Efficacy of a Brief Behavioral Intervention to Treat ADHD and Disruptive Behaviors In Preschoolers

This study is currently recruiting participants.

Verified August 2013 by Baylor College of Medicine

Sponsor:

Baylor College of Medicine

Information provided by (Responsible Party):

Marni Axelrad, Baylor College of Medicine

ClinicalTrials.gov Identifier:

NCT01919073

First received: August 6, 2013

Last updated: NA

Last verified: August 2013

History: No changes posted

- **Full Text View**
- **Tabular View**
- **No Study Results Posted**
- Disclaimer
- How to Read a Study Record

Purpose

The purpose of this study is to test the intervention using a more rigorous randomized controlled trial design in order to demonstrate its efficacy compared to a wait-list control, thus ensuring that change in behavior does not occur due to the passage of time alone. Using this design will also allow us to improve upon our prior clinical research by facilitating obtainment of post-treatment and follow-up data (as families in the clinical-only service stop attending treatment when behavior improves, and have often not followed-up for booster sessions or measure completion).

Condition	Intervention

Attention Deficit Hyperactivity Disorder **Attention Deficit** and Disruptive Behavior Disorders	Behavioral: Immediate Treatment Group Behavioral: Delayed Treatment Group

Study Type: Interventional

Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Efficacy of a Brief Behavioral Intervention to Treat ADHD and Disruptive Behaviors In Preschoolers

Resource links provided by NLM:

MedlinePlus related topics: Attention Deficit Hyperactivity Disorder Toddler Health

U.S. FDA Resources

Further study details as provided by Baylor College of Medicine:

Primary Outcome Measures:

- Parent Behavioral Assessment System for Children- 2nd Edition (BASC2) Externalizing Score [Time Frame: 3 months] [Designated as safety issue: No]

The primary outcome measure is the parent BASC2 Externalizing score at 3 months post-treatment. The mean score in the control group at 3 months is expected to be about 70 points with a standard deviation of 10 based on previous research. Assuming a 10 unit difference in scores is clinically significant (effect size = 1.0), 17 patients per group will be required to detect a statistically significant difference between groups with 80% power assuming an alpha = 0.05 level of significance.

Secondary Outcome Measures:

- Improved overall family functioning [Time Frame: 12 months]
  [Designated as safety issue: No]
    - The Eyberg Child Behavior Inventory (ECBI) and Sutter-Eyberg Student Behavior Inventory-Revised (SESBI-R) will be used to assess oppositional-defiant and conduct problem behaviors, yielding Problem and Intensity scales. The ECBI and SESBI-R were standardized on a large (N=798) sample of children between the ages of 2 and 16 from ethnically diverse backgrounds and exhibit good model fit across ethnic/racial groups. These scales have high internal consistency, good test-retest reliability, good model fit across racial/ethnic groups, enable prediction of membership in referred groups of children, and have good concurrent validity.
    - The Family Adaptability and Cohesion Evaluation Scales IV (FACES-IV) will be used to assess family cohesion and flexibility and has internal reliability and validity over .80 for all scales. The Parenting Stress Index - Short Form will be used to measure stress related to the child's behavior and mood and related to factors specific to the parent.

Estimated Enrollment:	34
Study Start Date:	December 2012
Estimated Study Completion Date:	December 2015
Estimated Primary Completion Date:	December 2013 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Immediate Treatment Group The immediate treatment group will fill out the questions at the initial appointment and again after five treatment appointments. They will fill the questions out again at the first follow-up treatment appointment (approximately 4-5 months from the initial appointment), and then at the next (and last) follow-up appointment (approximately 7-8 months). The participants teacher will also be asked to fill out sets of questions.	Behavioral: Immediate Treatment Group •The immediate treatment group will fill out the questions at the initial appointment and again after five treatment appointments. They will fill the questions out again at the first follow-up treatment appointment (approximately 4-5 months from the initial appointment), and then at the next (and last) follow-up appointment (approximately 7-8 months). The participants teacher will also be asked to fill out sets of questions.

Active Comparator: Delayed Treatment Group The wait list group will fill out the sets of questions again in 1-2 months. The question sets will then be completed again before beginning treatment four months from the initial completion and then again after five treatment appointments. The question sets will then be completed again at the first follow-up treatment appointment (approximately 8-9 months from the initial appointment) and at the next (and last) follow-up appointment (in about 11-12 months from the initial appointment).	Behavioral: Delayed Treatment Group •The wait list group will fill out the sets of questions again in 1-2 months. The question sets will then be completed again before beginning treatment four months from the initial completion and then again after five treatment appointments. The question sets will then be completed again at the first follow-up treatment appointment (approximately 8-9 months from the initial appointment) and at the next (and last) follow-up appointment (about 11-12 months from the initial appointment).

Detailed Description:

This pilot study will employ a randomized controlled clinical trial design comparing symptoms of children who complete the Brief Behavioral Intervention to a wait-list control. Children in the wait-list control will be waitlisted for four months prior to initiation of treatment, which is a typical wait for clinical care. Treatment will then be offered to the children on the wait-list.

All parts of the intervention and all measures of behavior and family functioning are part of standard clinical care. The parts of this protocol that are not standard clinical care are the following: 1. Randomization process with half of the patients on a waitlist for four months. Randomization will be block randomization stratified by gender. 2. Booster sessions for problem solving at three months and six months after last treatment session. In standard clinical care this occurs only if the patient calls and requests. 3. Collection of behavior and family functioning measures at three months and six months after the active treatment component.

Eligibility

Ages Eligible for Study: 2 Years to 5 Years

Genders Eligible for Study: Both

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Age 2-5 years
- Subject diagnosed with a Disruptive Behavior Disorder
- Subject who has an English-speaking parent willing to take part in intervention.

- Subject must meet criteria for a Diagnostic and Statistical Manual (DSM-IV) Disruptive Behavior Disorder (ADHD and/or ODD) based upon history, clinical interview, and clinically significant cut-off scores on parent rating forms. Parent and teacher of each child will also be involved.

Exclusion Criteria:

- Parents who are not fluent in English
- Subjects with a diagnosed anxiety disorder, pervasive developmental disorder, intellectual disability, adjustment disorder, mood disorder or language disorder will also be excluded and referred for more appropriate services.
- Children with less severe behavior problems will not be included in the study but will be referred for more appropriate services.
- Patients taking medication to treat behavior and patients who have previously received treatment will be excluded from the study.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01919073

Contacts

Contact: Marni Axelrad, PhD 832-822-3700 axelrad@bcm.tmc.edu

Locations

United States, Texas

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Principal Investigator: Marni Axelrad, PhD

Sponsors and Collaborators

Baylor College of Medicine

Investigators

Principal Investigator: Marni Axelrad, Ph.D. Baylor College of Medicine

More Information

Additional Information:

Physician Profile EXIT

No publications provided

Responsible Party:	Marni Axelrad, Associate Professor, Baylor College of Medicine
ClinicalTrials.gov Identifier:	NCT01919073 History of Changes
Other Study ID Numbers:	H-31413, H-31413
Study First Received:	August 6, 2013
Last Updated:	August 6, 2013
Health Authority:	United States: Institutional Review Board

Keywords provided by Baylor College of Medicine:

Attention Deficit, ADD, ADHD, ODD, Oppositional Behavior, Disruptive Behavior, Behavior Modification, Parent Management Training, Pre-School

Additional relevant MeSH terms:

Mental Disorders
Attention Deficit and Disruptive Behavior Disorders
Attention Deficit Disorder with Hyperactivity
Hyperkinesis
Mental Disorders Diagnosed in Childhood
Dyskinesias
Neurologic Manifestations
Nervous System Diseases
Signs and Symptoms

ClinicalTrials.gov processed this record on August 07, 2013