Purpose

The purpose of this study was to examine the feasibility and efficacy of computerized cognitive exercises from Scientific Brain Training (SBT), compared to the computer game Tetris as an active placebo, in a pilot study of adolescents with Attention-deficit/hyperactivity disorder (ADHD).

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
</tr>
</thead>
</table>
| Attention Deficit/Hyperactivity Disorder | Other: Scientific Brain Training (SBT)  
|                                 | Other: Tetris                                    |

Study Type: Interventional

Study Design:
Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A Double-Blind Randomized Pilot Trial Comparing Computerised Cognitive Exercises to Tetris in Adolescents With Attention-Deficit/Hyperactivity Disorder
Further study details as provided by Region Syddanmark:

Primary Outcome Measures:
- Activity Perception Questionnaire [Time Frame: 7 weeks] [Designated as safety issue: No]

Secondary Outcome Measures:
- Attention Deficit/Hyperactivity Disorder-Rating Scale [Time Frame: 7 weeks] [Designated as safety issue: No]
- Cambridge Neuropsychological Test Automated Battery (CANTAB) Rapid Visual Information Processing (RVP)(A) [Time Frame: 7 weeks] [Designated as safety issue: No]
- CANTAB: Stockings of Cambridge (SOC) (problems solved in minimum moves) [Time Frame: 7 weeks] [Designated as safety issue: No]
- CANTAB: DMS Delayed Matching to Sample (DMS) [Time Frame: 7 weeks] [Designated as safety issue: No]

Other Outcome Measures:
- CANTAB: Spatial Span (SSP) [Time Frame: 7 weeks] [Designated as safety issue: No]
- CANTAB: Intra-Extra Dimensional Set Shift (IED) [Time Frame: 7 weeks] [Designated as safety issue: No]
- CANTAB: Spatial Working Memory (SWM) [Time Frame: 7 weeks] [Designated as safety issue: No]
- Cambridge Neuropsychological Test Automated Battery (CANTAB) Rapid Visual Information Probability of hit [Time Frame: 7 weeks] [Designated as safety issue: No]

Enrollment: 18

Study Start Date: October 2010

Study Completion Date: December 2011

Primary Completion Date: December 2010 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental: Intervention</td>
<td>Other: Scientific Brain Training (SBT)</td>
</tr>
<tr>
<td>Scientific Brain Training (SBT)</td>
<td>Cognitive training</td>
</tr>
<tr>
<td>Placebo Comparator: Controle Tetris</td>
<td>Other: Tetris</td>
</tr>
</tbody>
</table>

Detailed Description:
Objective: To examine the feasibility and efficacy of computerized cognitive exercises from Scientific Brain Training (SBT), compared to the computer game Tetris as an active placebo, in a pilot study of adolescents with Attention-deficit/hyperactivity disorder (ADHD).

Method: Eighteen adolescents with ADHD were randomized to treatment or control intervention for seven weeks. Outcome measures were cognitive test, symptom and motivation questionnaires.

Eligibility

Ages Eligible for Study: 14 Years to 17 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
1. a clinical diagnosis of hyperkinetic disorder (F90.0, corresponding to ADHD combined type) (WHO, 1993);
2. age between 14-17 years;
3. IQ > 80.

Exclusion Criteria:
1. pharmacological treatment other than methylphenidate, dexamphetamine and/or atomoxetine;
2. comorbid conduct disorder, autism spectrum disorders or major depression;
3. history of head trauma or verified neurological disease;
4. motor or perceptual disabilities which prevented the use of a computer;
5. medical illness that required treatment;
6. no access to a computer and internet at home.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02728011

Locations

Denmark

Child and Adolescent Mental Health Services Aabenraa
Aabenraa, Denmark, 6200

Child and Adolescent Mental Health Services Augustenborg
Augustenborg, Denmark, 6440

Sponsors and Collaborators
Region Syddanmark
Region of Southern Denmark

Investigators
Principal Investigator: Aida Bikic, MSc  Region Syddanmark

No publications provided

Responsible Party: Aida Bikic, psychologist, ph.d. candidate, Region Syddanmark

ClinicalTrials.gov Identifier: NCT02728011  History of Changes

Other Study ID Numbers: 7/6/2010

Study First Received: March 24, 2016

Last Updated: April 4, 2016

Health Authority: Danish Data Protection Agency, Denmark

Additional relevant MeSH terms:
Attention Deficit Disorder with Hyperactivity  Mental Disorders Diagnosed in Childhood
Hyperkinesis  Nervous System Diseases
Attention Deficit and Disruptive Behavior Disorders  Neurologic Manifestations
Dyskinesias  Signs and Symptoms
Mental Disorders

ClinicalTrials.gov processed this record on April 05, 2016