



Evaluation of Sleepm Biocrystal Pillow/Topper/Mattress in Clinical Trials using 20 Subjects to Test for Pain Reduction, Sleep Improvement, Stress Reduction and Improvement in Circulation for Clients with Diabetes over 3 Months

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Abstract

Biofeedback testing (4 hours fasting) using Quantum Biofeedback Analyzers has been done before and after 3 months of the Sleep M Biocrystals to test for improvement using the SLEEPM Biocrystals Pillow/Topper/Mattress from SLEEPM in Markham, ON. Canada. These tests were complimentary for participants. This Biofeedback Testing method has been correlated with CBC Blood tests in previously published research papers by Prof. Dr. George Grant, Ph.D. Participants who were not using any medications given preference to avoid data accuracy. However if necessary, we selected participants who use up to 5 medications (including OTC and Rx).

Keywords: Pain Reduction; Stress Reduction; Sleep Improvement

Introduction

Sleepm Biocrystals and Thermo therapy in recent times has been considered as one of the important non-pharmacological treatment strategies in medical practice. It has been used in the medical science for medical (pain) therapy in physical therapy services and also found to be very beneficial in sport injury. The physiological benefits of Biocrystals/thermotherapy involve pain relief, increased blood flow, oxygen delivery, metabolism and elasticity of connective tissue extensivity. There is an evidenced based greater pain relief and disability in patients with chronic musculoskeletal conditions and acute low back pain in the use of superficial heat therapy than the use of cold therapy

Heat therapy in form of Electromagnetic wave has

been in use for about a century in physiotherapy, which is an infrared ray. In recent times, the Far infrared (FIR) rays have been used in medical devise for medical benefits to improve health of patients suffering from cardiovascular (CVS) disease, diabetes mellitus and chronic kidney disease. FIR is an invisible electromagnetic wave with a wavelength longer than that of visible light. It has been postulated at the molecular level that FIR therapy facilitates increased expression of endothelial nitric oxide synthase and nitric oxide production beneficial to chronic diseases without any known adverse effects

Sleepm Biocrystals technology comprises of three health stimulators: far infrared ray (6-12microns), the negative ion effects and the conductive properties of amethyst and 15 other semi precious stones channels. The synergistic effects

of which produce evidenced based healing effect.

The benefits of far infrared rays compare to infrared rays is that it has a deep penetrating but soothing heat that enhances regeneration of damaged cells in human body. Biocystals is a natural heating pad, the technology converts body electricity onto Far infrared Rays (FIR), nature' invisible light. NASA discovered FIR to be the safest and most beneficial light wave. Biocrystals also produces Negative ions, nature's energizer, which delivers a molecular level message by facilitating and deepens all healing and cleansing processes. Negative Ions alleviate allergies, migraines and sinus problems.

Amethyst Quartz and all other 15 stones are embedded into the entire Biocrystal surface as a scientific conductor for delivery of the Negative ions, far infrared light waves and the highest vibrational frequencies into the body. This confers a lot of clinical benefits and improved quality of life to many ill-health conditions as below:

The benefits of this Sleepm Biocrystal include:

- Stress and fatigue reduction,
- Reduces inflammation (swelling)
- Ceases joint pain and stiffness
- Provides warm, soothing pain relief
- Improves muscle tone and skin quality
- Eliminates toxins in the body
- Improves cardiovascular health
- Increases blood circulation
- Improves immune system function
- Alleviates migraine and tension headaches
- Increases the secretion of serotonin
- Relieves anxiety and promotes relaxation
- Improves sleep patterns
- Burns calories and control weight

Some medical literature reviews confirmed the effectiveness of FIR benefits in hemodialysis patients with arterio-venous fistula (AVF) by improving blood flow.

An improved access flow, maturation and patency of newly created AVFs in patients with chronic kidney disease stages 4 and 5 with a positive outcome. In another study by Su et al, FIR reduces the stress and fatigue level of hemodialysis patients thereby increasing their quality of life.

FIR in Postmenopausal Women

The use of FIR on menopausal and bone mineral density (BMD) in postmenopausal women had been documented. The study patients received FIR for 20 minutes daily,

twice a week and 20 sessions on their backs in supine position. Within 10 weeks, the patients' menopause-related symptoms (MRS) experienced reduced mean scores for vasomotor, musculoskeletal, urologic, reproductive and psychological domains. The study suggested FIR therapy as a potential alternative for the management of postmenopausal symptoms.

FIR in Type 2 Diabetes Mellitus

FIR Sauna use is associated with improved quality of life type 2 diabetes mellitus and it is more convenient than other lifestyle interventions. The study was of 20-minute, 3 times a week over a 3 -month period. Their physical health, general health, social functioning parameters improved including their Visual Analogue Scales for stress and fatigue.

FIR in Allergic Rhinitis

Allergic rhinitis is a common chronic illness that is debilitating and affecting the quality of life of the patient. Hu et al in their study on thirty-one patients on FIR therapy 40 min everyday for 7 consecutive days. It was observed that eye itching, nasal itching, nasal stiffness, rhinorrhea and sneezing were diminished pointing to the fact that FIR can improve allergic rhinitis symptoms and also the patient's quality of life.

Chronic Fatigue Syndrome and Depression

Syndrome like fatigue, pain, sleep disturbance, low grade fever with or without mild depression and appetite loss are common complaints patients suffering from chronic illness. Masuda et al, in their studies using FIR at 60 C, 5 days a week for a total of 20 sessions. An improved quality of life in terms of improved physical symptoms like pain, fatigue, relaxation effect and appetite were observed.

Sleepm Biocrystals Thermotherapy in Cancer Care

Heat therapy or hyperthermia (39-45C) has been recognized as an alternative complementary or adjuvant combination with radiation, chemotherapy and immune therapy in cancer therapy. At the molecular level, hyperthermia causes cell protein aggregation and denaturation leading to cell death by apoptosis and / or necrosis. Evidenced based medicine had confirmed improved tumor response with minimal risk of early disease progression free and disease - free survival compared to a monotherapy like chemotherapy.

Whole body thermotherapy using medical technology like the SleepM Biocrystals could be beneficial in metastatic cancer and other methods like flexible infrared chamber and heated blankets. Thermotherapy not only induced cell necrosis and protein inactivation of repair enzymes but also

enhances radiotherapy and chemotherapy sensitivity. This is however related to both the temperature and duration of treatment. A moderate (<40C) to severe temperature can increase tumor perfusion making the cells more susceptible to both radiotherapy and chemotherapy. Enzymes responsible for aerobic metabolism are inactivated decreasing oxygen consumption leading to tumor oxygenation. Beyond 42C tumor vasculature is damaged, resulting in decreased blood flow.

Aim of the Study

To demonstrate clinical improvement in the quality of life patients suffering from chronic or life threatening illnesses

Objectives

- To elicit improvement of pain control among the target patients
- To explore other evidences of symptoms control among the patients
- To evaluate the social and emotional well beings of the patients
- To explore other evidence-based benefits of Thermotherapy as an adjunct therapy among the target patients.

Methodology

Literature review on previous works revealed that very few studies have been done on Biocrystals thermotherapy. Both qualitative [Biofeedback]and quantitative methods [Questionnaire]will be adopted for this study.

Study Setting

A multicenter study at Prof. Dr. Grant clinic: 1111 Finch Ave. W. Suite 401, North York, Ontario, Canada, Sleep M Headquarter in Markham, ON. Canada as well as The Chiropractor Center of Dr. Stacey Cooper in Brantford, ON. Canada.

Pain Score Evaluation

A Qualitative pain Score would be used to assess the pain scores before and after the treatment. Numerical Rating Scale (NRS 0-10). 0 = No Pain; 5 =Moderate Pain and 10= Severe Pain.

Ethical Considerations

Approval for the study will be obtained from the tested 20 subjects. No Contraindicarion is expected by using the Biocrystals. A consent form was given to all participants.

➤ Sleepm Biocrystal Mattress

The Sleepm Biocrystal Mattress is an innovative new type of mattress that uses a powerful combination of modern technology with ancient medicinal properties.

The results are incredible:

- Gives you a full night of quality sleep
- Experience more energy and peace of mind
- Improve concentration
- Improve your immune system and body circulation
- Strengthen your muscular system
- Helps prevent neck pain and lower back pain

Better sleep and improved quality of life starts with Sleepm's incredible technology.

Our remarkable mattress technology includes our Biocrystal mixture, a special blend of 16 natural crystals that are blended with real gold and silver to maximize your body's healing

➤ Sleepm Biocrystal Topper

We take "smart" sleep technology to a new level with the Isotonic 7-zone Memory Foam Mattress Topper. This layered topper keeps you cool, comfortable, and supported all night with temperature-responsive technology.

Available is the Black Diamond One (with activated charcoal and latex), the Blue Diamond One (without activated charcoal and latex) and the original Sleepm Biocrystal Topper. The topper is filled with all the same biocrystals as our mattress, so it's perfect for someone who wants the benefits of biocrystals, but prefer to keep their existing mattress.

➤ Sleepm Biocrystal Pillow

The parts of the human body that have direct contact with the pillow are the cervical vertebrae. These cervical vertebrae are closely connected to the shoulder, back and waist muscles, ligaments, intervertebral discs, etc., and thus the pillow can have a tremendous impact on human health.

According to statistics, uncomfortable pillows are the reason for 150 million of the 600 million insomniacs in the world. So it's essentially important to choose the right pillow, which will work well for you, and help with your health. Never underestimate the role of the pillow.

Choosing the correct pillow has a crucial impact on comfortable sleep and the health of the cervical spine!

Unsuitable pillows and incorrect sleeping postures may cause excessive tension on cervical ligaments and muscles, accelerate the degeneration of intervertebral joints and lead to disorders in various body functions.

The Sleepm pillow not only supports the curved part of the neck, but also the back of the head. Because the lower skull is curved backwards, only with this support can the tissues and other parts of the neck be relaxed and rested.

The unique shape and design of the pillow edge, effectively supports the cervical spine, and the flatness and firmness of the pillow maintains the correct cervical curvature which helps prevent cervical spondylosis, or wear and tear on the neck.

The rear of the skull has a slightly lower resting point, which is designed to make the head and neck more comfortable during sleep.

As the pillow has different heights on either side, this allows users of different sizes to choose the most comfortable side to sleep on.

Both sides of the pillow core are designed to be slightly higher, so that the upper body weight is shared by the head, neck and shoulders when sleeping sideways, thus avoiding shoulder pain.

Research Consent Form for SleepM [Biocrystal Pillow, Biocrystal Topper & Biocrystal Mattress]

3 months clinical trials using 20 subjects who own a pillow, topper and mattress to test for:

1. Pain Reduction.
2. Sleep improvement.
3. Stress Reduction.
4. Improvement in Circulation for clients with Diabetes.

Biofeedback Testing (4 hours fasting) will be done at 0 and 3 months to test for improvement using the Sleep M Biocrystals. These tests are FREE for participants.

To avoid affecting the data, we prefer participants who are not using any medications. However if necessary, we will select participants who use up to 5 medications (including OTC and Rx). Researchers and participants have agreed to be free from any legal liability for using the Sleepm product.

See attached consent form.

Signed and agreed by participant to provide the requested data at 0, and 3 months.

Signed by:

Name:

Email:

Phone:

Conflict of Interest Disclosure

No conflict of interest between the researchers and the company Sleepm.

Results

Subject	Biofeedback Score at 0 [0 = Nil; 10 = High]	Biofeedback score after 3 months [0 = Nil; 10 = High]
#1	Pain 7	5
	Sleep 7	4
	Stress 8	6
	Circulation 6	6
#2	Pain 8	7
	Sleep 8	6
	Stress 9	7
	Circulation 5	5
#3	Pain 6	5
	Sleep 7	6
	Stress 8	6
	Circulation 8	6

#4	Pain 5 Sleep 7 Stress 7 Circulation 7	4 6 6 6
#5	Pain 8 Sleep 7 Stress 8 Circulation 6	5 5 6 6
#6	Pain 7 Sleep 6 Stress 7 Circulation 6	7 5 6 5
#7	Pain 6 Sleep 5 Stress 6 Circulation 7	6 5 5 7
#8	Pain 4 Sleep 8 Stress 6 Circulation 6	3 5 6 6
#9	Pain 5 Sleep 5 Stress 5 Circulation 6	5 5 5 6
#10	Pain 7 Sleep 6 Stress 6 Circulation 5	4 5 6 5
#11	Pain 6 Sleep 7 Stress 7 Circulation 5	5 6 5 5
#12	Pain 7 Sleep 7 Stress 6 Circulation 7	7 5 6 6
#13	Pain 8 Sleep 8 Stress 7 Circulation 7	7 5 6 7

#14	Pain 9	7
	Sleep 7	6
	Stress 7	6
	Circulation 6	6
#15	Pain 7	7
	Sleep 8	7
	Stress 7	7
	Circulation 9	7
#16	Pain 9	8
	Sleep 8	7
	Stress 9	7
	Circulation 4	3
#17	Pain 7	6
	Sleep 8	7
	Stress 7	7
	Circulation 4	4
#18	Pain 8	7
	Sleep 9	6
	Stress 9	6
	Circulation 7	7
#19	Pain 7	5
	Sleep 5	5
	Stress 6	6
	Circulation 5	5

Discussion

It appears that using the Sleepm Biocrystals helped the subjects to improve their pain, sleep, stress as well as circulation over 3 months testing period. Subjects who reported improvement in their pain, also found less sleep problems including reduced snoring which can lead to sleep apnea as well as resuced stress. Clients who reported problem with circulation as a result of diabetic neuropathy have reported slight improvement in their circulation [1-8].

It is recommended for future studies using the Sleep M Biocrystals to increase the number of subjects to 40 and the time for testing to 6 months to obtain more statistical significant results for Pain reduction, improvement of REM Sleep, stress reduction and improvement in circulation by using the Sleep M Biocrystals.

There were no reported negative side effects for using the SleepM Biocrystals even with clients who were using Prescription or over the counter medications for pain, sleep

or diabetes.

There were no significant difference by using the Sleep M Pillow, topper or mattress suggesting that any benefit is derived from the SleepM Biocrystals near infra-red & negative ions regardless of the gadget used.

The biofeedback test results have been correlated with CBC blood test results in the previously published studies by over 95% accuracy. That is why the subjects were not required to do the blood tests.

The result of this current study of Sleepm Biocrystals correlates with previously published study using Thermotherapy via infrared and negative ions on the tested subjects over 3 months period.

Using the Sleepm Biocrystals is far better and safer than using over the counter or prescription medications with numerous side effects particularly with diabetes medication Metformin that has been shown to contain carcinogens and

pain medications that are habit forming with enormous negative side effect on the liver and kidney.

It predicted that when the Sleepm Biocrystals becomes more known to the general public, it will be produced at lower costs due to increased volume and become economically a useful tool to improve pain, sleep, stress and circulation.

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