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Impact of insomnia treatment on mood, brain function and cardiovascular health

Submission date
06/08/2018

Recruitment status
No longer recruiting

Registration date
13/08/2018

Overall study status
Completed

Last Edited
27/09/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Individuals with chronic insomnia have persistent difficulty falling and staying asleep, as well as complaints of difficulty thinking, concentrating, and remembering. Individuals with insomnia have an overactivation of certain bodily systems and increased negative emotional states. The overactivation of bodily systems can be evaluated using heart rate variability, the fluctuations in time differences between heartbeats as well as with sleep spindles, which are specific brain waves produced during sleep. Negative emotional states can be assessed using questionnaires on current mood and stress. The overactivation of certain bodily systems and increased negative emotional states have been proposed as both a cause and consequence of chronic insomnia.

This study aims to look at whether a psychological treatment for insomnia will reduce physiological and emotional overactivation, or whether bodily and emotional overactivation before treatment will reduce the efficacy of the psychological treatment for insomnia. This study also aims to assess whether the psychological treatment for insomnia will improve concentration and memory, and whether bodily overactivation at baseline will be associated with less improvement in sleep quality and thinking abilities after the psychological treatment for insomnia.

Who can participate?
Adults who suffer from chronic insomnia

What does the study involve?
Participants will first complete a pre-treatment assessment of their sleep, mood, stress, and bodily functions. Participants will sleep at our laboratory for one night, where their blood pressure, heart rate, and brain waves will be recorded at night and during the day. Blood and saliva samples will also be collected. Participants will wear a watch-like device to record their activity during 14 days in a row. Participants will also complete questionnaires and interviews about sleep, stress, and mood. After the completion of this initial assessment, participants will be assigned either to an 8-week group cognitive-behavioural therapy for insomnia or an 8-week waiting period. Following the completion of therapy or waiting period, participants will complete the same assessment of sleep, mood, and bodily function that they did before treatment. This assessment will also be repeated 12 months after the completion of the group

therapy. Participants initially assigned to the waiting period will receive the group therapy after the completion of the post-waiting period assessment.

What are the possible benefits and risks of participating?
The possible benefit of participating in this study that participants may experience fewer insomnia symptoms and improved sleep quality as a result of the group therapy. The possible risks of participating are that the sensors used for assessment of bodily function may cause minor skin irritation, and the minor risk of pain and infection from taking blood samples.

Where is the study run from?
Concordia University, Montreal, Canada

When is the study starting and how long is it expected to run for?
December 2015 to January 2019

Who is funding the study?
Canadian Institutes for Health Research (Canada)

Who is the main contact?
Florence Pomares
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Contact information

Type(s)
Scientific

Contact name
Prof Jean-Philippe Gouin

Contact details
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Additional identifiers

Protocol serial number
Not applicable

Study information

Scientific Title
Physiological and emotional hyperarousal in chronic insomnia, and their relationships with insomnia treatment: a randomized controlled trial of cognitive-behavioural therapy for insomnia versus waitlist in participants with chronic insomnia

Study objectives

Greater physiological arousal at pre-treatment will be associated with less reduction in insomnia symptoms following cognitive-behavioural therapy for insomnia.

Participants with higher spindle density will show larger decrease in insomnia symptoms and greater improvement in cognitive functioning after cognitive-behavioural treatment for insomnia.

Cognitive-behavioural therapy for insomnia will lead to a significant reduction in emotional arousal.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Concordia University Human Research Ethics Committee, 17/12/2015, 30005506

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic insomnia

Interventions
Participants are randomised into 2 groups, either the cognitive-behavioural therapy (CBT) group or a waiting list control group, in a 1:1 allocation ratio.
Randomisation is conducted with block sizes of 4 participants. Randomisation results are contained in sealed opaque envelopes that are opened in the presence of the participants after the completion of the pre-treatment assessment. Participants in the cognitive behavioural therapy group will receive manual CBT therapy for insomnia.
In groups of 4-8 participants, CBT therapy will involve 8 weekly, 90 minute meetings involving psychoeducation about sleep and circadian rhythms, stimulus control, sleep restriction, relaxation and cognitive therapy.
Participants assigned to the waiting list control group will receive CBT therapy 3 months later, after completion of their post-waiting period assessment.
A 12 month follow up assessment will be conducted 12 months after the completion of the post-treatment assessment.

Intervention Type
Behavioural

Primary outcome(s)
The following are assessed at the baseline, post-treatment/post-waiting period and 12 month follow up:
1. Self-reported insomnia symptoms, assessed using the following, both of which are completed using online questionnaires:

1.1. Insomnia Severity Index (ISI)
1.2. 14-day sleep diary (sleep efficacy measure) based on the Consensus Sleep Diary
2. Physiological hyperarousal, assessed using the following:
2.1. Heart rate variability, measured using electrocardiogram leads
2.2. Sleep spindles, measured using electroencephalography leads during polysomnography
3. Emotional hyperarousal, assessed using the UCLA Life Stress Interview and a daily stress diary, completed conjointly with the sleep diary (1.2.)

Key secondary outcome(s))

1. Total sleep time, assessed using the Consensus Sleep Diary and actigraphy with an accelerometer over 14 consecutive days at the baseline, post-treatment/post-waiting period and 12 month follow up
2. Sleep latency, assessed using the Consensus Sleep Diary and actigraphy with an accelerometer over 14 consecutive days at the baseline, post-treatment/post-waiting period and 12 month follow up
3. Duration of wake-after-sleep-onset (WASO), assessed using the Consensus Sleep Diary and actigraphy with an accelerometer over 14 consecutive days at the baseline, post-treatment/post-waiting period and 12 month follow up
4. Sleep quality, assessed using the Pittsburgh Sleep Quality Index (PSQI) at the baseline, post-treatment/post-waiting period and 12 month follow up
5. Fatigue severity, assessed using the Fatigue Symptoms Inventory at the baseline, post-treatment/post-waiting period and 12 month follow up
6. Health-related quality of life, assessed using the 36-Item Short Form Survey (SF-36) at the baseline, post-treatment/post-waiting period and 12 month follow up
7. Presence of an insomnia disorder, assessed through a diagnostic interview with a trained interviewer using the Structured Clinical Interview for DSM-5 (SCID-V) at the baseline, post-treatment/post-waiting period and 12 month follow up
8. Polysomnography (PSG) measures, assessed at the baseline, post-treatment/post-waiting period and 12 month follow up:
8.1. PSG-derived sleep efficacy
8.2. Total sleep time
8.3. WASO
8.4. Sleep latency
8.5. Durations of sleep stages N1, N2, N3 and REM
9. Markers of physiological arousal:
9.1. Blood pressure, assessed using oscillometer measurements of systolic and diastolic blood pressure in the morning following overnight polysomnography
9.2. Cortisol levels, assessed using salivary samples collected at awakening, 30 minutes after awakening, at 4pm, and at bedtime for 2 consecutive days following overnight polysomnography
9.3. Plasma inflammatory markers, collected using antecubital venipuncture at the baseline, post-treatment/post-waiting period and 12 month follow up:
9.3.1. Interleukin-6 (IL-6)
9.3.2. Tumour necrosis factor alpha (TNFα)
9.3.3. C-reactive protein (CRP)
10. Markers of emotional arousal, assessed using online self-reported questionnaires at the baseline, post-treatment/post-waiting period and 12 month follow up:
10.1. Beck Depression Inventory (BDI)
10.2. State-Trait Inventory for Cognitive and Somatic Anxiety (STICSA)
10.3. Impact of Events Scale (IES-R)
10.4. Penn State Worry Questionnaire (PSWQ)
10.5. Gross Emotion Regulation Questionnaire (GERQ)

10.6. Behavioural Avoidance and Inhibition Scale (BIS/BAS)
11. Cognitive functioning, assessed using computerised N-back and Attention Network Tasks the morning following the overnight polysomnography at the baseline, post-treatment/post-waiting period and 12 month follow up

Completion date
14/07/2020

Eligibility

Key inclusion criteria
1. Meeting diagnostic criteria for chronic insomnia for at least 6 months
2. Aged 18 years or older

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Current neurological disorder
2. Past history of brain lesion
3. Major surgery requiring general anaesthesia in the past 3 months
4. Untreated thyroid disorder
5. Chronic pain syndrome self-reported as interfering with sleep
6. Recent and severe infection in the past 3 months (e.g. pneumonia, kidney infection)
7. Active cancer or treated cancer with post-cancer treatment for less than 2 years
8. Stroke
9. Myocardial infarction
10. Arterial bypass or angioplasty (e.g. coronary, carotid, femoral)
11. Pacemaker
12. Heart failure causing limitation of ordinary physical activity
13. Renal insufficiency
14. Sleep apnea with an apnea-hypopnea index greater than 15/h
15. Restless legs syndrome with symptoms occurring on 3 or more days per week (based on Restless Legs Syndrome Rating Scale)
16. Periodic limb movements during sleep with index greater than 15/h during polysomnography
17. REM sleep behaviour disorder with more than 1 episode per month (based on polysomnography)
18. Narcolepsy with cataplexy (based on Ullanlinna Narcolepsy Scale)

19. Sleepwalking more than once per month
20. Having worked on night shifts or rotating shifts for more than 2 weeks in the last 3 months, or expecting to do so during the study period
21. Poor cognitive function (diagnosed with dementia and/or Montreal Cognitive Assessment (MoCA) less than 26)
22. Severe mental disorders:
22.1. Type I bipolar disorder
22.2. Schizophrenia
22.3. Anxiety disorders other than generalised anxiety disorder, except if associated with major depressive disorder (MDD)
22.4. Current substance use disorder
22.5. Current post-traumatic stress disorder
23. Current suicidality
24. Frequency alcohol consumption (more than 10 glasses per week)
25. Use of illicit drugs (more than once per month)
26. Pregnant or breastfeeding
27. Current psychotherapy or past cognitive behavioural therapy for insomnia
28. Unable to stop hypnosedative medications for at least 2 weeks prior to the first assessment

Date of first enrolment
02/11/2016

Date of final enrolment
15/10/2018

Locations

Countries of recruitment
Canada

Study participating centre
Concordia University
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Sponsor information

Organisation
Concordia University

ROR
https://ror.org/0420zvk78

Funder(s)

Funder type
Not defined

Funder Name
Canadian Institutes for Health Research

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request from Jean-Philippe Gouin, Ph.D. (jp.gouin@concordia.ca). Anonymized, processed data will be available on 01/01/2021 for replication analysis and meta-analysis.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/09/2022	27/09/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes