Efficacy of the Nurtured Heart Approach to Reduce ADHD Behaviors in Children

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. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT03685279

Recruitment Status: Completed
First Posted: September 26, 2018
Last Update Posted: September 26, 2018

Sponsor:
University of Arizona

Information provided by (Responsible Party):
Velia Nuno, University of Arizona

Study Description

Brief Summary:
This study evaluates the efficacy of the Nurtured Heart Approach (NHA) to reduce inattention and hyperactivity and impulsivity in children ages 6 - 8 years. Participants are parents or guardians of children diagnosed with, or suspected of, attention deficit hyperactivity disorder (ADHD). Participants are randomized into the immediate (NHA) or delayed (Control) group.

Condition or disease

| Attention Deficit Hyperactivity Disorder | Behavioral: Nurtured |

Detailed Description:
The American Academy of Pediatrics recommends evidence-based parent and/or teacher behavioral therapy and/or medication to treat ADHD. A systematic review by Coates and colleagues found behavioral interventions decreased ADHD behaviors in children. The NHA is an intervention designed to teach parents a set of skills and attitudes to decrease ADHD in children. It has been applied in a number of settings from homes, schools, and foster care agencies both in several states in the U.S. and in over 16 countries. While widely accepted, the Approach has not been evaluated using scientifically rigorous methods.

Study Design

Study Type: Interventional (Clinical Trial)

Actual Enrollment: 104 participants

Allocation: Randomized

Intervention Model: Parallel Assignment
Masking: None (Open Label)

Primary Purpose: Treatment

Official Title: Testing the Efficacy of the Nurtured Heart Approach: A Randomized Controlled Trial

Actual Study Start Date: August 14, 2017

Actual Primary Completion Date: June 30, 2018

Actual Study Completion Date: June 30, 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>Experimental: NHA Group</td>
<td>Behavioral: Nurtured Heart Approach Based on three stands designed to reduce negative reactivity from parents/guardians, increase positive interactions, and set firm, clear limits.</td>
</tr>
<tr>
<td>Six-week, online intervention with weekly, sequential, content knowledge and skills practice. Each week included recorded, slide presentations (narrated by the developer of the NHA, Howard Glasser); readings from &quot;The Transforming the Intense Child Workbook&quot; by Howard Glasser with Melissa Lowenstein; participants' skills practice, web postings, and live sessions with Howard Glasser and Advanced NHA Trainers.</td>
<td>Behavioral: Nurtured Heart Approach Based on three stands designed to reduce negative reactivity from parents/guardians, increase positive interactions, and set firm, clear limits.</td>
</tr>
<tr>
<td>Control Group</td>
<td>Behavioral: Nurtured Heart Approach Based on three stands designed to reduce negative reactivity from parents/guardians, increase positive interactions, and set firm, clear limits.</td>
</tr>
<tr>
<td>The Control Group received the same intervention after the collection of NHA Group post-intervention surveys.</td>
<td>Behavioral: Nurtured Heart Approach Based on three stands designed to reduce negative reactivity from parents/guardians, increase positive interactions, and set firm, clear limits.</td>
</tr>
</tbody>
</table>

Outcome Measures

Primary Outcome Measures:

1. Inattention [Time Frame: Six-week change from pre-intervention inattention to post-intervention inattention.]

   Parent reported measure called Conners-3 Parent Short Form. Raw scores are converted into standardized T-scores using age- and sex-specific conversion standards. The minimum T-score is 40 and the maximum is 90. The six content subscales are inattention, hyperactivity/impulsivity, learning problems, executive function, defiance/aggression, and peer relations. Higher T-scores are worse.

2. Hyperactivity/Impulsivity [Time Frame: Six-week change from pre-intervention hyperactivity/impulsivity to post-intervention hyperactivity/impulsivity.]

   Parent reported measure called Conners-3 Parent Short Form. Raw scores are converted into standardized T-scores using age- and sex-specific conversion standards. The minimum T-score is 40.
and the maximum is 90. The six content subscales are inattention, hyperactivity/impulsivity, learning problems, executive function, defiance/aggression, and peer relations. Higher T-scores are worse.

Secondary Outcome Measures:

1. Parental Stress [Time Frame: Six-week change from pre-intervention parental stress to post-intervention parental stress.]

   Parent reported measure called Parenting Stress Index - 4 Short Form. Scores are summed. A minimum raw score possible is 36 and maximum is 180. Higher values are worse.

2. Parenting Competency [Time Frame: Six-week change from pre-intervention parenting competency to post-intervention parenting competency.]

   Parent reported measure called Parenting Sense of Competence. Scores are summed. A minimum score possible is 16 and maximum is 96. Higher value is a better outcome.

Eligibility Criteria

Go to ▼

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: Child, Adult, Older Adult
Sexes Eligible for Study: All
Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:

• Parent or guardian of a child diagnosed with ADHD or suspected of ADHD
• Child must be 6 - 8 years of age
• Access to a computer with Internet

Exclusion Criteria:

• Child with ADHD, or suspected of ADHD, cannot have a diagnosis of autism

Contacts and Locations

Go to ▼

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): NCT03685279
Locations

United States, Arizona
University of Arizona
Tucson, Arizona, United States, 85724

Sponsors and Collaborators
University of Arizona

More Information
Go to ▼

Responsible Party: Velia Nuno, Assistant Professor, University of Arizona
ClinicalTrials.gov Identifier: NCT03685279 History of Changes
Other Study ID Numbers: 1707672022
First Posted: September 26, 2018 Key Record Dates
Last Update Posted: September 26, 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

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