# Analysis of the clinical effects of head positional therapy with the Sleep Position Trainer Wave in the treatment of Positional Obstructive Sleep Apnea

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Evaluation of the effect of positional therapy with the SPT Wave on sleep apnea severity, i.e. re-duction of the apnea-hypopnea index (AHI).

Ethical reviewApproved WMOStatusRecruitment stoppedHealth condition typeOther conditionStudy typeInterventional

# **Summary**

#### ID

NL-OMON40474

## **Source**

ToetsingOnline

## **Brief title**

Sleep Position Trainer Wave for POSA patients

## **Condition**

- Other condition
- Upper respiratory tract disorders (excl infections)

#### Synonym

POSA (positional obstructive sleep apnea)

## **Health condition**

Obstructief Slaap Apneu Syndroom

## Research involving

Human

## **Sponsors and support**

**Primary sponsor:** Sint Lucas Andreas Ziekenhuis

Source(s) of monetary or material Support: Nightbalance, NightBalance B.V.

## Intervention

**Keyword:** Positional Obstructive Sleep Apnea (POSA), positional therapy, SPT Wave

#### **Outcome measures**

## **Primary outcome**

Primary endpoints; reduction of PSG parameters, in particular AHI, AI, HI, DI, reduction of % of sleeping supine sleep position of the head, without disturbance of the sleep quality.

## **Secondary outcome**

Secondary endpoints: Outcome of Quality of Life questionnaires; Epworth
Sleepiness Scale (ESS), Functional Outcomes of Sleep Questionnaire (FOSQ),
Subjective Treatment Satisfaction Questionnaire (STSQ). Compliance and
learning effect will also be evaluated after 50 days usage.

Demographic parameters: Sex, age, length, weight, BMI, alcohol intake,
medication will also be noted.

# **Study description**

## **Background summary**

Fifty-six percent of patients with Obstructive Sleep Apnea (OSA) are position dependent,

defined as having an Apnea hypopnea index (AHI), which is at least twice as high in supine sleeping position compared to the AHI during sleep in other positions. Standard therapy for patients with mild or moderate positional OSA

(POSA) is treatment with an Oral Appliance Trainer (OAT) or surgery. Recently the Sleep Position Trainer (SPT) has been studied for patients with POSA. In this research a new device that uses auditory stimulation, the SPT Wave, will be introduced for patients with POSA.

## Study objective

Evaluation of the effect of positional therapy with the SPT Wave on sleep apnea severity, i.e. re-duction of the apnea-hypopnea index (AHI).

## Study design

Multicentre clinical trial

#### Intervention

A new product for head positional therapy, the SPT Wave, has been developed based on the same working principle of the Sleep Position Trainer but now focusing specifically on head positional therapy. The SPT Wave is placed on the temporal bone, lateral from the eyes. It measures the head sleeping position and gives the patient auditory stimulation feedback when the patient\*s head is in the supine position. The patient is then able to react to the auditory signal and turn the head or head and trunk into a non-supine position. The PSG with the SPT Wave will be repeated after 50 days of usage and the results will be compared with the baseline PSG.

## Study burden and risks

The risks for patients participating in this study are negligible. Inconveniences of the SPT Wave can be discomfort caused by irritation of the band, difficulties with an increased sleeping period with the head in non-supine sleeping position or difficulties sleeping with the SPT Wave, as well as possible irritation in the ear canal or from the sound. This can be compensated by the expected improvement of sleep quality caused by the therapy.

## **Contacts**

## **Public**

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## Scientific

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## **Trial sites**

## **Listed location countries**

**Netherlands** 

# **Eligibility criteria**

## Age

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

## Inclusion criteria

- + 18 years and older.
- + Ability to speak, read and write the local country\*s language (Dutch, French or Spanish depending on the country).
- + Ability to follow up.
- + Diagnosis with symptomatic mild or moderate OSA (5 < AHI < 30).
- + Diagnosis of 10 to 90% head supine position during the night.
- + AHI head supine is 2 > as high as AHI non-supine.
- + AHI head and trunk supine is 2 > as high as AHI non-supine.
- + Own a Windows PC and ability to install SPT connection software and upload research data.
- + Expected motivation to wear the SPT Wave for 50 days.
- + Expected to maintain current lifestyle (sports, medicine, diet etc.).
- + Normal audiogram for both ears

## **Exclusion criteria**

- Central Sleep Apnea Syndrome.
- Night or shifting work.
- Medical history of known causes of tiredness by day or severe sleep disruption (insomnia, PLMS, Narcolepsy).
- Seizure disorder.
- Known medical history of mental retardation, memory disorders or psychiatric disorders.
  - 4 Analysis of the clinical effects of head positional therapy with the Sleep Posit ... 7-05-2025

- Inability to provide informed consent.
- Simultaneous use of other treatment modalities to treat OSA.
- Hearing loss, wearing other ear devices.
- Anatomic ear abnormalities which influences correct attachment of the SPT Wave to the head and ear
- BMI above 35
- Extreme Migraine

# Study design

## **Design**

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

## Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-03-2014

Enrollment: 10

Type: Actual

## Medical products/devices used

Generic name: SPT Wave

Registration: No

# **Ethics review**

Approved WMO

Date: 03-02-2014

Application type: First submission

Review commission: METC Amsterdam UMC

# **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

CCMO NL44820.029.13