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Oropharyngeal (mouth, tongue and throat) exercises to treat obstructive sleep apnea (a condition where the walls of the throat relax and narrow during sleep, interrupting normal breathing)

Submission date
21/12/2022

Recruitment status
Recruiting

Registration date
09/01/2023

Overall study status
Ongoing

Last Edited
20/01/2025

Condition category
Nervous System Diseases

[X] 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
Obstructive sleep apnea (OSA) is characterized by recurrent obstruction of the upper airway during sleep due to intermittent loss of tone in the muscles of the throat. It is linked with poor functional outcomes and an increased risk of death. Continuous positive airway pressure (CPAP) is the standard therapy for OSA but it is poorly tolerated by many patients. Oropharyngeal exercises (OPEs) which are commonly used by speech-language pathologists to improve oro-motor strength, serve as a promising alternative approach. We will run a randomized feasibility study involving 45 patients with OSA who are unable to tolerate CPAP. Patients will be randomized into a supervised OPE intervention arm vs unsupervised OPE intervention arm vs sham treatment for 10-weeks/5-days per week/two 20-minute sessions exercise protocol. The exercises will be administered via an app and we will assess several sleep-related and oro- motor physiological outcomes before treatment, immediately after treatment, and 4 weeks after treatment.

Who can participate?
Adults who have been diagnosed with obstructive sleep apnea, but are unable or unwilling to tolerate CPAP therapy

What does the study involve?
Participants with OSA will first complete baseline assessments and questionnaires and a home sleep apnea test. They will then be randomized into the supervised OPE intervention arm vs unsupervised OPE intervention arm vs. sham treatment arm. They will be given a tablet with either OPE or sham exercises, and be taught how to perform the exercises. Then they will complete the exercises for 10 weeks, 5 days a week, for two 20-minute sessions. Participants in the supervised arms will receive check-ins every other week to see if they need re-training on the study exercises. All participants will complete questionnaires again at 2 weeks, and 6 weeks

into training. Post-training, participants will complete the home sleep apnea test and the study assessments again. Then 4 weeks after they completed training, they will complete a final round of the home sleep apnea test and the study assessments. Participants will have the option to complete an open-label extension, where they will receive the OPE exercises to complete without supervision, then they will complete a final home sleep apnea test after 4 weeks of the OPEs.

What are the possible benefits and risks of participating?
Participants may or may not benefit directly from participating in this study. However, possible benefits include having their underlying sleep apnea treated. Treatment of sleep disorders may reduce the risk of future vascular events. Improvement may also be seen in quality of life, daytime sleepiness, attentional tasks, functional outcome, cognition, and depression.
Participants may experience side effects from participating in this study. They may find wearing the ambulatory sleep monitors to be mildly uncomfortable or time-consuming. They will be undergoing 3 (optionally 4) rounds of sleep testing.

Where is the study run from?
Sunnybrook Health Sciences Centre (Canada)

When is the study starting and how long is it expected to run for?
September 2022 to April 2026

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

Who is the main contact?
Dr Mark Boulos
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT05678088

Secondary identifying numbers
5541

Study information

Scientific Title
Strengthening oropharyngeal muscles as a novel approach to treat obstructive sleep apnea : a randomized feasibility study

Study objectives
1. A randomized controlled trial (RCT) of an oropharyngeal exercise regimen in patients with OSA will be feasible
2. Oropharyngeal exercises will reduce OSA severity, decrease daytime sleepiness, and improve sleep quality, mood, workplace performance, and quality of life over sham exercises

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/01/2023, Sunnybrook Health Sciences Research Ethics Board (Sunnybrook Health Sciences Centre, 2075 Bayview Ave., Room C8 23 or C8 27, Toronto, ON, M4N 3M5, Canada; +1 416-480-6100; REB@sunnybrook.ca), ref: 5541

Study design
Single-centre interventional double-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Patients with obstructive sleep apnea who are unable or unwilling to tolerate CPAP

Interventions
Participants will be evenly randomized (1:1:1) to three study arms:
1. Supervised oropharyngeal exercises
2. Unsupervised oropharyngeal exercises
3. Supervised sham exercises

The study has three arms. For all treatment arms, they will perform the exercises for 10 weeks, then complete a retention visit 4 weeks post-training. All participants will be initially taught via videoconference how to perform the exercises by one certified speech language pathologist. Randomization will occur after the baseline visit using an online generator. Participants will be randomly assigned 1:1:1 using random permuted blocks of varying sizes. The study tablets will be pre-programmed to deliver the oropharyngeal or sham exercises based on treatment number. The speech language pathologist will be the only person who will have access to the allocation log and this will remain concealed from the study investigators, site research assistants, participants, as well as the sleep technologist who will be reviewing the home sleep testing.

Supervised Oropharyngeal Exercises arm:
The oropharyngeal exercises protocol will consist of 10 standard isometric and isotonic oropharyngeal exercises that strengthen the tongue and pharyngeal muscles. The speech language pathologist will track adherence to the exercise protocol and review the face recordings of exercise performance from the first week to ensure accurate performance. The speech language pathologist will call or conduct videoconference visits with participants 1, 3, 5, 7 and 9 weeks after the baseline assessment to provide re-training (if needed) and to troubleshoot technical issues related to the use of the app.

Unsupervised Oropharyngeal Exercises arm:
These participants will complete the same oropharyngeal exercises. After the initial training visit there will be no further scheduled interactions with the study staff except during the follow-up telephone calls and study visits.

Supervised Sham Exercises arm:
The sham control protocol will consist of lip/face range of motion exercises that have no impact

on oropharyngeal (e.g., base of the tongue) muscle strength. Adherence to the protocol will also be tracked and the speech language pathologist will contact the participants every other week as specified above.

Intervention Type
Behavioural

Primary outcome measure
Feasibility measured using:
1. Rate of recruitment: The study team will maintain logs to track the number of patients screened, found to be eligible, and randomized into the trial; we will also track dropouts.
2. Patient adherence with the study exercises will be tracked (in minutes) by the OPEX app that will deliver the oropharyngeal/sham exercises. We will compute the percentage of exercises completed.
3. Ability to ascertain OSA severity, as assessed by completion rates for the three home sleep apnea tests during baseline, post-training (10 weeks of completing exercises), and retention (4 weeks after stopping exercises). A home sleep apnea test will be considered "completed" if ≥4 hours of flow, effort, and oxygen evaluation are obtained.

Secondary outcome measures
1. OSA severity will be measured using the apnea-hypopnea index, oxygen desaturation index and lowest oxygen desaturation from a home sleep apnea test at baseline, post-training (10 weeks of completing exercises), and retention (4 weeks after stopping exercises)
2. Objective sleep measures using actigraphy such as sleep efficiency, wake after sleep onset, and total sleep time will be measured at baseline, post-training and retention
3. Subjective sleep quality and daytime sleepiness will be measured with the Pittsburgh Sleep Quality Index and Epworth Sleepiness Scale score at baseline, 2 weeks, 6 weeks, post-training and retention
4. Mood will be measured using the Beck Depression Inventory at baseline, 2 weeks, 6 weeks, post-training and retention
5. Workplace performance will be measured using the Work Limitations Questionnaire at baseline, 2 weeks, 6 weeks, post-training and retention
6. Quality of life will be measured using the EQ-5D-5L and SF-36 Questionnaires at baseline, 2 weeks, 6 weeks, post-training and retention
7. Acceptability, appropriateness, and feasibility of the Intervention will be measured using a questionnaire at post-training

Overall study start date
01/09/2022

Completion date
01/04/2026

Eligibility

Key inclusion criteria
1. With OSA (defined as an apnea-hypopnea index ≥10/h) in whom >50% of the respiratory events are obstructive in nature
2. Unwilling to use CPAP or have been unable to tolerate CPAP after at least a 2-week trial
3. Not using an equipment-based treatment modality (e.g. PAP therapy, a dental appliance, or hypoglossal nerve stimulation) or surgery to manage their OSA

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
45

Key exclusion criteria
1. Planned airway surgery, use of CPAP, a dental appliance, or other equipment-based treatment modality to manage OSA during the course of the study
2. Central respiratory events account for ≥50% of the overall apnea-hypopnea index
3. Reduced cognition (Montreal Cognitive Assessment [MoCA] <18)
4. Any significant neurological condition that could impact oropharyngeal activity
5. Use of medications that may impact the tone of the upper airway (e.g. hypnotics, opiates) ≥3 nights per week during the 4 weeks prior to randomization
6. Use of a medical device that would interfere with the use of the home sleep apnea test
7. Plans to move to another city during the study that would impact compliance. As it would be unethical to withhold CPAP therapy (current first-line therapy for moderate to severe OSA), we will only be recruiting patients who are unwilling to use CPAP therapy or those who are unable to tolerate CPAP after at least a 2-week trial

Date of first enrolment
27/02/2023

Date of final enrolment
01/01/2026

Locations

Countries of recruitment
Canada

Study participating centre
Sunnybrook Health Sciences Centre
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Sponsor type
Hospital/treatment centre

Website
http://sunnybrook.ca/

ROR
https://ror.org/03wefcv03

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
Planned publication in peer-reviewed journals and presentations at research conferences.

Intention to publish date
01/01/2027

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study will be available upon request from Dr Mark Boulos (mark.boulos@sunnybrook.ca)

IPD sharing plan summary
Available on request