ISRCTN24516612 https://doi.org/10.1186/ISRCTN24516612

# Co-morbid insomnia and OSA (COMISA) treatment trial using Oral Appliance Therapy

**Submission date**
01/11/2024

**Recruitment status**
Recruiting

**Registration date**
07/11/2024

**Overall study status**
Ongoing

**Last Edited**
04/12/2025

**Condition category**
Nervous System Diseases

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

**Plain English summary of protocol**
Background and study aims
COMISA, which refers to co-existing insomnia and obstructive sleep apnea (OSA), is a highly debilitating disorder with a general population prevalence of 6%. Up to 50% of people with OSA have insomnia and 40% of people with insomnia have OSA. Positive airway pressure (PAP) use has been associated with a reduction in insomnia in some patients and is currently the standard of care for patients suffering from COMISA. Conversely, cognitive behavioural therapy for insomnia (CBTi) has been associated with a small decrease in OSA severity, probably because it consolidates sleep periods and reduces sleep-wake transitions to improve airway stability. Patients with COMISA experience significantly lower rates of PAP acceptance and use compared to those with OSA alone. Considering the high prevalence and mortality risk associated with unmanaged COMISA, alternative treatment approaches are required. Initial evidence suggests that oral appliance therapy (OAT) may be a favourable therapy in patients with COMISA, which will be more acceptable to patients, and reduce symptoms of both insomnia and OSA. To date, no previous study has investigated combinations of OAT and CBTi in patients with COMISA. Therefore, more research is required to investigate the real-world clinical utility of OAT paired with CBTi for the management of COMISA. This will be the focus of the POCC Pilot Study. The POCC Trial (pilot study) describes a clinical management protocol aimed at improving the care of patients with OSA, insomnia, and particularly those with overlapping conditions like COMISA. This observational study aims to investigate a novel management model for COMISA, combining CBTi, PAP therapy, and OAT.

Who can participate?
Consecutive patients aged between 18 and 80 years old enrolled in Ontario sleep clinics who are diagnosed with COMISA.

What does the study involve?
The protocol involves offering OAT after the prescription of PAP therapy for patients who refuse /cannot tolerate PAP. This sequential approach is not universally implemented for the care of OSA or COMISA, however, it is aligned with AASM and AADSM guidance.

Specifically, participants will be offered aPAP to manage their OSA. If adherent, they will be offered a cognitive behavioral therapy for insomnia (CBT-I) program for their insomnia. Once

complete, they will take a final in-lab sleep study. If intolerant to, or through refusal of aPAP, they will be offered OAT. If adherent, they will be offered a CBTi program for their insomnia. Once complete, they will take a final in-lab sleep study.

Questionnaires will be completed 3 and 12 months after the final sleep study to establish the continued benefits of therapy. Once all questionnaires have been completed, the study obligations end, and study participants will continue to be monitored by their doctors as per usual and customary protocols.

What are the possible benefits and risks of participating?
Potential benefits include formalized guidance-based care and systematic scheduling, compilation of patient-centred and laboratory outcomes and cost savings for participants who complete all protocol steps.

Where is the study run from?
Sleep Disorders Dentistry Research and Learning Centre (Canada)

When is the study starting and how long is it expected to run for?
November 2024 to December 2026

Who is funding the study?
1. Panthera Dental, Canada (partial)
2. Investigator initiated and funded

Who is the main contact?
Dr Sherif Elsaraj, sherifelsaraj.cissso@ssss.gouv.qc.ca, Sherif.Elsaraj@McGill.Ca

# Contact information

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Public, Scientific, Principal investigator


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# Additional identifiers

**Protocol serial number**
240-402

# Study information

**Scientific Title**
PAP-OAT-CBTi -COMISA Trial (POCC Trial)

**Acronym**
POCC Trial

**Study objectives**
High adherence to oral appliance therapy (OAT) positions it as the preferred treatment alternative for patients suffering from co-morbid insomnia and obstructive sleep apnea (COMISA) compared to continuous positive airway pressure (PAP) therapy, which shows significantly lower adherence rates among this population.

**Ethics approval required**
Ethics approval required

**Ethics approval(s)**
Not yet submitted

## Primary study design
Observational

## Study design
Observational case-crossover study

## Study type(s)
Screening, Treatment

## Health condition(s) or problem(s) studied
Co-existing insomnia and obstructive sleep apnea (OSA) (COMISA)

## Interventions
This is a patient management protocol with a formal care pathway. The goal is to offer the protocol to consecutive patients in Ontario sleep clinics. Oral appliance therapy (OAT) utilizes a custom-made, adjustable FDA-cleared appliance specifically made to assist breathing by keeping the tongue and jaw in a forward position during sleeping hours. The formalized sequence of offering OAT after a prescription of continuous positive airway pressure (PAP) therapy is not universally implemented for the care of obstructive sleep apnea (OSA) or more specifically co-morbid insomnia and obstructive sleep apnea (COMISA). Therefore, this pilot study will document outcomes associated with offering OAT for patients suffering from COMISA, if they prove intolerant to or refuse PAP. This trial is particularly important as the absence of data regarding outcomes with this protocol currently results in many of these patients remaining unmanaged.

Participants will be offered aPAP to manage their OSA. If adherent, they will be offered a cognitive behavioral therapy for insomnia (CBT-I) program for their insomnia. Once complete, they will take a final in-lab sleep study. If intolerant to, or through refusal of aPAP, they will be offered OAT. If adherent, they will be offered a CBTi program for their insomnia. Once complete, they will take a final in-lab sleep study.

Questionnaires will be completed 3 and 12 months after the final sleep study to establish the continued benefits of therapy. Once all questionnaires have been completed, the study obligations end, and study participants will continue to be monitored by their doctors as per usual and customary protocols.

## Intervention Type
Device

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
Panthera D-SAD

## Primary outcome(s)
The effectiveness of oral appliance therapy (OAT) in co-morbid insomnia and sleep apnea (COMISA) patients who are resistant or intolerant to PAP therapy is assessed using the following questionnaires at baseline, 3 and 12 months:
1. Daytime sleepiness measured using the Modified Epworth Sleepiness Scale (ESS)

2. The impact of sleepiness on daily activities measured using the Functional Outcomes of Sleep Questionnaire (FOSQ-10)
3. Patient-reported sleep quality and well-being measured using the Sleep Wellbeing Index for Treatment (SWIFT)
4. sleep duration, quality, and disturbances measured using the RAND Sleep Questionnaire
5. The severity of insomnia symptoms measured using the Insomnia Severity Index (ISI)

### Key secondary outcome(s)
1. Impact of insomnia symptoms on adherence to PAP or OAT: Outcome: Influence of insomnia severity measured using the ISI on treatment adherence at 3 and 12 months
2. Alternative management for PAP non-responders: Outcome: Proportion of patients with PAP intolerance effectively managed with OAT, assessed using improvements in questionnaire scores
3. Effect of OAT on insomnia symptoms: Outcome: Change in ISI scores at 3 and 12 months
4. Dose-response relationship between OAT use and insomnia improvement: Outcome: Correlation between OAT usage frequency (hours per night) and ISI score reduction
5. Integration of OAT into current models of care: Outcome: Feasibility based on adherence rates and patient satisfaction (SWIFT scores)
6. Prevalence of COMISA in in-lab sleep study patients: Outcome: Proportion with COMISA identified in baseline assessments using the modified ESS and ISI

### Completion date
31/12/2026

## Eligibility

### Key inclusion criteria
1. Adults 18-80 years of age
2. Non-pregnancy
3. Polysomnography (PSG) diagnosis available
4. Insomnia diagnosis
5. For OAT: More than 10 healthy teeth per arch with a healthy temporomandibular joint (TMJ)
6. For PAP: Must be a candidate for APAP set at 5-15 cmH2O pressure
7. Competent and able to comprehend English and sign consent form

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
18 Years

### Upper age limit
80 Years

### Sex

All

**Total final enrolment**
0

**Key exclusion criteria**
Not meeting the participant inclusion criteria

Added 17/02/2025:
1. Less than 18 years of age
2. Pregnancy
3. No polysomnography (PSG) diagnosis available
4. No insomnia diagnosis
5. Presents with TMJ-related pain
6. Not competent and able to comprehend English and unable to sign the consent form

**Date of first enrolment**
01/12/2025

**Date of final enrolment**
31/12/2026

# Locations

**Countries of recruitment**
Canada

**Study participating centre**
**Sleep Disorders Dentistry Research and Learning Centre**
5045 Orbitor Drive, Unit 10-300
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# Sponsor information

**Organisation**
Panthera Dental

# Funder(s)

**Funder type**
Industry

**Funder Name**
Panthera Dental

**Funder Name**
Investigator initiated and funded

# 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 Dr Sherif Elsaraj, sherifelsaraj.cissso@ssss.gouv.qc.ca. All data collected will be entered into an Excel document that is confidential. The study participants will be assigned a number in a computer hard drive which will be destroyed by https://www.shredit.com/en-ca/secure-shredding-services/hard-drive-destruction. Their names corresponding to the numbers assigned will be stored in a locked desk with a key in the private clinic office of Sleep Disorders Dentistry Research and Learning Centre.

Oral Appliance Bite Registration Data:
• Vertical and Level of Protrusion
o Baseline Mandibular range (Full Retrusive to Full Protrusive)
o Baseline Most Advanced Protrusive Position of Comfort
o Final Tested Position (Vertical and Level of Protrusion)

Modified ESS Questionnaire:
https://nasemso.org/wp-content/uploads/neuro-epworthsleepscale.pdf

FOSQ10 Questionnaire:
https://www.serenitymedicalservices.com/wp-content/uploads/2020/01/CEREVES_FOSQ_10_ENG.pdf

SWIFT Questionnaire:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3501668/

RAND Questionnaire: https://www.rand.org/content/dam/rand/www/external/health/surveys_tools/mos/mos_sleep_survey.pdf

ISI Questionnaire:
https://www.sleepprimarycareresources.org.au/questionnaires/isi

• At Baseline and all endpoints: All the above is captured with PSG and questionnaire.
• At 3 months patient will take 7 nights of Home Sleep Testing with the Belun Ring.
• At 3 and 12 months post reaching treatment endpoint: Questionnaires and questions provide ongoing assessment of maintenance of outcomes, and ongoing adherence.

**IPD sharing plan summary**
Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | version 1.01 | | 08/11/2024 | No | Yes |
| Participant information sheet | version 1.01 | | 08/11/2024 | No | Yes |
| Participant information sheet | | | 08/11/2024 | No | Yes |
| Participant information sheet | | | 08/11/2024 | No | Yes |
| Protocol file | version 3.2 | | 08/11/2024 | No | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |