

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

Submission date 09/04/2013	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 17/04/2013	Overall study status Completed	☐ Protocol
Last Edited 30/07/2014	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☒ 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

Protocol serial number

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?](https://helseforskning.etikkom.no/ikbViewer/page/prosjekterirek/prosjektregister?_ikbLanguageCode=us&p_dim=34977&9F508B87E7D8620DE040F28156A418DC.p_search_id=26503)

[_ikbLanguageCode=us&p_dim=34977&9F508B87E7D8620DE040F28156A418DC.p_search_id=26503](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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s))

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.

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

10 years

Upper age limit

12 years

Sex

All

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)

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

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