Purpose

Although women are diagnosed with Attention-deficit hyperactivity disorder (ADHD) at a 1:3 ratio with men, recent research suggests that women may experience the same levels of adult ADHD as men but are underdiagnosed because symptoms may be less severe and/or mistaken for anxiety and depression. Women with ADHD typically experience problems in managing worker, student, spousal, and parenting roles due to disorganization, poor time management, difficulty regulating internal and external stressors, and difficulty maintaining daily schedules and routines. Intervention effectiveness research has largely focused on pharmacological treatment of ADHD symptoms; however, while such pharmacological treatment tends to enhance concentration and reduce motor restlessness, it does not address the skills needed to successfully carry out daily life roles and activities dependent upon time management, prioritization of tasks, and regulation of emotional responses within the home, school/work, and community environments. In this study, the investigators aim to determine whether a 7-week tailored occupational therapy intervention addressing organization, time management, stress management, and sensory regulation in the home, school/work, and community environments can increase satisfaction in desired daily life activities, and reduce ADHD symptoms and stress levels in women with ADHD.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
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<tr>
<td>Attention Deficit Hyperactivity Disorder</td>
<td>Behavioral: Occupational Therapy Intervention for Women with ADHD</td>
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</table>
Study Type: Interventional

Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment

Intervention Model Description:
Two group randomized controlled study

Masking: No masking
Primary Purpose: Treatment

Official Title: Effectiveness of a Tailored Occupational Therapy Intervention for Women With Attention-Deficit/Hyperactivity Disorder (ADHD)

Resource links provided by NLM:

MedlinePlus related topics: Attention Deficit Hyperactivity Disorder

U.S. FDA Resources

Further study details as provided by Sharon Gutman, Columbia University:

Primary Outcome Measures:

- Difference in Score on World Health Organization Adult ADHD Self-Report Scale between pre- and post-intervention [Time Frame: baseline and 8 weeks]
  18-item, 5-point Likert scale that requires 5 minutes to complete

Secondary Outcome Measures:

- Difference in Score on Perceived Stress Scale between pre- and post-intervention [Time Frame: baseline and 8 weeks]
  10-item, 5-point, self-report Likert scale that requires 5 minutes to complete

- Difference in Score on Canadian Occupational Performance Measure [Time Frame: baseline and 8 weeks]
  5-item, 10-point rating scale designed to be completed conjointly by a therapist and participant and takes approximately 10 minutes to complete

Estimated Enrollment: 24

Anticipated Study Start Date: September 2017
Estimated Study Completion Date: September 30, 2018

Estimated Primary Completion Date: June 23, 2018 (Final data collection date for primary outcome measure)

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<th>Arms</th>
<th>Assigned Interventions</th>
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<tr>
<td><strong>Experimental: Occupational Therapy for Women with ADHD</strong>&lt;br&gt;7-week tailored intervention for women with ADHD who have difficulty carrying out student, worker, spousal, and parenting roles due to poor time management, organization of their physical environments, management of internal and external stressors, and regulation of internal and external stimulation. Implementation of organizational, time management, stress management, and sensory regulation strategies for the home, school/work, and community environments.</td>
<td><strong>Behavioral: Occupational Therapy Intervention for Women with ADHD</strong>&lt;br&gt;The intervention will run for 7 weeks and consist of the following 1-hour sessions. Each intervention session will be facilitated by two CUMC occupational therapy students in each participant’s home environment (or another environment of the participant's choosing such as the work or school environment).&lt;br&gt;Implementation of organizational, time management, stress management, and sensory regulation strategies for the home, school/work, and community environments.</td>
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<td><strong>No Intervention: Control</strong>&lt;br&gt;No treatment provided.</td>
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**Detailed Description:**

Attention-deficit hyperactivity disorder (ADHD) is believed to be neurologically based and characterized by enduring attentional problems, motor restlessness, and cognitive and motor impulsivity that impact one's ability to function optimally in daily life activities. ADHD is commonly diagnosed in childhood at a prevalence rate of 11% and a male to female ratio of 3:1. The prevalence of adult ADHD varies from 4 to 6% and it is estimated that two-thirds of adult ADHD disorders are extensions of childhood ADHD. Researchers have suggested that the male to female prevalence ratio is inaccurate and that females experience ADHD at similar levels to males but are underdiagnosed. While boys with ADHD are often identified by their teachers because of motor impulsivity and inattention, girls with ADHD who may experience attentional problems and impulsivity without significant hyperactivity, may fail to be identified by teachers as needing evaluation and treatment. Some studies have found that female children and adolescents who experience the ADHD symptoms of inattention, disorganization, poor time management, and distractibility are more likely to be misdiagnosed with depression and anxiety. When depression and anxiety occur in children and adolescents with undiagnosed ADHD symptoms, they may result from the inability to manage ADHD symptoms as they impact functional performance in the home, school, and community.

Much of the research exploring ADHD has been devoted to children and adolescents. The research examining adult ADHD has thus far largely attempted to describe the phenomenon of adult ADHD. Research investigating intervention effectiveness for adult ADHD has primarily focused on pharmacological treatment. The small body of research examining non-pharmacological treatment has found moderate effectiveness for pharmacological intervention combined with cognitive behavioral therapy and psychoeducation.
Missing from this body of literature is research specifically examining interventions for women with ADHD, who present symptoms that are both overlapping with and unique from their male counterparts.

Studies have found that women with ADHD tend to have difficulty maintaining and succeeding in employment, school, and parenting and spousal roles. The ability to organize and implement tasks associated with each role, follow daily schedules and routines needed to support desired roles, prioritize and manage tasks in a timely manner, and regulate internal and external stressors to maintain consistent emotional responses may be difficult for women with ADHD.

In this study, the investigators aim to provide a 7-week tailored intervention for women with ADHD who have difficulty carrying out student, worker, spousal, and parenting roles due to poor time management, organization of their physical environments, management of internal and external stressors, and regulation of internal and external stimulation.

This intervention effectiveness study will use randomization and control. Twenty-four women who self-report diagnoses of ADHD will be recruited to participate and randomly assigned to either the intervention group (n=12) or control group (n=12). The intervention group will receive the 6-week intervention; the control group will not receive intervention (but will receive an organization toolkit at study end).

Eligibility

Ages Eligible for Study: 21 Years to 55 Years (Adult)
Sexes Eligible for Study: Female
Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:

- Females aged 21-55 years
- English-speaking
- Self-reported ADHD

Exclusion Criteria:

- Severe co-morbid condition such as an eating disorder, major depression, bipolar disorder, schizophrenia spectrum disorder, or substance use disorder

Contacts and Locations

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, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT03203928

Contacts

Contact: Sharon Gutman, PhD  212-305-8703  sg2422@cumc.columbia.edu

Sponsors and Collaborators
Columbia University
Investigators

Principal Investigator: Sharon Gutman, PhD  Columbia University

Publications:

Responsible Party: Sharon Gutman, Professor of rehabilitation and Regenerative Medicine, Columbia University

ClinicalTrials.gov Identifier: NCT03203928  History of Changes

Other Study ID Numbers: AAAR4416
Study First Received: June 28, 2017
Last Updated: June 28, 2017

Individual Participant Data
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 Sharon Gutman, Columbia University:

ADHD
Occupational Therapy

Additional relevant MeSH terms:

Attention Deficit Disorder with Hyperactivity
Hyperkinesis
Attention Deficit and Disruptive Behavior Disorders
Neurodevelopmental Disorders
Mental Disorders

Dyskinesias
Neurologic Manifestations
Nervous System Diseases
Signs and Symptoms

ClinicalTrials.gov processed this record on June 29, 2017