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Working memory training effects on young children's functioning

Submission date	Recruitment status	[ ] Prospectively registered
22/01/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
01/02/2018	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/02/2018	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
If children with attention deficit hyperactivity disorder (ADHD) symptoms do not have effective interventions and prevention, they very often have other disorders, such as oppositional defiant disorder (ODD). Accurate evaluation combined with proper intervention allows for a smooth academic and social transition into the school environment. At first, working memory training generated great interest, with claims that the training interventions can have profound beneficial effects on children’s executive function, academic and intellectual attainment, and also reduce ADHD symptoms. Despite the promising results of working memory training studies, the current research of all of the available evidence of working memory training is less optimistic. Near transfer of working memory training to untrained memory tasks has been observed. However, not all studies have found positive far transfer of learning to other executive functions, and academic and intellectual attainment. The aim of this study is to find out whether computer working memory training improves memory function as well as cognitive performance, academic and intellectual attainment.

Who can participate?
Children aged 4 -7 either with diagnosed ADHD symptoms and children with typical development

What does the study involve?
Participants are randomly allocated to one of two groups. Group 1 receives the working memory training. Group 2 is put on a waiting list and then receives the working memory training for the last laboratory meeting. The computerized working memory training includes eight visuospatial memory tasks. The children in group 1 are asked to practice on the training three tasks for 15 minutes a day on their personal computers at home, 5 days a week for 8 weeks. Additionally, all children (groups 1 and 2) are assessed individually in the laboratory at three different times: before training, after training is completed and three months after completing training.

What are the possible benefits and risks of participating?
Benefits are expected in the working memory, intelligence and quality of educational and social life. No risks are expected.

Where is the study run from?
SWPS University of Social Sciences and Humanities, Interdisciplinary Center for Applied Cognitive Studies (ICACS), (Warsaw) (Poland)

When is the study starting and how long is it expected to run for?
September 2012 to March 2016

Who is funding the study?
National Science Centre (Poland)

Who is the main contact?
Dr Anna Orylska

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
National Science Centre: UMO-2011/03/N/HS6/04849

Study information

Scientific Title
Training, motivation and maturation influences on development of executive functions at early childhood

Study objectives
The main hypotheses were:
1. Intervention – computer working memory training (WMT) improves trained (outcomes that

are similar to those trained during WMT) memory function as well as untrained cognitive performance, academic and intellectual attainment of children
2. After intervention some participants achieve a greater benefits than others

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics of Empirical Research with the Participation of People as Persons Researched; SWPS University of Social Sciences and Humanities, Warsaw, Poland, 11/07/2012, ref: 2/V/11-12

Study design
Randomised; Interventional; Design type: Treatment, Stimulation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Attention Deficit Hyperactivity Disorder (ADHD), typically developing children

Interventions
At study intake, parents and children were informed of randomization to one of two groups. Both groups, clinical (ADHD) and control (typical developing participants), had a known probability of being selected (probability sampling) for one of two groups. For each group (clinical and control) the trialists used simple random sampling and applied random number tables.
1. Intervention group - computerized working memory training
2. Waiting group - without intervention

During pretest (before intervention), following parent consent and child assent, posttest (8 weeks later after intervention) and follow up (3 months after posttest), a description of children' s behavior and cognitive function – questionnaire was completed by the parents. Also working memory, attention control measures, educational achievement, IQ measure was completed by the children. All training was conducted at home and was scheduled to be completed over a 8-week (5 times per week) period based on the family's schedule.

The computerized WM training was developed by author Anna Orylska. It included eight visuospatial training tasks: five short-term (VSSTM) and three working memory (VSWM) tasks.

Each task had six levels of difficulty, with each level having three sub-levels. The training interface provided children with feedback for correct and incorrect performance (a smiley or sad face). The task was continuously adapted across training so that the difficulty level reflected current performance (i.e. three correct trials were required in order to advance to the next level, and for each incorrect trial, difficulty decreased by three sublevels). Children were expected to complete three tasks per session. The training was scheduled so that children worked on each task equally across 40 training sessions. Training task performance was recorded as the highest score obtained in each session and where each level corresponded to the number of items that the child had to remembered (from 2 items at level 1 to 7 items at level 6, and every level consists of 3 sublevels, possible score range = 1-18, counted as the sum of all sublevels). Performance (training efficiency) was calculated across eight blocks each with five sessions (possible score range for each block was 1-18).

Intervention Type
Other

Primary outcome measure
Working memory capabilities, assessed using (1) a counting span task, (2) a set switching task and (3) a spatial location memory task at three different timepoints: pretest - prior to training (T1), post-test - no more than 1 week after training was completed (T2) and follow up - three months after completing training (T3)

Secondary outcome measures
Measured at three different timepoints: pretest - prior to training (T1), post-test - no more than 1 week after training was completed (T2) and follow up - three months after completing training (T3):
1. Executive attention, assessed using the Flanker task
2. Parent-reported executive abilities, assessed using the Behaviour Rating Inventory of Executive Function (BRIEF)
3. Educational achievement, assessed using the Test of Knowledge and Competences (1) the numeracy skills scale, (2) the writing skills scale measures, (3) the reading skills scale measures
4. IQ, assessed using Raven’s CPM to measure general intelligence

Overall study start date
20/09/2012

Completion date
19/03/2016

Eligibility

Key inclusion criteria
Both groups:
1. IQ score of ≥ 85
2. An opinion about the child's educational and social functioning issued by a teacher

Control group:
1. Free of other disabilities and disorders

Clinical group:
1. Diagnosed with symptoms of ADHD by a psychologist or a psychiatrist

2. Experiencing clinically significant symptoms of inattention, hyperactivity and impulsivity (ADHD/C), inattention (ADHD/I), or hyperactivity and impulsivity (ADHD/H),observed in different settings (family and preschool/school)

Participant type(s)
Mixed

Age group
Child

Sex
Both

Target number of participants
187 children: 94 children diagnosed with ADHD symptoms and 93 children were typically developing (control group)

Key exclusion criteria
1. Under 4 and over 8 years old children
2. Participants had to be free of epilepsy, pervasive developmental disorder, central nervous system disease and pharmacological treatment
3. Children not meeting IQ score of ≥ 85

Date of first enrolment
01/09/2012

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
Poland

Study participating centre
SWPS University of Social Sciences and Humanities
ul. Chodakowska 19/31
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Sponsor information

Organisation
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University/education

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ROR
https://ror.org/0407f1r36

Funder(s)

Funder type
Government

Funder Name
Narodowe Centrum Nauki

Alternative Name(s)
National Science Centre, NCN

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Poland

Results and Publications

Publication and dissemination plan
The trialists have submitted an article and plan to publish one more article in a high-impact peer reviewed journal.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Anna Orylska. Data that will be shared: individual participant data that underlie the results reported in published articles. Data will be available: beginning 9 months and ending 36 months following article publication. Data will be available for researchers who provide a methodologically sound proposal, for individual participant data meta-analysis.

IPD sharing plan summary

Available on request