# The effect of neurosonic low-frequency therapy on the quality of sleep in patients with primary insomnia

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# Summary

The goal of the study was to find out the full-body vibrations given by the Neurosonic low-frequency chair (FCCA; Whole-Body Vibration; WBV) based on the effects of treatments for people suffering from primary insomnia. The research hypotheses were:
1. Neurosonic relaxation chair improves the sleep quality of a person suffering from insomnia
2. The use of a neurosonic relaxation chair relieves anxiety associated with insomnia

The study involved 16 people suffering from insomnia. They were randomized to the intervention and control groups (8 + 8). The admission criterion was a score of 15 or above in the ISI survey, which measures the difficulty of insomnia. Both groups received five times FCCA treatment. The control group had a three-week period at the beginning when they did not receive treatment. The research methods included actigraphy, SCL-90, WHO-5, PSQI, ISI, EQ-5D forms, and Vitalmed's extensive sleep questionnaire.

In both groups, there was a statistically significant decrease in ISI values after FCCA treatments. Anxiety also decreased to some extent after treatments.

The results obtained give an indication of the positive effects of FCCA treatment in the treatment of primary insomnia and anxiety. No significant side effects were observed. FCCA treatment may be useful, for example, in situations where medical treatment does not provide an adequate response. It should be noted that the number of subjects is small and theduration is short, so the results are indicative and further studies are necessary.

Keywords – Nyckelord – Keywords:
Primary Insomnia, Vibration, Insomnia, Relaxation, Anxiety

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# 1 Introduction

Insomnia is the most common sleep disorder (1). The treatment of chronic insomnia is problematic and alternative methods of drug therapy have been sought. On average, non-medicinal methods have yielded better results than using sleeping pills alone. (2), (3) An important part of non-medicinal methods are various relaxation methods (4).

The topic of the study was to find out whether the treatment given with the Neurosonic relaxation chair, which is based on mechanical vibrations, affects the sleep and mood of a person suffering from primary insomnia. The research hypotheses were:

1. Neurosonic relaxation chair improves the sleep quality of a person suffering from insomnia
2. The use of a neurosonic relaxation chair relieves anxiety associated with insomnia

## 1.1 Background

To the mechanical vibration of the whole body (FCCA; Whole Body Vibration; There are no previous studies on WBV-based relaxation methods related to sleep disorders. In contrast, there are some published studies on different types of low-frequency therapy based on sound waves. One study on the topic was conducted on rats. In the study, rats were exposed to low-frequency sinusoidal oscillations. The frequencies used ranged from 20 to 960 Hz with a steady acceleration of 50 $m/s^2$ and the duration was 240 minutes. In particular, the vibration of 120 Hz reduced the secretion of norepinephrine in the brains of rats compared to controls. In addition, changes were found in the levels of neurotransmitters such as serotonin and dopamine in the brain. Findings occurred at frequencies 20 Hz, 60 Hz, 120 Hz and 240 Hz. (5)

Another related study focused on a family that was exposed to low-frequency sound and the vibrations it produced for a long time. Family members reported experiencing various health hazards from exposure, such as sleep disturbances and headaches. The measured exposures were in the 10, 48 and 100 Hz ranges, but the decibel values of the sound emissions were clearly undetectable to their senses. The study concluded that further research on the topic is necessary. (6)

A 2004 review of vibroacoustic or physioacoustic (FA) therapy found that vibration based on sound waves as a treatment may help with pain, anxiety, reduce the feeling of illness as well as may be laskea blood pressure, respiratory rate and heart rate. The publication presents three possible explanations for the positive effects of therapy. The first explanation is that therapy causes relaxation, which helps with pain and reduces symptoms, as well as helping with fatigue and depression. In another theory, therapy works between 60 Hz and 600 Hz on Pacin's bodies, which would cause, through the regulation of the nervous system, a decrease in pain (inhibition of pain). In the third explanation, vibration may help at the cellular level with the mechanisms of cell purification and, consequently, with health. (7)

A study of patients with Parkinson's disease found indications that physioacoustic therapy would help with the motor symptoms of Parkinson's disease, especially muscle stiffness and tremors. The study used a physioacoustic chair (FAchair). (8) Another study related to FA treatment focused on its psychological effects on reasoning and creativity. In addition, the heart rate was monitored. No significant changes were found in the results and it was concluded that the FA chair helps with relaxation, but does not affect creativity. (9) A study published in 2009 investigated the effects of FA therapy on functional capacity, blood pressure and skeletal metabolism in the elderly. The results suggested that FA therapy may improve the mobility of the elderly. In addition, treatment may reduce serum cholesterol levels and increase bone remodeling. For hypertension, the treatment did not significantly affect. (10)

Thus, FA therapy has been shown to be beneficial in certain populations, but on the other hand, its use has been associated with various adverse reactions, limiting the use of the method. Research on the sick and the elderly , in particular, has begun to be carried out, and for these groups, FA treatment seems to be more effective than for healthy ones . (7–10). Closely related to the subject of this study, the subject of research is the effects of FA therapy on demented elderly people suffering from nighttime restlessness. The study is still inprogress and the results are not yet available. (11) More research has been carried out on the potentially negative effects of sound and vibration on health. These studies have focused on the noise generated by the environment, such as traffic and electronic devices. Studies have shown that the effects of vibration and sound perceived as noise are harmful or that there have been findings suggestive of

harmfulness. The main disadvantages have been the negative effects on the length and quality of sleep. (6.12–16) Since sound wave-based methods (FA) have been found to have beneficial effects and, on the other hand, disadvantages, newer methods have begun to be developed based on the to the mechanical vibration of the body (FCCA).

FCCA treatment is based on the transfer of mechanical energy to the body (17). Studies on the treatment method have mainly focused on its effects on musculature, bones and motor function (17–23). The effects of the treatment on the musculature have been positive, and according to a meta-analysis conducted in 2013, adding FCCA therapy to the training program produced better results in the strength of the extensor muscle of the knee than mere adherence to an internship programme (17). The skeletal effects are not so clear. In a twelve-month follow-up study, no changes in skeletal mineral density were observed (18). A review conducted in 2011 concluded that much more research is needed on FCCA treatment, and no definitive conclusions can be drawn on the clinical effects on skeletal density (23 ). No published studies on the effects of FCCA treatment on sleep were found.

# 2 Material

The study has been approved by the coordinating ethics committee of the Hospital District of Helsinki and Uusimaa and funded by Tekes (Finnish Funding Agency for Technology and Innovation).

The study included sixteen (N=16) volunteers (12 men and 4 women) suffering from primary insomnia. The demographic data of the subjects are presented in Table 1.

Of the sixteen participants, eight were randomized to the control group and eight to the intervention group. The subjects were randomised into groups by drawing lots. Two blocs were created (block 1 and block 2), both of which included control and intervention groups. The drawing was carried out using sealed envelopes , each of the sixteen envelopes containing placement in either the intervention or control group. Thus, in one block there were four subjects of the control group, as well as four subjects

of the intervention group, and in the entire study a total of sixteen subjects. The data was processed anonymously so that the subjects had access to identification numbers (NS001 , NS002, etc.). In addition to the data collected by the methods, the age and gender of the subjects were recorded.

Theresearch methods were recruited through Vitalmed and the recruitment was carried out by a Vitalmed employee. A research register was created for the research and a personal data register description required for scientific research. In addition, a research number was recorded for the research subjects. The description of the research register is attached (Appendix 1). The main admission criterion was at least fifteen points obtained in the ISI survey, which means clinically significant insomnia. An employee of Vitalmed prepared a bulletin and a consent statement for the person being investigated. Press release and consent form attached ( Appendix 2 and Appendix 3). The admission criteria for the study were age 18–65, primary stress-related or anxiety-related insomnia, and at least 15 points from the ISI survey. The exclusion criteria were acute ppsychiatric symptoms with a risk of psychosis; noted restless legs syndrome; diagnosed sleep apnea; multiple sclerosis; pregnancy; severe heart failure; untreated herniated disc and back-neck pain, as well as hypersensitivity to sensory stimulation, where, for example, in certain hereditary diseases, a person may be hypersensitive to sound and in others for touch. Temporary exclusion criteria included acute inflammation, flu and fever.

| Demographic data ($N_{intervention}$ 8 , $N_{control}$ = 8) | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Length (ka) | | BMI (ka) | | ISI (ka) | | Age (ka) | | Sex | |
| Group | Interv entio | Boar kki | Interv entio | Verr okki | Interv entio | Verr okki | Interv entio | Verr okki | Interv etnio | Verr okki |
| Value | 168,4 | 168,8 | 25,9 | 23,8 | 19,5 | 17,5 | 47,7 | 42,1 | 6 m, 2 n | 6 m, 2 n |
| Keskiha jonta | 8,6 | 13,0 | 4,0 | 3,3 | 4,3 | 2,6 | 13,0 | 9,6 | - | - |
| P-value | NS | | NS | | NS | | NS | | NS | |
| N = number of subjects, BMI = Body Mass Index (kgm-2); NS = not significant, ISI = Insomnia Severity Index, Age (in years), m = man, n = female, ka = average, Height (cm) | | | | | | | | | | |

Table 1. Demographics

Actigraphy, subjective questionnaires such as SCL-90, WHO-5, PSQI, ISI, EQ-5D, and Vitalmed's extensive sleep questionnaire were used to help collect the data.
The data collection was carried out by a Vitalmed employee.

# 3 Methods

## 3.1 Aktigrafiarekisteröinti

An actigrapher on wristwatch-looking device that attaches to the wrist of a non-dominant hand. The device measures motion activity and motion activity at a frequency of 32 Hz. The collected measurement data is driven through the program received with the device, from which four values are obtained. The measured values are sleep onset delay (SOL), waking up after sleep begins (WASO), total sleep time (TST), and sleep efficiency (SE). The device has a button that the subject presses when entering and getting out of bed. Pressing makes entries in the measurement data and it i easier to interpret. The research subject uses a sleep diary to support the actigrapher, in which he or she records things such as bedtime and the time of waking up. (24) Sleep diary and instructions for the actigrapher and sleep diary, Appendices 4 and 5.

Polysomnography (PSG) is the "gold standard" in sleep research. However, the actigrapher is inexpensive and more suitable for long-term sleep monitoring. In particular, measuring TST with an actigraph is equivalent to PSG measurements. (24–26)

## 3.2 Queries

Vitalmed's extensive sleep questionnaire is a survey based on the Nordic Sleep Survey (BNSQ) (27). The survey contains a wide range of questions related to underlying diseases, sleep quality and sleep disorders, medication use , leisure time use and education. The subject completes the questionnaire. (Annex 6)

The WHO-5 survey, or WHO-Five Well-being Index, contains five questions that map the quality of life and well-being of the research subject. In the survey, less than fifty

points often indicate depression. (28,29) The subject completes the questionnaire itself. (Annex 7)

The PSQI survey, or Pittsburgh Sleep Quality Index, includes questions about sleep length, quality and covers questions about subjective experiences of sleep quality. (30) The subject completes the questionnaire himself. (Annex 8)

The ISI survey, or Insomnia Severity Index, contains seven questions about insomnia. Each question is scored from zero to four points, where the maximum value is the worst situation. The maximum score of the survey is twenty-eight points. A person who has scored more than fifteen points in the survey has a clinically significant sleep disorder and therefore the score limit in question is also included in the admission criteria. The ISI survey is a valid and sensitive method to detect changes in sleep quality in the context of treatment. (31–34)
The subject fills out the survey himself. (Annex 9)

The SCL-90 Symptom Questionnaire, or Symptom Checklist-90 Symptom Questionnaire, consists of ninety questions. The questions focus on nine different variables, which are depression, anxiety, psychoticism, paranoia, interpersonal sensitivity i.e. emotional intelligence, obsessive-compulsive personality disorder, hostility , foobic anxiety, as well as somatization. The survey is widely used and has been found to be a useful tool for identifying mental illnesses. (35-40) The subject fills out the survey himself. (Appendix 10)

The EQ-5D survey, or European Quality of Life-5 Dimensions, comprises five questions and a visual scale, a line with a top value of one hundred and the lowest zero. On scale, the lowest value is the worst possible health , and the highest is the best possible health. The survey is used to map the health of the research subject. The survey is best used to identify the effects of musculoskeletal disorders and psychiatric conditions on health-related quality of life. (41–43) The subject fills out the survey himself. (Appendix 11)

## 3.3 Treatment with the Neurosonic method

The function of the chair is based on the vibration of the whole body and it oscillates at a frequency of 20-80 Hz, unlike FA chairs, which are based on acoustic vibration and have a frequency range of 27-113 Hz. The duration of treatment was 39 minutes per treatment. The chair developer had created a treatment program, the Neurosonic Sleep/Stress Program, which was used in the FCCA treatments performed in the study.

## 3.4 The course of the study

In the first phase, the people who were hoped to participate in the study were informed about the study at the reception. In this case, they were informed about the study, given a recruitment notice and told about the possibility of requesting more information about the study from the research group and/or announcing their willingness to participate in the study . Those interested in the study were given the information from the study to read at home (Appendix 2). During the first research visit, the research subject was given the opportunity to ask for more information and was informed about the course of the study and the research methods. Once the subject had received sufficient information, both in writing and verbally, his or her willingness to participate in the research was confirmed by signing a consent document. The subject was then randomised to the block as mentioned above and the actual research activities could be initiated.

In the intervention group, the subject filled in the above-mentioned questionnaires during the first research visit and was subjected to the above-mentioned measurements. After this, the research subject was instructed to use the actigrapher and sleep diary. The actigrapher was attached to the wrist of the non-dominant hand of the subject and the device was ready for measurement. The measurement data was collected for seven days, after which the subject returned the actigrapher. When restoring actigraphy, the second examination visit, the subject underwent treatment with a Neurosonic relaxation chair. The duration of treatment is thirty-nine minutes. From now on, the subject entered low-frequency therapy four more times, and during the last treatment, i.e. the sixth study visit, the subject was given aktigrafi and a sleep diary . Sleep was monitored for another week with an actigrapher, after which the subject arrived for the last time for a study visit, which was the seventh research visit.

The subject re-filled the same questionnaires as the first time and also measured height, weight, blood pressure, pulse and waist circumference. After three months, the subjects were sent by post with the same questionnaires that they filled out during the first and last visits. The completed queries they mailed back to Vitalmediin.

The first visit of the control group was exactly the same as that of the intervention group. Like the intervention group, the control group was monitored for a week with the help of an actigrapher and a sleep diary. Unlike the intervention group, the subjects in the control group returned the actigraph and sleep diary by post one week later, and the next visit to the subjects was held three weeks after the first visit. During these three weeks, the subjects had the opportunity to contact the research group if necessary. At the second visit, after three weeks, the study proceeded in the same way as the first visit of the intervention team and continued from now on, exactly the same as the study of the intervention group , the study of the week with aktigraf measurement and sleep diary. This was followed by a five-time treatment with a Neurosonic relaxation chair, a week's actigraph measurement together with a sleep diary, and a last-time examination visit where the subject fills out questionnaires and measure height, weight, blood pressure, pulse and waist circumference. After threemonths, the subjects were sent by post with the same questionnaires that they filled out during the first, second and last visits.
The completed queries they mailed back to Vitalmed.

The study does not blind the low-frequency care of the chair due to the function of the chair. It should be noted that after three weeks, the control group also receives low-frequency therapy as well as the intervention group.

## 3.5 Statistical processing of data

The collected measurement data was entered into an Excel spreadsheet and the handswere lived with the SPSS statistical software
(version 21). Averages, averages and confidence intervals were calculated from the results. The intervention group had two measurements, which were statistically treated as a pair. There was no treatment between the first and second measurements in the control group and this interval was treated as a pair statistically. Between the second

and third measurements in the control group, the subjects received treatment and the interval between these measurements was statistically treated as a pair. In addition, measurements of the treatment interval in the intervention and control groups were analysed together to provide better statistical strength. The results examined whether low frequency has a causal effect in improving sleep quality and reducing anxiety. The statistical differences between continuous variables were examined using either parametric methods (Student's t-test) or non-parametric methods (Mann-Whitney's U-test), depending on whether distribution normal or not. For paired comparisons of non-parametric variables, Wilcoxon's signed-rank test was used. The normality of the divisions was assessed using the Shapiro-Wilk test. The limit of the statistically significant bidirectional P-value was considered to be 0.10 (describes the trend).

## 1. Power calculations

## 3.5.1

The required sample size was calculated using nQuery. With a sample size of 10 + 10 and a P-value of 0.10, a power of 80 % is achieved, assuming that the value of the intervention group ISI is on average 14 and the value of the control group ISI is on average 20 with a dispersion of 5. We assume that the difference between the study groups may be even greater than this, in which case 10 + 10 subjects would already achieve more than 80% efficacy and, correspondingly, the confidence level would increase to the level of $P < 0.05$. We also made the force calculations by reducing the dispersion to 4, reducing the required sample size to six per group. Because of the pilot'stea, we left the conservative $P < 0.10$ level. If that level is reached, future further studies will be considered.

## 1. Conversion variables

The main variable (Primary outcome) was the severity of insomnia as measured on the ISI scale. The secondary result changes were WHO-5, SCL-90 and, among the aktigraf results, sleep efficiency and fragmentation.

# 4 Results

## 4.1 Review of the material

The intervention and the gender distribution of the control group were identical. There were also no major differences in the age distribution between the groups, the subjects in the control group were slightly younger than the intervention group in terms of average and median age. There were no major differences in length between the groups. In terms of weight, the members of the intervention group were, on average, about five kilograms heavier than the control group, so the Body Mass Index (BMI) was also higher in the intervention group than in the control group. The ISI baseline values for the intervention group were two units higher on average and 2.5 units higher on median. (Table 1)

## 4.2 ISI and WHO-5

Changes in the ISI value in the intervention and control groups, which describes the severity of insomnia, are presented in Tables 2 and 3. In the intervention group, the ISI value decreased after FCCA treatment and the result is statistically significant (N = 8, Z = 2.0; P = 0.042). In the control group, there were two measurements of the ISI value before the FCCA treatments and one after the treatments. The ISI value decreased even without treatments, but the decrease is not statistically significant (Z = 1.6; P = 0.105). After treatment, the ISI value decreased statistically significantly (N = 8, M = 5.1; SD = 4.9; P = 0.021). In the combined measurements of the groups, after treatment, a significant decrease in the ISI value was observed (N = 16, Z = 2.9; P = 0.003).

There was a statistically significant difference in the results of the who-5 questionnaires in the control group before treatment (N = 8, M = -5.1; SD =4.5; P = 0.022). There were no statistically significant differences between the other WHO-5 surveys in either group. When the measurements between the treatments of the groups were combined, a significant change was observed after treatment (N = 16, Z = -2.8; P = 0.004).

| Group | N | Difference | Average | Standard deviation | Keskivirhe | 90% CI | | P-value |
|---|---|---|---|---|---|---|---|---|
| | | | | | | Lower bound | Upper bound | |
| **Verrokki** | **8** | **CONTENTS [2] – [3]** | **5,1** | **4,9** | **1,7** | **1,0** | **9,2** | **0,021** |
| Intervention | 8 | WHO-5 [1] – [2] | -6,5 | 15,3 | 5,4 | -16,7 | -1,2 | 0,267 |
| **Verrokki** | **8** | **WHO-5 [1] – [2]** | **-5,1** | **4,5** | **1,7** | **-8,4** | **-1,9** | **0,022** |
| Verrokki | 8 | WHO-5 [2] – [3] | -5,0 | 16,0 | 5,6 | -15,7 | 5,7 | 0,405 |

N = tutkittavien määrä, WHO-5 = WHO (Five) Well-Being Index-asteikko, ISI = Insomnia Severity Index, [1], [2], [3]... = measurement 1, measurement 2, measurement 3, ...

Table 2. ISI and WHO-5 treated with Student's t-test

| Wilcoxon signed-rank testi | | | | |
|---|---|---|---|---|
| Group | N | Difference | With | P-value |
| **Intervention** | **8** | **CONTENTS [2] – [1]** | **-2,0[a]** | **0,042** |
| Verrokki | 8 | CONTENTS [2] – [1] | -1,6[a] | 0,105 |
| **Connected** | **16** | **CONTENTS [2] – [1]** | **-2,9[a]** | **0,003** |
| **Connected** | **16** | **WHO-5 [2] – [1]** | **-2,8[b]** | **0,004** |

N = number of subjects, WHO-5 = WHO (Five) Well-Being Index, ISI = Insomnia Severity Index, a = based on positive values, b = based on negative values, [1], [2], [3]... = measurement 1, measurement 2 , measurement 3, ...

Table 3. Changes in the ISI and WHO-5 measurements of the groups

# 1. Actigrapher

The results of the aktigraf were monitored as secondary result variables as sleep efficiency (SE) and sleep fragmentation (FRI). There was great variation in the results among the subjects. A significant change in the total amount of sleep (TST) in the control group was observed prior to treatment (M = -0:17:21; SD = 0:24:04; P = 0.081). No statistically significant changes were observed in the other measurements in either group. When the measurements between the treatments of the groups were combined, a significant change was observed after treatment (M = 0:21 :21, SD = 0:46:08, P = 0.095).

| Student t-test (N = 7) | | | | | | |
|---|---|---|---|---|---|---|
| Difference | Average | Standard deviation | Keskivirhe | 90% CI | | P-value |
| | | | | Lower bound | Upper bound | |
| WATCH with [1] – [2] | 0,87 | 5,3 | 2,02 | -3,0 | 4,8 | 0,681 |
| SE avg [1] – [2] | -0,57 | 6,2 | 2,36 | -5,2 | 4,0 | 0,816 |
| Onemin with [1] – [2] | 0,84 | 5,1 | 1,94 | -2,9 | 4,6 | 0,679 |
| FREE with [1] – [2] | -4,4 | 15,8 | 5,97 | -16,0 | 7,2 | 0,488 |
| FRI avg [1] – [2] | -2,1 | 8,5 | 3,22 | -8,3 | 4,2 | 0,548 |
| TST med [1] – [2] | 0:17:04 | 0:43:28 | 0:16:25 | -0:14:50 | 0:48:59 | 0,339 |
| TST avg [1] – [2] | 0:15:10 | 0:34:24 | 0:13:00 | -0:10:05 | 0:40:26 | 0,287 |
| N = number of subjects, [1], [2], [3]... = measurement 1, measurement 2, measurement 3, ...; med = median; avg = average ; TST = Total Sleep Time = total sleep (tt:mm:ss), SE = sleep efficiency (%); Onemin = minute immobility (%); FRI = bind pirstaleisuus (%) | | | | | | |

Table 4. Changes in intervention group actigraphy results

| Student t-test (N = 8) | | | | | | |
|---|---|---|---|---|---|---|
| Difference | Average | Standard deviation | Keskivirhe | 90% CI | | P-value |
| | | | | Lower bound | Upper bound | |
| TST med [1] – [2] | -0:18:30 | 0:44:12 | 0:15:37 | -0:48:06 | 0:11:06 | 0,275 |
| **TST avg [1] – [2]** | **-0:17:21** | **0:24:04** | **0:08:30** | **-0:33:29** | **-0:01:13** | **0,081** |
| WATCH with [1] – [2] | -2,26 | 5,71 | 2,01 | -6,09 | 1,56 | 0,299 |
| SE avg [1] – [2] | -0,96 | 5,64 | 1,99 | -4,73 | 2,82 | 0,646 |
| Onemin with [1] – [2] | 1,79 | 14,9 | 5,27 | -8,20 | 11,8 | 0,744 |
| Onemin avg [1] – [2] | 2,72 | 9,48 | 3,35 | -3,63 | 9,07 | 0,444 |
| FREE with [1] – [2] | 5,16 | 16,0 | 5,66 | -5,57 | 15,9 | 0,392 |
| TST med [2] – [3] | 0:22:30 | 0:41:42 | 0:14:44 | -0:05:26 | 0:50:26 | 0,171 |
| TST avg [2] – [3] | 0:26:45 | 0:56:19 | 0:19:54 | -0:10:58 | 1:04:29 | 0,221 |
| WATCH with [2] – [3] | -0,10 | 2,79 | 0,99 | -1,97 | 1,77 | 0,922 |
| SE avg [2] – [3] | 0,15 | 3,58 | 1,27 | -2,25 | 2,55 | 0,907 |
| N = number of subjects, [1], [2], [3]... = measurement 1, measurement 2, measurement 3, ...; med = median; avg = average ; TST = Total Sleep Time = total sleep (tt:mm:ss), SE = sleep efficiency (%); Onemin = minute immobility (%); FRI = bind pirstaleisuus (%) | | | | | | |

Table 5. Changes in the actigraph results of the control group

| Student t-test (N = 15) | | | | | | |
|---|---|---|---|---|---|---|
| Difference | Average | Standard deviation | Keskivirhe | 90% CI | | P-value |
| | | | | Lower bound | Upper bound | |
| **TST [1] – [2]** | **0:21:21** | **0:46:08** | **0:11:54** | **0:00:22** | **0:42:20** | **0,095** |

N = number of subjects, [1], [2], [3]... = measurement 1, measurement 2, measurement 3, ...; TST = Total Sleep Time = Total Sleep

(tt:mm:ss)

Table 6. Change in the combined total sleep (TST) of groups

| Wilcoxon signed-rank testi | | | | |
|---|---|---|---|---|
| Group | N | Difference | With | P-value |
| Intervention | 7 | Onemin avg [2] – [1] | 0,0[b] | 1,000 |
| Verrokki | 8 | FRI avg [2] – [1] | -0,56[a] | 0,575 |
| Verrokki | 8 | Onemin with [3] – [2] | -1,18[a] | 0,237 |
| Verrokki | 8 | Onemin avg [3] – [2] | -1,40[a] | 0,161 |
| Verrokki | 8 | FREE with [3] – [2] | -0,70[a] | 0,484 |
| Verrokki | 8 | FRI avg [3] – [2] | -1,12[a] | 0,263 |

N = number of subjects, [1], [2], [3]... = measurement 1, measurement 2, measurement 3, ...; med = median; avg = average ; TST = Total Sleep Time = total sleep (tt:mm:ss), SE = sleep efficiency (%); Onemin = minute immobility (%); FRI = sleep fragmentation (%), a = based on positive values, b = positive and negative values equal

Table 7. Changes in actigraphy results

## 4.3 The presence of psychiatric symptoms (SCL-90)

In the intervention group, the decrease in somatization after FCCA treatments was statistically significant (N = 8, Z = 1.709; P = 0.088). There were also statistically significant changes in somatization in the control group after FCCA treatments (N = 8, Z = 2.39; P = 0.017), in anxiety (N = 8, Z = 1.77; P = 0.076), in paranoid imaginings (N = 8, Z = 1.89; P = 0.059), as well as in obsessive compulsions before treatment (N = 8, M = 1.750; SD = 1.58 P = 0.017). When the results of the intervention and control groups were combined, statistically significant results of somatization (N = 16, Z = 2.88; P = 0.004), anxiety (N = 16, Z = 2.24; P = 0.025), as well as obsessive compulsions (N = 16, Z = 1.77; P = 0.078).

| Wilcoxon signed-rank testi (N = 8) |
|---|

| Difference | With | P-value |
|---|---|---|
| **As [ 2] - [1]** | **-1,709[a]** | **0,088** |
| Fob [2] - [1] | -0,557[a] | 0,577 |
| By [2] - [1] | 0,000[b] | 1,000 |
| Dogs [ 2] - [1] | -0,412[a] | 0,680 |

N = number of subjects, [1], [2], [3]... = measurement 1, measurement 2, measurement 3,...; Dep = depression, Obs = Obsessive-compulsive disorder, Anx = anxiety, Psy = Psychoticism, Int = interpersonal sensitivity, Hos = hostility, Fob = phobic anxiety , Par = paranoid fantasies, a = positive based on values, b = positive and negative values equal

Table 8. Changes in the results of the SCL-90 intervention group

| Student t-test (N = 8) | | | | | | | |
|---|---|---|---|---|---|---|---|
| Group | Difference | Average | Standard deviation | Keskivirhe | 90% CI | | P-value |
| | | | | | Lower bound | Upper bound | |
| Intervention | Obs [ 1] - [2] | 3,13 | 6,90 | 2,43 | -1,49 | 7,74 | 0,241 |
| Intervention | Int [1] - [2] | 0,13 | 2,53 | 0,90 | -1,57 | 1,82 | 0,893 |
| Intervention | Dep[1] - [2] | -0,25 | 6,76 | 2,39 | -4,78 | 4,28 | 0,920 |
| Intervention | Anx [1] - [2] | 1,38 | 2,45 | 0,87 | -0,26 | 3,01 | 0,156 |
| Intervention | Hos [ 1] - [2] | 0,75 | 2,61 | 0,92 | -1,00 | 2,50 | 0,442 |
| **Verrokki** | **Obs [ 1] - [2]** | **1,75** | **1,58** | **0,56** | **0,69** | **2,81** | **0,017** |
| Verrokki | Dogs [ 1] - [2] | 0,38 | 2,33 | 0,82 | -1,18 | 1,93 | 0,662 |

N = number of subjects, [1], [2], [3]... = measurement 1, measurement 2, measurement 3,...; Dep = depression, Obs = Obsessive-compulsive syndrome,

Anx = anxiety, Psy = Psychoticism, Int = interpersonal sensitivity, Hos = hostility

Table 9. SCL-90 control and intervention group results - Student's t-test

| Wilcoxon signed-rank testi | | | |
|---|---|---|---|
| Difference | N | With | P-value |
| As [ 2] - [1] | 8 | -0,524[a] | 0,600 |
| Int [2] - [1] | 8 | -0,516[a] | 0,606 |
| Dep[2] - [1] | 8 | -0,851[a] | 0,395 |
| Anx [2] - [1] | 8 | -1,268[a] | 0,205 |
| Hos [ 2] - [1] | 7 | -0,378[a] | 0,705 |
| Fob [2] - [1] | 8 | 0,000[b] | 1,000 |
| By [2] - [1] | 8 | -1,035[a] | 0,301 |
| **As [ 3] - [2]** | **8** | **-2,392[a]** | **0,017** |
| Obs [ 3] - [2] | 8 | -1,548[a] | 0,122 |
| Int [3] - [2] | 8 | -1,552[a] | 0,121 |
| Dep[3] - [2] | 8 | -1,014[a] | 0,310 |
| **Anx [3] - [2]** | **8** | **-1,772[a]** | **0,076** |

| | | | |
|---|---|---|---|
| Hos [ 3] - [2] | 7 | -0,957[a] | 0,339 |
| Fob [3] - [2] | 8 | -0,816[a] | 0,414 |
| By [3] - [2] | 8 | -1,890[a] | **0,059** |
| Dogs [ 3] - [2] | 8 | -1,511[a] | 0,131 |

N = number of subjects, [1], [2], [3]... = measurement 1, measurement 2, measurement 3,...; Dep = depression, Obs = Obsessive-compulsive disorder, Anx = anxiety, Psy = Psychoticism, Int = interpersonal sensitivity, Hos = hostility, Fob = phobic anxiety , Par = par anoids fantasies, a = based on positive values, b = positive and negative values equal

Table 10. Changes in SCL-90 control group results

| Wilcoxon signed-rank testi | | | |
|---|---|---|---|
| Difference | N | With | P-value |
| **As [ 2] - [1]** | **16** | **-2,884[a]** | **0,004** |
| **Obs [ 2] - [1]** | **16** | **-1,765[a]** | **0,078** |
| Int [2] - [1] | 16 | -1,203[a] | 0,229 |
| Dep[2] - [1] | 16 | -0,566[a] | 0,572 |
| **Anx [2] - [1]** | **16** | **-2,241[a]** | **0,025** |
| Hos [ 2] - [1] | 15 | -1,267[a] | 0,205 |
| Fob [2] - [1] | 16 | -1,035[a] | 0,301 |
| By [2] - [1] | 16 | -1,231[a] | 0,218 |
| Dogs [ 2] - [1] | 16 | -1,409[a] | 0,159 |

N = number of subjects, [1], [2], [3]... = measurement 1, measurement 2, measurement 3, ...; Dep = depression, Obs = Obsessive-compulsive disorder, Anx = anxiety, Psy = Psychoticism, Int = interpersonal sensitivity, Hos = hostility, Fob = phobic anxiety , Par = paranoid fantasies, a = based on positive values

Table 11. Changes in combined SCL-90 results

## 4.4 Quality of Life (EQ-5D)

The post-treatment change in the control group was significant (N = 8, M = -9.875; SD = 10.11; P = 0.028). When the measurements between the treatments of the groups were combined, a significant change was observed after treatment (N = 16, Z = 2.07; P = 0.038). No statistically significant changes were observed in other measurements.

| Wilcoxon signed-rank testi |
|---|

| Group | N | Difference | With | P-value |
|---|---|---|---|---|
| Intervention | 8 | EQ-5Q scale [2] - [1] | -0,701[a] | 0,483 |
| Verrokki | 8 | EQ-5Q scale [2] - [1] | -0,423[a] | 0,672 |
| **Connected** | **16** | **EQ-5Q scale [2] - [1]** | **-2,072[a]** | **0,038** |

N = number of subjects, EQ-5D = European Quality of Life-5 Dimensions, a = based on negative values, [1], [2],

[3]... = measurement 1, measurement 2, measurement 3, ...

Table 12. Changes in the results of the EQ-5D scale

| Student t-test (N = 8) | | | | | | | |
|---|---|---|---|---|---|---|---|
| Group | Difference | Average | Standard deviation | Keskivirhe | 90% CI | | P-value |
| | | | | | Lower bound | Upper bound | |
| **Verrokki** | **EQ-5Q scale [2] - [3]** | **-9,88** | **10,1** | **3,57** | **-16,6** | **-3,11** | **0,028** |

N = number of subjects, EQ-5D = European Quality of Life-5 Dimensions, [1], [2], [3]... = measurement 1, measurement 2, measurement 3, ...

Table 13. Changes in the results of the EQ-5Q scale of the control group

## 4.5 The subjects' own observations of Neurosonic low-frequency therapies

During the study, the subjects report any adverse reactions to the study nurse. The subjects reported very few adverse reactions, two of the subjects reported having headaches after treatment, which was temporary and did not recur during follow-up. No other side effects were reported. No serious side effects occurred.

At the last visit, the research nurse asked about the subject's experience with Neurosonic low-frequency chair treatments. All the subjects felt that the chair was a good tool for momentary relaxation, and the treatment was perceived as pleasant. About two-thirds of the subjects felt that they had received help for their insomnia problem during the study, about one-third did not feel that the treatment had any effect on the insomnia problem.

# 5 Speculation

The aim of the study was to find out whether FCCA treatment, when carried out with a Neurosonic chair, affects the sleep quality and mood of a person suffering from primary insomnia. The results obtained were positive. There was a statistically significant decrease in ISI values, in the combined results after treatment (N = 16, Z = 2.9; P = 0.003). Especially in the verrokki group, the ISI values decreased and, on average, the values fell below 15 units. The results show that there is a large dispersion in the ISI values of the intervention group, however, the values of the individually subjects show a clear trend of ISI impairment after the FCCA proceedings. It can be concluded that at least some of those suffering from primary insomnia benefit from KKV treatments.

No significant changes were observed in the WHO-5 scale in either group after treatment, but a significant improvement was observed when the combined results of the groups after treatment were observed (Z = -2.8; P = 0.004). Based on the scale, there are indications that the treatment improved the quality of life and well-being of the subjects.

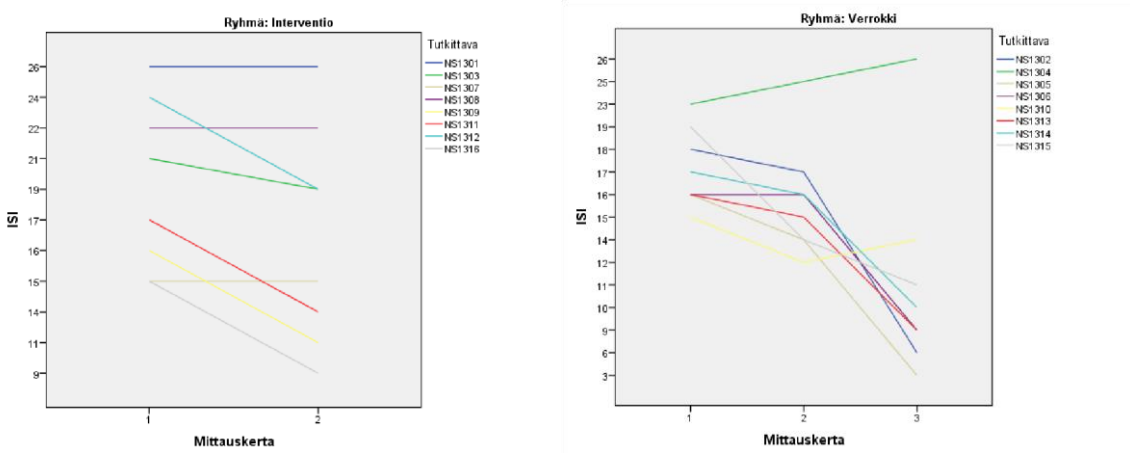


Figure 1. ISI values by study patient and group

Measurements with aktigraf showed that after treatment, the subjects' sleep length increased significantly (P = 0.95), but the lengthening was not great, on average about 21 minutes, and the dispersion was large (SD = 0:46:08). There was a large dispersion in the results and a larger sample count in the follow-up study is necessary to increase the statistical power.

The SCL-90 survey showed significant changes in the combined results in somatization (N = 16, Z = 2.88; P = 0.004), anxiety (N = 16, Z = 2.24; P = 0.025), as well as obsessive compulsions (N = 16, Z = 1.77; P = 0.078) and these three factors can significantly interfere with sleep. Significant changes in paranoid imaginings were also observed in the control group.

On the EQ-5D scale, a significant change was obtained by the combined values (N = 16, Z = 2.07; P = 0.038) when considering the effect of treatment. The use of scale in further studies can be an easy and cheap tool for monitoring the effects of treatment.

The results obtained give an indication of the positive effects of FCCA therapy in the treatment of primary insomnia, as well as anxiety. No significant side effects were observed. FCCA care may be useful, for example, in situations where medical treatment does not provide an adequate response. It should be noted that the number of subjects is small and the follow-up time is short, so the results are indicative and further studies are necessary.

If a further study is organized, it would be advisable to conduct polysomnography of the subjects, as well as to increase the sample size to detect significant differences. Since the changes in the ISI value were significant, further studies could follow the ISI value more frequently. For example, the subjects could independently fill in ISI questionnaires on a daily basis, which would be a cost-effective way to monitor the effects of FCCA treatment on sleep quality.

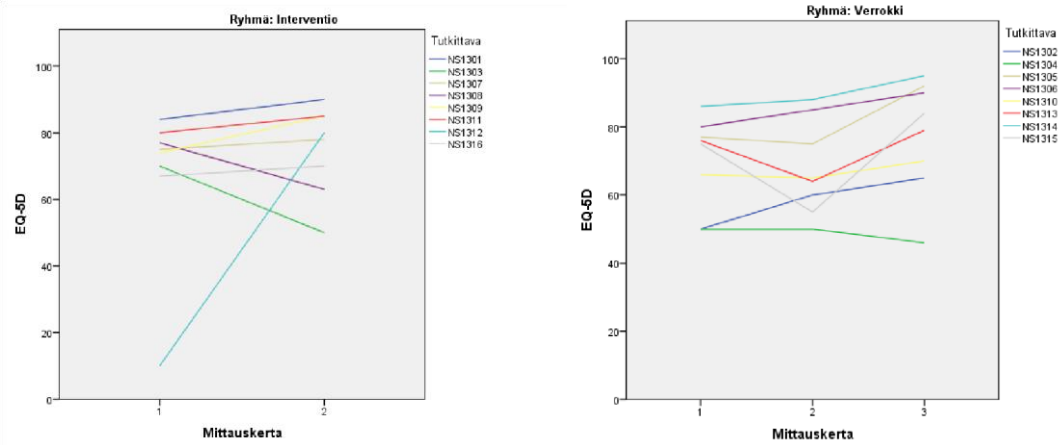


Figure 2. EQ-5D scale values by study patient and group

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