Comparison of Treadmill and Whole Body Vibration Training in Children With Attention Deficit Hyperactivity Disorder

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT03469180

Recruitment Status: Not yet recruiting
First Posted: March 19, 2018
Last Update Posted: March 19, 2018
See Contacts and Locations

Sponsor:
Bezmialem Vakif University
Collaborator:
Medipol University
Information provided by (Responsible Party):
Elif Durgut, Bezmialem Vakif University

Study Details

Tabular View
No Results Posted

Disclaimer
How to Read a Study Record

Study Description

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Brief Summary:
It is reported in the literature that children with attention deficit hyperactivity disorder (ADHD) may have executive function deficits, impaired social functions, emotional dysregulation, behavioral disorders and motor impairments. Furthermore, studies have shown that exercise, such as acute and chronic aerobic exercises and acute whole body vibration training, improves executive functions and motor abilities and so it is hypothesized that exercise may have a potential or additional treatment option for children with ADHD. Neurobiologic researches have already proven the effects on brain changes during exercise and in the case of ADHD, increasing levels of serotonin, dopamine, and norepinephrine within the front striatal lobes of the brain were highlighted when discussing the effects on this neurodevelopmental disorder. The literature emphasizes the importance of physical activity in children with ADHD, but there is no clarity regarding the frequency, intensity or duration of the exercise. Thus, the aim of this study was to investigate and compare the effects of treadmill training as an aerobic exercise and whole body vibration training on executive functions and balance in children with ADHD.

Condition or disease

<table>
<thead>
<tr>
<th>Condition or disease</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attention Deficit Hyperactivity Disorder</td>
<td>Other: Treadmill trainingOther</td>
</tr>
</tbody>
</table>

Study Design

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Study Type: Interventional (Clinical Trial)
Estimated Enrollment: 30 participants
Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Double (Participant, Outcomes Assessor)

Primary Purpose: Treatment

Official Title: Comparison of Treadmill and Whole Body Vibration Training in Children With Attention Deficit Hyperactivity Disorder

Anticipated Study Start Date: March 2018

Estimated Primary Completion Date: June 2018

Estimated Study Completion Date: June 2018

Resource links provided by the National Library of Medicine
MedlinePlus related topics: Attention Deficit Hyperactivity Disorder

U.S. FDA Resources

Arms and Interventions

<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention/treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active Comparator: Control Group</td>
<td>Other: Treadmill training Treadmill training Each season will be supervised and last 45 minutes. Treadmill speed will be adjusted to the child's maximal heart rate (MHR) (between 65 to 75 percent of the MHR).</td>
</tr>
<tr>
<td>Childrens in this group will receive treadmill training, three times a week for 8 weeks. Each season will be supervised and last 45 minutes.</td>
<td></td>
</tr>
<tr>
<td>Experimental: Training Group</td>
<td>Other: Treadmill training Treadmill training Each season will be supervised and last 45 minutes. Treadmill speed will be adjusted to the child's maximal heart rate (MHR) (between 65 to 75 percent of the MHR). Other: Whole body vibration training Whole body vibration training whole body vibration frequence will be 50 Hertz and childrens will be standing position on vibration platform.</td>
</tr>
<tr>
<td>In addition to treadmill training, childrens in this group (after a rest for 5 minutes) will also receive whole body vibration training for 15 minutes.</td>
<td></td>
</tr>
</tbody>
</table>

Outcome Measures

<table>
<thead>
<tr>
<th>Primary Outcome Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Change from baseline postural stability test score in Biodex Balance System SD at 8 weeks [ Time Frame: Eight weeks ]</td>
</tr>
<tr>
<td>2. Change from baseline limits of stability test score in Biodex Balance System SD at 8 weeks [ Time Frame: Eight weeks ]</td>
</tr>
<tr>
<td>3. Change from baseline sensory integration and balance test score in Biodex Balance System SD at 8 weeks [ Time Frame: Eight weeks ]</td>
</tr>
<tr>
<td>4. Change from baseline single leg balance test score in Biodex Balance System SD at 8 weeks [ Time Frame: Eight weeks ]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Secondary Outcome Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Change from baseline Stroop test score at 8 weeks [ Time Frame: Eight weeks ]</td>
</tr>
<tr>
<td>2. Change from baseline BRIEF score at 8 weeks [ Time Frame: Eight weeks ]</td>
</tr>
<tr>
<td>3. Change from baseline Conners score at 8 weeks [ Time Frame: Eight weeks ]</td>
</tr>
</tbody>
</table>

Eligibility Criteria
Information from the National Library of Medicine

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, Learn About Clinical Studies.

Ages Eligible for Study: 7 Years to 11 Years  (Child)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria
Inclusion Criteria:
- ADHD diagnosis (Previously not taking or not taking medication for ADHD)
- Being going to primary school

Exclusion Criteria:
- Having a chronic and serious medical condition
  - Seizure-like neurological impairment
  - Autism spectrum disorder, vision, speech, hearing problems

Contacts and Locations

Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): NCT03469180

Contacts

Contact: Elif Durgut, MSc,PT +90 212 523 22 88 ext 4640 durgutelif@yahoo.com

Locations

Turkey
Bezmialem Vakif University
Istanbul, Turkey, 34060

Sponsors and Collaborators
Bezmialem Vakif University
Medipol University

Investigators
Principal Investigator: Elif Durgut, MSc,PT Bezmialem Vakif University

More Information

Responsible Party: Elif Durgut, Lecturer, MSc, PT, Bezmialem Vakif University
ClinicalTrials.gov Identifier: NCT03469180
History of Changes
Other Study ID Numbers: bvuedurgut01
First Posted: March 19, 2018
Key Record Dates
Last Update Posted: March 19, 2018
Last Verified: March 2018
Individual Participant Data (IPD) Sharing Statement:
Plan to Share IPD: Undecided

Studies a U.S. FDA-regulated Drug Product: No
Studies a U.S. FDA-regulated Device Product: No

Keywords provided by Elif Durgut, Bezmialem Vakif University:
Treadmill Training
Whole Body Vibration Training

Additional relevant MeSH terms:
Disease
Attention Deficit Disorder with Hyperactivity
Hyperkinesis
Pathologic Processes
Attention Deficit and Disruptive Behavior Disorders
Neurodevelopmental Disorders

Mental Disorders
Dyskinesias
Neurologic Manifestations
Nervous System Diseases
Signs and Symptoms