Helping College Students With ADHD Lead Healthier Lifestyles

This study is currently recruiting participants. (see Contacts and Locations)

Verified July 2016 by University of Maryland

Sponsor:
University of Maryland

Collaborator:
University of Memphis

Information provided by (Responsible Party):
University of Maryland

ClinicalTrials.gov Identifier:
NCT02829970

First received: July 7, 2016
Last updated: NA
Last verified: July 2016
History: No changes posted

Purpose

There are currently no published randomized controlled studies examining psychosocial interventions for college students with ADHD, and none specifically targeting AUDs in this population at any age, despite the clear indication from emerging research of the need for such interventions. In the current study, we will develop BA-based treatment intended to increase involvement in healthy, goal-directed activities (e.g., academic, recreational or social activities) and to reduce problematic drinking behaviors and other risk behaviors (e.g., unsafe sex) among college students with ADHD (Behavioral Activation for Attention & Alcohol Disorders; BAAAD). Finalized treatment manuals, altered based on focus group feedback, will be tested in a stage I randomized controlled trial (RCT) among 80 college students randomized to BMI + BAAAD or BMI + supportive counseling (SC). We expect that BMI + BAAAD will be successful with college students with ADHD, in terms of decreasing the escalation of problematic alcohol use behaviors, as compared to BMI + SC. This treatment development study will set the stage for larger-scale RCTs.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attention Deficit Hyperactivity Disorder</td>
<td>Behavioral: SUCCEEDS Program</td>
</tr>
<tr>
<td>Alcohol-Related Disorders</td>
<td>Behavioral: Living a Healthy College Lifestyle</td>
</tr>
<tr>
<td>Substance-Related Disorders</td>
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</tbody>
</table>

Study Type: Interventional
Study Design:  Allocation: Randomized  
Endpoint Classification: Efficacy Study  
Intervention Model: Parallel Assignment  
Masking: Single Blind (Subject)  
Primary Purpose: Treatment  

Official Title:  Behavioral Activation To Reduce Problem Alcohol Use In College Students With ADHD  

Resource links provided by NLM:  

MedlinePlus related topics: Attention Deficit Hyperactivity Disorder  
U.S. FDA Resources  

Further study details as provided by University of Maryland:  

Primary Outcome Measures:  
- Brief Young Adult Alcohol Consequences Questionnaire 30 Day [ Time Frame: Baseline, Post-Treatment (Week 5), 1 Month Follow-up (Week 9), 3 Month Follow-Up (Week 17) ] [ Designated as safety issue: No ]  
Changes in problematic drinking behaviors  

Secondary Outcome Measures:  
- Barkley Functional Impairment Scale-Self Report [ Time Frame: Baseline, Post-Treatment (Week 5), 1 Month Follow-up (Week 9), 3 Month Follow-Up (Week 17) ] [ Designated as safety issue: No ]  
Changes in functional impairment  
- Alcohol Use Disorders Identification Test [ Time Frame: Baseline, Post-Treatment (Week 5), 1 Month Follow-up (Week 9), 3 Month Follow-Up (Week 17) ] [ Designated as safety issue: No ]  
Changes in problematic drinking behaviors  
- Beck Depression Inventory-II [ Time Frame: Baseline, Week 1, Week 2, Week 3, Post-Treatment (Week 5), 1 Month Follow-up (Week 9), 3 Month Follow-Up (Week 17) ] [ Designated as safety issue: No ]  
Changes in depressive symptoms  

Estimated Enrollment:  80  
Study Start Date:  September 2015  
Estimated Study Completion Date:  September 2018
Estimated Primary Completion Date: June 2018 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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</thead>
<tbody>
<tr>
<td><strong>Experimental: SUCCEEDS Program</strong></td>
<td>Behavioral: SUCCEEDS Program</td>
</tr>
<tr>
<td>Participants will meet individually with</td>
<td>Participants will receive ADHD</td>
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<tr>
<td>a research team member for three weekly</td>
<td>Psychoeducation, Brief Motivational Interviewing (BMI) and Behavioral</td>
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<tr>
<td>sessions, two bi-weekly sessions, and</td>
<td>Activation for Attention &amp; Alcohol Disorders (BAAAD).</td>
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<tr>
<td>complete 1-month and 3-month post</td>
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<tr>
<td>treatment follow-ups.</td>
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<tr>
<td>Participants will be engaged about</td>
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<tr>
<td>personalized alcohol feedback and</td>
<td></td>
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<tr>
<td>identify life values and specific</td>
<td></td>
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<tr>
<td>activities important to those values.</td>
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<tr>
<td>**Active Comparator: Living a Healthy</td>
<td>Behavioral: Living a Healthy College Lifestyle</td>
</tr>
<tr>
<td>College Lifestyle**</td>
<td></td>
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<td>treatment follow-ups.</td>
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<tr>
<td>Participants will engage in discussion</td>
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<tr>
<td>focused on experiences as an emerging</td>
<td></td>
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<tr>
<td>adult.</td>
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**Detailed Description:**

College students with Attention-Deficit/Hyperactivity Disorder (ADHD) are particularly vulnerable to problematic alcohol use (e.g., excessive alcohol consumption, failure to meet responsibilities because of drinking, or injury to self or others as a result of drinking) given their developmentally-inappropriate levels of inattention, hyperactivity and impulsivity, combined with the lifestyle associated with life on a college campus (including increased access to alcohol, decreased structure and parental supervision). Our prior research demonstrates elevated rates of alcohol related problems and disorders (AUDs) among college students with ADHD; 47% of college students with ADHD meet lifetime criteria for alcohol abuse and 23% meet criteria for dependence, as compared to 12% and 6% of college students from the general population, respectively. There are currently no published randomized controlled studies examining psychosocial interventions for college students with ADHD, and none specifically targeting AUDs in this population at any age, despite the clear indication from emerging research of the need for such interventions. Moreover, brief motivation-based alcohol interventions (BMIs) that generally have been successful for college students show limited benefits among individuals with elevated impulsivity and poor self-regulation, both hallmarks of ADHD, calling for the need to modify BMIs for this vulnerable group. Thus, it is crucial to determine core treatment components that are efficacious for treating AUDs and that are developmentally-appropriate for college students with ADHD and designed in a manner which promotes transportability to the university counseling center setting. Behavioral activation (BA) is a brief behavioral approach that aims to increase individuals' contact with valued environments through systematic efforts to increase rewarding experiences, enjoyment of daily activities, and goal-directed behaviors. We have successfully applied BA to substance users in a range of settings, including college students with problematic drinking patterns. Importantly, BA has clear relevance for addressing ADHD-related executive functioning deficits, which may be associated with an increased propensity for engagement in problematic alcohol use. Further, BA teaches individuals to engage in healthy, goal-directed rewarding behaviors (e.g., academic, recreational or social activities), rather than relying on drinking to provide immediate rewards. Finally, BA is a highly adaptable intervention approach. In the current study, we will develop BA-based treatment intended to increase involvement in healthy, goal-directed activities (e.g., academic, recreational or social activities) and to reduce problematic drinking behaviors and other risk behaviors (e.g., unsafe sex) among college students with ADHD (Behavioral Activation for Attention & Alcohol Disorders; BAAAD). This treatment will be developed in collaboration with the University Counseling Center, to ensure its applicability within this setting, utilizing focus group methodology with Center staff. Finalized treatment manuals, altered based on focus
group feedback, will be tested in a stage I randomized controlled trial (RCT) among 80 college students randomized to BMI + BAAAD or BMI + supportive counseling (SC). We expect that BMI + BAAAD will be successful with college students with ADHD, in terms of decreasing the escalation of problematic alcohol use behaviors, as compared to BMI + SC. This treatment development study will set the stage for larger-scale RCTs.

Eligibility

Ages Eligible for Study: 18 Years to 24 Years (Adult)
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Be between the ages of 18-24 years old
- Be enrolled full-time at University of Maryland - College Park (UMCP) as an undergraduate student
- Be fluent in English
- Live independently from their parents
- Meet full Diagnostic and Statistical Manual - 5th Edition (DSM-5) criteria for ADHD
- Meet cutoffs on AUDIT

Exclusion Criteria:

- Bipolar disorder or current psychosis, which would require more immediate/intensive treatment
- Current engagement in psychosocial therapy thought to interfere with this study (including participation in other treatment studies on campus)
- Suicidal risk that would place the individual at risk beyond the safety procedure available from the research team

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: NCT02829970

Contacts

Contact: Andrea Chronis-Tuscano, PhD  301-405-9640  achronis@umd.edu

Locations

United States, Maryland

University of Maryland

Recruiting

College Park, Maryland, United States, 20742-5141
Contact: John Vasko, BS  301-405-4606  jvasko@umd.edu
Contact: Michael Meinzer, PhD  301-405-4606  mmeinzer@umd.edu

Sponsors and Collaborators

University of Maryland
University of Memphis
Investigators
Principal Investigator: Andrea Chronis-Tuscano, PhD University of Maryland - College Park

Responsible Party: University of Maryland
ClinicalTrials.gov Identifier: NCT02829970
History of Changes
Other Study ID Numbers: 1R34AA022133-01A1
Study First Received: July 7, 2016
Last Updated: July 7, 2016
Health Authority: United States: Institutional Review Board

Individual Participant Data
Plan to Share IPD: No

Keywords provided by University of Maryland:
Attention Deficit Hyperactivity Disorder
Alcohol-Related Disorders
Substance-Related Disorders
Motivational Interviewing
Behavior Therapy

Additional relevant MeSH terms:
Disease
Attention Deficit Disorder with Hyperactivity
Hyperkinesis
Substance-Related Disorders
Alcohol-Related Disorders
Pathologic Processes
Attention Deficit and Disruptive Behavior Disorders
Neurodevelopmental Disorders
Mental Disorders
Dyskinesias

Neurologic Manifestations
Nervous System Diseases
Signs and Symptoms
Chemically-Induced Disorders
Ethanol
Anti-Infective Agents, Local
Anti-Infective Agents
Central Nervous System Depressants
Physiological Effects of Drugs

ClinicalTrials.gov processed this record on July 11, 2016