ISRCTN75915439 https://doi.org/10.1186/ISRCTN75915439

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

Submission date
10/09/2024

Recruitment status
No longer recruiting

Registration date
27/09/2024

Overall study status
Completed

Last Edited
06/06/2025

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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?
1. Anastasia Giannakopoulou, anastasia.giannakopoulou@beds.ac.uk
2. Joaquin A. Anguera, Joaquin.anguera@ucsf.edu

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Anastasia Giannakopoulou

ORCID ID
https://orcid.org/0000-0003-0698-1121

Contact details
Office: A212d
Park Square
Luton
United Kingdom
LU1 3JU
+44 (0)1582 489188
Anastasia.Giannakopoulou@beds.ac.uk

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Joaquin Anguera

ORCID ID
https://orcid.org/0000-0002-7216-0674

Contact details
675 Nelson Rising Lane
San Francisco
United States of America
94158
+1 (0)415 702 5322
joaquin.anguera@ucsf.edu

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

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. Prior to and after the intervention, children have their attention assessed and parents complete a questionnaire about their child’s inattention.

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 Sacades (%) 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
United Kingdom
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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes