Group-based Cognitive-behavioral Therapy for Adults With Attention-deficit/Hyperactivity Disorder Inattentive-type

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

Verified August 2016 by Karolinska Institutet

Sponsor:
Karolinska Institutet

Information provided by (Responsible Party):
Benjamin Bohman, Karolinska Institutet

ClinicalTrials.gov Identifier:
NCT02889354

First received: August 31, 2016
Last updated: NA
Last verified: August 2016
History: No changes posted

Purpose
The newly developed CBT for ADHD inattentive-type (ADHD-I) protocol is tested for feasibility and acceptability in a pilot study with a single group design. The study also evaluates measurements and recruiting possibilities, and effects of the intervention. Research hypotheses include: 1. There is a basis for recruiting ADHD-I patients for participation in an RCT at psychiatric outpatient units, 2. The measurements in the study are feasible and reasonable in regards to patient characteristics; that is, the patients are responding to the questionnaires as intended, 3. The CBT for ADHD-I intervention is feasible in terms of treatment completion, compliance to home assignments, and credibility and relevance, and is lacking of or involves a tolerable degree of adverse effects, and 4. The CBT for ADHD-I protocol reduces core symptoms of ADHD-I as well as symptoms of stress, depression, and anxiety, and improves quality of life.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
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<tbody>
<tr>
<td>Attention Deficit Disorder With Hyperactivity</td>
<td>Behavioral: Cognitive-behavioral therapy</td>
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</tbody>
</table>

Study Type: Interventional

Study Design: Intervention Model: Single Group Assignment
Primary Purpose: Treatment
Official Title: Group-based Cognitive-behavioral Therapy for Adults With Attention-deficit/Hyperactivity Disorder Inattentive-type: a Pilot Study

Resource links provided by NLM:

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

Further study details as provided by Karolinska Institutet:

Primary Outcome Measures:
- Brown ADD Scales [Time Frame: 14 weeks] [Designated as safety issue: No]
  Diagnostic measure

Estimated Enrollment: 30
Study Start Date: August 2016
Estimated Study Completion Date: June 2017
Estimated Primary Completion Date: June 2017 (Final data collection date for primary outcome measure)

<table>
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<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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<tbody>
<tr>
<td>Experimental: Cognitive-behavioral therapy</td>
<td>Behavioral: Cognitive-behavioral therapy</td>
</tr>
</tbody>
</table>

Eligibility

Ages Eligible for Study: 18 Years and older (Adult, Senior)
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
In addition to an ADHD inattentive-type diagnosis, inclusion criteria are:

1. 18 years or older,
2. intelligence quotient above 80-85, and
3. if on medication, it needs to be well-established since three months.

Exclusion Criteria:
1. autism spectrum disorder,
2. ongoing substance use disorder,
3. difficulties in compliance with medical or other treatment,
4. social and/or psychiatric problems to such an extent that it prevents focusing on treatment, or
5. ongoing cognitive-behavioral therapy.

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: NCT02889354

Contacts
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Sponsors and Collaborators
Karolinska Institutet

Investigators
Principal Investigator: Benjamin Bohman, PhD Karolinska Institutet

More Information

Responsible Party: Benjamin Bohman, Dr, Karolinska Institutet
ClinicalTrials.gov Identifier: NCT02889354 History of Changes
Other Study ID Numbers: KI-2016/255-31/5
Study First Received: August 31, 2016
Last Updated: August 31, 2016
Health Authority: Sweden: Regional Ethical Review Board
Individual Participant Data Plan to Share IPD: No

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

Dyskinesias
Neurologic Manifestations
Nervous System Diseases
Signs and Symptoms

ClinicalTrials.gov processed this record on September 05, 2016