EVALUATION OF THE EFFECTIVENESS OF A SLEEP REPAIR SYSTEM (THERAPEUTIC MATTRESS) IN THE REDUCTION OF MIGRAINE ATTACKS AND IN THE IMPROVEMENT OF SLEEP QUALITY

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ABSTRACT

A randomized clinical trial was conducted in twelve individuals to evaluate the therapeutic efficacy of a mattress with magnet elements and far-infrared emitting units, measured in the reduction of migraine attacks, insomnia, cramps and improvement in the circulation of the lower limbs. The evaluation was randomized using a placebo mattress (no therapeutic properties) and an active mattress (with numerous magnets and far-infrared emitting units). After 45 days of use of the therapeutic mattress, the effect with regard to migraine attacks was determined through a sensory evaluation and compared to the beginning of the study and the sleep quality was evaluated, using PSQI (Pittsburgh Sleep Quality Index). According to the results obtained in the sensory evaluation by clinical efficacy, the active mattress showed a tendency to be more effective in reducing the frequency and intensity of headaches, when compared to the placebo mattress, without statistical significance ($P>0.05$). This is probably due to the relatively small number ($n=12$) of study participants. In the evaluation of the mattresses, a significant improvement in sleep quality was identified and when the therapeutic was compared to the placebo mattress, the superior efficacy of the therapeutic mattress was statistically significant. With PSQI>10, the initial was a mean of 33, falling to 8 (eight) in the placebo group and to 0 (zero) in the group that used the therapeutic mattress ($P<0.05$), 45 days after the evaluation. This demonstrates that the use of the therapeutic mattress (magnets + far-infrared emitting units) has a tendency to decrease the frequency and intensity of migraine headache attacks and definitely provides a beneficial effect on improving sleep quality. This improvement in sleep can bring important clinical repercussions both in the quality of life and in the prevention and treatment of chronic degenerative diseases.

KEYWORDS: Magnets, magnetotherapy, insomnia, migraine headache.

1. INTRODUCTION

Migraine is the main and the most common type of primary headache related to sleep disturbance. This disease causes severe headaches, usually unilateral, whose symptoms are photophobia, phonophobia, nausea, vomiting, mood disorders and sensory changes. Migraines are closely linked to sleep and can occur during nighttime sleep, after a brief period of sleep during the day or after waking. These problems occur three times more in patients with migraine. Migraine attacks can be triggered by lack of sleep or oversleeping. However, it improves or disappears after a restful sleep period.

Originally, sleep is regulated by the circadian process, which involves a virtual internal clock, located in the suprachiasmatic nucleus of the hypothalamus. Its function is to regulate the daily cycle of approximately 24 hours, in order to regulate sleep time and consolidate the sleep-wake cycle.

Sleep disturbances, such as insomnia, apnea, snoring, cramps, somnambulism, among others, bring with them several repercussions for humans, causing loss of quality of life, autonomic dysfunction, decreased professional or academic performance, increased incidence of psychiatric disorders and reduced vigilance, with personal safety damage and, consequently, an increase in the number of accidents. People who sleep poorly are likely to have a higher risk of morbidities, shorter life expectancy and early aging.

Endowed with therapeutic properties related mainly to pain reduction, health maintenance and the process of cellular rejuvenation, the magnets have been used for this purpose for centuries, proving the presence of a magnetic field in humans capable of balancing the organic functions of the organism.

Over time, this finding has evolved, generating alternative methods of treatment based on the use of magnets, as well as its incorporation into high technology products, such as therapeutic mattresses. When associated with other elements, as the far-infrared emitting units, the magnets found in these products further enhance their benefits in maintaining the sleep process.

Since both insomnia and migraine are the most intensified disorders in recent years, causing a significant impairment in the quality of life of the general population, it becomes easy to understand the reasons that contribute to the therapeutic power of magnets regaining

their importance, especially due to the benefits generated by the reduction of symptoms associated with these disorders. International research results, as well as studies conducted in Brazil reveal how products, represented in most cases by therapeutic mattresses can help people affected by sleep disorders, highlighting the relevance of approach to a topic with potential for new discoveries and discussion of effective actions in the treatment of these and other diseases.

2. MATERIAL AND METHODS

The objective of the present study was to evaluate the efficacy of a therapeutic mattress equipped with magnetic activity and emission of far-infrared rays. The reduction in the frequency and intensity of migraine pain and sleep quality level, based on the Pittsburgh Sleep Quality Index (PSQI), was analyzed 45 days after and compared to a placebo mattress with no magnetic activity and no emission of far-infrared rays.

Original documents relating to subsequent items are archived in accordance to the Kosmoscience® Quality Procedures under the unambiguous identification BAP003-13. The study BAP003-13 was planned and conducted according to the determinations of Resolution 196/96 of the National Health Council, on the Guidelines and Norms Regulating Research involving humans. From the voluntary database of Kosmoscience® volunteers, 15 volunteer candidates were pre-selected.

The hypothesis of this study is that after 45 consecutive days of use of a mattress with therapeutic properties could benefit the quality of sleep and help reduce symptoms related to sleep disorders, such as migraine. To evaluate the efficacy of the product 45 days after, the same volunteer first used the placebo mattress, followed by the active version during the same period.

The PSQI was used to evaluate sleep quality, providing an index of severity and nature of the disorder, through 19 self-administered questions, grouped into 7 components, with weights distributed on a scale of 0 to 3.

In addition, a visual analogue scale was used to assess pain and its changes with placebo or therapeutic mattress intervention. This sensorial analysis allows evaluating perceived efficacy, with notes related to each question, according to the following range:

A) Notes 1 and 2 ("*I did not notice any improvement*" or "*I did not notice improvement*"): volunteers did not realize the effectiveness of the product;
B) Note 3 ("*I'm not sure I noticed improvement*"): volunteers were not sure that they realized the effectiveness of the product;
C) Notes 4 and 5 ("*I perceived the improvement slightly*" or "*I clearly saw the improvement*"): volunteers perceived some degree of product efficacy.

The therapeutic mattress used in this study was provided by Nipponflex. The mattress used in this study contains, among other technologies, the rabatan, a high polyurethane profiling, vulcanized to approximately 180 degrees Celsius, with numerous acupressure points stiffened, similar to the tips of a masseur's fingers, providing a relaxing self-massage. The technologies related to the FIR NG and FIR Bioceramic, promote an emission of far-infrared rays, as well as magnets (barium ferrite magnets), which can emit approximately 800 Gauss each of magnetic energy.

Aiming to establish the benefits of therapy with far-infrared ray and magnets in the reduction of symptoms caused by migraine attacks and sleep disorders, this article uses as analysis guidelines:

- Identify the central issue, in addition to its description factors and keywords;
- Define the criteria for inclusion or exclusion of research, according to the data available online, or specific books on the subject;
- Organize the most important information;
- Select the material to be used from the careful evaluation of your data;
- Establish what information from the data search described in the results are relevant for the elucidation of the subject in question;
- Describe conclusively how the available information is capable of contributing to a wide discussion on the subject.

This paper is based on the presentation of the results of a randomized trial comparing the action of a therapeutic mattress to a placebo mattress over a period of 45 consecutive days. In order to highlights the importance of magnetic therapy for health literature review was permormed. The review was based on studies contained in the LILACS (Latin American and Caribbean Health Sciences Literature), SciELO (Scientific Electronic Library online) and PubMed (National Center for Biotechnology Information – NCBI, US National Library of Medicine) data bases, as well as books on the subject, which trace a historic evolution of this alternative treatment method, since its discovery.

3. RESULTS

Divided into four different topics, research entitled *Evaluation of the efficacy of a therapeutic mattress in improving sleep quality and reducing migraine* evaluated the efficacy of a therapeutic mattress in improving sleep quality and reducing the symptoms of the disease in its first stage, defined as "Study 1", related to migraine and insomnia, when compared to a placebo mattress, 45 days after.

The active mattress versus placebo mattress ratio was based by the assessment for clinical and perceived efficacy; in addition, the PSQI was used as a subjective

measurement tool in clinical research in order to assess the sleep quality that is related to the means of an index of severity of the disorder and origin of the disorder. It is a self-administered questionnaire, which contain 19 questions, answered by participants who first used the placebo mattress, followed by the therapeutic, both for 45 days.

Table 1. Total PSQI score. Volunteers with migraine.

Voluntary Code	Initial	Placebo Mattress (After 45 days)	Active Mattress (After 45 days)
BAP003-13-01	10	6	3
BAP003-13-04	8	3	4
BAP003-13-05	7	7	6
BAP003-13-06	3	4	2
BAP003-13-08	9	9	6
BAP003-13-09	5	2	2
BAP003-13-10	4	4	0
BAP003-13-15	11	5	5
BAP003-13-16	11	4	2
BAP003-13-19	8	6	2
BAP003-13-22	13	13	5
BAP003-13-23	11	5	3
Mean	8	6	3
% Voluntary with PSQI between 5 and 10	50	50	33
% Voluntary with PSQI between > 10	33	8	0

Table 2. Summary results of the statistical analysis. P. value.

Initial vs. Placebo mattress	Initial vs. Active mattress	Placebo mattress vs. Active mattress
0.0207 (Significant)	0.0025 (Significant)	0.0090 (Significant)

Table 3. Data obtained in the clinical evaluation.

	Migraine (frequency)			Pain (type)			Intensity		
Voluntary Code	Initial	After using the placebo mattress	After using the active mattress	Initial	After using the placebo mattress	After using the active mattress	Initial	After using the placebo mattress	After using the active mattress
BAP003-13-01	Every day	Twice / No	No	Painless	Painless	Painless	–	–	–
BAP003-13-04	Three or more times / No	Beweekly	No	Headache	Headache	Headache	8	6	8
BAP003-13-05	Once/ No	No	No	Headache	Painless	Painless	8	–	–
BAP003-13-06	Every day	Once/ No	No	Headache	Headache	Painless	9	7	–
BAP003-13-08	Three or more times / No	Twice / No	Twice / No	Headache	Headache	Headache	7	4	3
BAP003-13-09	Once/ No	No	No	Headache	Painless	Painless	9	–	–
BAP003-13-10	Twice / No	Twice / No	Beweekly	Headache	Headache	Headache	8	8	4
BAP003-13-15	Every day	No	No	Headache	Painless	Painless	8	–	–
BAP003-13-16	Beweekly	Beweekly	No	Headache	Headache	Painless	9	5	–
BAP003-13-19	Once/ No	Beweekly	Beweekly	Headache	Headache	Headache	8	4	2
BAP003-13-22	Three or more times / No	Twice / No	Twice / No	Headache	Headache	Headache	10	6	3
BAP003-13-23	Three or more times / No	Twice / No	Once/ No	Headache	Headache	Headache	7	7	4

All three parameters described above were not statistically significant when comparing the active mattress with placebo (P>0.05); No: without migraine attacks.

The research was attended by with the participation of 12 volunteers, of both genders, with mean age of 41 ± 13 years. At first, 50% had poor sleep quality and 33% had sleep disorders. After the placebo mattress use for 45 days, it was found that 50% continued with poor sleep quality, but with a decrease in the percentage of sleep disorder from 33% to 8%.

In relation to the therapeutic mattress, among the 50% volunteers who presented poor quality sleep at the beginning of the study, only 33% remained without improvement 45 days after using the therapeutic mattress (Table 1); Of the 33% who had sleep disorder at the beginning, none presented this disorder during the 45 days of treatment (Table 1). Interestingly, 60% of volunteers with poor sleep quality or sleep disorders indicated good quality after use of the therapeutic mattress. The overall PSQI scores obtained at the start of the study were statistically different when compared to the scores obtained 45 days after of use of the placebo mattress and 45 days after of use of the active mattress (Wilcoxon Matched-Pairs Ranked Test, with a 95% confidence interval). It was also evaluated by the same statistical methodology, the significance between the results obtained between the placebo mattress and the therapeutic mattress. The summarized result of the statistical analysis with their respective values of "P" was presented in Table 2.

According to the result of the statistical analysis it was possible to conclude that:

1. In the group of volunteers who presented with migraine, the use of placebo mattress and the active mattress (both for 45 days) improved sleep quality. This can be evidenced by the significant reduction (P <0.05) in the scores of the overall PSQI score after the use of the mattresses in relation to the initial condition.

2. When compared to the placebo mattress with the

active mattress, the active mattress showed superior efficacy in improving sleep quality when compared to the placebo mattress. This can be evidenced by the significant difference ($P < 0.05$) between the scores of the overall PSQI; the active mattress was statistically better than the placebo mattress.

In order to go further, in the sensorial evaluation for clinical efficacy, we evaluated the frequency in which the volunteer presented migraine. All volunteers were also questioned about the occurrence and intensity of pain, and were asked to respond to a questionnaire aligned with the Visual Analog Pain Scale (Table 3).

According to the results, 45 days after using the placebo mattress, 58% of the volunteers had reduced frequency and 25% became asymptomatic, that is, they did not present any migraine symptoms. Due to the use of active mattress during 45 days, 50% of the volunteers presented reduction of migraine frequency and 50% became asymptomatic.

At the start of the study, 92% of the volunteers reported feeling headache; 45 days after using the placebo mattress, 27% of the volunteers, who reported feeling headache at first, no longer presented the symptom after the use of mattress, with a reduction of 29% in pain intensity.

After 45 days of active mattress use, 45% of the volunteers, who reported having a headache at the beginning of the study, stopped presenting the symptom after the mattress was used, registering a 52% decrease in pain intensity, besides to sleep and migraine, swelling in the legs, leg fatigue, body relaxation.

The results recorded allow us to evaluate that in relation to:

- **Swelling in the legs** - 100% of those who presented this symptom at the beginning of the study noticed a reduction with the use of the therapeutic mattress and 71% during the use of the placebo;
- **Tiredness in the legs** - 100% of those who presented this symptom at the beginning of the study noticed a reduction with the use of the therapeutic mattress and 89% during the use of the placebo;
- **Body Relaxation** - 100% of the researches noticed an improvement in the body relaxation provided with the therapeutic mattress, while 75% noticed the same with the placebo version.

4. DISCUSSION

Protected by a magnetic field that acts against some harmful forms of radiation, like cosmic rays and the solar wind, the Earth can be considered a powerful magnet, capable of influencing all life forms[3]. This includes humans, affected by constant changes in the earth's magnetic field, caused by sun exposure, lunar motions and electric currents[1].

Like the Earth, people have their own magnetic fields[36]. Present in all cells, with two poles (positive and negative), this polarity keeps the organism in balance, while the brain and the central nervous system are governed by the positive pole, the peripheral organs and tissues rely on the negative polarity[1].

This is one reason why magnets - better known as natural imams - offer great benefits, especially to health. However, it is interesting to note that, even in the face of proven facts, its therapeutic effects are still questioned. Few know, for example, that this is a millenarian technique, practiced more than 3,500 years ago, initially by Egyptians, Chinese and Indians[15].

The name "magneto", however, came much later. It refers to a story related to Thessaly, situated in the east of northern Greece. In this region is Magnesia, a city in which Pastor Magnus - a member of the local native tribe - noticed during a walk on Mount Ida on the island of Crete that something in the ground strongly attracted the tip of his rod and the parts of iron of their boots. When digging the earth, found a stone capable of attracting iron[14].

Since then, the therapeutic properties of the imams or magnets have been continually searched until the early middle Ages. At that time, European alchemists began to call it an imam's stone, attributing its medicinal benefits mainly to pain relief, health maintenance and the process of cellular rejuvenation. These studies continued until the sixteenth century, when the Swiss physician Philippus Aureolus Paracelsus (1493-1541) finally decided to use magnets in anti-inflammatory treatments, suppurative wounds, ulcerations and conditions in the uterus and intestine[43;29;16].

The results of years of research, however, became public only in 1600, the year in which William Gilbert of Rochester (1540-1603) - renowned doctor and president of the Medical College of the reign of Queen Elizabeth I - published the book "*The Magneto*", describing the scientific methods of magnetism. Through his work, Rochester is considered the first to discover that the Earth is a great magnet[41].

The Magneto was so innovative that it helped Newton to counter the mechanistic theories of his day, which argued that force was only a result of material bodies in contact. More than that, he assisted Michel Faraday - an English physicist - to prove, at the end of the 18th century, that all matter is magnetic, being attracted or repelled by a magnetic field, a fact that made him the founder of biomagnetism and magnetochemistry[13].

Faraday's proof made magnetism to be defined as the result of the combination of some natural substances with electric currents, and could be produced either by a moving charge or by an electric current submerged by force in front of Magnetic fields[13].

Published in 1766, the work of the Swiss doctor Frederik Franz Antón Mesmer also reinforced the high

healing power of the imams. According to him, all animals, including man, have a similar inner strength, called "animal magnetism", capable of healing the organs in which it is applied[13].

Studies on the properties of magnets and electromagnetic fields have never really ceased. The discovery that everything on Earth can be affected by this phenomenon has generated numerous findings, especially in the medical field[8].

One of them refers to the pineal gland, located near the center of the brain. Studies indicate the presence of magnetite crystals inside of the pineal gland, which is responsible by melatonin production. The pineal gland gains importance by controlling, through its hormone, some metabolic functions, such as maintenance of the sleep-wake cycle, reactions to external stimuli and stress and production of free radicals, influenced by the daily changes of the Earth's magnetic field[1].

Another consideration is that all the tissues and organs of the body have specific magnetic pulses, now known as biomagnetic fields, highlighting the importance of studies on the magnetic field for the maintenance of health and treatment of diseases[33].

Among the most recent discoveries on the subject, one of the highlights is Dr. Kyochi Nakagawa, considered the father of modern magnetotherapy, which ensures that many modern pathologies come from the Magnetic Field Deficiency Syndrome characterized by general malaise, Low energy, sleep apnea, circulatory problems, headaches, among others[26;27].

The justification, according to their statements, corresponds to a significant reduction of the magnetic field of the Earth, which until 500 or 1000 years ago, was 50% greater. This allowed man, in antiquity, to have a stronger immune system and more vitality. The diminution of this field, in turn, made human beings more easily fatigue, suffer from the symptoms of stress, develop respiratory problems and muscle pain[26;27].

In an article, Payne (1999) believes that magnetic fields have biostimulating, anti-inflammatory and analgesic action. For Takur (1995), magnet therapy is supported by natural laws for curing diseases, promoting health and quality of life for people[40;32].

Nowadays, it is not uncommon to find research promoted by companies, universities and scientific centers that seek to unravel new potentials of magnetism and its therapeutic capacity. According to Pittler *et al.* (2007), the magnets produce energy in the form of a magnetic field. The most commercialized type is the static magnet, in doses that vary in 30 and 50 mT, present in mattresses, pillows, insoles, bracelets, among other items of personal use[9;24].

To better understand the health benefits of magnets, first, it is important to know their physical properties. In simple terms, the magnets are composed of two magnetic poles (north and south), easily found at their ends, except for the disk-shaped magnets known as magnetic dipoles[4;10].

The identification of the poles is made from the suspension of the magnet, which aligns next to the North and South Pole geographically. For these poles to be determined, the magnet must be suspended by the center of mass and it will align approximately to the North and South geographic Pole, receiving equivalent nomenclature. Thus, the magnetic north pole should point to the geographic North Pole and the south magnetic pole to the geographic South Pole[4;10].

Specifically in health, these poles have their own electrical energy, leading them different therapeutic effects. According to Bhattacharya & Sierra (1994), while the North Pole corresponds to calm, the South Pole means energy, vitality. Thus, the North Pole fights pain, inflammatory and infectious processes. The South Pole, on the other hand, is indicated for atrophies, muscular weaknesses, fractures of bones and ligaments, osteoarthritis, among others[5].

Overall, the magnets act beneficially in the circulatory system, contributing to the relief of inflammatory pains and the regeneration of infected areas. As mentioned, the North Pole is therefore able to reduce pain and inflammation; exterminating pathogenic microorganisms; contribute to the reduction of certain types of tumors; attract red and white blood cells, decreasing infections; dissolve crystals, blood clots and fats; reduce fever and bleeding from wounds[5;22].

The South Pole, in turn, contributes to the increase of red blood cells; the flexibility of capillaries, veins, and hardened arteries; of the flexibility of organs and tissues, stimulating their functions; besides the strengthening of cardiac functions and fragile tissues[5;22].

Another advantage of magnet therapy over conventional therapy is the fact that it is safe, not harmful to health, low cost and without causing the side effects commonly caused by most medications[7].

For a long time, therapy with imams has evolved, offering new solutions for numerous pathologies. These treatment techniques are commonly known as magnetotherapy, low frequency magnetic field therapy (to enhance the body's natural defenses), high frequency magnetic field therapy (for cell restoration), permanent magnets (placed on different parts of the body) and electromagnetotherapy (pulsed magnetic fields)[34;37].

One of the most popularly known forms of magnetic therapy is the one that uses the power of magnets in different products. One of the first to offer this benefit were therapeutic mattresses, which now rely on other supportive technologies aimed at providing more effective results, especially in disorders that compromise sleep quality, which are increasingly common, causing innumerable health population[25;31].

One of the major sleep-related disorders is the insomnia, defined as a debilitating state due to the difficulty of initiating or maintaining sleep or by its compromised quality, even in a suitable environment[6;11;38;39].

According to the National Health Survey, by the Brazilian Institute of Geography and Statistics (IBGE), sleeping pills are used by about 11 million of Brazilians (7.6%), aged 18 years or older, who suffer of insomnia[2;18;19;20].

Considering this alarming index, it is important to highlight the benefits generated by the action of the magnets on sleep quality, especially when associated with other innovative discoveries. In the search *Evaluation of the efficacy of a therapeutic mattress in improving sleep quality and reducing migraine*, the comparative result between the efficacy of the therapeutic action of an active mattress with a placebo reveals a significant improvement, positively impacting the health of participants studied[28].

The same is true for migraine, a disorder that, according to the World Health Organization (WHO), already reaches 15% of the world population, ranking 10th among the most disabling diseases[17;23]. Characterized by episodes of headache, intolerance to sensory stimuli, nausea or vomiting and transient neurological symptoms or aura, its complete crisis involves four stages, known as prodromes, aura, headache and postdromes, capable of significantly compromising the quality of life of people affected[12;21;30;35;42].

Even as insomnia, migraine treatment most often requires the use of medications, which can trigger side effects or adverse reactions. Again, the results of the research on the efficacy of therapeutic mattresses, as mentioned, reinforce the benefits of magnetotherapy, raising important questions about the efficiency of its applicability in these currently so common disorders.

5. CONCLUSION

The results obtained by the research *Evaluation of the efficacy of a therapeutic mattress in the improvement of sleep quality and reduction of migraine,* although they have not presented significant statistical difference when compared in sensory evaluation for perceived efficacy, indicated that the therapeutic mattress showed a more effective tendency in reducing swelling, the sensation of leg fatigue, as well as providing a body relaxation in relation to the placebo mattress.

In the sensory evaluation for clinical efficacy, the results, in turn, demonstrate that the active mattress may be more efficient in reducing migraine episodes and the frequency and intensity of headache than the placebo mattress ($P > 0.05$). The lack of statistical relevance is possibly related to the reduced number of the sample ($n = 12$).

Importantly, both the active mattress and the placebo mattress provided a decrease in migraine, evidenced by the significant improvement in sleep quality. However, when compared to each other, the active mattress presented superior efficacy in improving sleep quality ($P < 0.05$), indicating the therapeutic benefits of magnets, especially when associated with modern technologies.

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