Establishing the presence and characteristics of snoring sounds in a sleep laboratory population

No registrations found.

Ethical review Not applicable **Status** Recruiting

Health condition type -

Study type Observational non invasive

Summary

ID

NL-OMON24210

Source

NTR

Brief title

EPiCSS

Health condition

Snoring

Sponsors and support

Primary sponsor: None

Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The presence of snoring sounds, snoring sound duration, inter-snore interval duration, frequency, intensity (sound pressure level, equivalent sound pressure level, and top 1, 5, and 10 percentile sound pressure level) and the diagnosis after the PSG will be the primary

outcome measures of this study.

Secondary outcome

The measured variables will be same with those in the primary objectives. Possible changes in the above mentioned outcomes will be assessed. The diagnosis, type of treatment and objective effect of the treatment (PSG) will be added to the results of the cross-sectional study outcomes.

Study description

Background summary

Obstructive sleep apnea (OSA) is characterized by repetitive complete or partial obstruction of the upper airway during sleep, often resulting in oxygen desaturations and arousals from sleep. OSA is associated with a host of negative health outcomes, amongst which a higher risk of hypertension and cardiovascular disease. Excessive daytime sleepiness, fatigue, lack of concentration, and snoring out loud as reported by a sleep partner are amongst the frequently reported subjective complaints. Objectively, OSA is diagnosed by means of polysomnography (PSG), which requires physiologic measurements of brain activity during sleep and measurements of the amount of airflow reductions and oxygen desaturations during sleep. Thus, OSA patients are diagnosed based on the apnea-hypopnea index (AHI) of at least 5 events/hour of sleep determined during a PSG recording. The severity of OSA is classified as mild (AHI 5-15), moderate (AHI 15-30), and severe (AHI >30). OSA is a major public health problem, with an estimated prevalence of 2% and 4% for women and men, respectively. Importantly, in the general population, approximately 80-90% of patients meeting the criteria of at least moderate OSA remain undiagnosed.

Proxy-reported snoring is one of the most disturbing subjective complaints of OSA, but it also commonly occurs in individuals without OSA. Reportedly, it affects about 25% of women and almost 50% of men in the general adult population. The condition in itself is not lifethreatening, but it is one of the most important risk factors for the development of OSA, especially when the snoring sounds are loud and occur frequently. Unfortunately, and unlike OSA, snoring has not been studied extensively. Given the potential risk that is associated with snoring for the development of OSA, a better understanding of snoring is called for.

Study objective

The characteristics of snoring sounds could be used to categorize different kinds of snoring sounds, and the treatment effect of OSA/snoring could be evaluated by measuring the characteristics of snoring sounds

Study design

When patient first came to Department of Neurology/ Clinic Neurophysiology (sleep

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laboratory), OLVG west, a specialist was available to consult with the patient about his/her sleep problem(s). If a whole-night polysomnography (PSG, snoring sounds recording and snoring questionnaire were embedded in PSG) was required to diagnose his/her sleep problem, a new appointment would be made for PSG and patients would wait for about two weeks for it.

All the data for primary outcome were collected during the appointment for PSG. Before the PSG, patients would complete a snoring questionnaire. After that, whole-night PSG and snoring sounds recording were performed. After recording, the results of PSG and snoring sounds recording would be analyzed by R, a programming software, in which all the parameters of snoring sounds would be extracted automatically using our programmed codes. This detailed and comprehensive description of snoring sounds is the primary outcome.

For patients who received treatment (surgery, oral appliance, etc.) for OSA and/or snoring, after-treatment PSG was needed to evaluate the treatment effect. These patients were included for secondary outcome. Three months after treatment, an appointment was made for PSG, and that all the procedure and required data for secondary outcome were same with that for primary outcome. The data were also extracted using R. The before and after treatment snoring sounds parameters would be compared using SPSS, providing objective and quantified treatment effect.

Contacts

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Eligibility criteria

Inclusion criteria

- People who are 18 years or older;
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- People who underwent sleep recording at sleep laboratory because of possible sleep disorders.

Exclusion criteria

- People who object to the use of their data.

Study design

Design

Study type: Observational non invasive

Intervention model: Other

Allocation: Non controlled trial

Masking: Open (masking not used)

Control: N/A, unknown

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 01-09-2019

Enrollment: 1000

Type: Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable

Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register ID

NTR-new NL8398

Other ACWO OLVG: WO 19.079

Study results