**ClinicalTrials.gov PRS DRAFT Receipt (Working Version)**
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**ClinicalTrials.gov ID:** [redacted]

## Study Identification

| | |
|---|---|
| Unique Protocol ID: | CBT-I CMM |
| Brief Title: | Cognitive Behavior Therapy for Insomnia: Analysis of Components, Mediators and Moderators |
| Official Title: | Cognitive Behavior Therapy for Insomnia: Analysis of Components, Mediators and Moderators |
| Secondary IDs: | |

## Study Status

| | |
|---|---|
| Record Verification: | April 2018 |
| Overall Status: | Completed |
| Study Start: | August 2016 [Actual] |
| Primary Completion: | November 2017 [Actual] |
| Study Completion: | November 2017 [Actual] |

## Sponsor/Collaborators

| | |
|---|---|
| Sponsor: | Stockholm University |
| Responsible Party: | Principal Investi_ator<br>Investigator: [redacted]<br>Official Title: PhD.<br>Affiliation: [redacted] |
| Collaborators: | |

## Oversight

| | |
|---|---|
| U.S. FDA-regulated Drug: | |
| U.S. FDA-regulated Device: | |
| U.S. FDA IND/IDE: | No |
| Human Subjects Review: | Board Status: Approved<br>Approval Number: [redacted]<br>Board Name: Section 3<br>Board Affiliation: Ethical review board Stockholm<br>Phone: 0046 8-524 870 00<br>Email: kansli@stockholm.epn.se<br>Address: |

Regionala etikprövningsnämnden i Stockholm
FE 289
171 77 STOCKHOLM

Data Monitoring: No

FDA Regulated Intervention: No

## Study Description

Brief Summary: The overall purpose with this investigation is to further our knowledge about cognitive behavioral therapy (CBT) for insomnia by examining treatment components, mediators, and moderators. The first aim that will be addressed is to explore the efficacy of the CBT components with a dismantling-treatment strategy. Two active CBT interventions, intended to define its components – cognitive therapy and behavior therapy – will be compared with one another as well as with a waitlist condition on a broad range of outcomes at five to nine assessment points depending on the measures. The design will thus enable us to examine what CBT component or components are necessary, sufficient and facilitative of therapeutic change. The second aim that will be explored is to investigate what processes occur in CBT that may contribute to treatment outcome with a treatment-mediator strategy. To examine mediators for CBT, the following mediators will be assessed; Anxiety and Preoccupation about sleep Questionnaire (APSQ), Dysfunctional Beliefs and Attitudes about Sleep (DBAS), Sleep Associated Monitoring Index (SAMI), Sleep-Related Behavior Questionnaire (SRBQ), time in bed, napping, bedtime variability, and rise time variability. The hypothesis is that cognitive processes will mediate cognitive therapy outcomes, and that behavioral factors will have a mediating role for behavior therapy improvements. The third aim that will be addressed is to examine what patient characteristics does CBT depend on to be effective with a treatment-moderator strategy. To investigate moderators for CBT, the following moderators will be assessed; age, gender, occupational status, level of education, initial insomnia severity, dysfunction, medication use, chronic pain, psychiatric co-morbidity, medical co-morbidity, behavioral and cognitive processes used as mediators will also be employed as moderators.

Detailed Description: NOTE : Detailed Description has not been entered.

## Conditions

Conditions: Sleep Initiation and Maintenance Disorders

Keywords: Cognitive therapy
Behavior therapy
Moderation
Mediation

## Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: N/A

Interventional Study Model: Parallel Assignment

Number of Arms: 3

Masking: None (Open Label)

Allocation: Randomized

Enrollment: 219 [Actual]

## Arms and Interventions

| Arms | Assigned Interventions |
|---|---|
| Experimental: Behavior Therapy | Behavioral: Behavior Therapy<br>Behavior Therapy involves the use of stimulus control and sleep restriction in order to reverse maladaptive sleep habits (time in bed, napping, bedtime variability, rise time variability) proposed to maintain insomnia. It also involves the practice of sleep hygiene principles. |
| Experimental: Cognitive Therapy | Behavioral: Cognitive Therapy<br>Cognitive Therapy involves challenging negative automatic thoughts about sleep and the use of behavioral experiments to challenge and test five cognitive processes (i.e., worry, dysfunctional thoughts, monitoring, safety behaviours, misperception) proposed to perpetuate insomnia. |
| Waitlist | Behavioral: Waitlist.<br>The waitlist serves as a passive control which will receive the same measures administered to the cognitive and behaviour therapy groups. |

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## Outcome Measures

Primary Outcome Measure:

1. Changes on the insomnia severity index (ISI).
   [Time Frame: Pretreatment (week 0), during treatment (i.e., at week: 2, 4, 6, 8), post-treatment (week 10) and follow-up at 6, 12, and 18 month after treatment.]

Secondary Outcome Measure:

2. Changes on the Work and Social Adjustment Scale (WSAS).
   [Time Frame: Pretreatment (week 0), post-treatment (week 10) and follow-up at 6, 12, and 18 month after treatment.]
3. Changes in sleep onset latency (SOL).
   [Time Frame: Pretreatment (week 0), during treatment (week: 2, 4, 6, 8) and post-treatment (week 10).]
4. Changes in wake time after sleep onset (WASO).
   [Time Frame: Pretreatment (week 0), during treatment (week: 2, 4, 6, 8) and post-treatment (week 10).]
5. Changes in early morning awakenings (EMA).
   [Time Frame: Pretreatment (week 0), during treatment (week: 2, 4, 6, 8) and post-treatment (week 10).]
6. Changes in total sleep time (TST).
   [Time Frame: Pretreatment (week 0), during treatment (week: 2, 4, 6, 8) and post-treatment (week 10).]
7. Changes in Hospital Anxiety and Depression Scale (HADS)
   [Time Frame: Pretreatment (week 0), post-treatment (week 10) and follow-up at 6, 12, and 18 month after treatment.]
8. Changes in nighttime symptoms, by using item 1 - 3 from the primary outcome measure.
   [Time Frame: Pretreatment (week 0), during treatment (week: 2, 4, 6, 8), post-treatment (week 10) and follow-up at 6, 12, and 18 month after treatment.]
9. Changes in impairment, by using item 5 and 6 from the primary outcome measure.

[Time Frame: Pretreatment (week 0), during treatment (week: 2, 4, 6, 8), post-treatment (week 10) and follow-up at 6, 12, and 18 month after treatment.]

10. Changes in distress, by using item 4 and 7 from the primary outcome measure.
[Time Frame: Pretreatment (week 0), during treatment (week: 2, 4, 6, 8), post-treatment (week 10) and follow-up at 6, 12, and 18 month after treatment.]

11. Changes in Brunnsviken Brief Quality of life index (BBQ)
[Time Frame: Pretreatment (week 0), post-treatment (week 10) and follow-up at 6, 12, and 18 month after treatment.]

Other Pre-specified Outcome Measures:

12. Credibility Expectancy Questionnaire (CEQ ).
[Time Frame: During the first treatment module.]

13. Client Satisfaction Questionnaire (CSQ-8).
[Time Frame: Post-treatment (week 10).]

14. Activity and adherence with treatment protocol (self developed questionnaire assessing treatment activity and adherence relating to text, homework and therapist support).
[Time Frame: Post-treatment (week 10).]

15. Sick-leave and other concomitant treatment (self developed questionnaire).
[Time Frame: Post-treatment (week 10).]

16. Adverse events (questionnaire from a previous similar study).
[Time Frame: Post-treatment (week 10).]

17. Changes in physical activity (self developed questionnaire).
[Time Frame: Pretreatment (week 0) and post-treatment (week 10).]

18. Changes in Ford Insomnia Response To Stress Test (FIRST).
[Time Frame: Pretreatment (week 0) and post-treatment (week 10) for the waitlist.]

19. Changes in Daytime Insomnia Symptom Response Scale (DISRS)
[Time Frame: Pretreatment (week 0) and post-treatment (week 10) for the waitlist.]

20. Montgomery Åsberg Depression Rating Scale (MADRS).
[Time Frame: Pretreatment (week 0).]

21. Changes in suicide risk (Item 9 from the MADRS).
[Time Frame: Pretreatment (week 0), post-treatment (week 10) and follow-up at 6, 12, and 18 month after treatment.]

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## Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Presence of insomnia more than three nights per week and for more than three months.
- Insomnia despite adequate opportunity to sleep.
- Insomnia severity typical for insomnia disorder, i.e. 11 points or more on the Insomnia Severity Index (ISI).
- Nighttime insomnia symptoms, i.e., two points or more on at least one of the first three ISI questions.
- Daytime insomnia symptoms, i.e. two points or more on one or both of the ISI distress and impairment items (numbers 5 and 7).
- Clinical insomnia symptoms from sleep diaries concerning three nighttime symptoms (difficulties with sleep initiation, difficulties with sleep maintenance, and early morning awakenings), i.e., thirty minutes or more on average on one or more of the symptoms.
- No current or past CBT-I treatment within the past 5 years.
- Time and opportunity to participate in treatment for ten weeks.
- Time and opportunity to read approximately fifteen pages per week and execute homework assignments for ten weeks.
- Access to a computer, email and internet.

Exclusion Criteria:

- Severe depression, i.e., more than 30 points on MADRS-S.
- Suicidal risk, i.e., 4 points or more on item 9 on MADRS-S.
- A high intake of alcohol or caffeine,
- Insomnia due to shiftwork or other sleep-disturbing events (e.g., pregnancy, small children, or animals in the sleep environment).
- Participants with a history of psychotic or bipolar disorder.
- If a somatic condition is reported, it is required that it is relatively stable and/or that the candidate is receiving treatment for the condition.
- When a candidate fulfills criteria for a psychiatric or somatic condition, it is required that insomnia is the disorder currently most distressing and disabling or that the insomnia remains despite treatment for the comorbid condition.
- Participants with the following primary sleep disorders will be excluded via the Duke Structured Interview for Sleep Disorders (DSISD): sleep apnea, restless legs syndrome, periodic limb movement disorder, circadian rhythm disorder, and parasomnias.
- If sleep medication is used, it is required that the use has been relatively stable during three months.
- If Selective Serotonin Reuptake Inhibitors (SSRI) use is reported, it is required that the onset of the medication was at least three months prior to the telephone interview.
- Participants who regularly consume sleep-disturbing medications.

## Contacts/Locations

Central Contact Person: [redacted]
Telephone: [redacted]
Email: [redacted]

Central Contact Backup:

Study Officials: [redacted]
Stud Princi al Investigator
[redacted]

Locations: [redacted]
Contact: [redacted]

## IPDSharing

Plan to Share IPD: No

## References

Citations:

Links: [redacted]

Available IPD/Information: