on the CRF.

8.9 Participant Withdrawal

8.9.1 Reasons for withdrawal

The investigators may withdraw a participant from the study intervention if the participant:

- Experiences a subsequent brain injury
- Commences chemotherapy
- Undergoes any neurosurgical intervention or treatment
- Commences medication for the purpose of treating inattention
- Commences any therapy or other intervention for the purpose of treating inattention
- Is in violation of the study protocols
- Experiences a serious or intolerable adverse event
- Experiences a decline in wellbeing.

The investigators will also withdraw all participants from the study intervention if the study is terminated. Participants are free to withdraw from the study at any time upon their request. Withdrawing from the study will not impact their ability to access interventions in future, nor will this affect their relationship with the hospital.

8.9.2 Handling of withdrawals and losses to follow-up

When a participant withdraws from the study, the reasons for withdrawal shall be recorded by the investigator on the relevant page of the CRF. Participants who fail to return for study assessments will be contacted by the research team in an attempt to have them comply with the protocol. This will entail two documented phone calls and one registered letter. If a period greater than 2 weeks has passed from the scheduled assessment date then participants will be recorded as having "missed" this assessment.

8.9.3 Replacements

The study will continue to recruit participants for a period for 12 months with the aim of achieving the required sample size.

8.10 Trial Closure

If the study is terminated prematurely, then all participants will be contacted via phone to explain the reasons for termination and the impact this may have on them. Termination or extension of the study can only be made by the Chief Investigator, in this case Professor Kim Cornish.

8.11 Continuation of therapy

After the 5-week intervention period, participants will be unable to access their assigned program. Researchers will collect the tablet devices that contain the assigned program at the post intervention assessment.

9 OUTCOMES

9.1 Primary outcome

The primary outcome is an improvement in cognitive attention, as measured by the Test of Everyday Attention for Children (selective and sustained attention) and experimental paradigms of attentional control (interference control with the Child ANT test and response inhibition with the anticipated response task) between the intervention and control group at post-training.

9.2 Secondary outcome(s)

The secondary outcome measures are as follows;

- Behavioural attention as measured by the SWAN

- Visuospatial working memory as measured by the Corsi Block-Tapping task
- Auditory working memory as measured by the digit span task
- Social skills as measured by the PEERS
- Mathematics ability as measured by the WIAT-II

10 ADVERSE EVENTS AND RISKS

10.1 Definitions

Unanticipated Problems

Unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets all of the following criteria:

- unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, and (b) the characteristics of the participant population being studied;
- related or possibly related to participation in the research; and
- suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognised

Adverse Event (AE)

Any untoward medical occurrence in a patient enrolled into this study regardless of its causal relationship to study/interventions.

Serious Adverse Event (SAE)

Adverse events are classified as serious or non-serious.
An SAE is defined as any AE that:

- results in death; or
- is immediately life threatening; or
- requires inpatient hospitalisation; or
- requires prolongation of existing hospitalisation; or
- results in persistent or significant disability/incapacity; or
- is a congenital anomaly/birth defect.

Important medical events will be considered an SAE when, based upon appropriate medical judgement, they may jeopardise the patient and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

10.2 Assessment and documentation of adverse events

If researchers notice a decline in the child's or parent/caregivers wellbeing during weekly check-ins, or during follow up assessment they are able to provide a referral to an appropriate service for support. Alternatively where the child is currently receiving care from another department, permission may be sought to notify the child's treating clinician to ensure that support is being provided. Researchers will notify the PI's Kim Cornish and Vicki Anderson of any declines in wellbeing identified, and a determination will then be made whether it is in the child's best interests to be withdrawn from the study. Any concerns and outcomes will be recorded in the participant's CRF. Serious adverse events

will be reported to the HREC within 24-72 hours of occurrence. Families are reminded that they may withdraw from the study at any time.

For the purposes of this study the investigator is responsible for recording all Adverse Events, regardless of their relationship to study intervention, with the following exceptions:

- Conditions that are present at screening and do not deteriorate will not be considered adverse events.

The description of each AE on the CRF will include:

- A description of the AE;
- The onset date, duration, date of resolution;
- Severity (mild, moderate or severe);
- Any action taken;
- The outcome (recovery, death, continuing, worsening);
- The likelihood of the relationship of the AE to the study intervention (Unrelated, Possible, Probable, Definite).

The severity and relationship of an AE will be assessed as per appendix D. The seriousness of an AE will be assessed by an investigator according to the definition in section 9.1

Changes in the severity of an AE will be reported. AEs characterised as intermittent will be documented for each episode. All AEs will be followed to adequate resolution, where possible.

10.3 Eliciting adverse event information

Safety events will be recorded from the time the participant signs the informed consent form until 48 hours after the last study visit. For participants in the active control group who take up the offer to complete the TALI program, safety events will be recorded until the tablet provided with the TALI program has been returned. At each point of contact with participants caregivers, researchers will enquire as to how the participants has been since their last contact in order to elicit any changes in their wellbeing. At each study visit participants and their parent/caregiver will be asked “How have you felt since your last visit?” in order to elicit any changes in their wellbeing.

10.4 Serious adverse event reporting

10.4.1 SAES

Any SAE occurring in a study participant will be reported to the HREC within 24-72 hours of occurrence, in accordance with the safety reporting policy of the HREC. The HREC safety reporting form will be completed, signed and submitted by an investigator.

11 DATA MANAGEMENT

11.1 Data Collection

The investigators are responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data. The investigators will maintain adequate case histories of study participants, including accurate case report forms (CRFs), and source documentation.

11.1.1 Source Data

Source data will include original records in medical records and research initiated data. Access to EMR will be restricted to those investigators who have received training and undergone relevant criminal records checks.

11.1.2 Data Capture Methods

Paper and electronic data will be collected. All electronic data will be stored in a password secured study database (REDCap), accessible at Monash University and MCRI. Deidentified data files will be stored on a password protected computer within the Monash University lab, and on an encrypted, password protected USB.

11.2 Data Storage

All data collected will be entered into a password protected study database (REDCap) 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). Identifiable data, such as names and contact details, will be kept in a separate section of the database with restricted access, which can only be accessed by specific members of the research team (i.e. investigators). All paper based data will be stored in participant files (CRFs) in secured filing cabinets at the Murdoch Children's Research Institute.

The information collected from this study will only be available to members of the research team involved in this study. In the event that a caregiver (i.e. parent or guardian) request for certain information or summary reports of cognitive assessment to be provided to a third party (e.g. school teacher, paediatrician), a Permission to Share Information form will be completed and signed by the caregiver in order for the study information to be released and shared. All members of the research team, including students, are trained in confidentiality.

11.3 Record Retention

Storage of the data collected will adhere to the Monash University regulations and will be kept on University premises in a locked filing cabinet until the 25th birthday of the youngest participant in accordance with the requirements of the Health Privacy Principles. Electronic information will be stored on a password protected computer.

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. As the lead researcher (Professor Kim Cornish) is located at Monash University, participant files will be transported to Monash University in a secure document case following the completion of the study. Files will be stored in the School of Psychological Sciences at Monash University in locked filing cabinets, accessible only by members of the research team, until such time (as stated above) that they may be confidentially destroyed.

Paper-based information collected as part of this study will be destroyed after the above stated timeframe has lapsed. All documents will be disposed of in a secure document disposal bin. De-identified electronic data collected both directly and derived from the paper-based information will be kept indefinitely for future analyses.

12 STUDY OVERSIGHT

12.1 Governance structure

This project will sit within the Monash University School of Psychological Sciences and the Murdoch Children's Research Institute. Therefore, governance will sit within these existing structures. A specific steering committee is not required.

12.2 Quality Control and Quality Assurance

The Quality Control and Quality Assurance guidelines will be detailed in the standard operating procedures (SOP) document.

- Staff contacting families for screening or contact at the time of baseline and follow-up assessments will be trained by the study co-ordinator.
- Compliance with the study protocol will be assessed by the study co-ordinator monthly
- To ensure a high degree of proficiency, staff providing interventions will receive clinical neuropsychology training to a level consistent with AHPRA regulations.

13 STATISTICAL METHODS

13.1 Sample Size Estimation

A priori power analysis using G*Power 3.1 estimated a required sample between 40 (for a large effect size) and 98 (for a medium effect size) participants based on the following parameters:

- ANOVA: repeated measures between factors
- estimated effect size *f* .4 (large) and .25 (medium)
- alpha .05
- power .8
- Number of groups: 2
- Number of measurements: 2
- Correlation among measures: .5

13.2 Statistical Analysis Plan

Primary outcome – Cognitive attention: selective attention, sustained attention, response inhibition, and interference control

- Mean scores for selective and sustained attention, response inhibition and interference control for the intervention and control groups, across each time point will be presented.
- Latent Growth Curve Modelling will be used to analyse the difference in scores both within and between the intervention and control group, across all four time points.

Secondary outcomes – (include) behavioural attention, working memory, social skills, and mathematic ability

- Mean scores for each variable, for each group, across each time point will be presented.
- Latent Growth Curve Modelling will be used to analyse the difference in scores on the above variables both within and between groups, across all four time points.

13.2.1 Population to be analysed

An intention to treat approach will be taken, where all children enrolled in the trial will be analysed.

13.2.2 Handling of missing data

Prior to investigating treatment effect, analyses will assess whether children who did not adhere to the program (<20 sessions) differed from those who did adhere to the program (>20 sessions).

Statistical methods that will be used to handle missing data will depend on the amount of missing data and the pattern of missing data. These methods will include either regression methods of imputation in cases where missing data is <20% and Missing Completely at Random, or in cases where missing data is Missing at Random, Expectation Maximisation method of data imputation will be used.

13.2.3 Methods of analysis

Primary outcome measure

To meet the primary objective of the study, the four primary outcome measures: response inhibition, interference control, selective attention, and sustained attention as measured by the Anticipated Response task, Child ANT, and TEA-Ch 2 respectively, will be analysed using Latent Growth Curve Modelling (LGCM) using a multigroup approach. An alpha level of .05 and two-tailed tests will be used for this analysis. LGCM will be conducted through R. Participants will be compared to their own baseline at each of the three subsequent testing time points, and further comparisons will be made between time points (e.g. 5 week follow up and 3 month follow up, 5 week follow up and 6 month follow up). Participants in the TALI program group and the active contact group will also be compared at each time point. LGCM will allow for baseline ability to be taken into consideration.

Secondary outcomes measures

To meet the secondary objective of determining whether improvements in cognitive attention transfer to improvements in other domains including mathematics ability , working memory and social functioning in children with ABI who complete the TALI attentional training program, further LGCM will be used as described above with the secondary outcome variables listed in section 9.2.

Additional analysis

To meet the secondary objective of identifying factors which predict improvement in attention in children with ABI who complete the TALI attentional training program, LGCM will be used. Predictor variables will be obtained through data collected from the demographic screening survey including age at time of injury, type of injury, length of time since injury, severity of attentional deficits and socio-economic background, as well as from data obtained through assessment measures relating to motivation, sleep, mental health and family functioning.

To meet the final secondary objective of investigating whether there are differences in the types of attentional deficits found in typically developing children, when compared with children with ABI, children's scores on the Connor's EC/3 will be compared using an independent samples, two-tailed ANOVA with an alpha level of .05

Data on typically developing children will be obtained from previous study database, whereby participants consented to their de-identified data being used for further research.

13.3 Interim Analyses

Screening data will be analysed to give an indication of different attention profiles across children with ABI and TBI. No further interim analyses will be conducted and researchers will be blinded to group allocation throughout the trial including analyses.

14 ETHICS AND DISSEMINATION

14.1 Research Ethics Approval

This protocol, explanatory statement, informed consent document, additional supporting documents and any subsequent modifications will be reviewed and approved by the Royal Children's Hospital human research ethics committee (HREC). A letter of protocol approval by HREC will be obtained prior to the commencement of the study, as well as approval for other study documents participant to HREC review.

14.2 Modifications to the protocol

This study will be conducted in compliance with the current version of the protocol. Any change to the protocol document or Informed Consent Form that affects the scientific intent, study design, patient safety, or may affect a participants willingness to continue participation in the study is considered an amendment, and therefore will be written and filed as an amendment to this protocol and/or informed consent form. All such amendments will be submitted to the HREC, for approval prior to becoming effective.

14.3 Protocol Deviations

All protocol deviations must be recorded on the CRF and must be reported to the PI. Protocol deviations will be assessed for significance by the Principal Investigator (Sponsor). Those deviations deemed to have a potential impact on the integrity of the study results, patient safety or the ethical acceptability of the trial will be reported to the HREC in a timely manner. Where deviations to the protocol identify issues for protocol review, the protocol will be amended as per section 14.2.

14.4 Confidentiality

Participant confidentiality is strictly held in trust by the participating investigators, research staff, and the sponsoring institution and their agents. The study protocol, documentation, data and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorised third party, without prior written approval of the sponsoring institution. Authorised representatives of the sponsoring institution may inspect all documents and records required to be maintained by the Investigator. The clinical study site will permit access to such records. All evaluation forms, reports and other records that leave the site will be identified only by the Participant Identification Number to maintain participant confidentiality. Clinical information will not be released without written permission from the participant's guardian, except as necessary for monitoring by HREC or regulatory agencies.

14.5 Participant Reimbursement

To assist with the costs of taking part in this research, participants will be reimbursed up to $50 per assessment visit for travel time and parking. At each assessment visit, participants will receive a supermarket voucher valued at $30, with up to $20 provided to cover parking costs if required. Families will receive the Samsung Tab A tablet (estimated value $397) which they used during the trial, either at the close of the trial if they were allocated to the intervention group, or when they are offered the intervention if they were allocated to the control group. In addition, participants will

receive a movie voucher (to the value of a standard child ticket, approximately $14) at the end of the study, and this will only be disclosed to the participant after their final study visit.

14.6 Financial Disclosure and Conflicts of Interest

Dr Hannah Kirk and Professor Kim Cornish are co-inventors of the TALI Train program. All intellectual property (IP) associated with TALI Train is currently owned by Monash University, who have granted a license to commercialise their IP to TALI Health Pty Ltd. As a result Monash University, including co-inventors, Dr Kirk and Professor Cornish receive a small portion of predefined royalties from the licensee (TALI Health). Dr Kirk holds a small number of personal shares in TALI Health's public-listed holding company Novita Healthcare Ltd (ASX: NHL). Professor Vicki Anderson, Associate Professor Cathy Catroppa, Dr Sally Richmond, Ms Danielle Courtney, Mr James Morgan, and Ms Erin Mckay are independent researchers and as such do not have any personal or financial interests in TALI Health Ltd.

14.7 Dissemination and translation plan

Families of participants in the study will receive a six-monthly email newsletter that will update them on the research outcomes to date (e.g. collated trial information) and future research direction. At the conclusion of the study, a summary of their child's results will be provided to parents if requested. In addition, the overall collated results of the trial and its outcomes will be provided to parents electronically and the researchers will also organise an information evening to present the findings to participants, and answer any questions. It is anticipated that this information evening will be held in early 2021 once data analysis has concluded.

The research findings will be published in journal articles and conference proceedings, and will form part of a PhD thesis. All data used for this purpose will be de-identified and analysed as a group to protect the privacy of participants and ensure confidentiality is maintained.

As this study forms the basis of a PhD by publication, primary responsibility for publication of results will be held by PhD student Ms Erin McKay, and supervisors/investigators Professor Kim Cornish, Dr Hannah Kirk and Associate Professor Cathy Catroppa.

15 EQUIPMENT

Tablets will be Monash devices. These devices do not require an internet connection for the completion of the TALI program and are not set up with internet access, however can be connected to the internet via wifi. Devices will be provided to families following the pre-intervention assessment, to be returned at the post-intervention assessment approximately 5 weeks later. Technical support will be provided by the unblinded researcher where needed. No other application will be loaded on to the tablet, other than the TALI program or Active Control task, dependent on which condition the participant has been allocated to.

Laptops to be used for assessment will be provided by Monash University and will be stored at the Monash University School of Psychological Sciences. These laptops will be utilised by members of the research team only.

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17 APPENDICES

17.1 Appendix A - Informed consent materials

HREC Project Number:	38132		
Short Name of Project:	TALI-Train 2		
Full Name of Project:	Training Attention in Children with Acquired Brain Injury: A Randomised Control Trial of the TALI Attention Training Program		
Principal Researcher:	Professor Kim Cornish, Monash University		
Version Number:	7	**Version Date:**	18 September 2019

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 6 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. If you decide you do not want your child to take part, it will not affect the treatment and care your child gets at The Royal Children's Hospital.

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 following childhood brain injury, with up to 20% of children with a brain injury developing secondary attention deficit hyperactivity disorder.

Monash University has developed a world first computerised attention training program for young children, TALI™. TALI™ 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 TALI™.

The aim of the current project is to examine the effectiveness of the TALI™ program in improving attention, broader cognitive skills (e.g. memory), social skills and academic skills in children with Acquired Brain Injuries.

2. Who is running the project?

This project will take place at the Murdoch Children's Research Institute, based at The Royal Children's Hospital, for children who live in Melbourne and surrounding areas. The study is a joint study between Monash University and the Murdoch Children's Research Institute. The research team for this study includes researchers and psychologists from Monash University and the Murdoch Children's Research Institute. The protocol for the study was written by the research team. This study is being funded by a National Health and Medical Research Council (NHMRC) grant.

Dr Hannah Kirk and Professor Kim Cornish are co-inventors of the TALI Train program. All intellectual property (IP) associated with TALI Train is currently owned by Monash University, who have granted a license to commercialise their IP to TALI Health Pty Ltd. As a result Monash University, including co-inventors, Dr Kirk and Professor Cornish receive a small portion of predefined royalties from the licensee (TALI Health). Dr Kirk holds a small number of personal shares in TALI Health's public-listed holding company Novita Healthcare Ltd (ASX: NHL). Professor Vicki Anderson, Associate Professor Cathy Catroppa, Dr Sally Richmond, Ms Danielle Courtney, Mr James Morgan, Ms Erin Mckay, and Ms Anna Werbik are independent researchers and as such do not have any personal or financial interests in TALI Health Ltd.

Professor Vicki Anderson is a co-developer of the Tea-Ch 2; a measure of childhood attention which is widely used in research setting. Professor Anderson is also a co-developer of the Paediatric Evaluation of Emotions, Relationships and Socialization (PEERS); a measure of social skills for use with children. Both of these measures will be utilised in the study to assess attention and social skills.

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 4 and 9 years and has experienced an illness or injury that may fall under the category of an 'Acquired Brain Injury (ABI)'.

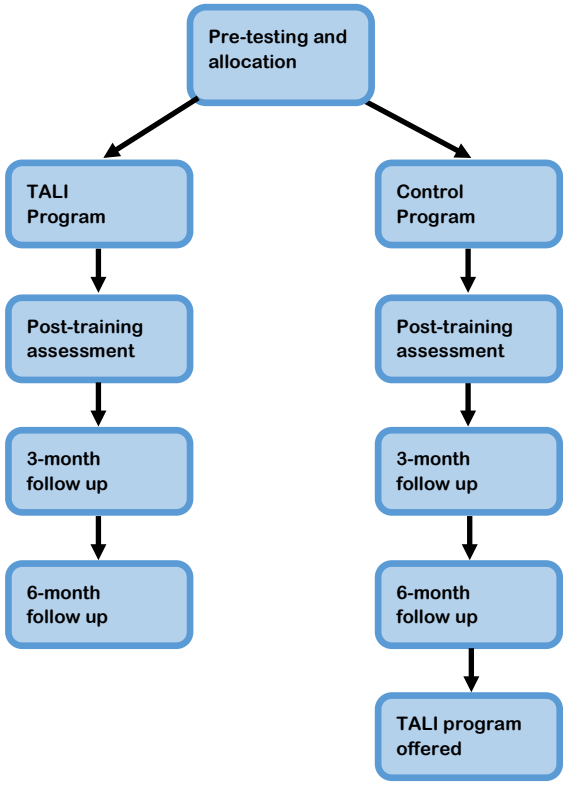
We are using this term in this study as an umbrella term to cover different kinds of injuries or conditions which could have affected the brain after birth. For example, it includes mild conditions like a concussion or head injury, as well as potentially more severe conditions like a stroke, or an infection like meningitis.

As this study is being run with the Royal Children's Hospital, we are contacting families where medical records indicate they may have experienced an injury or condition which falls into this board category.

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

You will be asked to complete a short questionnaire to determine your child's eligibility. If your child meets the eligibility criteria they will have an individual attention, social and learning assessment at the Murdoch Children's Research Institute. 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 general health, 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 a) the TALI 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 TALI 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 contact you each week to answer any questions you may have and address any concerns that may arise.

After completing the program, you and your child will then come in again for assessments 5 weeks after the start of the project, 3 months after the start of the project, and 6 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 – 2.5 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.

At the completion of the study, children in the control group will be given access to the TALI program should they be interested.

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 the TALI program is feasible for use with children with Acquired Brain Injuries, and if it promotes improvements in attention and academic 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 TALI 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.

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 Principle 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, 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.

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. The information may be disposed of in a confidential manner when the youngest participant turns 25 years old, as per law.

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

You will receive a six-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. In addition, the overall results of the trial will be included in a final email newsletter and the researchers will also organise an information evening to present the findings to you, and answer any questions.

The research findings will be published in journal articles and conference proceedings, and will form part of a PhD thesis. All data used for this purpose will be de-identified and analysed as a group to protect the privacy of participants.

10. Will I be reimbursed for participating?

To assist with the costs of taking part in this research, you will be reimbursed up to $50 per assessment visit for travel time and parking. At each assessment visit, you will receive a supermarket voucher valued at $30, with up to $20 provided to cover parking costs if required.

At the end of the study, you'll also receive the tablet on which you completed your allocated program during the study.

11. Who should I contact for more information?

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

Name:	Erin McKay or Danielle Courtney
Contact telephone:	9905 3255
Email:	TALI.Train2@monash.edu

You can contact the Director of Research Ethics & Governance at The Royal Children's Hospital Melbourne if you:

- have any concerns or complaints about the project
- are worried about your child's rights as a research participant
- would like to speak to someone independent of the project.

The Director can be contacted by telephone on (03) 9345 5044.

CONSENT FORM

HREC Project Number: 38132

Short Name of Project: TALI-Train

Version Number: 2 **Version Date:** 16th October 2018

- 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 Royal Children's Hospital Melbourne Human Research Ethics Committee. 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

☐ I do	☐ I do not	consent for my child's de-identified data to be used in other related studies by Monash University and the Murdoch Children's Research Institute
☐ I do	☐ I do not	consent to be contacted about future research projects related to Acquired Brain Injury
☐ I do	☐ I do not	consent for researchers to record information about my child's injury or illness, specifically injury severity, from the Royal Children's Hospital Electronic Medical Records

Child's Name		
Parent/Guardian Name	Parent/Guardian Signature	Date
Name of Witness to Parent/Guardian's Signature	Witness Signature	Date

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.

17.2 Appendix B – Child Information Sheet

Child info sheet v2.docx

Version 2, dated 19 November 2018

Approved: 19 November 2018 (HREC Reference Number: HREC/43027/RCHM-2018)

17.3 Appendix C - Tracing Letter

Treating department: VPRS

Date

Name

Address

Dear Ms/Mr (insert surname)

We are trying to make contact with (patient name), concerning possible involvement in a research project. Our records show that he/she may reside at this address.

It would be most helpful if you could please return the form below in the reply paid envelope provided, even if you are not the person we are looking for.

Your help in this matter is much appreciated.

Kind regards

A/Prof. Adam Scheinberg
Statewide Medical
Victorian Paediatric
Rehabilitation Service
The Royal Children's Hospital
Melbourne
50 Flemington Rd
Parkville
VIC 3052
Ph: TBC

Prof. Vicki Anderson
Head of Psychology
The Royal Children's Hospital
Melbourne
Ph: (03) 9345 4679

A/Prof. Cathy Catroppa
Honorary Research Fellow
Department of Psychology
The Royal Children's Hospital
Melbourne
Ph: 1300 766 439

✂ ……

(Please tick appropriate box)

Dear A/Prof. Scheinberg, Prof. Anderson and A/Prof Catroppa,

I would like further information about the research project ☐

I would not like further information about the research project ☐

I am not the person you are looking for. Please remove my details ☐

My name is: _____

My address is: _____

My contact phone number is: _____ Mobile: _____

Email: _____

Preferred contact method: Email ☐ Postal Address

Treating department: Other

Date

Name

Address

Dear Ms/Mr (insert surname)

We are trying to make contact with (patient name), concerning possible involvement in a research project. Our records show that he/she may reside at this address.

It would be most helpful if you could please return the form below in the reply paid envelope provided, even if you are not the person we are looking for.

Your help in this matter is much appreciated.

Kind regards

TBC	Prof. Vicki Anderson	A/Prof. Cathy Catroppa
Head of Department	Head of Psychology	Honorary Research Fellow
The Royal Children's Hospital Melbourne	The Royal Children's Hospital Melbourne	Department of Psychology
50 Flemington Rd	Ph: (03) 9345 4679	The Royal Children's Hospital Melbourne
Parkville		Ph: 1300 766 439
VIC 3052		
Ph: TBC		

✂ ……

(Please tick appropriate box)

Dear TBC, Prof. Anderson and A/Prof Catroppa,

I would like further information about the research project ☐

I would not like further information about the research project ☐

I am not the person you are looking for. Please remove my details ☐

My name is: _____

My address is: _____

My contact phone number is:_____ Mobile:_____

Email: _____

Preferred contact method: Email ☐ Postal Address ☐

Treating department: Psychology/None

Date

Name

Address

Dear Ms/Mr (insert surname)

We are trying to make contact with (patient name), concerning possible involvement in a research project. Our records show that he/she may reside at this address.

It would be most helpful if you could please return the form below in the reply paid envelope provided, even if you are not the person we are looking for.

Your help in this matter is much appreciated.

Kind regards

Prof. Vicki Anderson
Head of Psychology
The Royal Children's Hospital Melbourne
50 Flemington Rd
Parkville
VIC 3052
Ph: (03) 9345 4679

A/Prof. Cathy Catroppa
Honorary Research Fellow
Department of Psychology
The Royal Children's Hospital Melbourne
Ph: 1300 766 439

✂ ……

(Please tick appropriate box)

Dear Prof. Anderson and A/Prof Catroppa,

I would like further information about the research project ☐

I would not like further information about the research project ☐

I am not the person you are looking for. Please remove my details ☐

My name is: _____

My address is: _____

My contact phone number is: _____ Mobile: _____

Email: _____

Preferred contact method: Email ☐ Postal Address ☐

17.4 Appendix D - Causality and Assessment of Severity – Adverse Events

The severity of an Adverse Event will be assessed as follows:

- Mild: Events that require minimal or no treatment and do not interfere with the patient's daily activities.
- Moderate: Events that cause sufficient discomfort to interfere with daily activity and/or require a simple dose of medication.
- Severe: Events that prevent usual daily activity or require complex treatment.

The relationship of the event to the study intervention will be assessed as follows:

- Unrelated: There is no association between the study intervention and the reported event. AEs in this category do not have a reasonable temporal relationship to exposure to the test product, or can be explained by a commonly occurring alternative aetiology.
- Possible: The event could have cause or contributed to the AE. AEs in this category follow a reasonable temporal sequence from the time of exposure to the test product and/or follow a known response pattern to the test article, but could also have been produced by other factors.
- Probable: The association of the event with the study medication seems likely. AEs in this category follow a reasonable temporal sequence from the time of exposure to the test product and are consistent with the known pharmacological action of the intervention, known or previously reported adverse reactions to the intervention or judgement based on the investigators clinical experience.
- Definite: The AE is a consequence of administration of the test product. AEs in the category cannot be explained by concurrent illness, progression of disease state or concurrent medication reaction. Such events may be widely documented as having an association with the test product or that they occur after rechallenge.

17.5 Appendix E – Recruitment Letter

Recruitment letter V1.docx

Version 1, dated 29 March 2019

Approved: 9 April 2019 (HREC Reference Number: 38132)

17.6 Appendix F – Additional Recruitment Material

See Protocol V6 for previously approved materials.

Approved: 24 June 2019 (HREC Reference Number: 38132)

Website content

Title: TABI trial

Description: Testing a novel attention training programme for children with an acquired brain injury

Main Text:

Researchers at MCRI and Monash University are interested in understanding whether a game-based attention training program can strengthen attention in children who have experienced an acquired brain injury (ABI).

An acquired brain injury can sometimes have a big impact on the way a person thinks, feels and behaves. The term describes any type of brain injury that happens after birth, and includes damage due to infection, tumours, stroke, lack of oxygen, or trauma. Sometimes these kinds of injuries are also called head injuries or a concussion.

It is estimated that as many as 20% of children with an ABI will go on to develop significant attention deficits.

How to get involved

We're looking for children aged 4 - 9 years who have been diagnosed with an ABI.

At least 6 months will need to have passed since the time of their injury or, in the case of ABI due to cancers, since the conclusion of treatment.

If your child currently has difficulty with their attention, has experienced a brain injury and may be interested in taking part in our project, we would like to hear from you.

To receive an information pack or ask questions contact the team on:

Ph: 03 9905 3255

Email: tali.train2@monash.edu

Additional Social Media activity

Version 1.

When it comes to attention difficulties in childhood, early intervention is critical. A new study based at MCRI and [@Monash.University] is interested in whether a game-based attention training

program improves attention skills in children who've experienced an acquired brain injury (ABI, also sometimes called a head injury).

We're looking for children aged 4 - 9 years who have experienced an ABI to take part. Please get in touch with the research team for more information tali.train2@monash.edu

[Link to project page on MCRI website] [Image]

Version 2.

Can playing a game help improve attention after a brain injury? A new study based at MCRI and [@Monash.University] is interested in finding the answer.

We're looking for children aged 4 - 9 years who've experienced an acquired brain injury (ABI, also sometimes called a head injury) to take part, and help us understand whether a game-based attention training program can improve attention.

Get in touch with the research team if you'd like more information tali.train2@monash.edu

[Link to project page on MCRI website] [Image] Additional community organisation materials

Social media

Can playing a game help improve attention after a concussion or head injury? A new study based at MCRI and [@Monash.University] is interested in finding the answer.

We're looking for children aged 4 - 9 years who've experienced a concussion, head injury or an acquired brain injury (ABI) to take part, and help us understand whether a game-based attention training program can improve attention.

Get in touch with the research team if you'd like more information tali.train2@monash.edu

[Link to project page on MCRI website] [Image]

Newsletter, email or website blurb

Can playing a game help improve attention after a concussion or head injury?

Researchers at the Murdoch Children's Research Institute (MCRI) and Monash University are interested in understanding whether a game-based attention training program can strengthen attention in children who have experienced a concussion, head injury or an acquired brain injury (ABI).

An acquired brain injury describes any type of head or brain injury that happens after birth, and includes damage due to concussions, infection, tumours, stroke, lack of oxygen, or other trauma.

An ABI can sometimes have a big impact on the way a person thinks, feels and behaves. It is estimated that as many as 20% of children with an ABI will go on to develop significant attention deficits.

We're looking for children aged 4 - 9 years who have been diagnosed with a concussion or an ABI. At least 6 months will need to have passed since the time of their injury.

If your child currently has difficulty with their attention, has experienced a head injury and may be interested in taking part in our project, we would like to hear from you.

To receive an information pack or ask any questions, please contact the research team on: 03 9905 3255 or email: tali.train2@monash.edu

Study flyer

Title: Can playing a game help improve attention after a concussion or head injury?

Researchers at the Murdoch Children's Research Institute (MCRI) and Monash University are interested in understanding whether a game-based attention training program can strengthen attention in children who have experienced a concussion, head injury or an acquired brain injury (ABI).

The term 'acquired brain injury' describes any type of head or brain injury that happens after birth, and includes damage due to concussions, infection, tumours, stroke, lack of oxygen, or other trauma.

An ABI can sometimes have a big impact on the way a person thinks, feels and behaves. It is estimated that as many as 20% of children with an ABI will go on to develop significant attention deficits.

We're looking for children aged 4 - 9 years who have been diagnosed with a concussion or an ABI to take part. At least 6 months will need to have passed since the time of their injury.

If your child currently has difficulty with their attention, has experienced a head injury and may be interested in taking part in our project, we would like to hear from you.

To receive an information pack or ask any questions, please contact the research team on: 03 9905 3255 or email: tali.train2@monash.edu

Approved by Royal Children's Hospital Human Research Ethics Committee: #38132