

## The HUMMING MASK SCIENTIFIC STUDY

Conducting a neuropsychological test with up to 20 subjects as part of a clinical study.

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The result below indicates that an increase of NO was found due to the use of the mask. However, whether the sleep improvement that occurred directly due to the increase of NO was obtained (perception = literal perception) has to be further investigated.

### **"buzzing mask" improves the sleep of healthy elderly people:**

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**(April 2017) Use of the "humming mask" improves sleep of healthy elderly**

#### Introduction

The humming mask is a massaging device stimulating the paranasal sinuses through vibration. There were anecdotal reports that sleep benefits from the use of this device. Aim of this open-label pilot study was to investigate the effect of the humming mask on sleep perception in healthy elderly subjects without relevant sleep disorders, but complaining about "bad sleep". Furthermore effects on intranasal NO were assessed.

#### Methods

Eighteen aged subjects (12 female, 6 male, mean age 67 years,  $5 < \text{PSQI} < 11$ ) were included in the study. As cover task the subjects were instructed to keep dream diaries. After the screening visit the study consisted of two blocks of each one week, ended by a visit. In a cross over design, subjects used the humming mask for 20 minutes directly before lights of in one block and did not in the other. Primary endpoint was change in the subjective sleep quality as assessed with a modified version of the PSQI. The secondary endpoint was subjective sleep latency as assessed by a sleep diary.

#### Results

Despite being blind for the study's endpoints, subjects reported improvements in subjective sleep quality (PSQI start:  $8.4 \pm 1.5$ , without:  $7.3 \pm 2.4$ , with:  $6.4 \pm 2.8$ , RM-ANOVA ;  $F(2,53) = 3.185$ ;  $p = 0.0070$ ) and reduction in sleep latency (without:  $35 \pm 33$  min; with:  $26 \pm 24$  min, t-test  $p = 0.08$ , tendency) by the use of the humming mask. In the preliminary analyses no correlation was seen between NO increase and subjective sleep improvements.

#### Conclusion

Our results support the observation that use of the humming mask improves sleep (perception). There are several limitations of this pilot study. Firstly, only subjective measures were assessed. Secondly, subjects were blinded for the study outcome, but not for the intervention.

In total, the results of this pilot study encourage us to follow-up with a sham controlled, double-blind experiment, including objective assessments of sleep quality and intranasal NO. This would be a prerequisite to address the potential mechanisms of action of the humming mask.