The Efficacy of Intra-oral Neuromuscular Stimulation Training on Snoring in Individuals with Primary Snoring and Mild Sleep Apnoea

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The aim of this study is to see if the Snoozeal device is as effective as the previous methods and if it can reduce snoring and improve sleep quality.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Upper respiratory tract disorders (excl infections)
Study type	Observational non invasive

Summary

ID

NL-OMON55000

Source
ToetsingOnline

Brief title
eXciteOSA study (Snoozeal)

Condition

- Upper respiratory tract disorders (excl infections)

Synonym
apnea, Snoring

Research involving
Human

Sponsors and support

Primary sponsor: Signifier Medical Technologies
Source(s) of monetary or material Support: Signifier Medical Technologies

Intervention

Keyword: Daytime, Mild obstructive sleep apnea, Neuromuscular stimulation, Snorring

Outcome measures

Primary outcome

Primary Objective

1) To assess the efficacy of daytime trans-oral neuromuscular stimulation

training on respiratory indices of Sleep disordered breathing

Change in AHI and ODI (Comparison of pre and post therapy sleep studies)

2) To assess the efficacy of daytime trans-oral neuromuscular stimulation

training on objective snoring in Sleep disordered breathing

Change in Objective snoring pre and post therapy (% snoring at 40, 45 and 50dB)

Secondary outcome

Secondary Objectives

1) To assess the efficacy of daytime trans-oral neuromuscular stimulation

training on snoring sleep quality.

Comparison of sleep quality questionnaires at start and end of therapy (PSQI,

ESS, EQ-5D-5L)

2) To assess the efficacy of daytime trans-oral neuromuscular stimulation

training on snoring reported by sleep partner

Comparison of visual analogue scale of snoring reported by partner

Study description

Background summary

It has been shown that a common cause for snoring and throat obstruction (obstructive sleep apnoea) is excessive loss of muscle tone in the throat when we go to sleep. This results in the partial collapse of the throat (snoring) or complete collapse (obstructive sleep apnoea) during sleep.

45% of the male population snore. Sleep apnoea affects 4 to 6% of the population and is associated with increased incidence of raised blood pressure, heart attacks and strokes. Although there are several lifestyle practices associated with snoring such as smoking, obesity and drinking, a significant proportion of people may snore despite not being associated with these.

A solution to this issue is to improve the muscle tone of the throat so that it doesn*t collapse so easily. Several studies have shown that certain types of throat exercises can help reduce snoring. Further studies have also shown that using electrical stimulation to exercise the tongue muscles has the same effect.

From this, doctors in the UK have developed a new type of device, Snoozeal, that allows a more accurate and comfortable way of delivering this energy to exercise the tongue muscles. The device works by stimulating the tongue muscles during the day so that the tongue is less likely to collapse during sleep. It is a form of *workout* for the tongue and like other physical exercise regimes, it needs to be repeated regularly for a few weeks to take effect.

Study objective

The aim of this study is to see if the Snoozeal device is as effective as the previous methods and if it can reduce snoring and improve sleep quality.

Study design

Multi centre, observational, prospective, post market surveillance study

Intervention

Intra-oral neuromuscular stimulation training with a a device using 20 minutes during daytime

Study burden and risks

not applicalble

Contacts

Public
Signifier Medical Technologies

Hammersmith Grove 5-17
london W6 0LG
GB
Scientific
Signifier Medical Technologies

Hammersmith Grove 5-17
london W6 0LG
GB

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Participant is willing and able to give informed consent for participation in the trial
Male or female, aged 18 years or above
AHI 5-15/hr as confirmed by polysomnography
Bedpartner

Exclusion criteria

* BMI >35 kg/m2
* 5< AHI >15/h, i.e. evidence of moderate to severe OSA from polysomnography
* Symptomatic nasal pathology i.e. septal deviation, nasal polyposis or chronic

rhinosinusitis
* Tonsil Hypertrophy (Tonsil size * Grade 3 or greater)
* Tongue or lip piercing
* Pacemaker or implanted medical electrical devices
Pregnancy or planned pregnancy (device has not been tested or approved for use in pregnant women)
* Previous oral surgery for snoring
* Relevant facial skeletal abnormalities (i.e. syndromic facial deficiencies, severe micrognathia etc.)
* Any criteria that, in the opinion of the investigator, would make the participant unsuitable for the study due to inability to complete required study procedures

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-02-2021
Enrollment:	16
Type:	Actual

Medical products/devices used

Generic name:	intra-oral neuromuscular stimulation device (eXiteOSA)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	12-11-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-01-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-03-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-04-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
ClinicalTrials.gov	NCT04392765
CCMO	NL73741.100.20