International Field Test

Anti-Snoring Device GOODNITE™

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Contents

Descriptive Information

Location of Field Test
Home environment of participants, International

Supervising Clinical Director for Field Test
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Manufacturer
Nitetronic (Europe) GmbH

Device Model
Goodnite™ by Nitetronic

Test Type
This test is an analysis on the effect of Goodnite™ on snoring reduction.

Test Design
This test is an efficacy test of using Goodnite™ as an anti-snoring device in home environment. Suitable candidates with the symptom "snoring" are chosen for this test. Two nights with in-active pillow are compared with two nights with active pillow.

Arms, Group and Cohorts
The purpose of this test is to determine the snoring time. The experimental is the usage of the pillow during four consecutive nights – two nights inactivated pillow (just recording of snoring) and two nights activated pillow (recording snoring and pillow activity).

Eligibility

Ages Eligible for Field Test
The test accepts any candidates over the age of 18 for inclusion.

Sexes Eligible for Field Test

There is no exclusion on the basis of sex. Both men and women were eligible.

Inclusionary Criteria

The participants must be over the age of 18, snoring and must be able to provide informed consent.

Exclusionary Criteria

There are no exclusionary criteria except overweight (BMI > 40).

Purpose

Change in head position has a positive impact on snoring. This has led to the development of the pneumatic pillow as a uniquely device to minimize or stop snoring. The aim of this test is to measure and document the benefit of Goodnite™ on snoring.

Implementation

Goodnite™ will be approved for the use with a selection of participants in their home environment. The test begins with the selection of participants, the delivery of the pillows and a short instruction in the monitoring software. Goodnite™ had to be used by each involved user during four consecutive nights – two inactive and two active. Snoring was determined with integrated microphones and the software created an individualized data pool for every night that can be evaluated by statistics.
Spouse should fill out a simple snore-scale questionnaire (0 = “absolutely no snoring” up to 10 = “intolerable snoring”).

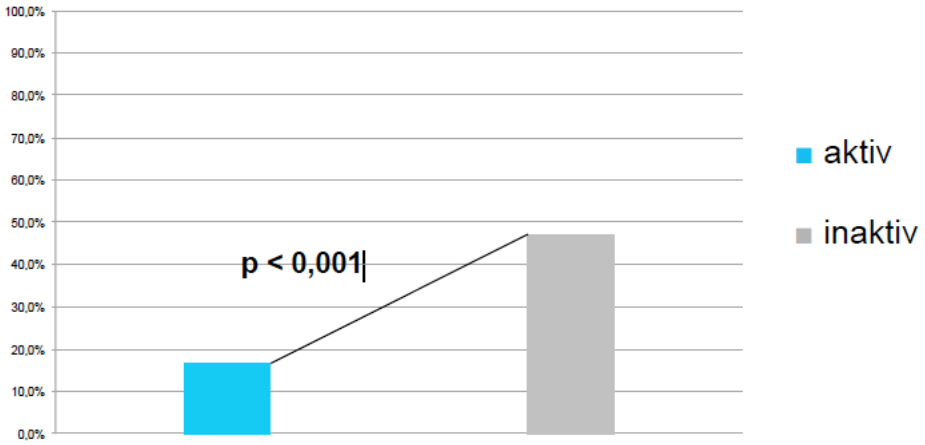
Expectations of Test Results

Without the support offered by Goodnite™, it is expected that user will snore continuously. By using Goodnite™, it is expected, that user will snore significantly less and have an improvement of sleep quality.

Graphical Data from Test

The test includes **157 participants** who completed the total number of four consecutive nights. The comparison of the percentage of snoring duration of nights with inactive and active pillow shows a significant reduction of snoring (inactive: 48 ± 17 %; active: 16 ± 9 %; $p < 0{,}001$).

Average of percentage of snoring
during all nights with an inactive and active pillow



Analysis of Graphical Data

All of the 157 chosen participants (142 male; 15 female, average age: 54 ± 9,6 years) were snoring and had a decreasing quality of life caused by snoring. The comparison of two inactive nights with two active nights showed a significant reduction of snoring (inactive: 48 ± 17 %; active: 16 ± 9 %; $p < 0,001$). That is a percentage **snoring reduction of 67 ± 14 %** in average.

Limitations

There are always limitations to conduct a test of this nature. First is, this test design was just made to determine if Goodnite™ is able to reduce snoring by easy use in the home environment. The data for statistics were collected by special monitoring software. No PSG or PS was used. Secondly, there are no pre-existing clinical studies on devices to change the head position to stop or minimize snoring. The shown effect cannot be compared to results of other studies or clinical trails.

Conclusion

This first Field Test was conducted to determine the influence of change of the head position on snoring with Goodnite™. The results of the monitoring software as well as the spouse snoring-questionnaire reflect significant reduction of snoring.
Additional examinations and clinical studies can be beneficial and further confirming the demonstrated effect with Goodnite™.

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