ISRCTN63989489 https://doi.org/10.1186/ISRCTN63989489

Cognitive behavioural therapy combined with exercise training for adults with both insomnia and obstructive sleep apnea

Submission date
23/02/2022

Recruitment status
No longer recruiting

Registration date
04/04/2022

Overall study status
Completed

Last Edited
31/03/2022

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Individuals with both obstructive sleep apnea (OSA) and chronic insomnia report difficulty falling asleep and staying asleep in addition to breathing difficulty when they are asleep. This group of individuals shows worse daytime functioning and fatigue in comparison to individuals with only one of the two disorders. Cognitive behavioural therapy for insomnia (CBTi) is a proven treatment for insomnia but will not improve OSA severity alone. A new therapy to target both disorders is warranted. Research suggests that exercise improves subjective sleep quality and breathing patterns in individuals with insomnia and OSA, respectively. Our goal is to assess whether a combination of exercise and CBTi will improve insomnia symptoms in individuals with both OSA and insomnia.

Who can participate?
Adults over the age of 18 with both insomnia disorder and mild to moderate obstructive sleep apnea.

What does the study involve?
Participants will be randomly assigned to either receive digital relaxation therapy for eight weeks followed by eight more weeks of CBTi and exercise training or to receive exercise training for the full 16 weeks. Participants in both groups will be required to come in for a total of three overnight recordings and three cardiopulmonary exercise tests at pre-treatment, mid-treatment, and post-treatment.

What are the possible benefits and risks of participating?
Participants in both treatment groups may benefit from improved sleep and improved physical fitness from the treatment.

The risks associated with participation in this study are no greater than the risks associated with routine psychological or medical tests. The risks for each study task are described below:
- Questionnaires: mild discomfort while answering questions of a personal
nature;

- Heart rate and brain activity recordings: mild skin irritation from the electrodes placed on the skin;
- Exercise testing and training: engaging in physical activity may result in discomfort generally related to the exercise: fatigue, breathlessness, dryness in the mouth. These discomforts rapidly subside when the activity is stopped. It is possible that participants may develop muscle or joint pain requiring them to temporarily stop exercising. There is also a risk of injury associated with high volumes of physical exercise. Participants will also be taught proper form for resistance training and stretching exercises, and be advised on the types of exercise to favor given their build, with consideration for their preferences.

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

When is the study starting and how long is it expected to run for?
June 2017 to November 2020

Who is funding the study?
This study is funded by Breathing As One: Allied Health Research Grant from the Lung Association and PERFORM's Innovative Research Project in Preventive Health. (Canada)

Who is the main contact?
Dr Veronique Pepin
veronique.pepin@concordia.ca
514-848-2424 # 5806

Contact information

Type(s)
Principal investigator

Contact name
Prof Véronique Pepin

ORCID ID
https://orcid.org/0000-0002-3446-153X

Contact details
Department of Health, Kinesiology and Applied Physiology
S.P. Building 165.03
Concordia University
7141 rue Sherbrooke Ouest
Montréal
Canada
H4B 1R6
+1 514-8482424 ext 5806
veronique.pepin@concordia.ca

Type(s)
Principal investigator

Contact name

Prof Jean-Philippe Gouin

Contact details
Department of Psychology
Concordia University
PY Building, Office 170-14
7141 Sherbrooke Street West
Montreal
Canada
H4B1R6
+1 514-848-2424 ext 7538
jp.gouin@concordia.ca

Additional identifiers

Study information

Scientific Title
A pilot randomized trial of combined cognitive behavioural therapy & exercise training versus exercise training alone for the treatment of co-morbid insomnia disorder and obstructive sleep apnea.

Acronym
APNex

Study objectives
Primary outcome:
During the first phase of the study, the exercise training alone group will be associated with larger decrease in the Insomnia Severity Index, compared to the relaxation group. During the second phase of the study, the combined CBTi plus exercise training intervention group will show larger decrease in the Insomnia Severity Index, compared to the exercise training alone group.

Secondary outcomes:
During the first phase of the study, the exercise training alone group will be associated with larger increase in cardiopulmonary fitness, as assessed by VO2 peak during a cardiopulmonary exercise test, compared to the relaxation group. During the second phase of the study, the combined CBTi plus exercise training intervention group will show similar increase in VO2 peak, compared to the exercise training alone group.
During the first phase of the study, the exercise training alone group will be associated with larger decrease in the oxygen desaturation index during the overnight polysomnography, compared to the relaxation group. During the second phase of the study, the combined CBTi plus exercise training intervention group will show similar decrease in the oxygen desaturation index, compared to the exercise training alone group.
During the first phase of the study, the exercise training alone group will be associated with a larger decrease in cumulative time spent below 90% SpO2 during the overnight polysomnography, compared to the relaxation group. During the second phase of the study, the combined CBTi plus exercise training intervention group will show similar decrease in the cumulative time spent below 90% SpO2, compared to the exercise training alone group.
During the first phase of the study, the exercise training alone group will be associated with

higher sleep efficiency during the overnight polysomnography, compared to the relaxation group. During the second phase of the study, the combined CBTi plus exercise training intervention group will show higher increase in sleep efficiency during the overnight polysomnography, compared to the exercise training alone group.
During the first phase of the study, the exercise training alone group will be associated with a larger decreased in BMI, compared to the relaxation group. During the second phase of the study, the combined CBTi plus exercise training intervention group will show similar decrease in BMI, compared to the exercise training alone group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/07/2017, Concordia University Human Research Ethics Committee (Office of Research – Research Ethics and Compliance Unit: GM 900, Montreal, Quebec, Canada; +1 514.848.2424 ex. 7481; oor.ethics@concordia.ca), ref: 30007287

Primary study design
Interventional

Study design
Single-centre interventional randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment for comorbid chronic insomnia and obstructive sleep apnea.

Interventions
This study is a 16-week randomized controlled trial. Participants are randomized to receive either relaxation therapy for eight weeks followed by a combination of cognitive-behavioural therapy for insomnia and exercise training for the second eight weeks (CBTi-Ex group) or 16 weeks of exercise training alone (Ex group) using a 1:1 allocation ratio. At the pre-treatment baseline, after phase 1 (mid-treatment) and after phase 2 (post-treatment), participants will complete self-report measure of insomnia severity, overnight polysomnography, as well as a symptom-limited cardiopulmonary exercise test on a cycle ergometer. Randomization will be conducted by block of 4 to ensure similar group size in this pilot study.

The CBTi component of treatment includes psychoeducation about sleep and circadian rhythms, stimulus control, sleep restriction, relaxation, and cognitive therapy. The applied relaxation treatment during phase 1 of the CBTi-Ex group includes self-guided digital audio-recordings of relaxation exercises to be completed at home at least 3 times per week. The relaxation exercises include exercise diaphragmatic breathing, progressive muscle relaxation and guided imagery.

The exercise component of treatment involves three weekly 60-minute sessions of structured moderate-intensity aerobic exercise and individualized resistance training. The aerobic training component includes 5 minutes of warm-up, followed by 40 minutes of aerobic exercise (walking, cycling, elliptical, etc.) performed at a heart rate corresponding to the ventilatory threshold, and

5 minutes of cool-down. The resistance training component consists of 1 set of 12–15 repetitions for 6-8 different exercises. One weekly session is supervised with a licensed kinesiologist, and two sessions are completed at home or in the community.

Intervention Type
Behavioural

Primary outcome(s)
Insomnia severity is assessed using the Insomnia Severity Index (ISI) questionnaire at baseline, following phase 1 (8 weeks) and following phase 2 (16 weeks)

Key secondary outcome(s)
1. Peak oxygen consumption (VO2 peak) during a symptom-limited cardiopulmonary exercise test on a cycle ergometer conducted at pre-treatment, mid-treatment (8 weeks), and post-treatment (16 weeks).
2. Oxygen desaturation index during the overnight polysomnography conducted at pre-treatment, mid-treatment, and post-treatment.
3. Cumulative time spent below 90% SpO2 during the overnight polysomnography conducted at pre-treatment, mid-treatment, and post-treatment.
4. Sleep efficiency (i.e. the ratio of total sleep time overtime over the time spent in bed) during overnight polysomnography at pre-treatment, mid-treatment, and post-treatment.
5. Body mass index (BMI; kg/m^2) measured at pre-treatment, mid-treatment, and post-treatment.

Completion date
12/11/2020

Eligibility

Key inclusion criteria
1. Meeting diagnostic criteria for a DSM-5 insomnia disorder.
2. Diagnosed with mild to moderate obstructive sleep apnea (AHI 30/h during baseline polysomnography).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
20

Key exclusion criteria

1. Younger than 18 years old
2. Current neurological disorder
3. Past history of brain lesion
4. Major surgery (i.e., requiring general anesthesia) in the past 3 months
5. Untreated thyroid disorder
6. Chronic pain syndrome self-reported as interfering with sleep
7. Recent and severe infection in the past 3 months (e.g., pneumonia, kidney infection)
8. Active cancer or treated cancer with post-cancer treatment for less than 2 years
9. Stroke
10. Myocardial infarct
11. Arterial bypass or angioplasty (coronary, carotid, femoral, etc)
12. Use of a pacemaker
13. Heart failure causing limitation of ordinary physical activity
14. Renal insufficiency
15. Restless legs syndrome with symptoms 3 days or more per week (based on RLS questionnaire)
16. Periodic limb movements during sleep with index > 15/h during polysomnography
17. REM-sleep behavior disorder with more than 1 episode/month (based on screening questionnaire and PSG)
18. Narcolepsy with cataplexy
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 dementia and/or MOCA less than 26)
22. Severe mental disorders:
22.1 Bipolar disorder (Type I)
22.2 Schizophrenia past or anxiety disorder
22.3 Anxiety disorders other than GAD if not associated with MDD: Exclude.
22.4 Current Substance use disorder
22.5 Current post-traumatic stress disorder
23. Current Suicidality
24. Frequent alcohol consumption (>10 glasses/week) or use of illicit drugs (more than once a month)
25. Pregnant or breastfeeding women
26. Current psychotherapy or past CBTi
27. Unable to stop hypnosedative medications for at least 2 weeks prior to the first assessment (e.g., benzodiazepines, zolpidem, zopiclone, quetiapine, antihistamines)
28. Currently engaging in moderate or vigorous physical activity for over 150 minutes per week.

Date of first enrolment
25/07/2017

Date of final enrolment
02/03/2020

Locations

Countries of recruitment
Canada

Study participating centre
PERFORM center
7141 Sherbrooke St. W.
Montreal
Canada
H4B 1R6

Sponsor information

Organisation
Concordia University

ROR
https://ror.org/0420zvk78

Funder(s)

Funder type
Charity

Funder Name
The Lung Association (Breathing As One: Allied Health Research Grant)

Funder Name
PERFORM Centre (Innovative Research Project in Preventive Health)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Véronique Pepin at veronique.pepin@concordia.ca.
-Type of data: outcome data.
-When the data will become available and for how long: on demand until 2026.
-By what access criteria data will be shared including with whom: researchers from public institutions (university or research centre).
-For what types of analyses: systematic reviews and meta-analyses.
-By what mechanism: contact the principal investigator by email.

-Whether consent from participants was obtained: no.
-Comments on data anonymisation: all data is identified only with a code with no identifying information.

IPD sharing plan summary

Available on request