Ongoing Tai Chi Training for Children with ADHD

ClinicalTrials.gov Identifier: NCT03434509

Recruitment Status : Enrolling by invitation
First Posted : February 15, 2018
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Sponsor:
Hugo W. Moser Research Institute at Kennedy Krieger, Inc.
Information provided by (Responsible Party):
Hugo W. Moser Research Institute at Kennedy Krieger, Inc.

Study Description

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Brief Summary:

Attention Deficit Hyperactivity Disorder (ADHD) has tremendous individual and societal impact, and the effectiveness of current standard treatments is limited. Thus, there are potential public health benefits for novel behavioral training programs that could remediate the core features of ADHD and contribute to sustained improvements in behavioral control. There is mounting evidence that children with ADHD show difficulties with motor control, and that these motor deficits are strongly associated with the core behavioral features of ADHD. Based on this information, the CNIR initiated a feasibility trial of a movement-based intervention, utilizing Tai Chi practice, targeting improved behavioral control through engagement of the motor system and results are highly promising. The investigators therefore will employ an extension of our ongoing Tai Chi programs for children with ADHD, beginning with children who have already completed one of the previous Tai Chi sessions. This program will provide the basis for studying the long-term effects of mindful movement, as well as creating a foundation for exploring the way that such interventions can be expanded into a more realistic support setting for the community.

Hypothesis: After participating in the ongoing Tai Chi program, children with ADHD will show improvements in behavioral measures of motor, cognitive, and attentional control. The investigators further expect movement-based training will result in decreases in ADHD symptom severity.

Condition or disease	Intervention/treatment
ADHD	Other: Continuous Tai Chi and Mindful Movement classes

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Study Design

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Study Type : Interventional (Clinical Trial)

Estimated Enrollment : 50 participants

Intervention Model: Single Group Assignment

Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	Effects of Ongoing Movement-Based Mindfulness Training for Children With ADHD
Actual Study Start Date :	November 2, 2017
Estimated Primary Completion Date :	December 2022
Estimated Study Completion Date :	December 2022

Arms and Interventions

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Arm	Intervention/treatment
Experimental: Tai Chi Ongoing, continuous Tai Chi and mindful movement instruction, 1 hour, twice per week	Other: Continuous Tai Chi and Mindful Movement classes Participants will be enrolled in ongoing Tai Chi and mindful movement classes throughout the year, for 1 hour twice a week. Class sessions will consist of warm up (yoga- and mindfulness-based practices), postural and breathing exercises, Tai Chi form practice, and Tai Chi games (including push hands). Children on stimulant medications will remain on these medications during the training period (though they will be asked to stop medications one day prior to motor and cognitive testing). Other Names: • tai chi • taichi • tai ji • taiji • t'ai chi • t'ai ji

Outcome Measures

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Primary Outcome Measures :

1. Cognitive Motor Control: Response inhibition [Time Frame: From date of baseline and at every 6 months following, assessed up to 60 months.]

   RDoC (research domain criteria) battery for cognitive control targeting response inhibition delivered via laboratory computer (Go/No-Go) examining percentage of error rate and successful inhibition. Significant improvements in response inhibition are expected over the course of the intervention.

2. Cognitive Motor Control: Response inhibition [Time Frame: From date of baseline and at every 6 months following, assessed up to 60 months.]

   RDoC (research domain criteria) battery for cognitive control targeting response inhibition delivered via laboratory computer (Flanker) examining percentage of error rate and successful inhibition. Significant improvements in response inhibition are expected over the course of the intervention.

3. Cognitive Motor Control: Response inhibition [Time Frame: From date of baseline and at every 6 months following, assessed up to 60 months.]

   RDoC (research domain criteria) battery for cognitive control targeting response inhibition delivered via laboratory computer (Stop-Signal) examining percentage of error rate and successful inhibition. Significant improvements in response inhibition are expected over the course of the intervention.

4. Cognitive Motor Control: Response inhibition [Time Frame: From date of baseline and at every 6 months following, assessed up to 60 months.]

   RDoC (research domain criteria) battery for cognitive control targeting response inhibition delivered via laboratory computer (Mirror Tracing Persistence Task) examining percentage of error rate and successful inhibition. Significant improvements in response inhibition are expected over the course of the intervention.

5. Cognitive Motor Control: Response inhibition [Time Frame: From date of baseline and at every 6 months following, assessed up to 60 months.]

   RDoC (research domain criteria) battery for cognitive control targeting response inhibition delivered via laboratory computer (DKEFS Trail Making Task) examining percentage of error rate and successful inhibition. Significant improvements in response inhibition are expected over the course of the intervention.

6. Behavioral Assessment of Motor Persistence [Time Frame: From date of baseline and at every 6 months following, assessed up to 60 months.]

   Measure of oculomotor persistence and inhibition using the Lateral Gaze Fixation task. Improvements in oculomotor persistence are expected over the course of the intervention.

7. Behavioral Assessment of Motor Persistence [Time Frame: From date of baseline and at every 6 months following, assessed up to 60 months.]

   Measure of motor persistence and inhibition using the NEPSY Statue Task ("A Developmental NEuroPSYchological Assessment"). Improvements in motor persistence are expected over the course of the intervention.

8. Behavioral Assessments of Motor Overflow [Time Frame: From date of baseline and at every 6 months following, assessed up to 60 months.]

   Measure of motor overflow from the PANESS (Physical and Neurologic Examination of Subtle Signs). Improvements in motor overflow are expected over the course of the intervention.

9. Behavioral Assessments of Basic Motor Control [Time Frame: From date of baseline and at every 6 months following, assessed up to 60 months.]

   Measure of motor control from the mABC-2 (Movement Assessment Battery for Children). Improvements in motor control are expected over the course of the intervention.

10. Clinical Measure of ADHD Symptom Severity [Time Frame: From date of baseline and at every 6 months following, assessed up to 60 months.]

    The Conners-3 survey (parent and teacher). Improvements on this measure are expected over the course of the intervention. In particular, based on previous findings from the CNIR initiated mindful movement feasibility study, marked improvements on Connors-3 subscales for Inattentiveness and Hyperactivity are expected.

Secondary Outcome Measures :

1. Clinical Measure of Mindfulness [Time Frame: From date of baseline and at every 6 months following, assessed up to 60 months.]

   The CAMM (Child and Adolescent Mindfulness Measure) will be administered. Improvements on this measure are expected over the course of the intervention.

2. Clinical Measure of Quality of Life [Time Frame: From date of baseline and at every 6 months following, assessed up to 60 months.]

   The PedsQL (Pediatric Quality of Life Inventory) (parent and child) will be administered. Improvements on this measure are expected over the course of the intervention.

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:	8 Years to 15 Years (Child)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Children must meet diagnostic criteria for ADHD, based on information from previous participation in "Movement-Based Mindfulness Training for Children with ADHD: A Feasibility Study." Additionally, children must meet criteria on the parent and teacher Conners-3

- Comorbid oppositional defiant disorder (ODD) and anxiety disorders are permitted
- Stimulants, psychoactive medications, or no medication are allowed

Exclusion Criteria:

- diagnosis of Intellectual Disability, Developmental Language Disorder, Reading Disability, or Autism (screened for using the Social Competence Questionnaire (SCQ)
- neurologic disorder (e.g., epilepsy, cerebral palsy, traumatic brain injury, Tourette Syndrome)
- documented hearing impairment ≥ 25 dB (decibel) loss in either ear.
- a Full Scale IQ (Intelligence Quotient) score on the WISC-IV (Wechsler Intelligence Scale for Children) below 80
- a standard score below 85 on the Word Reading Subtest, regardless of IQ score
- foster care
- Female participants will be excluded if they are pregnant or may be pregnant

Contacts and Locations

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Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT03434509***

Locations

United States, Maryland

LEAP Facility at Kennedy Krieger Institute
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Sponsors and Collaborators

Hugo W. Moser Research Institute at Kennedy Krieger, Inc.

Investigators

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More Information

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Responsible Party:	Hugo W. Moser Research Institute at Kennedy Krieger, Inc.
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Plan to Share IPD:	Yes
URL:	http://

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

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Motor Control
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