Purpose
Cognitive Behavioral Therapy (CBT) is treatment of choice for insomnia (CBT-i). Many patients in psychiatric care have sleep problems including insomnia, but are rarely given the choice to participate in CBT to improve their sleep. Patients with ADHD is a patient group with high levels of sleep difficulties. Sleep problems in this patient group can be both more general such as insomnia, but can also be related to the ADHD itself and to the use of ADHD medication. In a previous pilot study, the investigators developed a version of CBT-i that would target sleep problems in this population. The basis was CBT-i, but with more emphasis on sleep promoting behaviors specific to ADHD (e.g. appropriate timing of ADHD-medication), techniques that would also alleviate sleep phase problems, (e.g. the systematic use of light and darkness), and techniques to target more general sleep disturbing habits (e.g. not winding down before bed time), that are also common in patients with ADHD. This treatment was well tolerated and gave moderate effects on insomnia severity in the pilot study. In a naturalistic randomized controlled trial, the investigators now evaluate the effects of this psychological treatment on sleep and symptoms of ADHD in patients at the ADHD-clinics, Northern Stockholm Psychiatry, Sweden.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
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<tbody>
<tr>
<td>Sleep Problem ADHD</td>
<td>Behavioral: Adjusted CBT-i for ADHD Other: Treatment as Usual</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 (Investigator)
Primary Purpose: Treatment

Official Title: Better Sleep in Psychiatric Care - ADHD. A Randomized Naturalistic Study of a Psychological Group Treatment for Sleep Problems in Psychiatric Patients With Attention Deficit Hyperactivity Disorder.

Resource links provided by NLM:

MedlinePlus related topics: Sleep Disorders
U.S. FDA Resources

Further study details as provided by Karolinska Institutet:

Primary Outcome Measures:
- Insomnia Severity Index [ Time Frame: Changes from base-line to 10 weeks and 3 months ]  
  [ Designated as safety issue: No ]
  7-item, self-rated questionnaire measuring change in insomnia severity.

Secondary Outcome Measures:
- Actigraphy [ Time Frame: Continuously from treatment start (week 1) to the last week of treatment (week 10) ]  
  [ Designated as safety issue: No ]
An actigraph is placed on the participant's arm for one week. It measures participants' activity in the form of movements. It can be used for acquiring data on sleep and daytime activity, including calculated sleep latency, total sleep time, sleep efficiency, wake after sleep onset, variability in sleep timing and daytime activity.

- Sleep diary [ Time Frame: Changes from base-line to 10 weeks and 3 months ]  
  [ Designated as safety issue: No ]
Daily self-ratings on a number of sleep parameters, resulting in several measures including sleep latency, wake after sleep onset, total sleep time, sleep efficiency, subjective sleep quality and variability in sleep timing

Other Outcome Measures:
- Brunsviken brief quality of life scale [ Time Frame: Changes from base-line to 10 weeks and 3 months ]  
  [ Designated as safety issue: No ]
12-items self-rating questionnaire measuring quality of life.
• Adult ADHD Self-Report Scale [ Time Frame: Changes from base-line to 10 weeks and 3 months ]
  [ Designated as safety issue: No ]
  18-items self-report questionnaire measuring ADHD-symptoms.

• Dysfunctional Beliefs and Attitudes about Sleep [ Time Frame: Changes from base-line to 10 weeks and 3 months ]
  [ Designated as safety issue: No ]
  10-items self-rating questionnaire measuring sleep related cognitions.

• Sleep Problems Acceptance Questionnaire [ Time Frame: Changes from base-line to 10 weeks and 3 months ]
  [ Designated as safety issue: No ]
  8-items self-rating questionnaire measuring acceptance of sleep problems.

• Sleep habits and behaviors [ Time Frame: Changes from base-line to 10 weeks and 3 months ]
  [ Designated as safety issue: No ]
  Self-rating questionnaire regarding the use of sleep promoting behaviors. The questionnaire was constructed for the current project and consists of two parts. The first part includes 16 statements such as "Last week I got out of bed within 15 minutes of waking up" to be answered by number of days the last week this was true (i.e. from 0 to 7). The other part is to be answered on a 6-point Likert scale from "Not at all true" to "Entirely true", with 7 statements like "I get out of bed the same time every morning".

Estimated Enrollment: 50
Study Start Date: December 2016
Estimated Study Completion Date: June 2018
Estimated Primary Completion Date: June 2018 (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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</table>
| Experimental: Behavioral: Adjusted CBT-i for ADHD
  Cognitive Behavioral group intervention for sleep problems in ADHD, based on Cognitive Behavioral Therapy for insomnia and behavioral treatment for Sleep Phase Disorders. | Behavioral: Adjusted CBT-i for ADHD
  This is a version of CBT for insomnia (CBT-i) developed during the pilot phase of this Project. Traditional CBT-i is adjusted for use in the adult ADHD population. This behavioral intervention addresses not only traditional aspects of insomnia, but also sleep phase problems and other aspects of sleep specifically relevant to the ADHD-population. Treatment is given as 10 weekly group sessions with telephone calls from the therapist between sessions to increase adherence and address individual patient needs. |
| Treatment as Usual                        | Other: Treatment as Usual                                                             |
Treatment as Usual. (After about ten weeks, participants in this condition are offered the experimental group treatment.)

Usual care at the ADHD-clinic. This mostly entails managing pharmacological treatment for ADHD, comorbid psychiatric problems and/or sleep problems. The clinic also provides different group treatments, for instance mindfulness groups and groups for developing behavioral strategies for managing ADHD symptoms, and individual therapy.

### Eligibility

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

#### Criteria

Inclusion Criteria:
- Being a patient at the ADHD-clinics Northern Stockholm Psychiatry
- Experiencing sleep problems (subjective report)

Exclusion Criteria:

#### 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: NCT03015636

#### Locations

**Sweden**

Department of ADHD, Northern Stockholm Psychiatry
Stockholm, Sweden, 113 21

**Sponsors and Collaborators**

Karolinska Institutet
Department of ADHD, Northern Stockholm Psychiatry

**Investigators**

Principal Investigator: Susanna Jernelöv, PhD, LP Karolinska Institutet

**More Information**

Publications:


Responsible Party: Susanna Jernelöv, PhD, LP, Karolinska Institutet
ClinicalTrials.gov Identifier: NCT03015636
History of Changes
Other Study ID Numbers: 2016/1988-31
Study First Received: January 6, 2017
Last Updated: January 9, 2017
Health Authority: Sweden: Regional Ethical Review Board
Individual Participant Data
Plan to Share IPD: Undecided

Keywords provided by Karolinska Institutet:

Cognitive Behaviour Therapy
Psychological Intervention

Additional relevant MeSH terms:

Attention Deficit Disorder with Hyperactivity Neurodevelopmental Disorders
Dyssomnias Mental Disorders
Sleep Wake Disorders Nervous System Diseases
Parasomnias Neurologic Manifestations
Attention Deficit and Disruptive Behavior Disorders Signs and Symptoms

ClinicalTrials.gov processed this record on January 10, 2017