Effects of Cognitive Training on Children With Attention Deficit Hyperactivity Disorder

Using a single blind, randomized controlled design to study the additional therapeutic effects of cognitive training on traditional rehabilitation programs for children with attention deficit hyperactivity disorder and developmental delays.

Condition or disease

| Attention Deficit Hyperactivity Disorder | Other: interactive cognitive training |

Detailed Description:

A total of 30 children with attention deficit hyperactivity disorder and developmental delays who are receiving traditional rehabilitation programs will be enrolled.

The participants will be randomized into two groups, including study group (traditional rehabilitation program with additional cognitive training: 2 times per week, 15 min per session, a total of 24 sessions) and control group (traditional rehabilitation program without additional cognitive training).

Memory related functions, quality of life, and physical function evaluations will be performed at baseline, 3 months and 6 months later, respectively.

Evaluator will be blinded to the group's classification during the whole course of study.

Study Design

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: Treatment Effects of Cognitive Training on Children With Attention Deficit Hyperactivity Disorder and Developmental Delay

Estimated Study Start Date: August 2018
Estimated Primary Completion Date: March 2019
Estimated Study Completion Date: March 2019

Resource links provided by the National Library of Medicine
MedlinePlus related topics: Attention Deficit Hyperactivity Disorder
U.S. FDA Resources

Arms and Interventions
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<th>Arm</th>
<th>Intervention/treatment</th>
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<tr>
<td>Active Comparator: study group</td>
<td>Other: interactive cognitive training Using interactive brain club system training to</td>
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<tr>
<td>3 months of individualized interactive</td>
<td>children with attention deficit hyperactivity disorder with developmental delay</td>
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<tr>
<td>cognitive training, 2 times per week,</td>
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<td>15 min per session, a total of 24</td>
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<td>sessions, in addition to traditional</td>
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<td>rehabilitation programs.</td>
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<tr>
<td>No Intervention: control group</td>
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<tr>
<td>3 months of traditional rehabilitation</td>
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<td>programs, without individualized interactive cognitive training.</td>
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Outcome Measures
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Primary Outcome Measures:
1. change of attention [Time Frame: scores change from baseline to 3 months of treatment, and 3 months after treatment]
   score assessed by Swanson, Nolan and Pelham questionnaire

Secondary Outcome Measures:
1. change of visual motor integration [Time Frame: scores change from baseline to 3 months of treatment, and 3 months after treatment]
   score assessed by Beery-Buktenica Visual Motor Integration Test
2. change of sensory integration  
   Time Frame: scores change from baseline to 3 months of treatment, and 3 months after treatment  
   score assessed by Sensory Profile questionnaire

3. change of intelligence  
   Time Frame: scores change from baseline to 3 months of treatment, and 3 months after treatment  
   score assessed by Wechsler Intelligence Scale for Children, including verbal, performance and total scores, the average score is 100, with higher scores indicating higher than average intelligence and lower scores indicating lower levels of intelligence

4. change of functional performance  
   Time Frame: changes from baseline to 3 months of treatment, and 3 months after treatment  
   score assessed by Pediatric Outcome Data Collection Instrument

5. change of health-related quality of life  
   Time Frame: changes from baseline to 3 months of treatment, and 3 months after treatment  
   score assessed by Pediatric Quality of Life Inventory-Generic Core Scales, including physical, psychosocial, and total scores, with higher scores representing better health-related quality of life

Eligibility Criteria
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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: 4 Years to 8 Years  (Child)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: Yes

Criteria
Inclusion Criteria:
- children diagnosed with attention deficit hyperactivity disorder with developmental delay receiving regular rehabilitation programs intelligence quotient 70 or greater

Exclusion Criteria:
- age less than 4 years or elder than 8 years children diagnosed with attention deficit hyperactivity disorder receiving regular rehabilitation programs intelligence quotient less than 70

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): NCT03632629

Contacts

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Locations

Taiwan

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Sponsors and Collaborators
Taipei Medical University

Investigators

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More Information

Responsible Party: Ru-Lan Hsieh, Principal investigator, Taipei Medical University

ClinicalTrials.gov Identifier: NCT03632629  History of Changes

Other Study ID Numbers: 2018SKHADR028

First Posted: August 15, 2018  Key Record Dates
Last Update Posted: August 15, 2018
Last Verified: August 2018

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

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

Keywords provided by Ru-Lan Hsieh, Taipei Medical University:
cognitive training
developmental delay
children
therapeutic effect

Additional relevant MeSH terms:
Disease  Mental Disorders
Attention Deficit Disorder with Hyperactivity  Dyskinesias
Hyperkinesis  Neurologic Manifestations
Pathologic Processes
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