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Efficacy of working memory training in children with Attention Deficit Hyperactivity Disorder (ADHD)

Submission date
30/05/2013

Recruitment status
No longer recruiting

Registration date
27/11/2013

Overall study status
Completed

Last Edited
21/01/2019

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Children with Attention Deficit Hyperactivity Disorder (ADHD) have deficits in executive functions, especially in working memory. These have a negative impact on academic performance, clinical symptoms and functional impairment. Previous studies have shown the effectiveness of working memory training on working memory, but the effects on clinical symptoms of ADHD are controversial. Our study aims to find out the effect of working memory training on relevant aspects in ADHD not previously studied, including other cognitive functions and functional impairment as well as clinical symptoms of ADHD. Moreover, according to recent studies, the effectiveness of this program may be influenced by genetic factors, so it is proposed to investigate the genetic influence on the effectiveness of the program.

Who can participate?
Children with ADHD combined type aged 7 to 12 years.

What does the study involve?
Children with combined-type ADHD who were not receiving pharmacological or psychological treatment were randomly assigned to one of two treatments: computerized training working memory program RoboMemo® (Cogmed Working Memory Training™), or placebo (dummy) training. The intervention lasted for five weeks. Assessments were conducted before, one week after the end of training, and at six months follow-up. We investigated genes associated with cognition to determine their influence on training effectiveness.

What are the possible benefits and risks of participating?
RoboMemo ® can increase tics (rapid, repetitive, involuntary contractions of a group of muscles) in vulnerable patients. This training is contraindicated in people with photosensitive epilepsy. There were no other risks to the participants in the study. At the end of the study we offered to the participants who took part in the placebo training the possibility of doing RoboMemo ® for they could also benefit from it.

Where is the study run from?
The study was conducted at the Child and Adolescent Mental Health Unit, Hospital Universitari Mutua Terrassa, Barcelona, Spain.

When is the study starting and how long is it expected to run for?
The study ran from June 2010 to December 2012.

Who is funding the study?
This study has received financial support through the award 22è PREMI FERRAN SALSAS I ROIG Salut Mental i Comunitat granted by the City Council of Rubi (Spain), 2010.

Who is the main contact?
Dr Amaia Hervás Zúñiga

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BE0045

Study information

Scientific Title
Near-transfer and far-transfer effects (other cognitive functions, clinical symptoms and functional impairment) in children with Attention Deficit Hyperactivity Disorder: influence of genetic variants associated with cognition, executive functions and working memory: a randomized controlled trial

Study objectives
Participants of the working memory training will improve their performance in working memory, other cognitive functions, scales of executive functions and a reduction of ADHD

symptomatology. All this will be reflected by an improvement in functional impairment. The effectiveness of treatment may be influenced by genetic variants, whose knowledge could help improve the effectiveness of the program.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Research Ethics Committee (CEIC), University Hospital Mutua de Terrassa, 28/04/2010

Study design
Randomized double-blind placebo-controlled parallel-group clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Attention Deficit Hyperactivity Disorder (ADHD)

Interventions
The experimental group performed the computerised working memory training program, RoboMemo®, consisting of exercises on visuospatial and auditory working memory tasks. Training was carried out 5 days a week for five weeks, a total of 25 sessions. Each training session included 90 trials of working memory tasks. The mean total time of each training session (excluding breaks) was about 40 min/day. The training included motivational elements like feedback on performance in each task and a game at the end of each training session. The level of difficulty was automatically adjusted to the performance of each participant.

The control group (placebo training) performed the same working memory tasks (90 trials per session, 5 sessions a week for five weeks, with motivational elements) but without automatic adjustment of the level of difficulty, so the tasks remained at a low level of difficulty.

Both groups performed the baseline, post-intervention and 6 months follow-up assessments.

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
Working memory index, consisting of: Digit Span Backward of the Wechsler Intelligence Scale - IV (WISC-IV), total score in Letters and Numbers WISC-IV, and Spatial Span Backward of the Wechsler Memory Scale - III (WMS-III)

Secondary outcome measures
Cognitive functions:
For the evaluation of executive functions:
1. Commission Errors of the Conners' Continuous Performance Test (CPT II) for the assessment of response inhibition
2. Detectability of CPT II for sustained attention
3. Total correct score of the Tower of London DX 2nd Edition for planning
4. Perseverative errors of the Wisconsin Card Sorting Test - 64 (WCST-64) for cognitive flexibility
5. Trail Making Test part B (TMT B) for task switching

For the assessment of learning:
1. Reading comprehension test
2. Mathematical problem solving test of the Probes Psicopedagògiques d'Aprenentatges Instrumentals en Català

To evaluate social cognition:
1. IOWA Gambling Task for decision-making
2. Child Eyes Test for recognising facial expressions
3. Happe Strange Stories for Theory of Mind

Scales of executive functions:
1. Behavior Rating Inventory of Executive Function (BRIEF) for parents and teachers

For the assessment of clinical symptoms:
1. Conners Parent Rating Scale and Conners Teacher Rating Scale to assess core symptoms of ADHD and opposition
2. Child Behavior Checklist/4-18 CBCL for Parents and Teachers Report Form/5-12 TRF for teachers
3. Strengths and Difficulties Questionnaire for parents and teachers to evaluate other clinical symptoms.

For evaluation of functional impairment:
1. Weiss Functional Impairment Rating Scale - parent report (WFIRS-P)

Overall study start date
01/06/2010

Completion date
01/12/2012

Eligibility

Key inclusion criteria

1. Combined-type ADHD according to DSM-IV-TR criteria. Comorbility with other Disruptive Behaviour Disorders was accepted (i.e., Oppositional Defiant Disorder or Conduct Disorder) according to DSM-IV-TR criteria
2. Age between 7 and 12 years
3. T scores for Conners ADHD index for parents and teachers >70 at the time of diagnosis
4. No previous psychological or pharmacological treatment for ADHD
5. Access to a personal computer with internet connection

Participant type(s)
Patient

Age group
Child

Lower age limit
7 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
66. We calculated the sample size based on the variables that were part of the primary outcome measure.

Key exclusion criteria
Current exclusion criteria as of 30/09/2014:
1. Global intellectual capacity below 80 (previous exclusion criteria: below 85)
2. Comorbidity with autism spectrum disorder, psychosis, affective or anxiety disorder, consumption of toxic substances, learning disorder
3.History of traumatic brain injury in the last two years
4. Perceptual-motor alterations which would preclude the use of a computer
5. Participants with whose educational or socio-economic context would make it unlikely for families to comply with the study requirements and follow the treatment procedure

Date of first enrolment
01/06/2010

Date of final enrolment
01/12/2012

Locations

Countries of recruitment
Spain

Study participating centre
Rambla de Egara 386-388
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Sponsor information

Organisation
Mutua de Terrassa Education and Research Foundation (Fundació Docència i Recerca Mutua de Terrassa) (Spain)

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Sponsor type
Research organisation

ROR
https://ror.org/02h74qa12

Funder(s)

Funder type
Government

Funder Name
This study has received financial support through the award 22è PREMI FERRAN SALSAS I ROIG Salut Mental i Comunitat granted by the City Council of Rubi (Spain)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results of long-term far-transfer effects of working memory training in children with ADHD	01/08/2016	21/01/2019	Yes	No
Results article	results of the impact of working memory training on hot executive functions (decision-making and theory of mind) in children with ADHD	01/01/2016	21/01/2019	Yes	No