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A possible treatment approach for children with Attention Deficit/Hyperactivity Disorder (AD /HD)

Submission date
09/04/2013

Recruitment status
No longer recruiting

Registration date
17/04/2013

Overall study status
Completed

Last Edited
30/07/2014

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
The objective of the study is to comprehensively evaluate the near and far-transfer short and long-term effects of computerized working memory training. Near-transfer effects refer to a gain in skill within the same training context, whereas far-transfer effects refer to learning that is transferable to other training contexts. Proponents of computerized working memory training propose that PC-based training programs can be used as an alternative to medication to improve cognitive performance and behaviour. This is a very controversial proposition, with inconsistent support in existing research.

Who can participate?
The candidates for participation are children in the age range of 10-12 years previously diagnosed with Attention Deficit/Hyperactivity Disorder (ADHD).

What does the study involve?
A total of between 70-80 children will be randomly allocated to one of two groups: a control and a training group. They will be assessed extensively with questionnaires and neuropsychological tests before, after and six months after the testing. By comparing the results on the various measures of the training group with that of the control group, the aim is to investigate whether the training has resulted in any effect.

What are the possible benefits and risks of participating?
The study does not involve any danger for the participants, and any participants who are allocated to the control group will have the opportunity to participate in the training program after the end of the study period. All of the children in the study will also be followed up in a regular way by child health specialist services during the course of the study.

Where is the study run from?
Telemark and Vestfold hospitals (Norway).

When is the study starting and how long is it expected to run for?
The study ran between August 2008 and December 2010.

Who is funding the study?
The study was funded with grants from the Centre for Child and Adolescent Mental Health, Eastern & Southern Norway and from the Nowregian Resource Center for ADHD, Tourette and Narcolepsy.

Who is the main contact?
Professor Jens Egeland
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2009/252

Study information

Scientific Title
Near and far-transfer effects of Working Memory training in ADHD: a randomized study

Study objectives
Various studies indicate that daily training sessions using PC-based programs lasting five weeks may improve working memory for persons diagnosed with Attention Deficit/Hyperactivity Disorder (AD/HD). In this collaborative project between the child psychiatric health services in Vestfold and Telemark, the short-term and long-term effects of training 10- and 11-year-old children diagnosed with AD/HD will be investigated.

The study will test the hypothesis that a five-week computerized working memory program will lead to improvements in performance on neuropsychological tasks and improvements in behaviour as rated by the children's parents and teachers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the Regional Committee for Medical and Health Research Ethics (REK sør-øst) in Norway. Ref. no. 2009/252. Approval was issued on 18.06.2009, with Project start: 01.08.2009 and Project end: 31.12.2010.
The regional ethics committee (there are four of them in Norway) serves the same purpose as an international registry in that all projects that are accepted by one of the committees are listed on their homepage and publicly accessible. The text is in Norwegian (a translation may be provided on request). The web-address where information about the study and details about the approval prior to inclusion of participants is published at the following: https://helseforskning.etikkom.no/ikbViewer/page/prosjekterirek/prosjektregister?_ikbLanguageCode=us&p_dim=34977&9F508B87E7D8620DE040F28156A418DC.p_search_id=26503

Study design
Randomized study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Interventions
The study will take place at two hospitals - Telemark and Vestfold hospitals.
The participants will be assessed with various questionnaires, as well as neuropsychological testing before, after and a half year after completing the training.

Participants meeting the inclusion criteria will be randomized into an experimental group (5-week PC-based working memory training program) or a comparable control group receiving treatment as usual. Both groups will continue receiving their pre-existing school and health care

follow up, which may include medication. Participants will be tested immediately before the start of the training period, immediately after, and six months later. Children assigned to the control group will be offered the opportunity to participate in the training program after completion of the study.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Neuropsychological measures: Digit span, Leiter International Performance Scale-Revised, Letter-Number Sequencing task, Sentence span task, Color Word and Trail Making (from Delis-Kaplan Executive Function System), Conners' Continuous Performance Test-II, Children's Auditory Verbal Learning Test-2, BVRT, Key Math and LOGOS.
Administered immediately before the 5-week training program , after the training program and six months later.

Secondary outcome measures
Parent reported behavior rating scales: ADHD-Rating Scale IV, Strengths and Difficulties Questionnaire and Behavior Rating Inventory of Executive Function.
Administered immediately before the 5-week training program , after the training program and six months later.

Overall study start date
01/08/2009

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Between 70-80 children aged 10-12 years will be invited to participate in the study.
2. All participants must have been previously diagnosed with F90.0 Hyperkinetic disorder (ICD-10) equivalent to the DSM-IV diagnosis of ADHD combined type and be in treatment for ADHD within the Departments for Child and Adolescent Psychiatry in Vestfold or Telemark Hospital Trusts.

Participant type(s)
Patient

Age group
Child

Lower age limit
10 Years

Upper age limit

12 Years

Sex
Both

Target number of participants
70-80

Key exclusion criteria
1. IQ below 70 (WISC-III or WISC-IV), or
2. A comorbid diagnosis of Pervasive Developmental Disorder, Tourette's Disorder, Bipolar Disorder, Conduct Disorder or evidence of psychosis

Date of first enrolment
01/08/2009

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Norway

Study participating centre
Boks 2267
Tønsberg
Norway
3103

Sponsor information

Organisation
Vestfold Hospital Trust (Norway)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04a0aep16

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Centre for Child and Adolescent Mental Health, Eastern & Southern Norway

Funder Name
The Norwegian Resource Center for ADHD, Tourette and Narcolepsy

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	04/10/2013		Yes	No
Results article	results	09/12/2013		Yes	No