Cognitive-Motor Rehabilitation, Stimulant Drugs, and Active Control in the Treatment of ADHD (ADHD)

This study is ongoing, but not recruiting participants.

Sponsor:
Allameh Tabatabai University

Information provided by (Responsible Party):
Saeed Azami, Allameh Tabatabai University

ClinicalTrials.gov Identifier:
NCT02780102

First received: May 19, 2016
Last updated: May 20, 2016
Last verified: May 2016

Purpose
The investigators administered a randomized controlled trial (RCT) through random assignment of children with ADHD into three different groups to compare the effects of cognitive-motor rehabilitation, immediate release methylphenidate, and an active control on the executive functioning, learning, and behavioral symptoms of children with ADHD.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attention Deficit Hyperactivity Disorder</td>
<td>Other: Cognitive-Motor Rehabilitation</td>
</tr>
<tr>
<td></td>
<td>Drug: Ritalin</td>
</tr>
<tr>
<td></td>
<td>Other: Active Control</td>
</tr>
</tbody>
</table>

Study Type: Interventional

Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Single Blind (Outcomes Assessor)
Primary Purpose: Treatment

Official Title: Comparison of the Effects of Cognitive-Motor Rehabilitation, Stimulant Drugs, and Active Control on Executive Functions and Clinical Symptoms of Attention Deficit/ Hyperactivity Disorder
Primary Outcome Measures:

- Forward/backward digit span tasks from the Wechsler intelligence scale for children 4th edition (WISC-IV)  
  [ Time Frame: 12 months ] [ Designated as safety issue: Yes ]
- Span board task from the Lumosity.com online brain training software  
  [ Time Frame: 12 months ] [ Designated as safety issue: Yes ]
- Listening span task (L.SPAN)  
  [ Time Frame: 12 months ] [ Designated as safety issue: Yes ]
- Stroop color-word test  
  [ Time Frame: 12 months ] [ Designated as safety issue: Yes ]
- Tower of London test (TOL)  
  [ Time Frame: 12 months ] [ Designated as safety issue: Yes ]
- Restricted academic situation scale (RASS)  
  [ Time Frame: 12 months ] [ Designated as safety issue: Yes ]
- Arithmetic task from WISC-IV testing battery  
  [ Time Frame: 12 months ] [ Designated as safety issue: Yes ]
- Swanson, Nolan, and Pelham's parent rating scale (SNAP-IV)  
  [ Time Frame: 12 months ] [ Designated as safety issue: Yes ]
- Dictation and Spelling examination  
  [ Time Frame: 12 months ] [ Designated as safety issue: Yes ]

Enrollment: 48

Study Start Date: September 2015

Estimated Study Completion Date: September 2016

Primary Completion Date: March 2016 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental: Cognitive-Motor Rehabilitation</td>
<td>Other: Cognitive-Motor Rehabilitation</td>
</tr>
<tr>
<td>Cognitive-Motor Rehabilitation (CMR): 20 sixty-minute sessions of cognitive-motor rehabilitation</td>
<td>Cognitive-Motor Rehabilitation (CMR) group received 20 sixty-minute sessions of cognitive-motor exercises</td>
</tr>
<tr>
<td>Experimental: Ritalin</td>
<td>Drug: Ritalin</td>
</tr>
<tr>
<td>2 to 3 doses of 10 mg Ritalin tablets per day during 8 week.</td>
<td>2 or 3 doses of 10 mg tablets of immediate-release Methylphenidate (Ritalin) per day for 8 week.</td>
</tr>
<tr>
<td>Active Comparator: Active Control</td>
<td>Other: Active Control</td>
</tr>
</tbody>
</table>
Active Control group simultaneously received 20 sixty-minute sessions of low dose cognitive-motor exercises

Eligibility

Ages Eligible for Study: 9 Years to 12 Years
Genders Eligible for Study: Male
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Receiving ADHD diagnosis
- Aged between 9 and 12 years
- Intelligence Quotient (IQ)>90

Exclusion Criteria:

- Severe co-morbid disorders, such as depression, oppositional defiant disorder and conduct disorder
- A history of seizures during past 2 years
- Disability or handicap preventing the child from participating cognitive-motor exercises
- Sever medical conditions requiring immediate medical treatment

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: NCT02780102

Sponsors and Collaborators
Allameh Tabatabai University

Investigators

Principal Investigator: Saeed Azami, PhD Student Semnan University
Study Director: Siavash Talepasand, PhD Semnan University
Study Director: Morteza Nazifi, PhD University of Bojnord
Study Chair: Isaac Rahimian Boogar, PhD Semnan University
Study Chair: Kimberley Lakes, PhD University of California, Irvine

More Information

Responsible Party: Saeed Azami, Mr., Allameh Tabatabai University
ClinicalTrials.gov Identifier: NCT02780102 History of Changes
Other Study ID Numbers: 328/94/16090