Purpose
Organizational, time management and planning (OTMP) skills deficits are seriously impairing features of developmental disorders, such as Attention Deficit Hyperactive Disorder (ADHD) and autism, which compromise school performance and family relations. The manualized Organizational Skills Training program (OST) was designed to target children's specific OTMP deficits. However, the brain mechanisms of treatment-induced changes remain unknown. The current study combines a training intervention with non-invasive MRI imaging in a pre-/post-design to address this question.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADHD Attention Deficit Hyperactivity Disorder</td>
<td>Behavioral: OST Intervention for participants with Organizational skill difficulties</td>
</tr>
</tbody>
</table>

Study Type: Interventional
Study Design: Intervention Model: Single Group Assignment
Masking: No masking
Primary Purpose: Treatment
Official Title: Brain Plasticity Underlying Acquisition of New Organizational Skills in Children

Further study details as provided by New York University School of Medicine:

Primary Outcome Measures:
- Change in Children's Organizational Skills Scales (COSS) total T-scores following OST intervention. [Time Frame: 1 Day]
  Parents (COSS-P) and teachers (COSS-T) will serve as informants (only the child is a study subject) who will provide baseline and outcome ratings.

Secondary Outcome Measures:
- Strengths and Weaknesses of ADHD Symptoms and Normal Behavior (SWAN) [Time Frame: 1 Day]
  provide dimensional measures of inattention, hyperactivity, and oppositionality.
- Wechsler Individual Achievement Test-3rd ed. (WIAT-III) [Time Frame: 1 Day]
  an abbreviated assessment of spelling, mathematics and reading achievement.
- Social Responsiveness Scale-2 (SRS-2) [Time Frame: 1 Day]
  widely used dimensional index of autism spectrum disorder (ASD).

Estimated Enrollment: 50

Anticipated Study Start Date: July 1, 2017

Estimated Study Completion Date: July 1, 2020

Estimated Primary Completion Date: July 1, 2019 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental: OST Intervention</td>
<td>Behavioral: OST Intervention for participants with Organizational skill difficulties</td>
</tr>
<tr>
<td>10 Weekly sessions, each lasting approximate 1 hour, targeting 3 core organizational skills domains - Tracking Assignments, Managing Materials and Time Management</td>
<td>Will undergo two magnetic resonance imaging (MRI) sessions: one within 2 weeks prior to OST treatment and one within 2 weeks of completion of the OST treatment.</td>
</tr>
</tbody>
</table>
Eligibility

Ages Eligible for Study: 8 Years to 11 Years (Child)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:

- Age at entry: age ≥ 8.0 and ≤ 11.9 years corresponding to grades 3-5
- Written assent by child and consent by parent or legal guardian
- IQ: Estimated full scale IQ ≥ 85 and language comprehension scores ≥ 80 is required as in past studies to assure that children are able to comply with specific skills training and to minimize neurobiological heterogeneity
- Organizational skills deficits defined as elevated (≥ 1SD) pre-treatment COSS Parent Total T-score and at least one COSS Parent Interference item rated as either a 3 or 4 (indicating an above-average level of impairment)
- Handedness: given the greater prevalence of non-right-handedness in neurodevelopmental disorders, we will track handedness but not exclude left-handed individuals
- Medication: To minimize variability due to medication effects, we will preferentially recruit currently unmedicated individuals (no psychoactive medications in the previous 3 months). For stimulants, we will require that dosage be stable for >1 month before study entry and parents will be asked to consult their physician regarding discontinuation for 48 hours before evaluation, mock scanning and scanning sessions.
- Must provide adequate MRI data at baseline

Exclusion Criteria:

- Enrolled in a self-contained special education classroom or served by a 1:1 paraprofessional in their classroom
- A learning disability on Individualized Education Plan
- Absence of signed consent by parent or legal guardian
- Children who dissent regardless of parental permission
- Full scale IQ < 85
- Participants for whom stimulant discontinuation for 48 hours prior to evaluation, mock scan and scanning sessions is deemed medically impermissible
- Children with a recent (past 6 months) or current history of neuroleptic treatment or current treatment with psychotropic medications other than stimulants
- Per history (and medical records if needed) medical illness requiring chronic current treatment
- History of intrathecal chemotherapy or focal cranial irradiation
- Premature birth (< 32 weeks estimated gestational age or birth weight < 1500g)
- History of leukomalacia or static encephalopathy, intracerebral hemorrhage beyond grade 2, other specific or focal neurological or metabolic disorder including epilepsy (except for resolved febrile seizures)
- History of traumatic brain injury
- Contraindication for MRI scanning (metal implants, pacemakers, metal foreign bodies or pregnancy)
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: NCT03148782

Contacts
Contact: Yuliya Yoncheva  646 754 5147  yuliya.yoncheva@nyumc.org
Contact: Cielo Diaz  Cielo.Diaz@nyumc.org

Locations

United States, New York
New York University School of Medicine  Not yet recruiting
New York, New York, United States, 10016
Contact: Yuliya Yoncheva  646-754-5147  yuliya.yoncheva@nyumc.org
Principal Investigator: Francisco Castellanos, MD

Sponsors and Collaborators
New York University School of Medicine

Investigators

Principal Investigator:  Francisco Castellanos, MD  New York University School of Medicine

More Information

Responsible Party:  New York University School of Medicine
ClinicalTrials.gov Identifier:  NCT03148782  History of Changes
Other Study ID Numbers:  17-00263
Study First Received:  May 9, 2017
Last Updated:  May 9, 2017

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

Additional relevant MeSH terms:
Attention Deficit Disorder with Hyperactivity
Attention Deficit and Disruptive Behavior Disorders
Neurodevelopmental Disorders
Mental Disorders

ClinicalTrials.gov processed this record on May 11, 2017