

Virtual reality versus tablet cognitive training: a school-based randomized controlled trial

Submission date 10/09/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/09/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/06/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Cognitive control functions (e.g. attention, working memory, goal management) dictate our ability to learn and accomplish selected behavioral goals, with deficiencies in these processes found in a range of mental illnesses including ADHD (among others). Cognitive training interventions have been successfully used to enhance deficient cognitive control abilities across a variety of populations, including children with issues of inattention. New technologies including Virtual Reality hold the potential promise of further improving the efficacy of such treatments through the immersive experience that they bring about. However, it is still unknown what the right 'dosage' is for such types of technology. For the main study, we propose to utilize a novel video game-based intervention (MasterMindVR) that incorporates adaptive algorithms critical for cognitive training, as well as vision-based exercises into gameplay to potentially improve not only cognitive features, but academic measures of reading and math as well.

Who can participate?

Children 8-10 years old attending either Dunstable Icknield Lower School, Parklea Primary School, or Leagrave Primary School.

What does the study involve?

All participants will play a game called 'MasterMind' either on a tablet or in a VR headset, and some students will be randomized to an active control group who will play math and coding games (but will be given access to the MasterMind platform at the completion of the study). Participants are asked to participate in this study 3 days a week for 10 weeks, with each day consisting of two 7-minute sessions, or two 3.5-minute sessions. A research assistant will monitor participation and provide support and feedback to the parents and children during training. Before and after the intervention, children have their attention assessed and parents complete a questionnaire about their child's inattention.

What are the possible benefits and risks of participating?

There are no direct benefits or risks associated with participating in this study.

Where is the study run from?
University of Bedfordshire (UK)

When is the study starting and how long is it expected to run for?
May 2024 to July 2025

Who is funding the study?
Mastermind Cognitive Training, Inc. (USA)

Who is the main contact?
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2. Joaquin A. Anguera, Joaquin.anguera@ucsf.edu

Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

RCAP072024

Study information

Scientific Title

Evaluation of dosage and technology types: a randomized controlled trial involving adolescent students using a digital intervention

Acronym

DT-RCT

Study objectives

Between-group differences involving academic abilities as measured via objective measures will emerge when comparing:

1. Device type (tablet versus virtual reality)
2. Dose amounts (full dosage versus half dose)
3. Targeted intervention versus expectancy-matched control

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 01/09/2024, University of Bedfordshire Research Centre for Applied Psychology (RCAP) Research Ethics Committee (REC) (Vicarage St, Luton, LU1 3JU, United Kingdom; +44 (0) 1582 489056; international@beds.ac.uk), ref: RCAP072024

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Healthy adolescents

Interventions

Cognitive Training

Mastermind has developed distinct cognitive training games focused on differing skills and

delivery methods. All training games are built in a “gamified” format, meaning they have the look, feel, and playability of a video game. The backgrounds and themes are built in futuristic space themes giving the feel of playing a video game, but you are participating in hardcore cognitive training exercises. Training games are intended to create competition and opportunities for comparison to other users. Each game has auto-leveling features that cater to the user’s current skill level. They also have scoring features, which will show where you rank against other users, as well as top performer leaderboards. These training games are built to improve cognitive function and skills and require repetition to develop new and more efficient neural pathways. Each training day consists of two training protocol games.

Eye Exercises

Eye movement, control and strength are critical not only to vision, but also to your ability to visually process information, focus, follow targets, and react. Mastermind has partnered with neuroscientists and eye movement and exercise experts to develop a robust eye-strengthening program intended to help improve performance in varied situations. The exercises include:

1. Optokinetics: Compensatory reflex that supports visual stabilization.
2. Saccades: Rapid movement of the eyes between fixation points.
3. Convergence/Divergence: Convergence is the ability to turn two eyes inward towards each other to look at a close object. Divergence is the opposite of convergence and is the ability to turn two eyes outward to look at a distant object.
4. Fixation: Maintaining the gaze on a single object or location.
5. Near/Far Shift: Shifting focus from a near object(s) to a far object(s) quickly and continually

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Method of randomisation

Block randomization (groups of 5) per classroom (30 students per classroom)

Intervention Type

Device

Phase

Phase I

Drug/device/biological/vaccine name(s)

Mastermind Cognitive Training

Primary outcome(s)

1. Objective behavioral measures of academic performance will be assessed via a custom application assessing reading basic academic performance called SEA (reading, math) at baseline, post-training, and at the end of the academic year. A Rate Correct Score metric is used for each domain, taking into account the number of correct responses in 3 minutes while controlling for the response time taken for each correct measure.
2. Eyetracking behavior: Percentile of Saccades (%) as well as Eye Movement Efficiency (mm)

assessed using an eye-tracking task at baseline, mid-point of training, post-training, and at the end of the academic year

Key secondary outcome(s)

1. An objective behavioral measure of attention via a custom continuous performance task (mCPT), comparable to the Test of Variables of Attention (TOVA), to assess vigilance at baseline, post-training, and at the end of the academic year. The metric of interest on the mCPT task will be response time and variance to targets presented.
2. The researchers will also collect the inattention portion of the Vanderbilt Survey at baseline, post-training, and at the end of the academic year to assess parent and/or teacher perceptions of attention in real-world scenarios, with the metric of interest being the total score across all questions presented as directed by the Vanderbilt Scoring Schema.

Exploratory outcome measures:

Objective measures of attention and working memory via a Multiple Object Tracking task (Measuring the level of difficulty reached by participants) and a derivative of the Corsi Block Task (measuring the level of difficulty reached by participants) designed to assess how well participants were able to identify targets in the presence of task-irrelevant information (at baseline, post-training and the end of the academic year).

Completion date

01/07/2025

Eligibility

Key inclusion criteria

Children between the ages of 8 and 10 years of age at participating schools

Participant type(s)

Learner/student

Healthy volunteers allowed

No

Age group

Child

Lower age limit

8 years

Upper age limit

10 years

Sex

All

Key exclusion criteria

Does not meet the inclusion criteria

Date of first enrolment

05/09/2024

Date of final enrolment

01/07/2025

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Dunstable Icknield Lower School

Burr Street

Dunstable

United Kingdom

LU6 3AG

Study participating centre

Parklea Primary School

Cranbrook Drive

Luton

United Kingdom

LU3 3EW

Study participating centre

Leagrave Primary School

Strangers Way

Luton

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LU4 9ND

Sponsor information

Organisation

Mastermind Cognitive Training, Inc.

Funder(s)

Funder type

Industry

Funder Name

Mastermind Cognitive Training, Inc.

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request (anastasia.giannakopoulou@beds.ac.uk).

IPD sharing plan summary

Available on request