Lifestyle Enhancement for ADHD Program (LEAP)

ClinicalTrials.gov Identifier: NCT03690674

Recruitment Status : Not yet recruiting
First Posted : October 1, 2018
Last Update Posted : October 1, 2018
See **Contacts and Locations**

Sponsor:
Seattle Children's Hospital
Collaborator:
National Center for Complementary and Integrative Health (NCCIH)
Information provided by (Responsible Party):
Pooja Tandon, Seattle Children's Hospital

Study Description

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Brief Summary:
The purpose of this study is to investigate if physical activity (PA) can increase in children with Attention Deficit/Hyperactivity Disorder (ADHD) using a modified behavioral management training (BMT) program.

Condition or disease	Intervent
ADHD	Behavioral: Lifestyle Enhancement for ADHD Program

Detailed Description:
The purpose of this study is to increase physical activity (PA) in children with ADHD using a novel, family-based intervention that promotes PA within the context of evidence-based behavioral management training (BMT) for parents, enhanced with mobile health (mHealth) behavior change strategies. Our first aim is to test the feasibility and acceptability, of an 8-week, family-based, multi-level intervention (BMT-Health) to promote PA in young children with ADHD. Our second aim is to derive an estimate of the effect size of the intervention on PA.

Study Design

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Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	30 participants
Intervention Model:	Single Group Assignment
Masking:	None (Open Label)
Primary Purpose:	Supportive Care

Official Title:	Lifestyle Enhancement for ADHD Program
Estimated Study Start Date :	October 1, 2018
Estimated Primary Completion Date :	October 1, 2020
Estimated Study Completion Date :	October 1, 2020

Arms and Interventions

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Arm	Intervention/treatment
Experimental: Lifestyle Enhancement for ADHD Program There is no comparison/control arm.	Behavioral: Lifestyle Enhancement for ADHD Program The LEAP intervention consists of 3 components: 1) an enhanced 8-week, group-based BMT curriculum, 2) parent and child use of the Garmin daily activity tracker accompanied by personalized goal setting, and 3) parent participation in a private Facebook group to encourage PA goal achievement and promote social support and positive parenting. Other Name: LEAP

Outcome Measures

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Primary Outcome Measures :

1. Moderate to vigorous physical activity (MVPA) [Time Frame: Change from baseline to week 9]

   Measured by accelerometer

2. Garmin Wear Time [Time Frame: Weeks 1 - 9]

   The length of time each participant wore the Garmin device is a measure of feasibility

3. Facebook Engagement [Time Frame: Weeks 1 - 9]

   The amount of contribution to the Facebook page (comments, likes, etc) by each participant is a measure of feasibility

4. Attendance at the Focus Group [Time Frame: Weeks 1 - 9]

   Attendance will be taken at the focus group as a measure of study acceptability

5. Treatment Adherence Inventory [Time Frame: Week 9]

   Completed at the end of the study, the caregiver fills out the questionnaire indicating how much they used each skill learned in the focus group. This is a measure of acceptability. The caregiver rates the frequency as Almost Never, Very little of the time, some of the time, most of the time, or almost always.

Secondary Outcome Measures :

1. Stop Signal Reaction Time (SSRT) Task [Time Frame: Change between baseline and week 9]

   Measure of executive function completed by the child

2. Digit Span (DS) Task [Time Frame: Change between baseline and week 9]

   Measure of executive function completed by the child

3. Finger Windows (FW) Task [Time Frame: Change between baseline and week 9]

   Measure of executive function completed by the child

4. Behavior Rating Inventory of Executive Function (BRIEF) [Time Frame: Change between baseline and week 9]

   Measure of executive function completed by the parent. Parent rates whether the child displays each behavior never, sometimes, or often

5. Impairment Rating Scale (IRS) [Time Frame: Change between baseline and week 9]

   Measure of functional impairment completed by the parent. The rating scale measures from 0 to 7, where 0 equals no problem and 7 equals extreme problem.

6. Alabama Parenting Questionnaire (APQ) [Time Frame: Change between baseline and week 9]

   Measure of parenting completed by the parent. The responses are on a 1-5 scale, 1 equals never and 5 equals always

7. Health Behaviors Survey [Time Frame: Change between baseline and week 9]

   Measure of physical activity, sleep, media use, medication use and complementary/alternative medicine use

8. Children's Sleep Habit Questionnaire (CSHQ) [Time Frame: Change between baseline and week 9]

   Measure of sleep problems completed by the parent. The parent rates each behavior based on their frequency: Usually if something occurs 5 or more times in a week, Sometimes if it occurs 2-4 times in a week, or rarely if something occurs never or 1 times during a week. Parents can also indicate whether or not a sleep habit is a problem by choosing Yes, Nor or Not applicable

9. Body Mass Index (BMI) [Time Frame: Baseline & 9 weeks]

   Measure of body using height and weight

10. Clinical Global Impression - Severity (CGI-S) [Time Frame: Change between baseline and week 9]

    Severity of ADHD symptoms determined by the clinician. The scale ranges from 1 to 7 with 1 equaling normal, not ill and 7 equaling very severely ill

11. Conners-3 Questionnaire [Time Frame: Change between baseline and week 9]

    Measure of ADHD symptoms reported by the parent. The scale ranges from 0 to 3 with 0 equaling not true at all and 3 equaling very much true

12. Teacher Vanderbilt [Time Frame: Change between baseline and week 9]

    measure of ADHD symptoms reported by the teacher. The scale ranges from 0 to 3, with 0 equaling never and 3 equaling very often.

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:	5 Years to 10 Years (Child)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	Yes

Criteria

Inclusion Criteria:

- age 5-10 years
- ADHD diagnosis
- engage in <60 min/day on average across 3 days of moderate-vigorous physical activity (MVPA), as measured by accelerometer
- CGI-S rating >4 and <7
- One adult caregiver willing to participate in the study and complete baseline/follow-up measures
- Caregiver able to complete forms in English
- Caregiver owns a smart phone or similar Garmin compatible mobile device (e.g. iPod Touch) or willing to borrow iPod from study coordinators during the study period

- Agree to install and share data from the Garmin smart phone app with investigators

Exclusion Criteria:

- younger than 5 years old or older than 10 years old
- do not meet criteria for ADHD diagnosis
- engage in >60 min/day of MVPA on average across 3 days, as measured by accelerometer
- Meet diagnostic criteria for psychiatric co-morbidities including Autism

Contacts and Locations

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Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT03690674***

Contacts

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Sponsors and Collaborators

Seattle Children's Hospital
National Center for Complementary and Integrative Health (NCCIH)

Investigators

Principal Investigator:	Pooja Tandon, MD	Seattle Children's
Principal Investigator:	Erin Gonzalez, MD	Seattle Children's

More Information

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Responsible Party:	Pooja Tandon, Assistant Professor, Seattle Children's Hospital
ClinicalTrials.gov Identifier:	NCT03690674 History of Changes
Other Study ID Numbers:	STUDY00001046 R21AT010041-01 (U.S. NIH Grant/Contract)
First Posted:	October 1, 2018 Key Record Dates
Last Update Posted:	October 1, 2018
Last Verified:	September 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 Pooja Tandon, Seattle Children's Hospital:
ADHD
Physical Activity
Behavioral Management Training
Mobile Health