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Digital cognitive training in children with attention-deficit/hyperactivity disorder: a study protocol of a randomised controlled trial

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ABSTRACT

Introduction Attention-deficit/hyperactivity disorder (ADHD) is one of the most prevalent neurodevelopmental disorders and is a persistent pattern of inattention and/or hyperactivity-impulsivity that interferes with daily functioning. Children with ADHD are developmentally vulnerable, with the disorder linked to emotional regulation difficulties, behavioural disturbances, as well as academic challenges. Emerging evidence suggests that children with ADHD may benefit from cognitive training interventions, including those focused on attention. This study aims to assess the immediate and long-term efficacy of an attention training intervention in children with ADHD.

Methods and analysis This study is a preregistered, parallel, double blind, randomised controlled trial. Participants will comprise 104 children with a diagnosis of ADHD aged 5–8 years 11 months. Participants will be randomly allocated to either an adaptive, digital game-based (1) attention training programme (intervention) or (2) a numeracy programme (control). Both programmes will be delivered on a touchscreen tablet, and children will complete five 20 min sessions per week for a 5-week period at home (25 sessions in total). Assessments of the primary outcome (ie, attention and inhibitory control) and secondary outcomes (ie, selective attention, interference control, sustained attention, inhibition, behavioural attention, impairment in everyday functioning, working memory and executive functioning) will occur at preintervention, immediately postintervention and at 3-month follow-up. Multivariate linear regression will be employed to examine primary and secondary outcomes. The data analyst will be blinded to group membership.

Ethics and dissemination Ethics approval has been obtained from the Monash University HREC (20495). Results will be disseminated through peer-reviewed journals, conference presentations, media outlets, the internet and various community/stakeholder activities.

Trial registration number ACTRN12620000964910, UTN U1111-1250-2620.

Strengths and limitations of this study

- ⇒ Parallel, double-blind, randomised controlled, superiority trial comparing an attention training programme to an active control programme.
- ⇒ The intervention and control programmes are matched on adaptiveness, reinforcers and training time.
- ⇒ Examination of psychosocial factors as potential predictors of attention training outcomes in children with attention-deficit/hyperactivity disorder.
- ⇒ Long-term follow-up at 3 months.
- ⇒ A relatively small sample size is a potential limitation and multiple recruitment strategies will be implemented to increase the likelihood of obtaining an adequate number of participants.

INTRODUCTION

Attention-deficit/hyperactivity disorder (ADHD) is among the most prevalent mental disorders, affecting approximately 5% of children and adolescents worldwide, and is associated with a large economic and social cost.[1–4] The essential diagnostic features of ADHD are a persistent pattern of inattention and/or hyperactivity-impulsivity that interferes with daily functioning or development, leading to emotional and behavioural disturbances, as well as academic challenges.[5–7] Pharmacological treatments have been effective in improving attention outcomes for children and adolescents with ADHD, however, their long-term developmental impact remains unclear.[8] There is a growing focus on exploring non-pharmacological digital treatment approaches, specifically cognitive training, for ADHD in a two times per day to promote longer-term changes in both behavioural and cognitive functioning.[9–13] If cognitive training can improve the cognitive abilities of children with ADHD then there may be important implications for developmental trajectories. Investigating this impact for children who have just started school is particularly important because attention processes are undergoing rapid

development and this may represent an important period for intervention.[14]

The premise of cognitive training is that repeated practice of a cognitive skill will result in gains for that skill. Cognitive training is theoretically based on the concept of neuroplasticity, the brain's capacity to alter structure and function in response to environmental factors.[15] Meta analyses have shown that there are robust performance deficits in psychological processes for people with ADHD.[4] Specifically, for children and adolescents with ADHD, moderate impairments in the domains of attention and inhibitory control are common.[4 16] Cognitive training aims to strengthen neurocognitive functioning by external stimulation.[17]

The focus of most cognitive training approaches has been to achieve improvements in both directly trained domains but also in other untrained domains. When gains are observed for tasks that share many elements with the trained task they are said to illustrate near transfer, whereas tasks that share fewer elements are said to illustrate far transfer.[18] An optimal result will be that training benefits generalise, and improvements will be observed both across similar tasks (near transfer) and in domains associated with the trained skill (far transfer). Several meta-analyses and reviews have examined the outcomes of cognitive training interventions for children and adolescents with ADHD.[19–23] Evidence of small to moderate near transfer effects to the domain being trained have been found, including the domains of attention, inhibitory control and working memory for school-aged children[19 21] and working memory and inhibitory control for preschoolers.[20 22] The evidence for far transfer to untrained domains is limited with less support for the effect of cognitive training on outcomes such as, educational, interpersonal and behavioural.[19 21 22]

Drawing conclusions from the outcomes of cognitive training studies has been difficult as many of the studies contain methodological limitations, including non-random assignment of participants and inadequate control conditions. Two recent randomised controlled trials (RCTs) of cognitive training for children with ADHD (N=238, 8–12 years; 9, N=80, 7–14 years; 10) have addressed many of these limitations by, for example, incorporating active control conditions that are matched to the intervention condition by time-on-task and reinforcers. These RCTs demonstrate targeting attention and inhibitory control can improve performance on objective measures for children with ADHD, including the Test of Variable Attention (TOVA) a validated, continuous performance test that measures attention and inhibitory control.[9 10] For both RCTs however, there was no difference between the intervention and control conditions, on a range of secondary outcomes including parent and clinician ratings of ADHD symptoms, academic outcomes and functional impairment.[9 10] These studies indicate that cognitive training may be useful in improving aspects of cognitive functioning for children with ADHD, but that further research is required to understand the lack of improvement for parent or clinician reported outcomes.

One programme that has demonstrated training related improvements in attentional processes is an adaptive cognitive training programme, TALI Train.[24–26] TALI Train was developed to address the lack of effective, non-pharmacological treatments for children with significant cognitive and attention deficits such as those with intellectual and developmental disorders. The TALI Train programme comprises four game-based exercises presented to children via a touchscreen tablet. A key advantage of the TALI Train programme is that it can be used at home, in schools, or in clinical settings, without need for coaching or attendance at regular clinical appointments.

TALI Train has been shown to improve cognitive attention and numeracy outcomes in children with intellectual delay due to conditions such as, autism spectrum disorder and Down syndrome.[24 25] Further, for children with intellectual delay, TALI train has been found to be more beneficial for those with lower adaptive functioning and higher pre-intervention attention abilities.[27] When delivered in the classroom to primary school children, TALI Train has been shown to improve inattentive and/or hyperactive behaviours in the classroom and at home[26]

Objectives

For children with ADHD, this study aims to assess: (1) whether TALI Train improves core attention and inhibitory control abilities (selective attention, sustained attention, response inhibition and interference control); (2) whether TALI Train improves performance on the following untrained domains: working memory, behavioural attention, functional impairment, executive and social functioning; (3) the long-term effects of TALI Train; and (4) predictors of the training outcomes.

Trial design

This study is designed as a double blind, randomised, controlled, superiority trial with two parallel groups (equal allocation ratio). The efficacy of TALI Train (here referred to as the intervention) compared with the placebo control programme will be evaluated at baseline, immediately postintervention, and at 3-month follow-up. The trial was designed in accordance with the Consolidated Standards of Reporting Trials statement and will be conducted and reported on the same basis. Roles and responsibilities for the trial are defined in the Site Signature and Delegation of Duties Log (refer to online supplemental file 1).

METHOD AND ANALYSIS

Study setting

The study will be conducted in a predominantly urban setting. All assessments will occur at the Monash University Turner Psychology Clinics, Clayton, Victoria, Australia. The intervention and the control programme will both be

completed by participants in their homes for the 5-week training period.

Eligibility criteria

To be eligible to participate in the trial, children must: (1) be aged between 5 years and 8 years 11 months at the time of randomisation; (2) have a primary Diagnostic and Statistical Manual of Mental Disorders (DSM) diagnosis of ADHD (DSM-4 or DSM-5); (3) have caregivers that agree to not initiate any other therapy or intervention for the purpose of treating their child's inattention and/or hyperactivity-impulsivity for the 5-week training period and (4) have caregivers that agree to keep a stable dose of ADHD medication (if the child is medicated) for at least 4 weeks prior to trial entry, and for the 5-week training period. Any changes to medication dosage, type and/or frequency will be reported for the full duration of the trial.

Children will be excluded from the study if they: (1) are unable to comprehend and follow study instructions, including where sensory or physical impairments are present; (2) have a history of major trauma; (3) have a diagnosed or borderline intellectual delay (full-scale IQ (FSIQ) <80 on the Wechsler Intelligence Scale for Children (WISC) or Wechsler Preschool and Primary Scale of Intelligence (WPPSI), table 1); (4) have a known monogenic cause for their ADHD diagnosis; (5) have a comorbid diagnosis other than ASD with significant symptoms that may confound study data; (6) have a sibling also enrolled in the trial or (7) have previously participated in a study of a cognitive training programme.

Children who meet all the inclusion criteria and none of the exclusion criteria will be invited to progress to screening. Attention difficulties will be screened via a parent-reported online questionnaire (108 items, Conners 3 (6–10 years) or 110 items, Conners Early Childhood (EC, 5–6 years), table 1). Participants scoring above the clinical cut-off of 65 (T-score, 'Elevated Score') on either of the two subscales relating to inattentive behaviour (inattention or DSM Inattentive) on the Conners 3, or on the inattention/hyperactivity subscale of the Conners EC will be deemed eligible for the current study. Caregivers will also be required to complete the Development and Well-Being Assessment (DAWBA, table 1), a semistructured diagnostic schedule. The DAWBA will be administered online and interpreted by a qualified clinician (and reviewed by a panel of research team members). The DAWBA will be used to independently confirm whether the child meets Diagnostic and Statistical Manual of Mental Disorder criteria, DSM-5, for a diagnosis of ADHD. Children who have not undergone IQ testing within the last 2 years will be administered either the WISC Fifth edition (WISC-V) or the WPPSI-Fourth edition (WPPSI-IV; dependent on age) to determine if their FSIQ is greater than 80. Children who pass the screening criteria will be invited to enrol in the trial.

Intervention programme

The intervention is administered on a touchscreen tablet device provided to participants for the duration of the intervention. The intervention programme consists of four game-based tasks that are completed during a 20 min training session. Children will be required to complete five, 20 min sessions per week for 5 weeks, 25 sessions in total. The intervention programme was initially designed for children with an intellectual disability. Additional difficulty levels were added for each task when the intervention programme was evaluated for primary school children and this is the version used in this study.[26] At the end of each training task, children will be rewarded with a virtual toy. The tasks of the intervention target selective attention, sustained attention, response inhibition and interference control. The tasks are designed to be adaptive, such that the difficulty level increases depending on the participant's performance. (1) Selective attention—this task aims to improve the ability to attend to specific sensory information.[28] Children are required to locate targets among a series of distractors that differ from the target in size, colour, pattern, and orientation. (2) Sustained attention—this task aims to improve the ability to maintain alertness via a vigilance task. Children are required to monitor a moving target and to indicate when the target stops moving as quickly as they can. (3) Inhibition—this task is based on the Go/No-Go paradigm and aims to improve the ability to inhibit a motor response.[29] Children are required to press the screen when a target appears but to withhold responding when a non-target appears. (4) Interference control—this task aims to improve the ability to ignore interference from distractors. This task presents a target that is flanked by non-targets facing in either the same (ie, congruent) or opposite (ie, incongruent) direction to the target. Children are required to make a response (left or right) depending on the direction the target is facing.

Training adherence will be monitored remotely via the TALI online platform by an unblinded researcher. Compliance will be determined by the number of sessions completed; with non-compliance to be recorded if a participant completes less than 20 full training sessions or takes longer than 6 weeks to complete the programme. However, if participants miss sessions for a period of time, they will be encouraged to try and make these sessions up. For example, if only two sessions are completed in Week 1 of training, then participants will be encouraged to complete the missed three sessions in the subsequent 4–5 weeks. All participants, regardless of compliance will be invited to attend the postintervention and 3-month assessment.

Control programme

The control programme is a commercially available programme that requires children to practise age-appropriate mathematics and numeracy skills such as counting, addition and geometry. The control programme requires minimal attentional skills and can be matched

Table 1 Schedule of measures

Outcome	Measure	Administration	Screening	Time 1	Time 2	Time 3
Screening						
Inattention and DSM inattention/inattention-hyperactivity	Conners 3/Conners EC	Parent report	x	–	–	–
FSIQ*	WISC/WPPSI	Child	x	–	–	–
Demographics	Demographic and Medical Questionnaire	Parent report	x	–	–	–
Development and well-being	DAWBA	Parent report	x	–	–	–
Primary outcome						
Attention and Inhibitory Control	T.O.V.A. Attention Comparison Score	Child		x	x	x
Secondary outcomes						
Selective attention	TEA-Ch 2 J, Balloon hunt/TEA-Ch2 Hector Cancellation†	Child	–	x	x	x
	TEA-Ch2 J Balloons 5/ TEA CH 2 A, Hector B‡	Child	–	x	x	x
Sustained attention	T.O.V.A, Target 'infrequent' half	Child	–	x	x	x
Response inhibition	T.O.V.A, Target 'frequent' half	Child	–	x	x	x
Interference control	Child Attention Network Task	Child	–	x	x	x
Inattentive and impulsive/ hyperactive behaviour	Strengths and weaknesses of ADHD symptoms and normal behaviour	Parent report	–	x	x	x
Impairment in everyday functioning	Impairment Rating Scale	Parent report	–	x	x	x
Visuospatial working memory	Corsi Block Tapping Test	Child	–	x	x	x
Auditory working memory	Digit Span Task	Child	–	x	x	x
Executive functioning	Behaviour Rating Inventory of Executive Functions (BRIEF2)	Parent report	–	x	x	x
Executive functioning	BRIEF2	Parent report	–	x	x	x
Prognostic factors						
Child sleep habits	Children's Sleep Habits Questionnaire	Parent report	–	x	x	x
Intrinsic Motivation	Dimensions of Mastery Questionnaire	Child	–	x	x	x
Sleepiness	Stanford Sleepiness Scale	Child, pre- and post-assessment	–	x	x	x
Parental mental health	Depression Anxiety Stress Scales-21	Parent self-report	–	x	x	x
Family functioning	Parenting Stress Index 4-SF	Parent self-report	–	x	x	x
Child depressive symptoms	Children's Depression Inventory-2	Parent report	–	x	x	x

Continued

Table 1 Continued

Outcome	Measure	Administration	Screening	Time 1	Time 2	Time 3
Child anxiety symptoms	Spence Children's Anxiety Scale-P	Parent report	–	x	x	x
Expectancy survey		Parent report	–	x	x	x

*Children who have not undergone IQ testing within the last 2 years, will be asked to complete either the WISC or the WPPSI (dependent on age).
†Outcome, number of responses.
‡Outcome, response time.
ADHD, attention-deficit/hyperactivity disorder; DAWBA, Development and Well-Being Assessment; DSM, Diagnostic and Statistical Manual of Mental Disorders; EC, Early Childhood; FSIQ, full-scale IQ; T.O.V.A, Test of Variable Attention; WISC, Wechsler Intelligence Scale for Children; WPPSI, Wechsler Preschool and Primary Scale of Intelligence.

to the intervention programme on other design aspects, including, time, reinforcers and adaptiveness. The control programme is computerised, game-based and delivered on a tablet. The control programme is also motivational, reward-based and will be played for five 20 min sessions per week for 5 weeks, 25 sessions in total.

Discontinuation criteria

Participants may be withdrawn if they: (1) commence medication, any therapy or other intervention for the purpose of treating inattention and/or hyperactivity-impulsivity during the 5-week training period; (2) violate the study protocol; (3) experience a serious or intolerable adverse event (AE) or (4) experience a decline in well-being.

All participants will be withdrawn if the study is terminated. Termination of the study can only be made by the Chief Investigator. Participants are free to withdraw from the study at any time on their request. Withdrawing from the study will not impact their ability to access interventions in future.

Adherence

Adherence to the training schedule for both conditions will be monitored via secure online platforms that record usage. If any issues with adherence are detected, contact will be made by an unblinded researcher with the participant's family to check on progress. Caregivers can also contact the unblinded researcher at any time to address any questions or concerns. All caregivers are additionally asked to complete a training log to record each completed session, to be returned at the postintervention assessment. At each point of contact, where possible, researchers will ask participants and their caregivers questions to elicit any changes in well-being. If researchers notice a decline in the child's or caregiver's well-being, they will provide information for appropriate support services. Caregivers will also be asked to rate their expectation regarding the effectiveness of the programme on their child's attention abilities (from 1 'no improvement' to 10 'substantial improvement') after the first week of training, immediately postintervention and at 3-month follow-up.

Outcomes

All outcome and predictor measures have been developed and/or used with children between the ages of 5–8 years. All measures were selected based on their frequency of use within paediatric ADHD samples and their psychometric properties (table 2).

Primary outcome

The primary endpoint is change in attention and inhibitory control performance as measured by the T.O.V.A. Attention Comparison Score (ACS).[30] The T.O.V.A. ACS is a composite score consisting of the sum of three component scores: (1) reaction time (RT) mean Half-1 (highly infrequent targets), (2) RT variability total (both halves) and (3) d-prime Half-2 (highly frequent targets).

The primary objective is to test for a difference between the intervention group and the control group in the improvement in attention performance on the T.O.V.A. ACS between baseline (preintervention) and the immediate postintervention time point.

Secondary outcomes

The first major secondary objective is to test for a difference between the intervention group and the control group in the improvement in performance on the T.O.V.A. ACS (with endpoint defined as above for the primary objective) between baseline (preintervention) and the 3-month postintervention follow-up time point.

The other major secondary endpoints are as follows:

- Selective attention as measured by the TEACh 2 (Balloon Hunt/Hector Cancellation subtest: mean targets located).[31]
- Interference control as measured by the Child Attention Network Task (ANT; difference in mean RT on congruent vs incongruent trials).[32]
- Sustained attention performance as measured by the T.O.V.A. (response time variability and omission errors).[31]
- Inhibition as measured by the T.O.V.A (commission errors and anticipatory responses).[31]
- ADHD symptoms as measured by the SWAN parent questionnaire (total score).[33]

Table 2 Psychometric properties of study measures

Measure	Domain	Administration	Psychometrics
Conners 3/conners EC	Behavioural Inattention	Parent report	Conners 3, population 6–18 years; US norms; four-point Likert scale ranging from 'not true at all (never/seldom)' to 'very much true (very often, very frequently)'; six content scales (Inattention, Hyperactivity/Impulsivity, Learning Problems, Executive Functioning, Defiance/Aggression, Peer/Family Relations) and four symptom scales (ADHD/Inattentive, ADHD/Hyperactive-Impulsive, Conduct Disorder, Oppositional Defiance Disorder); reliability, internal consistency parent report >0.90; test–retest reliability parent coefficients, 0.72–0.98; established discriminant validity.[49] Conners EC, population 2–6; US norms; four-point Likert scale as per the Conners 3; six behaviour scales (Inattention/Hyperactivity, Defiant/Aggressive Behaviours, Anxiety, Mood and Affect, Physical Symptoms) and five development milestones scales (Adaptive skills, Communication, Motor Skills, Play, Pre-Academic/Cognitive); reliability, internal consistency parent coefficients 0.64–0.94 (behaviour scales); retest reliability parent, 0.73–0.98; convergent and divergent validity established.[50]
WISC-V/WPPSI-IV	Intelligence	Child	WISC-V, population 6–16 years 11 months; split-half reliability 0.96; established concurrent validity.[51] WPPSI-IV, population; 2–6 – 7–7; internal consistency (0.95–0.96 for FSIQ), test–retest stability, and inter-scorer agreement established; established content validity, internal structure data, and convergent validity.[52]
Demographic and Medical Questionnaire	Demographics	Parent report	Not applicable
Development and Well-Being Assessment (DAWBA)	Development and Well-being	Parent Report	DAWBA, population suitable for use with parents of children aged 5–16 years; symptoms are typically rated on a three-point Likert scale ('No/No more than other', 'A little/A little more than others', 'A lot/A lot more than others); generates ICD-10 and DSM-5 diagnoses, including internalising and externalising disorders; inter-rater reliability coefficients 0.79–0.89[53] and high specificity, 0.97 for ADHD diagnosis.[54]
Test of Everyday Attention for Children, second Ed. TEA-Ch 2 J/A	Selective attention	Child	Population, ages 5–16 years; Australian norms; test–retest reliability, 0.57–0.87; strong to moderate correlations for construct validity.[31]
Test of Variables of Attention	Sustained attention and response inhibition	Child	Population, ages 4–17 years; US norms for children aged 6–16 stratified by age and gender.[30] Omission errors have good internal consistency, *r*=0.52–0.94[55] and satisfactory test–retest reliability *r*=0.51–0.61[56] when used with children with ADHD. Commission errors have slightly less robust internal consistency, r=0.32–0.76[55] and moderate test–retest reliability, r=0.58–0.71[46] for children with ADHD. measures of sustained attention and inhibitory control.
Child Attention Network Task	Interference control	Child	Population, 6–10 years; test–retest reliability, 0.94 overall RT, 0.93 overall error rate.[32]
Stanford Sleepiness Scale	Sleep	Child	Population, from age 7; one-item questionnaire; seven-point Likert scale ranging from 'Feeling active, vital, alert, or awake' to 'No longer fighting sleep…'; One item therefore internal consistency and inter-rater reliability not applicable; Adequate content validity in adults.[57–59]
Corsi Block Tapping Test	Visuospatial working memory	Child	Developmental norms available; inconsistencies in task administration have generated inconsistent psychometrics.[35 60]
Digit Span Task	Verbal working Memory	Child	Computerised tests of digit span, increased test–retest reliability and precision.[36 61]

Continued

Table 2 Continued

Measure	Domain	Administration	Psychometrics
Dimensions of Mastery Questionnaire Self-Report (DMQ)	Intrinsic Motivation	Child	Population, school age; 41 items, five-point Likert scale ranging from 'Not at all like me' to 'Exactly like me'; General competence scale and six mastery motivation scales: cognitive/object persistence, gross motor persistence, social persistence with adults, social persistence with children/peers, mastery pleasure and negative reactions to challenge in mastery situations. adequate internal consistency and test–retest reliability.[39]
Strengths and weaknesses of ADHD symptoms and normal behaviour	Behavioural attention and hyperactivity	Parent report	Population, from age 4; 18 items, seven-point Likert scale ranging from 'far below average' to 'far above average'; Two subscales, Inattentive and Hyperactive/Impulsive; Adequate reliability and validity reported in recent review.[33 62]
Children's Sleep Habits Questionnaire	Sleep	Parent report	Population, from age 2; 33 items, three-point Likert scale from 'usually' to 'rarely'; subscales: Bedtime Resistance, Sleep Onset Delay, Sleep Duration, Sleep Anxiety, Night Wakings, Parasomnias, Sleep Disordered Breathing and Daytime Sleepiness; Low to moderate construct validity compared with actigraphy and polysomnography.[38]
Parenting Stress Index-4-SF	Family functioning	Parent self-report	Population, parents of children aged 1 month to 12 years; 36-item measure, 5-point Likert scale, from 'strongly agree' to 'strongly disagree' (majority of items); subscales: Parental Distress, Parent-Child Dysfunctional Interaction and Difficult Child; good test–retest reliability, α=0.84, internal consistency, Cronbach's α=0.81, and convergent and discriminant validity.[40 63]
Depression Anxiety Stress Scales-21	Psychological status	Parent self-report	Population, from 14 years; 21 items, 3 scales, 7 items per scale; four-point Likert scale, from 'Did not apply to me at all' to 'Applied to me very much, or most of the time'; subscales: Depression, Anxiety and Stress; good internal consistency and temporal stability; support for general distress factor underlying depression and anxiety.[41 64 65]
Children's Depression Inventory (CDI-2)	Psychological status	Parent report	Recommended population, 7–17 years; 17 items, four-point Likert scale ranging from 'Not at all' to 'Much or most of the time'; subscales: Emotional Problems, Functional Problems; responses are rated on parental observations over the past week. Evidence for concurrent validity with the CDI child report.[42 66]
Spence Children's Anxiety Scale	Psychological status	Parent report	Population, 6–18 years; 38 items; four-point Likert scale ranging from 'Never' to 'Always'; rated over the past week; subscales: Obsessive Compulsive, Social Phobia, Panic Agoraphobia, Separation Anxiety, Physical Injury Fears, Generalised Anxiety; good psychometric properties for children with comorbid anxiety and ADHD.[43 67 68]
Behaviour Rating Inventory of Executive Functions	Executive functioning	Parent report	Population, 5–18 years, 63 items, three-point Likert scale ranging from 'Never' to 'Often; rated over the past week; subscales: Inhibit, Self-monitor, Shift, Emotional Control, Initiate, Working Memory, Plan/Organise, Task-monitor, Organisation of Materials; high reliability (α=0.90) and good construct validity.[69]
Impairment Rating Scale	Impairment in everyday functioning	Parent report	Population, 3–12 years; seven-point Likert scale ranging from 'No problem, definitely does not need treatment or special services)' to 'Extreme problem, definitely needs treatment or special services'; Seven domains (relationship with peers, relationship with siblings, relationship with parents, academic progress, self-esteem, influence on family functioning, and overall impairment) rated over the past week; good temporal stability, correlations with other impairment ratings and behavioural measures, and evidence of convergent and discriminant validity.[34]

Continued

Table 2 Continued

Measure	Domain	Administration	Psychometrics
DMQ Parent Report	Intrinsic Motivation	Parent report	Population, from 3 years; 41 items; five-point Likert scale ranging from 'Not at all like my child' to 'Exactly like my child'; General competence scale and six mastery motivation scales as per DMQ self-report;. internal consistency (Cronbach's α, 0.79–0.96), and temporal stability adequate to excellent (tester–test reliabilities, .79 to .89); inter-rater reliabilities satisfactory; rated over the past week.[39 70 71]

ADHD, attention-deficit/hyperactivity disorder; DSM, Diagnostic and Statistical Manual of Mental Disorders; EC, Early Childhood; FSIQ, full-scale IQ; ICD-10, International Classification of Diseases, 10th Revision; WISC-V, Wechsler Intelligence Scale for ChildrenFifth edition; WPPSI-IV, Wechsler Preschool and Primary Scale of Intelligence Fourth edition.

The other secondary endpoints are as follows:

- Impairment in everyday functioning as measured by the Impairment Rating Scale (average score).[34]
- Visuospatial working memory as measured by the Corsi Block-Tapping task (total performance score – product of the maximum span length and the number of correctly repeated sequences).[35]
- Auditory working memory as measured by the Backward Digit Span task (total performance score – product of the maximum span length and the number of correctly repeated sequences).[36]
- Executive functioning as measured by the BRIEF 2 (total GEC score).[37]

The secondary objectives, then, are to test for a difference between the intervention group and the control group in the improvement in each of the above secondary endpoints:

- Between baseline (preintervention) and the immediate postintervention time point.
- Between baseline and the 3-month postintervention time point.

Exploratory analysis prognostic factors

To assess the impact (change in T.O.V.A. ACS from preintervention to postintervention) of each of the below baseline (preintervention) characteristics:

- Sleep (CSHQ-total score).[38]
- Intrinsic motivation (DMQ-total mastery motivation score).[39]
- ADHD medication status (medicated vs unmedicated).
- Number of sessions completed.
- Family functioning (PSI parent: total score).[40]
- Pparent expectancy (intervention vs control vs unknown).

The outcome measures and their psychometric properties are listed in tables 1 and 2, respectively. The secondary outcome measures cover the following domains: cognitive attention, behavioural attention (inattention and hyperactivity), impairment in everyday functioning, working memory, and executive functioning and have been included to assess whether far transfer occurs as a result of the intervention.[30–37] The prognostic factors cover the domains of sleep, intrinsic motivation, family functioning and mental health (parent report).[38–43] Prognostic factors were selected because they have been linked to cognitive development in children and may influence the efficacy of the intervention.[44–48]

Participant timeline

The time schedule of enrolment, interventions and assessments are presented in figure 1 and table 1. The trial will involve a 5-week training period with assessments at baseline (time 1), immediately postintervention (time 2, baseline +5 weeks) and at 3-month follow-up (time 3, baseline +3 months).

Sample size calculation

A sample size calculation using G*Power 3.1 determined that a sample size of 50 participants per group is sufficient to detect a difference between groups with >80% power given an effect size of 0.57 using a two tailed, independent groups t-test allowing for a type 1 error (α) of 0.05.

Recruitment

The primary recruitment methods will be via social media, community outreach and participating paediatric clinics. Information on the study will be distributed via social media (eg, Facebook) including organisations that provide ADHD support services, and websites linked to Monash University. Additionally, posters/flyers containing information about the trial will be circulated to independent schools, universities and libraries within 50 km of Monash University. Participants from existing Monash University studies who meet the inclusion criteria and have provided prior consent to be contacted regarding future research projects will be emailed information about the current trial. Recruitment commenced in March 2021 and is anticipated to finish in September 2021 with data collection to be completed in December 2021. Due to the requirement for face-to-face assessments it is anticipated that participants will be residents of Victoria.

Caregivers will be instructed to contact the research team directly if they would like further information about participation. Caregivers will be given at least 2 weeks to consider participation and will also be provided with an opportunity to ask any questions, to ensure that participants understand the purpose, extent and possible risks

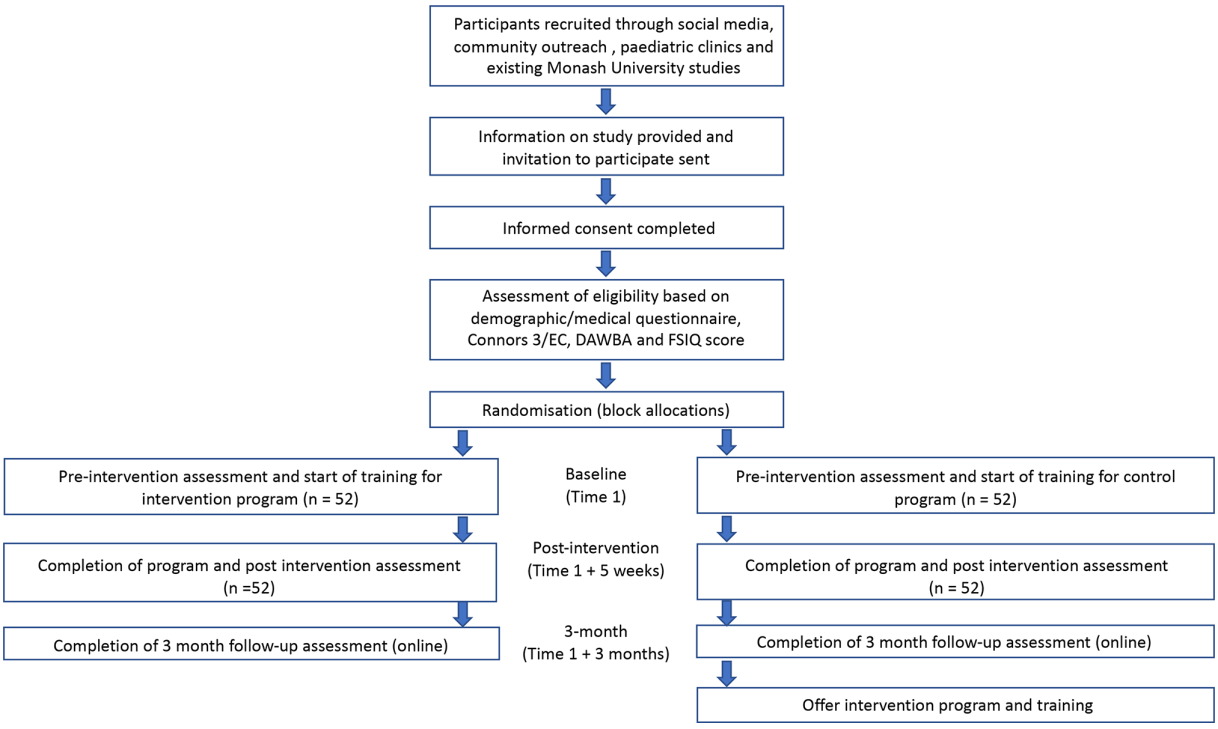

Figure 1 Protocol flow chart. DAWBA, Development and Well-Being Assessment; EC, Early Childhood; FSIQ, full-scale IQ.

associated with their involvement in the study. If informed consent is received, families will be invited to participate in screening.

Screening will be conducted online. Caregivers will be emailed an invitation to complete a demographic and medical questionnaire, the Conners 3 or Conners EC and the DAWBA (table 1). The demographic and medical questionnaire will include questions pertaining to parental education and occupation, and child medication type and dosage. If a child has completed an IQ assessment in the previous 2 years, caregivers will be asked to provide the FSIQ result of this assessment. Children who have not undergone an IQ assessment within the last 2 years will be invited to complete the WISC or the WPPSI (dependent on age) administered by a trained team member. Following completion of screening, researchers will assess eligibility for the study based on the inclusion/exclusion criteria.

Allocation

An unblinded researcher will allocate participants based on computer-generated random numbers. Block randomisation (ratio 1:1, blocks of 10) will be used to maintain balance between intervention arms. Randomisation will be stratified based on medication status at screening with two strata: takes medication for ADHD symptoms or does not take medication for ADHD symptoms.

Concealment mechanism

Randomisation documentation will be securely stored online and inaccessible to researchers undertaking recruitment and testing. Group allocation information will not be available to researchers conducting screening and assessments for the duration of the trial (including during data analysis). Participants will be explicitly instructed not to discuss the contents of their assigned programme with the researchers at the beginning of each assessment session. Group allocation details and randomisation codes will only be available once all data collected have been entered into the study database for every participant and the database has been finalised, except in the case of an emergency. If the study blind is broken for a participant, the date, time, participant ID and reason for unblinding will be documented.

Data collection

Preintervention, postintervention and 3-month follow-up assessments will be conducted by researchers blinded to group allocation (refer to table 1 for schedule for assessments). The assessments are estimated to take 2 hours to complete and if participants find the sessions to be tiring, small breaks will be provided as needed. If children are unable to complete the full assessment the session will be concluded, and any remaining measures will not be administered. Caregivers will be asked to complete a number of tablet-based parent-report measures during assessments. If the caregiver who completed the measures at the first time point does not attend subsequent assessment sessions with the child, they will be invited via email to complete the measures remotely. All study measures are described in table 1 with available psychometric information in table 2.

Researchers will be trained in all study procedures and requirements, including the assessment measures. Trial checklists will be used to monitor data collection and for

each participant all data will be recorded in a case report form (CRF). One of the researchers from the initial assessment will be present, wherever possible, at subsequent assessments.

Data management

Study data will be collected as paper and electronic files and managed within a Research Electronic Data Capture database, which will form an electronic CRF for each participant. All data will be securely stored, checked, monitored and analysed according to study standard operating procedures. This will include identifying data by ID number only. All confidential participant contact information and identifiable data (eg, signed consent forms) will be stored separately within the database. All study documents will be stored in accordance with relevant government regulations regarding retention and disposal of participant records.

The recording of AEs is the responsibility of the investigators, regardless of their relationship to study intervention, with the exception of conditions that are present at screening and do not deteriorate. AEs will be detailed within the participant's file and will include a description of the AE, the onset date, duration, date of resolution, the severity (mild, moderate or severe), any action taken, the outcome (recovery, continuing, worsening), and the likelihood of the relationship of the AE to the study intervention (unrelated, possible, probable, definite).

The clinical monitoring plan defines the requirements for data monitoring and has been provided in online supplemental file 2.

Statistical methods

Screening data will be analysed to assess the attention profiles of participants. No further interim analyses will be conducted. At the conclusion of the trial, investigators approved by Monash University HREC will have access to the trial data. An Intention to Treat approach will be taken, where data from all children enrolled in the trial will be analysed regardless of compliance.

For all outcomes (primary and secondary), estimates and 95% CIs for the mean scores for the intervention and control groups for each time point will be presented.

Multivariate linear regression will be used to estimate the difference between arms (intervention vs control) in the change in outcome scores (1) from baseline until postintervention assessment at 5 weeks (immediate effect) and (2) from baseline until post-intervention assessment at 3 months (sustained effects). Point estimates, 95% CIs and p values for the hypothesis test with null hypothesis of no difference between arms will be provided.

For both the immediate and sustained effects models, baseline outcome and age will be controlled for as covariates in the analysis.

Additional models of the primary outcome (T.O.V.A. ACS, immediate postbaseline time point) will be constructed to assess the effect of the following prognostic factors assessed at baseline (preintervention):

- Sleep (CSHQ total score).
- Intrinsic motivation (DMQ total score).
- ADHD medication status (medicated vs unmedicated).
- Adherence to assigned programme (number of sessions completed).
- Family functioning (PSI total score).

Multivariate linear regression models which consider treatment arm, baseline T.O.V.A. ACS score and the prognostic factor of interest as independent variables and the immediate change in T.O.V.A. ACS as the dependent variable will be constructed. The estimated effect of each of the baseline factors of interest, its 95% CI, and the p value for the hypothesis test with a null hypothesis that the baseline factor has no effect when controlling for the other baseline factors will be reported.

The above analysis method will be repeated for the key secondary outcome of change in ADHD symptoms (SWAN total score). Treatment arm and baseline score will be included in the model as independent variables, and parent expectancy will be considered as the only prognostic factor of interest.

Baseline demographic and characteristics of ADHD will be summarised descriptively to give an indication of different attention profiles across children with ADHD.

Researchers will be blinded to group allocation throughout the trial including analyses.

ETHICS AND DISSEMINATION

Research ethics approval

The study was approved by the Monash University Human Research Ethics Committee (HREC) on 23 June 2020, reference number 20495. Reporting of the protocol adheres to the Standard Protocol Items: Recommended for Interventional Trails (SPIRIT checklist). For all participants under the age of 18, assent and written caregiver consent will be obtained. The parent/guardian information and consent form (PICF) has been provided as online supplemental file 3.

Dissemination

Participants and their families will receive a 6-montly email newsletter that will update them on the study outcomes and future research direction. At the conclusion of the study, a summary of their child's results will be provided to caregivers if requested. In addition, the overall collated results of the trial and its outcomes will be provided to caregivers electronically. The research findings will be published in journal articles and conference proceedings. All data used for this purpose will be deidentified and analysed as a group to protect the privacy of participants and ensure confidentiality is maintained as per the Monash University HREC requirements.

Contributors HK, MAB and KC made substantial contributions to the conception and design of the RCT and obtained the funding. SR, TG and MB also made substantial contributions to the design of the RCT, specifically to the selection of study measures. HK, MAB, KC, SR, TG and MB contributed to the development of drafts, provided feedback and read and approved the final manuscript. HK,

MAB, KC, SR, TG and MB all agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Competing interests HK and KC are coinventors of the intervention program. The intervention programme is owned by a commercial company (Tali Digital).

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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