Psychological Treatment for Adults With Attention-Deficit/Hyperactivity Disorder (ADHD)

This study is ongoing, but not recruiting participants.

Sponsor:
Karolinska Institutet
Collaborator:
Stockholm County Council, Sweden
Information provided by (Responsible Party):
Viktor Kaldo, Karolinska Institutet
ClinicalTrials.gov Identifier:
NCT01659164

First received: August 3, 2012
Last updated: January 16, 2013
Last verified: January 2013
History of Changes

Purpose

The purpose of this uncontrolled pilot study is to develop and make an initial evaluation of a new treatment manual for treatment of **ADHD** in adults. The objectives in the treatment is to build relational skills, skills in organizing and structuring everyday life, handle difficult emotions and impulses etc. The treatment will be in a group format and it is hypothesized that the psychological intervention will result in reduced **ADHD** symptoms and to decreased experience of stress and depressive symptoms. The uncontrolled design does not allow for any causal inferences from the results, this pilot study is primarily to be seen as a preparation before a subsequent RCT.

Condition	Intervention
ADHD	Behavioral: Group treatment for adults with **ADHD**

Study Type: Interventional

Study Design: Endpoint Classification: Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Psychological Treatment for **Attention-Deficit/Hyperactivity Disorder** (**ADHD**) - Pilot Evaluation of a New Treatment Manual Based on CBT and DBT

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:

- Change (from baseline) in ASRS- v 1.1 [Time Frame: 14 weeks (post)] [Designated as safety issue: No]
  ADHD Self Report Scale (self rating)

Secondary Outcome Measures:

- Change (from baseline) in **ADHD** Rating Scale [Time Frame: 14 weeks (post)]
  [Designated as safety issue: No]
  ADHD Rating Scale - assessed by a clinician

- Change (from baseline) in EQ-5D [Time Frame: 14 weeks (post)] [Designated as safety issue: No]
  Euroqol - (self report) to measure general health and quality of life

- Change (from baseline) in ISI [Time Frame: 14 weeks (post)] [Designated as safety issue: No]
  Insomnia Severity Index - (self report) to measure insomnia symptoms

- Change (from baseline) in PSS-4 [Time Frame: 14 weeks (post)] [Designated as safety issue: No]
  Perceived Stress Scale - (self report) to measure level of stress in everyday life

- Change (from baseline) in Sheehan Disability Scale [Time Frame: 14 weeks (post)]
  [Designated as safety issue: No]
  Sheehan Disability Scale - (self report) to measure level of disability in everyday life

- Change (from baseline) in MADRS-S [Time Frame: 14 weeks (post)] [Designated as safety issue: No]
  Montgomery-Åsberg Depression Rating Scale - (self report) to measure level of depression

- Change (from baseline) in DERS [Time Frame: 14 weeks (post)] [Designated as safety issue: No]
  Difficulties of Emotion Regulation Scale - (self report)

Other Outcome Measures:

- Treatment evaluation [Time Frame: 14 weeks (post)] [Designated as safety issue: No]
  The investigators design own questions in order to evaluate how the participants have experienced the intervention regarding to knowledge, usage of the treatment methods and possible difficulties that they have experienced during treatment. Our aim is to use these evaluations to evolve and improve the quality of the treatment manual.

Estimated Enrollment: 20

Study Start Date: August 2012

Estimated Study Completion Date: June 2013

Estimated Primary Completion Date: June 2013 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Group treatment (uncontrolled) Psychological treatment in group for adults with **ADHD** (pilot) during 14 weeks with focus on decreasing disabilities due to the**condition**.	Behavioral: Group treatment for adults with**ADHD** 14 weeks of group treatment for adults with**ADHD**

Detailed Description:

Approximately one-third of children with ADHD continue to be fully symptomatic into adulthood and many of the remainders often retain some residual problems that require treatment. Thus ADHD is a prevalent and chronic disabling disorder. Drugs provide first line treatment for adults with ADHD but are not enough for everybody, while we still lack proper evidence for promising psychological treatment. In addition to core symptoms of ADHD including regulatory difficulties of attention, activity level and impulses, difficulties with emotional regulation are common.

Follow-up studies of adults with ADHD have shown that only a few patients were offered sufficient treatment and support after the neuropsychiatric assessment and testing. The majority of adults diagnosed with ADHD are offered pharmacological treatment (stimulant medication) as the sole treatment. However, stimulant medication is not effective for up to 20-50 percent of adults as they may not experience symptom reduction or they are unable to tolerate the medication.

Consequently, the possible benefits of identifying and treating individuals with ADHD are extensive. Treatment of ADHD is preferably multimodal, i.e. consisting of more than one intervention.

There has been limited research to date concerning psychosocial treatments for adult ADHD. Studies of cognitive behavioral therapy (CBT) and dialectical behavior therapy (DBT) show that structured short-term therapies are promising in reducing ADHD related symptoms and increasing life quality. Focus in the CBT treatment is to build skills, increasing and compensating for deficits in the executive functioning due to impairments of the frontal lobe. DBT combines change-oriented skills from CBT with acceptance-oriented skills and core mindfulness skills. DBT skills have been tried out and validated as a promising intervention package for adults with ADHD through the research of Steven Safren and Bernd Hesslinger.

The objective of the planned study is to evaluate a new manual for group treatment, with a combination of treatment methods from Safrens and Hesslingers evidence-based treatment manuals. The aim of the pilot project is to create a clinically effective combination of the different methods of treatment, with a high degree of understanding, acceptance, use and perceived usefulness of the patients undergoing treatment. Both qualitative and quantitative data about patients' perceptions and use of the different methods will be collected during and after treatment to increase knowledge of how treatments can be developed and combined in order to better match the needs of patients.

Eligibility

Ages Eligible for Study: 18 Years to 65 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

1. * Clinical diagnosis of AD/HD
2. * Age 18-65
3. 17 or more on the Adult ADHD Self Report Scale (ASRS v1.1)
4. Not medically treated for adhd symptoms, or medically treated with central stimulants or comparable substance since at least one month with no significant changes in dosage and where no change in medical treatment is anticipated during the study time frame for the participant.
5. No change in any other medical treatment is anticipated during the study time frame for the participant.
6. Participant are by investigators considered able to follow through the training protocol and take part in measures taken during the study time frame
7. The participant hasn´t used drugs the last 3 months.

Exclusion Criteria:

8. Diagnosed substance abuse according to DSM-IV criteria within 3 months prior to screening. Earlier episodic substance abuse is not excluding
9. Co-existing psychiatric condition that investigators believe will unable the participant to follow through the training protocol and take part in measures taken during the study time frame.
10. IQ ≤70 according to a neuropsychological assessment
11. * Suicidality risk which is assessed during the first assessment interview.
12. Organic brain syndrome
13. Serious somatic condition which will unable the participant to participate (through the training protocol)or, is anticipated to have a negative impact on the treatment results
14. Autism spectrum disorder (severe)
15. Severe depression
16. Other current psychological treatment for AD/HD

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01659164

Locations

Sweden

Internetpsykiatrienheten, Psykiatri Sydväst, SLSO
Stockholm, Sweden

Sponsors and Collaborators

Karolinska Institutet
Stockholm County Council, Sweden

Investigators

Principal Investigator: Viktor Kaldo, Ph.D. Karolinska Institutet

More Information

No publications provided

Responsible Party:	Viktor Kaldo, Principal Investigator, Karolinska Institutet
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Study First Received:	August 3, 2012
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Keywords provided by Karolinska Institutet:
Cognitive Behavioral Therapy
Dialectical Behavioral Therapy
Group Treatment

ADHD

Additional relevant MeSH terms:

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

ClinicalTrials.gov processed this record on July 02, 2013