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# Cognitive-behavioral therapy for insomnia during benzodiazepine withdrawal in older individuals

**Submission date**
23/02/2021

**Recruitment status**
No longer recruiting

**Registration date**
26/02/2021

**Overall study status**
Completed

**Last Edited**
11/06/2025

**Condition category**
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

## Plain English summary of protocol

Background and study aims
Insomnia is a common sleep disorder that can make it hard to fall asleep, hard to stay asleep or cause you to wake up too early and not be able to get back to sleep. Benzodiazepines (BZD) and benzodiazepine receptor agonists (BZRA) are medications often used to treat insomnia. However, the chronic use of these medications is associated with health concerns, especially in the elderly. For example, their use in older individuals has been shown associated with an increased risk of falls and cognitive impairment. It is therefore recommended to limit their use in older individuals and to encourage progressive withdrawal in those with chronic use. BZD and BZRA withdrawal are however challenging to implement in clinical practice.
Cognitive-behavioral therapy for insomnia (CBTi) is a psychological intervention that includes psychoeducation about sleep and circadian rhythms, stimulus control, sleep restriction, relaxation, and cognitive therapy. It is the first-line treatment for chronic insomnia, including in older individuals. Few studies have assessed the effects of CBTi during BZD and BZRA withdrawal in older individuals with chronic insomnia.
The objective of this study is therefore to investigate the sleep changes following CBTi during a structured and progressive BZD/BZRA withdrawal program, as compared to the withdrawal program alone (waitlist). Participants will be randomly assigned to one of the two groups.

Who can participate?
Adults (60 years old and over) with chronic insomnia and chronic use of BZD or BZRA for sleep (more than 3 times per week and for more than 3 months).

What does the study involve?
Participants will sleep at our laboratory for two nights, separated by at least one week. At the lab, they will be recorded during their overnight sleep with polysomnography (simultaneous recording of brain waves, muscle tone, eye movements, heart rate and breathing). The first night will serve as a habituation night, as well as to screen for other sleep disorders (e.g., sleep apnea). The second night will be used as a baseline assessment. Participants will wear a watch-like device (actimeter) to record their activity for 14 days in a row. They will also complete a sleep diary for 14 days. Participants will complete questionnaires about sleep, mood and anxiety, and

they will have a neuropsychological assessment to assess their cognitive performances across multiple domains.
After the completion of this initial assessment, participants will be randomly assigned either to a 16-week group CBTi or a 16-week waiting period. The program will involve 8 weekly, 90-minute; at first, spaced one week apart (first 4 sessions) and then every two weeks (last 4 sessions); meetings involving psychoeducation about sleep and circadian rhythms, stimulus control, sleep restriction, relaxation and cognitive therapy. Weaning will consist of a 16-week program, illustrated on an information leaflet given to the patient. Following the completion of the therapy or waiting period, participants will complete the same questionnaires about sleep, mood and anxiety, and they will complete the same neuropsychological assessment. Their sleep will be assessed during another night at our laboratory and they will have to wear the actimeter to record their activity again for 14 days in a row while completing the sleep diary for 14 days.
Participants initially assigned to the waiting period will receive CBTi therapy after the completion of the post-waiting period assessment. Following the completion of the therapy, they will complete the same questionnaires about sleep, mood and anxiety, and they will complete the same neuropsychological assessment. Their sleep will be assessed during another night at our laboratory and they will have to wear the actimeter again for 14 days in a row while completing the sleep diary for 14 days.
Questionnaires, sleep diary and actimetry assessments (actigraphy) will be repeated for both groups 3 and 12 months after the completion of the therapy.

What are the possible benefits and risks of participating?
Participants may benefit from the study by experiencing fewer insomnia symptoms and improved sleep quality as a result of the CBTi program.
The possible risks are minor and may include minor skin irritation from the electrodes used for sleep recordings and mild fatigue from the neuropsychological assessment.

Where is the study run from?
Centre de Recherche de l'Institut Universitaire de Gériatrie de Montréal (CRIUGM) (Canada)

When is the study starting and how long is it expected to run for?
July 2014 to June 2025

Who is funding the study?
1. Comité aviseur pour la recherche clinique (CAREC), CRIUGM
2. Canadian Institutes for Health Research (CIHR)

Who is the main contact?
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# Contact information

### Type(s)
Scientific

### Contact name
Dr Thanh Dang-Vu

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
Nil known

# Study information

### Scientific Title
Effects of cognitive-behavioral therapy for insomnia during a structured benzodiazepine withdrawal program in older individuals with chronic insomnia

### Study objectives
Participants in the CBT-I group will show an improvement in sleep (after completion of the 16-week weaning program compared to baseline) that will be greater than that of participants in the weaning alone group.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 28/07/2020, IUGM Research Ethics Committee (Vice-présidente et conseillère en éthique Comité central d'éthique de la recherche 500, Sherbrooke Ouest Street, bureau 800 Montréal (Québec) H3A 3C6, Canada; +1 514 873-2114; jdechamplain@frq.gouv.qc.ca), ref: CER-IUGM-14-15-015

### Study design
Interventional randomized controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

## Study setting(s)
Other

## Study type(s)
Treatment

## Participant information sheet
See additional file ISRCTN10037794_PIS_French_11Jan2016 (added 01/03/2021)

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

## Interventions
Participants will be randomized into 2 groups: the CBTi group and a wait-list control group, in a 1:1 allocation ratio. Randomization will be conducted with block sizes of 4 participants.
Participants in the CBTi group will receive a manualized CBTi program in groups of 4-8 participants. The program will involve 8 weekly, 90-minute; at first spaced one week apart (first 4 sessions) and then every two weeks (last 4 sessions); 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 CBTi 4 months later, after completion of their post-waiting period assessment.

The weaning program will be administered to all patients regardless of their group. Weaning will consist of a 16-week program, illustrated on an information leaflet given to the patient. This leaflet will visually detail the gradual decrease in the intake of BZD or BZRA over the 16 weeks, with a gradual transition from whole tablets to half-tablets, then quarter-tablets, with doses alternating from one day to another, until gradually leading to complete withdrawal. The leaflet will also contain recommendations for sleep hygiene. A telephone follow-up will be carried out every two weeks to monitor the progress of the withdrawal program, note any withdrawal symptoms, and provide support and encouragement.

## Intervention Type
Behavioural

## Primary outcome measure
The following are assessed at the baseline, post-treatment/post-waiting period:
1. Questionnaire: Insomnia Severity Index (ISI)
2. Sleep efficiency from polysomnographic recordings and sleep diary
3. N3 sleep stage duration from polysomnographic recordings
4. Sleep spindle density from polysomnographic recordings

## Secondary outcome measures
1. Questionnaires, assessed at the baseline, post-treatment/post-waiting period, and at the 3- and 12-months follow-up:
1.1. Pittsburgh Sleep Quality Index (PSQI)
1.2. Geriatric Anxiety Inventory
1.3. Geriatric Depression Scale
1.4. Epworth Sleepiness Scale
2. Sleep diary measures, assessed at the baseline, post-treatment/post-waiting period, and at the 3- and 12-months follow up:

2.1. Total Sleep Time
2.2. Sleep latency
2.3. Duration of wake-after-sleep-onset (WASO)
3. Actigraphy measures, assessed at the baseline, post-treatment/post-waiting period, and at the 3- and 12-months follow up:
3.1. Total Sleep Time and Time in Bed
3.2. Sleep latency
3.3. Duration of wake-after-sleep-onset (WASO)
3.4. Sleep Efficiency
4. Polysomnography (PSG) measures, assessed at the baseline, post-treatment/post-waiting period:
4.1. Total sleep time
4.2. WASO
4.3. Sleep latency
4.4. Durations of sleep stages N1, N2 and REM
4.5 Other sleep spindle variables: amplitude, frequency, spectral power and number
5. Neuropsychological assessment, assessed at the baseline, post-treatment/post-waiting period:
5.1 Global cognitive function using the Mini Mental State Examination (MMSE)
5.2 Verbal Memory using the Free and Cued Selective Reminding Test (FCSRT)
5.3 Executive Function using the Color Word Interference Test – a subtest of Delis–Kaplan Executive Function Scale, as well as the Trail Making Test
5.4 Attention and Concentration using the Digit Symbol Substitution Test
5.5 Visuospatial Abilities using the Modified Taylor Complex Figure (MTCF)
5.6 Psychomotor Performance and Manual Dexterity using the Purdue Pegboard test
6. Withdrawal success:
6.1 Percentage decrease of self-reported BZD or BZRA consumption from baseline to the completion of the 16-week weaning program for each participant, the proportion of participants achieving complete withdrawal in each group.

### Overall study start date
28/07/2014

### Completion date
01/06/2025

# Eligibility

### Key inclusion criteria
1. Meeting DSM-V diagnostic criteria for insomnia disorder:
1.1. sleep initiation difficulties (sleep latency > 30min after switching off the lights)
1.2. and/or sleep maintenance difficulties (waking up > 30min during the night)
1.3. negative diurnal repercussions
• for more than 3 months, at least 3 times per week
2. Aged 60 years or older
3. Ability to speak and understand French (as CBTi sessions are conducted in French)
4. Chronic BZD or BZRA use: more than 3 times per week, for more than 3 months

### Participant type(s)
Patient

### Age group

Senior

### Sex
Both

### Target number of participants
50

### Total final enrolment
48

### Key exclusion criteria
1. Cognitive deficits with MMSE score equal to or less than 23/30
2. Dementia
3. Parkinson's disease
4. Severe sensorimotor deficit (including severe visual or hearing impairment)
5. Epilepsy, anti-epileptic medication
6. Major depression
7. Psychotic disorder, anti-psychotic medication
8. Other psychotropic drugs prescribed for sleep
9. Recent history of alcoholism or drug abuse
10. Moderate to severe sleep apnea syndrome
11. Palliative care

### Date of first enrolment
01/10/2014

### Date of final enrolment
30/12/2021

## Locations

### Countries of recruitment
Canada

### Study participating centre
**Centre de recherche de l'Institut universitaire de Gériatrie de Montreal (CRIUGM)**
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## Sponsor information

### Organisation

Institut Universitaire De Gériatrie De Montréal

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### Sponsor type
University/education

### Website
http://www.iugm.qc.ca/

## Funder(s)

### Funder type
Government

### Funder Name
Canadian Institutes of Health Research

### Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
Canada

## Results and Publications

### Publication and dissemination plan
Results of the main study hypotheses will be published in peer-reviewed journals within the two years following the completion of the trial.

### Intention to publish date

01/09/2025

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to ethical restrictions.

## IPD sharing plan summary

Not expected to be made available

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | | 11/01/2016 | 01/03/2021 | No | Yes |