

# Positional therapy with the Sleep Position Trainer versus oral appliance therapy with the MRA in patients with position dependent Obstructive Sleep Apnea; A Randomised Controlled Trial

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Objective: To compare the effect of positional therapy with the SPT versus OAT on polysomnographic (PSG) parameters, to evaluate the compliance and measuring the possible learning effect that might occur with POSA patients using the SPT for...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Upper respiratory tract disorders (excl infections)
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON40088

### Source

ToetsingOnline

### Brief title

SPT vs MRA in patients with POSA

### Condition

- Upper respiratory tract disorders (excl infections)

### Synonym

sleepingdisorder with apnoeas

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Fonds NutsOhra cf brief dd 30-11-2011

## Intervention

**Keyword:** Mandibular repositioning apparatus, Obstructive Sleep Apnoea, Positional Obstructive Sleep Apnoea, Sleep Position Trainer

## Outcome measures

### Primary outcome

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

### Secondary outcome

Secondary endpoints: Outcome of Quality of Life questionnaires; ESS, FOSQ, OHIP-14 and MFIQ. Compliance and learning effect will also be evaluated in 3 and 12 months. Finally the cardiovascular parameters like blood pressure, pulse rate and BMI/neck circumference will be assessed.

## Study description

### Background summary

Rationale: 56% of patients with Obstructive Sleep Apnea (OSA) are position dependent, defined as having an 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 having mild or moderate POSA is treatment with an Oral Appliance Trainer (OAT). Recently a new device Sleep Position Trainer (SPT) is been introduced especially for patients with POSA.

### Study objective

Objective: To compare the effect of positional therapy with the SPT versus OAT

on polysomnographic (PSG) parameters, to evaluate the compliance and measuring the possible learning effect that might occur with POSA patients using the SPT for positional therapy over a long term.

## **Study design**

Study design: Randomised controlled trial

## **Intervention**

Intervention: The SPT is a sensor positioned in an elastic band attached around the body. The SPT measures the body position and vibrates when the patient lies in supine position. Oral appliance therapy (OAT) is an intra-oral prosthesis, which holds the mandible in a protrusive position. Because of this position more pharyngeal space will be available and the AHI will decrease.

After randomisation the first group (n=38) will sleep for a period of 90 +/- 2 days with the SPT every night. The second group (n=38) will also sleep for a period of 90 +/- 2 days only with MRA. After this period the PSG is repeated. Long-term outcome in AHI is measured by repeating the PSG after 1 year.

## **Study burden and risks**

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The risks for patients participating in this study are negligible. Inconveniences of the SPT can be discomfort caused by irritation of the band, difficulties with an increased sleeping period on the side or difficulties sleeping with the SPT. This can be compensated by the expected improvement of sleep quality caused by the therapy. Short term side effects of OAT may be discomfort in the jaw and dry mouth. Whereas in long term usage changes in the jaw can cause pain and sensitivity of the teeth. Withdrawing from this therapy means immediate relief of inconveniences.

## **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**

- + Diagnosis with symptomatic mild or moderate OSA ( $5 < \text{AHI} < 30$ ).
- + Diagnosis of 10 to 90% supine position during the night.
- + AHI supine is  $>2$  times as high as AHI non-supine.

### **Exclusion criteria**

- Many dental problems; insufficient teeth for wearing MRA.
- Medication used/ related to sleeping disorders
- Central Sleep Apnoea Syndrome.
- Night or shifting work.
- Severe chronic heart failure.
- 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.
- Patients with old type of pacemakers (It is possible that old types of pacemakers are not compatible with the electromagnetic radiation of the electronics of the SPT).
- Shoulder, neck and back complaints
- Reversible morphological upper airway abnormalities (e.g. enlarged tonsils).
- Inability to provide informed consent.
- Simultaneous use of other treatment modalities to treat OSA.
- Previous treatment for OSA
- Pregnancy

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	17-04-2013
Enrollment:	90
Type:	Actual

### Medical products/devices used

Generic name:	Sleep Position Trainer
Registration:	Yes - CE intended use

## Ethics review

Approved WMO	
Date:	15-10-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	05-03-2013
Application type:	Amendment
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	NL41516.018.12