# Adaptive Response to Intervention (RTI) for Students With ADHD



ClinicalTrials.gov Identifier: NCT03511976

Recruitment Status : Recruiting
First Posted : April 30, 2018
Last Update Posted : April 30, 2018
See **Contacts and Locations**

**Sponsor:**
Florida International University
**Collaborator:**
University at Buffalo
**Information provided by (Responsible Party):**
Florida International University

- **Study Details**

- **Tabular View**
- **No Results Posted**

- Disclaimer
- How to Read a Study Record

**Study Description**

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Brief Summary:

Purpose: The primary purpose of the proposed project is to investigate the efficacy of Tier 1 and Tier 2 interventions delivered through a Response to Intervention (RTI) framework for children with attention-deficit/hyperactivity disorder (ADHD). Further, for children who do not respond to initial Tier 2 strategies, the proposed study will assess which additional course of intervention is most effective: (1) enhanced Tier 2 strategies or (2) stimulant medication. The majority of youth with ADHD are in general education settings, whether classified as special education students or not. Thus, experimentally evaluating the efficacy of well-developed and evidence-based behavioral interventions within a problem-solving framework such as RTI would significantly inform practice within school-based behavioral intervention teams.

Project Activities: This study will employ a sequential multiple assignment randomized trial design (SMART). Prior to the beginning of the academic year, students will be randomly assigned to one of two conditions: (1) Business as Usual in which children receive whatever sequence of academic supports and interventions their teachers, school, and parents would typically put into place throughout the entire academic year and (2) an RTI approach to begin with Tier 1 classroom-wide management strategies with opportunities to add Tier 2 strategies for youth who do not respond to the initial Tier 1 approach.

| Condition or disease | Intervention/treatment |
|---|---|
| Attention Deficit Disorder With Hyperactivity | Behavioral: Tier 1 Classroom ManagementBehavioral: Daily Report Card (DRC)<br>DRC (DRC-E)Drug: Stimulant |

**Show Detailed Description**

**Study Design**

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| Study Type : | Interventional (Clinical Trial) |
| Estimated Enrollment : | 300 participants |
| Allocation: | Randomized |
| Intervention Model: | Sequential Assignment |
| Masking: | None (Open Label) |
| Primary Purpose: | Treatment |
| Official Title: | Adaptive Response to Intervention (RTI) for Students With ADHD |
| Estimated Study Start Date : | April 2018 |
| Estimated Primary Completion Date : | June 2021 |
| Estimated Study Completion Date : | June 2021 |

**Resource links provided by the National Library of Medicine**
MedlinePlus related topics: Attention Deficit Hyperactivity Disorder

U.S. FDA Resources

**Arms and Interventions**
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| Arm | Intervention/treatment |
|---|---|
| No Intervention: Business as Usual (BAU)<br>One-third of participants will be assigned to this condition and will receive academic accommodations and interventions as deemed appropriate by their teachers, school personnel, and parents. This condition is intended to mirror current standard procedures for youth with ADHD. Thus, the specific accommodations and interventions are expected to vary across students. Some students' parents and physicians may choose to start stimulant medication with a goal of improving classroom performance. | |
| Experimental: Response to Intervention (RTI): Tier 1<br>Two-thirds of participants will be assigned to the RTI Tier 1 Arm. Teachers of students in this arm will receive consultation in RTI Tier 1 Classroom Management strategies. | Behavioral: Tier 1 Classroom Management<br>The primary classroom teacher for each participating student will receive consultation related to implementing Tier I management strategies at a classroom level for all students including the target child (see Appendix C). Consultation will be provided by trained study personnel (i.e., M.A.-level psychology or special education professionals) and the strategies will be implemented by the general education teacher (i.e., the end user of the intervention) Each teacher will receive two consultation visits at the beginning of the academic year. The purpose of the first visit will be to establish a plan for implementing Tier 1 strategies. During the second visit, the consultant will work with the teacher to assess progress with the Tier 1 strategies and adapt as needed (Fabiano et al., under review). |

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| Experimental: RTI: Daily Report Card (DRC)<br>Students assigned to the RTI Tier 1 Arm, who do not respond to the initial RTI Tier 1 Classroom Management strategies, will move to the RTI DRC Arm of the study. Teachers of students in this arm of the study will receive consultation to implement a daily report card. | Behavioral: Tier 1 Classroom Management<br>The primary classroom teacher for each participating student will receive consultation related to implementing Tier I management strategies at a classroom level for all students including the target child (see Appendix C). Consultation will be provided by trained study personnel (i.e., M.A.-level psychology or special education professionals) and the strategies will be implemented by the general education teacher (i.e., the end user of the intervention) Each teacher will receive two consultation visits at the beginning of the academic year. The purpose of the first visit will be to establish a plan for implementing Tier 1 strategies. During the second visit, the consultant will work with the teacher to assess progress with the Tier 1 strategies and adapt as needed (Fabiano et al., under review).<br>Behavioral: Daily Report Card (DRC)<br>Students in the RTI DRC condition will receive Tier II strategies, namely an individualized DRC. Behavioral consultants will meet with teachers to identify appropriate behavioral targets and establish a DRC according to established protocol (see our website for an example http://ccf.fiu.edu/for-families/resources-for-parents/printable- information/). Consultants will also meet with parents to develop a plan for reinforcing the DRC at home using a hierarchical menu of rewards/privileges that will be provided contingent on meeting daily goals. |
| Experimental: RTI: Enhanced<br>Half of students in the RTI DRC Arm who do not respond to the DRC intervention will be randomly assigned to the RTI: Enhanced Arm. Students in this arm will receive a more intensive classroom behavioral intervention directed at individual target behaviors through an enhanced DRC. | Behavioral: Tier 1 Classroom Management<br>The primary classroom teacher for each participating student will receive consultation related to implementing Tier I management strategies at a classroom level for all students including the target child (see Appendix C). Consultation will be provided by trained study personnel (i.e., M.A.-level psychology or special education professionals) and the strategies will be implemented by the general education teacher (i.e., the end user of the intervention) Each teacher will receive two consultation visits at the beginning of the academic year. The purpose of the first visit will be to establish a plan for implementing Tier 1 strategies. During the second visit, the consultant will work with the teacher to assess progress with the Tier 1 strategies and adapt as needed (Fabiano et al., under review).<br>Behavioral: Daily Report Card (DRC)<br>Students in the RTI DRC condition will receive Tier II strategies, namely an individualized DRC. Behavioral consultants will meet with teachers to identify appropriate behavioral targets and establish a DRC according to established protocol (see our website for an example http://ccf.fiu.edu/for-families/resources-for-parents/printable- information/). Consultants will also meet with parents to develop a plan for reinforcing the DRC at home using a hierarchical menu of rewards/privileges that will be provided contingent on meeting daily goals. |

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| | Behavioral: Enhanced DRC (DRC-E)<br>In this condition, students who did not show sufficient response to the Phase 1 DRC will receive additional and more intensive Tier II supports.<br><br>Following student assignment to RTI-E, the teacher will have meet with one of the consultants to complete a functional behavior analysis (FBA) to identify remaining target behaviors and ascertain their function. The consultant and teacher will then use the completed FBA to develop a treatment plan for an enhanced DRC (DRC-E).<br><br>Tier II enhancements will be chosen to directly map on to the functions of the target behaviors as outlined in the FBA. |
| Experimental: Medication<br>Half of students in the RTI DRC Arm who do not respond to the DRC intervention will be randomly assigned to the Medication arm and will receive stimulant medication as an additional intervention. | Behavioral: Tier 1 Classroom Management<br>The primary classroom teacher for each participating student will receive consultation related to implementing Tier I management strategies at a classroom level for all students including the target child (see Appendix C). Consultation will be provided by trained study personnel (i.e., M.A.-level psychology or special education professionals) and the strategies will be implemented by the general education teacher (i.e., the end user of the intervention) Each teacher will receive two consultation visits at the beginning of the academic year. The purpose of the first visit will be to establish a plan for implementing Tier 1 strategies. During the second visit, the consultant will work with the teacher to assess progress with the Tier 1 strategies and adapt as needed (Fabiano et al., under review).<br>Behavioral: Daily Report Card (DRC)<br>Students in the RTI DRC condition will receive Tier II strategies, namely an individualized DRC. Behavioral consultants will meet with teachers to identify appropriate behavioral targets and establish a DRC according to established protocol (see our website for an example http://ccf.fiu.edu/for-families/resources-for-parents/printable- information/). Consultants will also meet with parents to develop a plan for reinforcing the DRC at home using a hierarchical menu of rewards/privileges that will be provided contingent on meeting daily goals.<br>Drug: Stimulant<br>Students will receive either a long-acting methylphenidate preparation or a long-acting mixed amphetamine salts preparation based on parent consultation with the study physician. The prescribed medication will be taken daily.<br>Other Name: long-acting methylphenidate, long-acting mixed amphetamine salts |

**Outcome Measures**

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Primary Outcome Measures :

1. Observations of Classroom Behavior [ Time Frame: End of academic year 1 of enrollment ]

Independent observations will be conducted using the Student-Behavior Teacher-Response observation system (SBTR; Pelham, Greiner, & Gnagy, 2008; Vujnovic, Fabiano et al., 2014). The SBTR is an observation code that collects information on: (1) the frequency of student rule violations; (2) whether a teacher observed the misbehavior; (3) if observed, whether the teacher enacted a consequence and whether it was an appropriate consequence. The SBTR system also records the number of praise statements and commands issued. The SBTR is a well-defined and validated observation system for use with children with ADHD in classroom settings. The SBTR system documents child functioning across a number of disruptive behavior categories (e.g., be respectful, obey adults, work quietly, stay on task), and it is consistent with an evidence-based assessment procedure for ADHD (Pelham, Fabiano, & Massetti, 2005).

**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.*

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| Ages Eligible for Study: | Child, Adult, Senior |
| Sexes Eligible for Study: | All |
| Accepts Healthy Volunteers: | No |

**Criteria**

Inclusion Criteria:

- Child meets DSM-V diagnostic criteria for Attention-Deficit/Hyperactivity Disorder
- Child will be entering grades 1 - 5

Exclusion Criteria:

- Child has past or present use of psychoactive medication
- Child is currently classified as a student in special education or has a pending or ongoing evaluation for a special education placement
- Child has an IQ less than 70
- Child has psychosis or a pervasive developmental disorder
- Child is in a classroom that already has a study participant
- Child is home-schooled

**Contacts and Locations**

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*Please refer to this study by its ClinicalTrials.gov identifier (NCT number):* ***NCT03511976***

**Locations**

**United States, Florida**

Florida International University Center for Children and Families **Recruiting**
Miami, Florida, United States, 33199
Contact: William E Pelham, PhD 305-348-0477 wpelham@fiu.edu
Principal Investigator: William E Pelham, Ph.D.
Sub-Investigator: Nicole K Schatz, Ph.D.

**United States, New York**

Center for Children and Families, University at Buffalo **Recruiting**
Buffalo, New York, United States, 14214
Contact: Gregory A Fabiano, PhD 716-645-1130 fabiano@buffalo.edu
Principal Investigator: Gregory A Fabiano, Ph.D.

**Sponsors and Collaborators**
Florida International University
University at Buffalo

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| Responsible Party: | Florida International University |
| ClinicalTrials.gov Identifier: | NCT03511976 History of Changes |
| Other Study ID Numbers: | R305A170532 |
| First Posted: | April 30, 2018 Key Record Dates |
| Last Update Posted: | April 30, 2018 |
| Last Verified: | April 2018 |

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| Studies a U.S. FDA-regulated Drug Product: | Yes |
| Studies a U.S. FDA-regulated Device Product: | No |
| Product Manufactured in and Exported from the U.S.: | Yes |

Additional relevant MeSH terms:
Attention Deficit Disorder with Hyperactivity
Attention Deficit and Disruptive Behavior Disorders
Neurodevelopmental Disorders
Mental Disorders
Methylphenidate
Amphetamine
Central Nervous System Stimulants
Physiological Effects of Drugs
Dopamine Uptake Inhibitors
Neurotransmitter Uptake Inhibitors
Membrane Transport Modulators
Molecular Mechanisms of Pharmacological Action
Dopamine Agents
Neurotransmitter Agents
Sympathomimetics
Autonomic Agents
Peripheral Nervous System Agents
Adrenergic Agents
Adrenergic Uptake Inhibitors