

## FITNESS STUDY /

Randomized double-blind study with CV-HC \* application in Bad Neuenahr / Germany (pilot study)

### Introduction

According to literature and experimental findings, the therapeutic effect of CV-HC can primarily be seen in a longer application. This is especially evidenced by the CV-HC customer field study with a one-year application period. On the basis of experience in individual cases and theoretical considerations, however, there was the hypothesis that positive effects in the area of fitness-relevant performance parameters could already be demonstrated after a single 8-minute application.

**Objective:** As part of a test event of the DSSV (German Solar and Fitness Studio Association) performance parameters should be checked. The focus was on a parameter known as a balance measurement (BBM = Body Balance Measure) using a newly developed device, as well as some classic parameters of fitness status: lactate, blood gases, vital signs.

methods

**Design:** The study was a prospective, randomized, double-blind study that was carried out on a single day in a fitness studio (with 3 verum - \*\* or placebo devices). Inclusion criteria were all fitness enthusiasts from the age of 14. Before the start of the treatment, the criteria parameters were recorded and a fitness training was carried out afterwards. Further measurements were taken after this fitness activity before the CV-HC therapy, after the CV-HC therapy and after a second fitness activity (41 placebo, 35 verum).

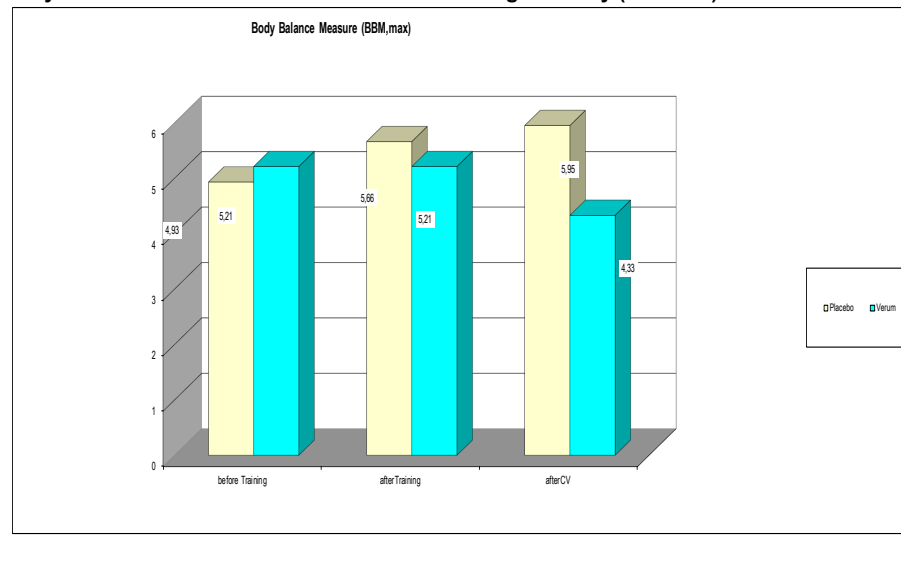
The criteria of the effect were mainly the so-called BBM measure (0 - 9: 0-2 = normal range, o.B .; 3-6 slight to moderate tension; 7-9 = strong tension). The next most important criterion was the lactate measurement as a measure of the (aerobic) performance of the muscles.

**Subjects collective:** 75 subjects (50% male; mean age = 41 years, standard deviation 13 years) were available for the analysis. There was no significant difference in age, gender and diagnosis between verum and placebo. With 27% (even 44% among the first diagnoses) the stated (!) Joint diseases were the most common, followed by metabolic diseases (14%), psycho-vegetative diseases (13%) and cardiovascular diseases (11%), of which approx. 54% stated that they were under medical treatment for this reason.

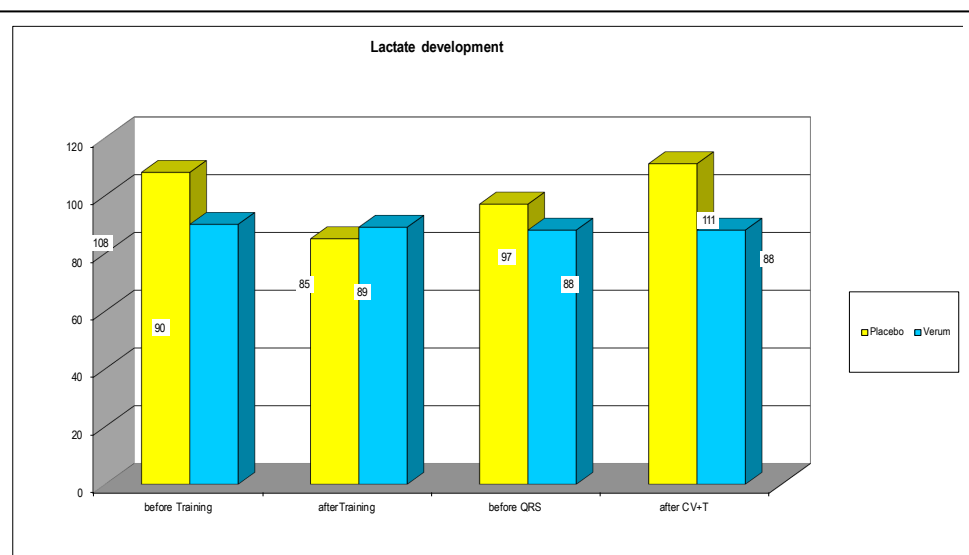
## Results

Results in the criteria: The general condition in the collective was 2.4 on average between good and satisfactory. The same applies to 2.3 for the physical and psychological state of mind. Despite a mean value of 2.3 for pain (2 = occasionally mild, 3 = temporarily significant), 27% stated that they sometimes or even often had significant to severe pain. In terms of performance, the participants rated themselves as somewhat better than average, but in terms of subjective fitness status, which is made up of four variables, as almost good. With regard to acute health restrictions (incapacity to work, infectious diseases), the collective was significantly below the population average. There were also no significant differences between verum and placebo.

**Fig. 1: Change in BBM after training and after CV-HC. Only with verum does the BBM value decrease significantly ( $P < 0.001$ ).**



Comparative evaluation: In the two most important parameters BBM and lactate, there was an improvement only in the verum group. (see Fig. 1). The number of participants who were within the normal range with their BBM had dropped from 17 to 10% in the placebo group. On the other hand, this rate rose from 15 to 30% in the consumption group, so it doubled.



**Fig. 2: A lactate increase after the 2nd training takes place only in the placebo, not in the verum group. Advantage verum significant ( $P < 0.01$ )**

Lactate development in the verum group increased after training and decreased marginally before CV-HC, but remained constant after CV-HC + 2nd training in contrast to placebo (= greater distance from the anaerobic threshold;  $P_{O2} < 0.01$ , Fig. 2), The course of the respiratory rate pointed - albeit less clearly - in the same direction. The other parameters  $O_2$  and  $pO_2$  partial pressure as well as pulse show no clear results.

## Discussion

Delaying the lactate increase after CV-HC makes it interesting for fitness programs, because a performance program can only be carried out with advantage until the anaerobic threshold is reached. The same applies to the respiratory rate. The improvement in the BBM is remarkable and encouraging, but of course needs further investigation.

The differential diagnostic evaluation of the other parameters (pulse, partial pressures) would probably have required a design in which the performance requirements were generally set higher. In both groups, the training improves the variable TOP (= state of mind + performance + pain). The TOP course of the placebo group appears to be more favorable, if not significant.

## Credentials

**Acknowledgments:** The author would like to thank the following people and institutions for their help with this study: DSSV association chairman for providing the premises, family Neumann for considerable help in carrying out the experiment; Ms. Dumitrescu, drake for organization and implementation.

**Participants:** Thomas Neumann, Erpel / Rhld. (Idea and concept of the study, test sheet, test plan, organization, implementation of the study), Dr. med. Faber, Erpel / Rhld. (Medical examinations); Prof. Dr. Rainer B. Pelka, Munich (test sheet development, test plan, monitoring and auditing, statistical analysis).

\* CV-HC = Cellvital Homecare I \*\* Verum: real form of treatment

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## **INSOMNIA/**

### **Double-blind, placebo-controlled study**

#### **Introduction**

Insomnia is characterized by the inability to fall asleep, or to sleep through for a reasonable period of time, so that fatigue is a constant companion. Insomnia can occur with illnesses, especially if they are associated with painful symptoms. However, more common causes are psychological conflicts and stress.

Despite somewhat different findings, it is certain that over 50% of adults in the western world between 30 and 65 years suffer from insomnia more frequently. Approximately 6% therefore need medical help. Older people are affected more often than younger people. The indirect costs resulting from insomnia are difficult to estimate. The cost of medication in Germany alone is at least DM 3 billion a year.

As with all chronic developments, appropriate therapies are complex and not as clear in terms of effectiveness and efficiency as with most acute diseases. In addition to the certainly essential concepts of a "better" way of life, therapies based on magnetic fields could have a favorable influence on the course of sleep, despite the fact that opposite effects are also reported at higher frequencies or field strengths.

It has now been shown that magnetic fields have an impact on the pineal gland. This particularly magneto sensitive organ converts environmental information into an endocrine message, which leads to the release of melatonin. In addition, she is involved in the regulation of the various sleep phases, especially in the circadian rhythm of REM sleep (Sandyk 1997, 92, 93). There is stringent evidence that amplitude-modulated EM fields significantly increase the willingness to sleep and extend the duration of certain sleep phases (Lebet 1996, Reite 1994).

The aim of the study was to verify the hypothesis that low-frequency ( $\sim 4$  Hz) pulsating MF with low field strengths ( $= 5 \mu\text{T}$ ) are able to reduce sleep problems, due to their positive influence on the blood circulation system, especially through a Improve blood flow.

#### **Methods**

A PEMF device with a 3 Hz field (non-sinusoidal) was randomized in a double-blind study in 101 test subjects (55% female) between 16 and 78 years with primary sleep disorders, mostly with initardia (difficulty falling asleep: 59%) or Pleisomnie (sleep disorders: 40%) used for 4 weeks (51 placebo, 50 verum). There were no significant differences between the test groups with regard to diagnosis, age and gender. Exclusion criteria were acute infections or serious organic diseases in the previous 12 months and the use of certain medications.

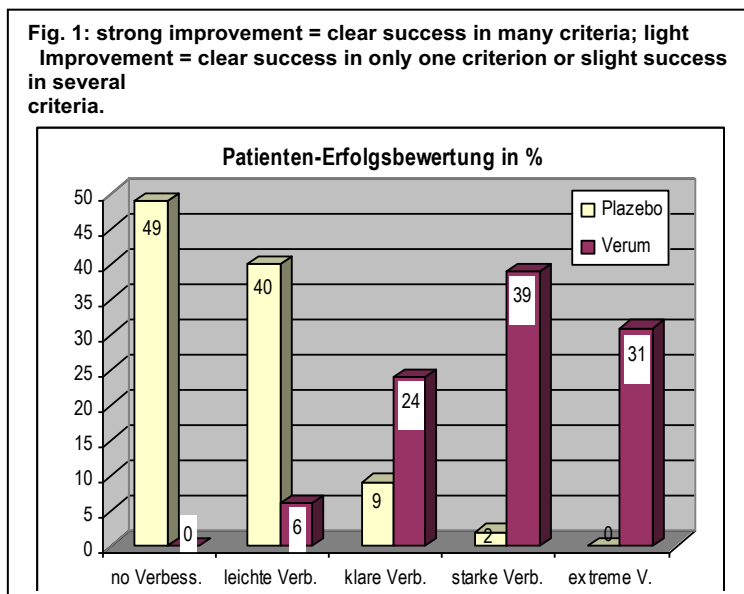
A medical examination was carried out before and after the four-week therapy. Success criteria were the sleep intensity, the frequency of sleep interruptions, the tiredness after getting up, the sleepiness during the day, concentration problems and existing headaches during the day. The patients performed the evaluation on an 11-point scale (0 = not at all, 10 = extreme).

The U test, the Wilcoxon test, the t test and the  $\chi^2$  test were used as statistical tests.

## Results

Compliance and complications: 5 patients were eliminated during the study (1 verum group, 4 placebo). However, her resignation was not visibly related to the therapy. The remaining 96 patients (47 placebo, 49 verum) were included in the analysis. No complications were known.

Findings: All criteria in the verum group improved highly significantly ( $P < 0.001$ ), the difference in course from the placebo group was also highly significant. This is particularly evident in the summary scale of the symptoms of sleep disorders (see Fig. 1).



The difference between placebo and verum could hardly be clearer. While only a few patients (10.5%) showed at least a clear improvement in the placebo group, this was 94% in the verum group. There was no improvement in almost 50% of the placebo group. The vital functions determined before and after the treatment were within the normal range in both groups.

## Discussion

The results found support the findings of previous studies on the effectiveness of ELF fields in sleep disorders. They demonstrate a positive effect of suitable, therapeutically used magnetic fields for symptoms that are difficult or inadequate to date or can only be treated with side effects, such as insomnia. The magnetic field therapies examined had no undesirable effects here.

credentials

Participants: Dr. Markus de Moliere (co-development of the test sheet and implementation of the investigations including data collection); Prof. Dr. Rainer B. Pelka (concept and design development, monitoring and auditing, biometric analysis).

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## **DISC PROLAPSE**

### **Pilot study in patients with intervertebral disc disorders**

Whole-body magnetic therapy measures are becoming increasingly important in the treatment of pain in the muscular and skeletal areas. At the orthopedic clinic of the Edith Stein specialist clinic in Bad Bergzabern / Germany, 25 patients with intervertebral disc disease (CV-HC) were involved in the rehabilitation treatment measures, specifically 19 men and 6 women between the ages of 31 and 74 years. Essentially, it was a question of intervertebral discs in the lumbar spine, with segments L2, L3, L4 and L5 once, segments L3, L4, L5 and S1 twice, segments L4 / L5 / L1 once, and segments L4 / L5 eleven times and L5 / S1 were affected nine times. In addition, there was a herniated disc at HWK six and seven.

Surgical intervention was already necessary in eight of the patients, in three of which there was a so-called post-nucleotomy syndrome.

At the time of starting CVHC treatment, 16 patients were taking pain reliever medications, particularly NSAIDs. Of the 25 patients observed and treated, all complained of pain in the spine that had lasted from two months to 30 years.

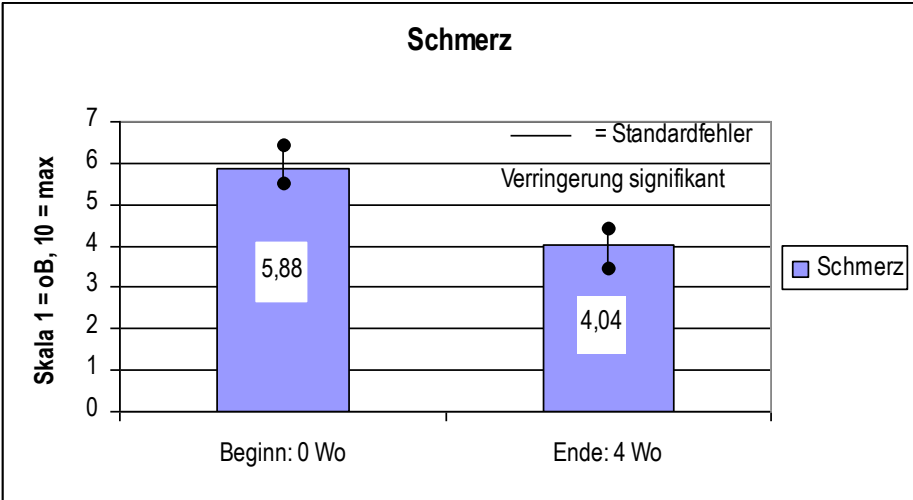
The treatment was usually given twice a day, i.e. in the morning and in the afternoon, with a step load in the morning between 5 and 10 and in the afternoon between 2 and 5. In addition to the mat treatment, the pillow treatment was also used, especially if the symptoms did not improve after one week ,

Under CV-HC therapy, the mean pain intensity values of the treated patients decreased from 5.9 to 4.04 on the 10-valued pain scale.

Overall, based on our initial experience, it can be assumed that the CV-HC is a very important piece of the mosaic in the treatment of chronic diseases in the musculoskeletal area. A device is available here. which meets the requirements of a modern therapy device in its handling and application. The application on the patient is very simple, the user guidance of the CV-HC control unit is clear, so that the patient can operate the device himself.

Overall, we were able to achieve significant relief from a small number of patients with chronic spine patients.

Fig. 1: Changes in the pain intensities of the treated patients under CV-HC





# Untersuchungen über akute Effekte von pulsierenden Magnetfeldern auf die Erholung von physischer Belastung an Thermen-Gästen – Eine Pilotstudie

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## Einleitung

In der humanmedizinischen Fachliteratur über Magnetfeldtherapie wurden bislang meist Studien an Patienten mit klar umschriebenen Krankheitsbildern publiziert. Metaanalysen (1, 2) fundierter Untersuchungen ergaben, dass Schmerzminderung bei degenerativen Gelenkerkrankungen und Förderung der unkomplizierten Frakturheilung als gesichert angesehen werden können. Weiters kann der analgetische Effekt am Bewegungs- und Stützapparat eine Steigerung der Motilität und des Allgemeinbefindens nach sich ziehen (3). Aber auch bei gravierendem neuropathologischem Geschehen war ein solcher feststellbar (4). Darüber hinaus existieren therapeutische Arbeiten mit pulsierenden Magnetfeldern bezogen auf viele andere Erkrankungen, wobei in der Mehrzahl der Fälle Erfolge zugunsten der Verumprozedur verzeichnet werden konnten; dabei handelt es sich allerdings vielfach um nicht replizierte, des öfteren auch mit versuchstechnischen und/oder statistischen Mängeln versehene Untersuchungen. Zweck der vorliegenden, doppelblind durchgeführten Studie war es, eventuelle Unterschiede in Dauer und Art der Erholung nach kurzzeitiger Belastung bei Schein- bzw. Verummagnetfeldexposition festzustellen. Als Probanden rekrutierte man auf freiwilliger Basis „gesunde“ Tagesgäste (keine Rehab-Patienten) der Park-Therme Bad Radkersburg mit einem Alter zwischen 39 - 83 Jahren, die Randomisierung der Zuordnung zur Verum- bzw. Placebobehandlung erfolgte alternierend gemäß der Reihenfolge des Eintreffens der Interessenten beim Untersuchungsteam nach Lautsprecherdurchsage. Der Stresszustand sollte anhand von 12 Elektrolyt- und Blutgasparametern bewertet werden (Clinical Stress Assessment Methode). In der Literatur finden sich keine vergleichbaren Publikationen mit der hier gewählten Fragestellung über Einflüsse magnetischer Wechselfelder auf das Verhalten

von Stressparametern an „gesunden“ Personen, dies in zweifacher Hinsicht: Seit etwa 40 Jahren bestehen keine klaren Aussagen über magnetfeldbedingte Stressauslösung bei Netzfrequenz (50/60 Hz) am Menschen; zum zweiten ist festzuhalten, dass zwar Berichte über Auswirkungen solcher Felder auf die klassischen Stresshormone (Katecholamine, Glucocorticoide) bei anderer Zielsetzung der Untersuchungen existieren, jedoch keine mit der hier verwendeten Parameterkombination (5, 6). Wegen der Kurzzeitexposition eines Durchschnittskollektivs in speziell gepulsten Magnetfeldern handelt es sich vorliegend um eine Pilotstudie. Noch immer stehen viele Wirkungsmechanismen als Erklärungsmodell bei Magnetfeldexposition zur aktuellen Diskussion; nachgewiesenermaßen spielen dabei induzierte Wirbelströme, der Hall- und der magnetohydrodynamische Effekt eine wesentliche Rolle. Auf zellulärem Niveau gesehen stellt die Zellmembran mit ihren Ionenkanälen (gap-junctions) den Hauptangriffspunkt des angelegten pulsierenden Magnetfeldes dar; weiters werden Veränderungen im extra-/intrazellulären Milieu und die Aktivierung von Botenstoffen in Betracht gezogen. Den im Folgenden beschriebenen Messungen im doppelten Blindversuch wurden zwei Prämissen zu Grunde gelegt:

1. Eine einzige Exposition auf einem matratzenartigen Applikator kann den Allgemeinzustand gesunder Durchschnittspersonen in entspannter Lage nicht verbessern.
2. Daher wurden auf freiwilliger Basis Gäste einer Kurtherme vor der Magnetmattenexposition körperlich belastet, um eventuelle Unterschiede in der Dauer und Art der sowohl unter Placebo - als auch unter Verumbedingungen stattfindenden Erholung feststellen zu können.

Dazu wurden alle Probanden zum ersten Mal 3 Minuten nach Absolvierung einer kurzen sportlichen Belastungssituation und zum zweiten

## BODY BIOELECTRICITY

Ion displacement in the human body due to the influence of electromagnetic fields (double-blind study)

A living organism is unthinkable without bioelectricity. All physiological, biochemical and informative processes in living organisms are linked to electrical charges.

The free-moving electrons form electrical currents in the body (stimulus, displacement or eddy currents), but the free-moving ions (ion migration) are known to have functional significance as a substance (e.g. for membrane potential, strength of electrolysis as well as acid and base balance):

H<sup>+</sup> = carrier of the acidic properties (pH),

OH ions = carrier of the basic (alkaline) properties (pH)

K<sup>+</sup> ions = causes cell membrane potential to decrease (stimulates vagus)

Na<sup>+</sup> ions = mainly involved in membrane potential formation

Ca<sup>2+</sup> ions = "sympathetic ion", influences regulation of cellular processes

By shifting essential ions in the body, important processes such as B. blood pressure, respiration (redox process), digestion, circulation, hormone control, entire smooth muscles, urogenital apparatus, waking and sleeping conditions can be influenced favorably. With weak stimuli, which are not able to trigger action potential, further effects (e.g. synergistic) can be caused, also (with the participation of acetylcholine) a capillary dilation.

For example, the following dominant free-moving ion concentration changes were found in the blood from the turkey (roughly comparable to human blood) after 2-week daily 2-hour CV-HC whole body treatment as mean values [40 treated animals, 40 control animals; measured with the atomic absorption measuring device Perkin-Elmer AAS 4100] determines:

	Na <sup>+</sup> [mg/l]	K <sup>+</sup> [mg/l]	Ca <sup>++</sup> [mg/l]
Treated pets (P)	3815	126	123
Control group (K)	3593	157	111
Differency (Δ)	+ 222	- 31	+ 12
Differency in (%)	+ 5,8	- 24,6	+ 9,8

It has been shown that under PEMF the generation of ion transport by electromagnetic forces is of this magnitude, regardless of the bronchial molecular motion. The latter has no binding power and therefore generally no influence on the ion transport. It was also determined that the maximum possible magnetic field flux density under PEMF generates 54 times less current density than the stimulus threshold of excitable cells. It is therefore not possible to speak of harmful side effects here, but therapeutic effects can be achieved by appropriate ion shifts in the human body.

## **Extract from hair loss and regrowth after the application of the pulsating electromagnetic field**

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This type of experimental study compared to placebo, which was carried out on healthy male and female subjects, demonstrates the positive biological effect of the pulsating electromagnetic field in combination with essential oils for hair loss and regrowth. This study lasted 26 weeks and was carried out in accordance with the regular treatment schedule. 83% of the subjects showed a decrease in hair loss and 20% hair growth over the base in 53% of the patients.

This process showed no side effects or unwanted reactions. Histological examinations correlate with clinical studies. Simultaneous immunohistochemical examination showed an increase in the proliferation index. If the indicator of cell proliferation Ki67 increases, the mitosis is hardly visible in the histological examinations. The reason for this phenomenon is the electrophysiological effect of the resting hair follicle.