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Evaluation of an online cognitive-behavioral therapy for insomnia and anxiety in older adults

Submission date
24/11/2021

Recruitment status
No longer recruiting

Registration date
13/12/2021

Overall study status
Completed

Last Edited
16/01/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Insomnia symptoms increase with age, affecting up to 50% of older individuals. Seniors' vulnerability to sleep and mental health issues is further enhanced in the context of COVID-19. As sleep becomes more fragmented with age, older age may thus constitute a predisposing factor to develop sleep disturbances in the face of a precipitating factor such as the pandemic. Furthermore, social isolation in the elderly has been further exacerbated by the pandemic and constitutes a well-known risk factor for stress, insomnia, and anxiety. It is therefore critical to implement sleep and mental health interventions to address challenges faced by older adults during and after the pandemic.

Insomnia and anxiety are highly comorbid and share overlapping pathophysiological mechanisms. Untreated insomnia exacerbates psychiatric symptoms and hinders the response to standard psychiatric treatments. Cognitive-behavioral therapy for insomnia (CBTi), the first-line treatment for insomnia, involves a combination of cognitive restructuring, psychoeducation, and behavioral strategies. CBTi trials have consistently shown 70-80% response rates and better long-term efficacy than pharmacotherapy, including in older individuals. Considering the high rates of hypnotic medication use, complex polypharmacotherapy, and a marked sensitivity to adverse events in this group, CBTi is especially relevant for older adults. In addition to improving sleep, CBTi leads to sustained improvements in anxiety symptoms.

In line with the movement towards integrated mental health treatments, further therapeutic gains may be attained by combining CBTi with intervention components directly targeting psychiatric symptoms (i.e. CBTi+). Multicomponent interventions were found to be efficacious for anxiety and may result in slightly greater effects than single-disorder interventions. Multifaceted responses to complex stressors such as the current pandemic can complicate orientation towards disease-specific therapies. CBTi+ has the advantage of addressing multiple symptoms at the same time.

CBTi has been proposed as an effective approach for improving mental health at the population level. However, major barriers to accessibility result from insufficient insomnia screening in primary care settings, the lack of knowledge about CBT in the general population and healthcare providers, and the paucity of trained therapists. The need to travel for in-person visits and

therapy costs further limit access in the context of social distancing and financial consequences of the outbreak. This is especially true for older individuals with COVID-19 risk factors, physical limitations, or without private health insurance.
Part of the solution may reside in the delivery of CBT+ via virtual online platforms (eCBT+) well suited for large-scale screening and intervention. A recent meta-analysis reported that online CBTi attenuates anxiety symptoms with similar effect sizes compared to its face-to-face alternative. Online platforms thus represent a cost-effective strategic alternative. This is especially relevant to the current context in which the healthcare system is overloaded, and where older individuals should limit their visits to healthcare facilities. eCBT+ may not be optimal for all cases but may be well suited as a first-line intervention that could subsequently be integrated into stepped-care models.

The aim of this pilot study is to assess the effectiveness, usability (satisfaction) as well as acceptance of an eCBT+ program to address mental health challenges in the late and post pandemic phases in older adults.

Who can participate?
Older individuals aged 65 years or older, with at least mild insomnia symptoms or at least mild symptoms of anxiety, who have reliable internet access, ability to use a smartphone, tablet, or computer.

What does the study involve?
Participants will be randomly assigned to either an immediate intervention with our eCBT+ program or a wait-list period of 2 months (followed by the eCBT+ intervention after the post-assessments). To access the eCBT+ program, participants will be invited to subscribe on the e-SPACE webpage (www.e-space.ca).

What are the possible benefits and risks of participating?
Participants may benefit from the study by experiencing fewer anxiety and insomnia symptoms and improved sleep quality as a result of the program. There is no foreseeable risk.

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?
From March 2021 to June 2023

Who is funding the study?
Centre de Recherche de l'Institut Universitaire de Gériatrie de Montréal (CRIUGM) (Canada)

Who is the main contact?
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Type(s)
Scientific

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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
Online cognitive-behavioral therapy (CBT) for insomnia and anxiety in older adults: a pilot study using e-SPACE, a multidomain web platform for health promotion

Study objectives
The study aims to evaluate the effectiveness, usability (satisfaction), and acceptance of online CBT for insomnia and anxiety (eCBT+) using the e-SPACE platform in a sample of older individuals in the community. We hypothesize that the program will show high levels of satisfaction and acceptance and that there will be significantly greater improvements in insomnia and anxiety symptoms from pre- to post-intervention in the eCBT+ group as compared to the wait-list control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/03/2021, 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 VN 20-21-12

Study design

Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
See additional files (in French)

Health condition(s) or problem(s) studied
Older adults with insomnia or anxiety symptoms.

Interventions
Participants will be divided using a stratified (sex and use of medication) randomization method using an online tool.
Updated 24/01/2022: Participants will be divided using a stratified (Geriatric Anxiety Inventory, GAI, score) randomization method using an online tool.

The eCBT+ program includes seven modules that will teach the participants strategies for good quality sleep and better mental health (stress and anxiety management) through the use of tools from the cognitive-behavioral approach. It includes a presentation with audio and video recordings as well as short questionnaires and interactive quizzes that will allow the participants to follow their progress. They will have to complete seven modules of approximately 30 minutes each, one per week. Participants who need technical support will have the possibility to contact the research coordinator (contact by phone or in-person training).

The control group will have wait-list period of 2 months (followed by the eCBT+ intervention after the post-assessments)

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures:
1. User satisfaction, defined as the level of comfort felt by the user when using the program and what the user thinks about different functionalities, measured using an adapted version of the System Usability Scale (SUS) at 8 weeks
2. User acceptance, defined as the extent to which the user is eager to adopt the web-based solution in the future, measured using an adapted version of the Technology Acceptance Model-2 (TAM-2) questionnaire at 8 weeks

Previous primary outcome measures:
1. User efficiency, defined as the time for task completion and frequency of clicks on the wrong

button, collected through the platform during the 8-week intervention
2. User satisfaction, defined as the level of comfort felt by the user when using the program and what the user thinks about different functionalities, measured using an adapted version of the System Usability Scale (SUS) at 8 weeks
3. User acceptance, defined as the extent to which the user is eager to adopt the web-based solution in the future, measured using an adapted version of the Technology Acceptance Model-2 (TAM-2) questionnaire at 8 weeks

Secondary outcome measures
Current secondary outcome measures as of 24/01/2022:
Intervention effectiveness measured using the following:
1. Sleep efficiency measured using sleep diaries at baseline and 8 weeks
2. Insomnia measured using the insomnia severity index (ISI) at baseline and 8 weeks
3. Anxiety measured using the Geriatric Anxiety Inventory (GAI) at baseline and 8 weeks

Previous secondary outcome measures:
Intervention effectiveness measured using the following:
1. Sleep efficiency measured using sleep diaries at baseline and 8 weeks
2. Insomnia measured using the insomnia severity index (ISI) at baseline and 8 weeks
3. Anxiety measured using the Geriatric Anxiety Inventory (GAI) and Generalised Anxiety Disorder Assessment (GAD-7) at baseline and 8 weeks

Overall study start date
08/03/2021

Completion date
21/06/2023

Eligibility

Key inclusion criteria
Current inclusion criteria as of 24/01/2022:
1. Aged ≥65 years
2. Insomnia Severity Index score >7
3. Ability to read and understand French
4. Reliable internet access
5. Ability to use a smartphone, tablet, or computer

Previous inclusion criteria:
1. Aged ≥65 years
2. Mild symptoms of insomnia (Insomnia Severity Index score >8) or anxiety (Generalized Anxiety Disorder 7 score >5)
3. Ability to read and understand French
4. Reliable internet access
5. Ability to use a smartphone, tablet, or computer

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
60

Total final enrolment
49

Key exclusion criteria
1. Currently hospitalized or expected to require hospital admission within 3 months
2. Suicidal thoughts
3. Uncorrected and severe hearing or vision impairment
4. Diagnosis of major neurocognitive disorder or bipolar disorder

Date of first enrolment
01/07/2021

Date of final enrolment
01/09/2022

Locations

Countries of recruitment
Canada

Study participating centre
Centre de recherche de l'Institut universitaire de gériatrie de Montréal (CRIUGM)
4545, chemin Queen-Mary
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Sponsor information

Organisation
Institut Universitaire de Gériatrie de Montréal

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Sponsor type
Research organisation

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https://criugm.qc.ca/

ROR
https://ror.org/031z68d90

Funder(s)

Funder type
Research organisation

Funder Name
Research Center of the Institut Universitaire de Gériatrie de Montréal

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 restrictions set by the ethics board.

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	version French language	21/06/2021	09/12/2021	No	Yes