

Scientific report

∴

October 5th, 2021

**THE IMPACT OF CHRONIC EXPOSURE TO
MLX I³DOME ON PEOPLE UNDER STRESS:**

Effects on body detoxification, immune function, and mood state.

**Pr. Hausswirth C.^{1,2,3}, Dr. Nesi X.¹, Dr. Gueneron J. MD¹ - cardiologist¹,
Dr. V. Raimondi MD⁴, A. Dubois⁵, Dr. Duforez F. MD⁵**

1. beScored Institute, Sophia-Antipolis (France); 2. University of Côte d'Azur, Nice (France);
3. University of Technology, Sydney (Australia); 4. Cerballiance Laboratory, Cagnes-sur-Mer (France);
5. European Sleep Center, Hôtel Dieu, Paris (France)

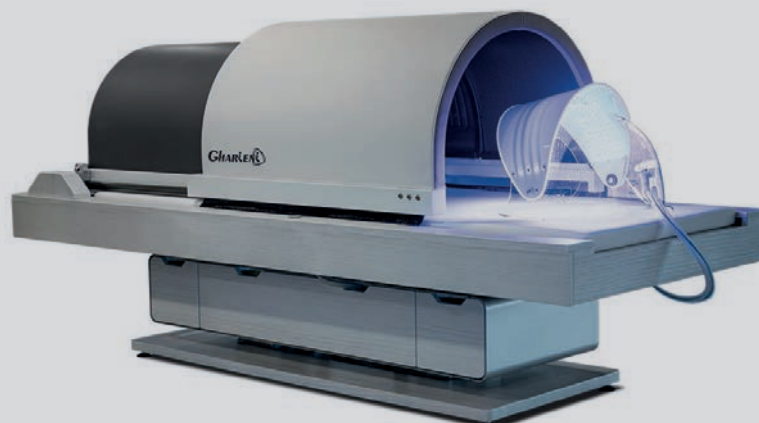
beScored
Institute

UNIVERSITÉ
CÔTE D'AZUR

UTS

Cerballiance

European
sleep
center
PARIS



GHARLENI

Table of contents

| | |
|--|-----------|
| Context | 3 |
| Introduction | 3 |
| Materials and Methods | 4 |
| Participants and recruitment | 4 |
| Experimental design | 4 |
| Data recording | 5 |
| <i>Blood parameters</i> | 5 |
| <i>Blood pressure and body weight</i> | 5 |
| <i>Muscular and joint soreness level</i> | 6 |
| <i>Psychological disturbances questionnaires</i> | 6 |
| <i>Sleep evaluation scales</i> | 6 |
| <i>Sleep monitoring</i> | 6 |
| <i>Heart Rate Variability (HRV)</i> | 7 |
| <i>Wellbeing</i> | 7 |
| <i>Statistical Analysis</i> | 8 |
| Results | 8 |
| Blood parameters..... | 8 |
| Blood pressure and body weight | 9 |
| Muscular and joint soreness level (DOMS) | 9 |
| Psychological disturbances questionnaires | 10 |
| Sleep evaluation scales | 10 |
| Sleep monitoring | 11 |
| Heart Rate Variability (HRV) | 12 |
| Wellbeing..... | 12 |
| Take-home messages | 12 |
| References | 14 |

Context

Clearly, the post-COVID-19 period is a time when all people are taking care of their health. According to the World Health Organization (WHO), health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. Mental health is an essential component of health and is much more than the absence of mental disorder or disability. According to the WHO, mental health is “a state of well-being that enables people to achieve their potential, cope with the normal challenges of life, work successfully and productively, and be able to contribute to the community”. Currently, it is important to be able to rely on care pathways or devices that can not only improve and/or preserve our health status in general but also our mental health status in particular. Decreasing our stress level is becoming essential in order to achieve daily well-being, sleeping better is becoming a must as well as freeing ourselves from toxins.

The study described below was initiated in a particular context where the participants had previously experienced a high level of anxiety. The general state of mood, immune defenses, and access to detoxification of the body were our main research axes.

Introduction

Recently, not only have many kinds of negative air ion (NAI) generator become commercially available, but also various electrical devices (e.g., air conditioners, air purifiers, etc.) have been provided with the function of generating such ions. A number of negative ions exist in places used for relaxation (e.g., in forests or near waterfalls) and are said to contribute, at least in part, to the positive effects of such places on human health; therefore, much attention has been paid to their effects on health and comfort. In fact, many reports have described the favorable effects of negative ions (Johns et al. 2016; Hawkins and Baker, 2018). The effects of negative air ions on the stress encountered in daily life have not been examined physiologically. One of the major results concerning the impact of atmospheric air ions was proposed by Nakane (2003). He showed that exposure to the ions during working significantly decreased anxiety level. In addition, the cognitive task performance was significantly improved by the generation of negative ions during the task. In this context, it is obvious that negative air ions are effective for reduction of and prompt recovery from stress. These effects were ascertained by a biochemical evaluation of stress response.

Used in a context of well-being such as in SPAs, this could have a direct and sustainable positive effect. On the contrary, positive air ionization has a negative impact on the mood and learning process (Giannini et al., 1983) because it is associated with a sustainable settlement of fatigue and an increase in systolic blood pressure (Charry and Hawkinshire, 1981). Due to its benefits, the clinical use of NAIs has long been recommended, especially in treatments for burns, asthma and allergic rhinitis (Kellogg, 1984). Practically, treatments using NAIs have been studied in hypertension treatments, fostering healing of known state of stress (Kondrashova et al., 2000). Studies show that short-term exposure to NAIs is a physiotherapeutic method that works with humans (Iwama et al., 2004), including to inhibit certain inflammations or boost the immune system. More recently, it has also been proven that a continuous exposure to NAIs generates antibacterial effects and could stimulate a quick return to homeostasis, which is so important in our daily life, especially in this post-COVID-19 period (Tyagi et al., 2008). However, the short-term efficiency of NAIs in the improvement of mood state (anxiety, depression, stress level) and immune function has not been demonstrated to this day, and even less so combined with far-infrared energy and light-therapy (i³Dome).

A variety of authorized strategies are proposed to alleviate muscle pain whatever the context (sport, daily life) (Hauswirth and Mujika, 2013). One recovery modality that is often employed is the far-infrared (FIR) therapy, also used to relieve pain in patients with muscular disorders (Masuda et al. 2005a; Masuda et al. 2005b). FIR therapy generally consists in a 30 min body exposure to FIR in a specially built apparatus. FIRs are invisible to the human eye, but they are felt because of the warmth they produce, in the order of 45°C. The potential positive effects of FIR therapy are mainly based on the increase of the peripheral flow due to vasodilatation under the influence of heat, which could improve drainage of the edema, limit the inflammation and perceived pain and thus improve muscle repair (Lin et al. 2007). Furthermore, by penetrating the skin, the FIR energy could break down the clusters of water molecules, which could reduce the edema and facilitate the release of metabolic wastes (Lin et al. 2007), all the while providing a feeling of already proven well-being (Hauswirth et al. 2011). The effect of FIR therapy on recovery is mainly based on the observations and the usual recourse. To this day, the only verified effect of FIR is a reduction of perceived pain and muscle fatigue, induced by a raise of endorphin production (Melzack and Well, 2015). In addition, negative air ionization for people, such as in the case of in

Polish salt caves, could have complementary effects with far infrared energy to increase immune function (Zajac et al. 2014). Moreover, no technology has allowed us to consider the combination of far infrared rays associated with the production of negative air ions on the detoxification of the body and oxidative stress.

Underlying individuals' unique, invaluable, and enigmatic metaphysical qualities, the human organism is, in a physical sense, essentially a self-regulating biochemical machine. At any moment, our thoughts and feelings, our actions, metabolism and physical well-being all stem from the sum of dynamic, intricate biochemistry working within a distinctive genetic context; innumerable biochemical reactions are taking place to prepare the enzymes, hormones, neurotransmitters and all that we need to undertake the tasks required for daily life (Genuis et al. 2013). Like any functional system, however, in order to thrive we must receive the raw materials that we need to carry out our biological processes and we must stay away from influences that are harmful and can prevent our machine from functioning normally. The widespread introduction of assorted toxic chemical agents into our intricate biochemical workings has the potential to disrupt sophisticated biochemical processes, thus becoming a widespread source of harm. Early life exposures can have life-long consequences, even at levels commonly experienced and thought to be safe (WHO 2013). Attention to toxic chemical exposures and environmental health sciences has been expanding at an impressive rate. Extensive research by independent scientists as well as governments has prompted numerous toxicology, medical, public health and other scientific journals to report on the impacts of environmental determinants on human health. Many toxic compounds have long half-lives; they biomagnify up the food chain, and some are increasingly found in the air we breathe, the water we drink, the food we consume, and the assorted personal care products we apply to our skin. As a consequence, many individuals now carry heavy body burdens of persistent toxicants, which often increase with advancing age as a result of ubiquitous exposures. In this context, the body regularly retains more and more traces of these heavy metals, which are sometimes toxic or carcinogenic. While changes in nutritional intake have shown positive effects on the detoxification of the body (Jung et al. 2020), different technologies have been developed using, in particular, exposure to far infrared rays to eliminate heavy metals in sweat through perspiration. A program of repeated exposure to these FIRs would not only increase certain trace elements but also decrease the concentrations of toxic metals (Blanchemaison et al. 2012).

In order to analyze the profile of mood state (POMS) and wellbeing on stress-related people, this study compared multi-exposures to FIR combined with NAI [I3Dome] and a control situation [CON] on anxiety and stress levels parameters. We hypothesize that a MLX i3Dome program of ten sessions could decrease the general level of stress, increase the wellbeing score and help in body detoxification. This new technology must also have a positive influence on participants' immune function and oxidative stress.

Materials and Methods

Participants and recruitment

Participants aged 35-65 years of either sex were recruited. Participants had to meet 3 on the 4 following inclusion criteria:

- I. a score strictly greater than 7 on the insomnia severity index (ISI).
- II. a global score greater than 14 on the Hospital Anxiety and Depression Scale (HADS)
- III. a pain notation equal to at least 5 out of the 11 points on the Likert scale (0-10)
- IV. a current blood pressure at rest higher than normal (i.e. 120/80 mmHg)

Participants with illnesses and/or undergoing treatments liable to interfere with sleep disorders and/or psychological disturbances were not eligible for this study. All Participants received written information about the study and gave their written consent before participating in it.

Experimental design

This study was conducted in order to analyze the effects of MLX i³Dome compared to a control condition, on measurements related to body detoxification, immune function, and mood state.

The 21 recruited participants were randomly assigned to the experimental group (Gexp, N = 11) or the control group (Gcon, N = 10).

The Gexp completed a MLX i³Dome program of 10 sessions (20-min) over a 4-week period (2-3 sessions per week).

Some days before the first session (i.e. Baseline) and within the 2-3 days after the last session (i.e. Post), Gexp completed several assessments to determine the changes made by the MLX i³Dome program (Figure1):

For both Gexp and Gcon

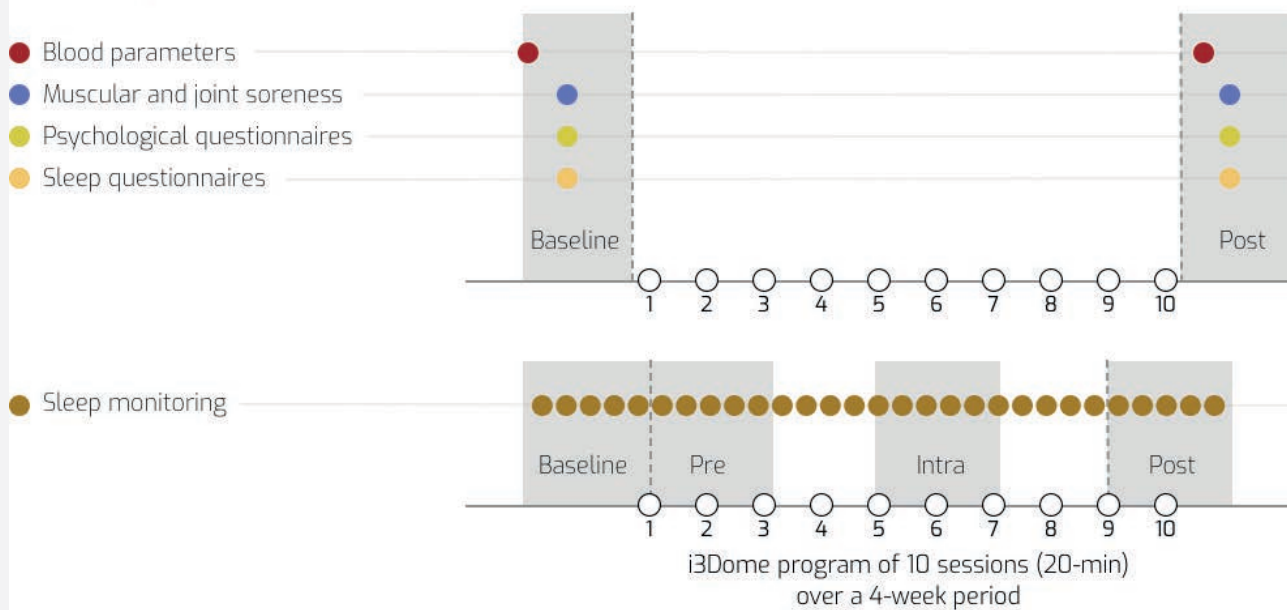


Figure 1. Schematic representation of the experimental design displaying the measurements completed throughout the study in Gexp and Gcon.

- ▶ blood tests to evaluate the trace elements profile,
- ▶ muscular and joint soreness level on an 11-point Likert scale
- ▶ questionnaires related to psychological disturbances: Profile of Mood State (POMS), Hospital Anxiety and Depression Scale (HADS)
- ▶ questionnaires related to sleep disorders: insomnia severity index (ISI), Ford Insomnia Response to Stress Test (FIRST) and the Spiegel Sleep Quality (SSQ)

Also, sleep was monitored from 4 days before and throughout the entire MLX i³Dome program. In the Gcon, these assessments were completed twice separated by a 4-week period, and the sleep monitoring was completed over the same period.

For the participants of the Gexp, heart rate variability (HRV) was measured at the beginning of each session, and wellbeing was evaluated just before and after each session (Figure 2). Moreover, resting blood pressure and body weight measurements were assessed just before and after the first and last session of the program.

Data recording

Blood parameters

The blood concentration of trace elements (Zinc, Copper, Selenium, Magnesium, Magnesium in red blood cells), toxic metals (Chromium, Nickel, Manganese, Cobalt, Aluminium,

Cadmium, Mercury, Lead) and cortisol, as well as a complete blood count (i.e., the counts of white blood cells, red blood cells and platelets, the concentration of hemoglobin, and the hematocrit) was measured in a fasted state, in the morning before 9 a.m., some days before and after the MLX i³Dome program in all participants.

Blood pressure and body weight

Diastolic (DBP) and systolic blood pressure (SBP) were measured by electrospigmomanometry (Tango; Suntech Medical, Flaxlanden, France; Picture 1) on patients sitting, with a cuff placed on the upper arm and a microphone over the brachial artery to detect Korotkoff sounds. Blood pressure was measured before the first session and 2-3 days after the last session of MLX i³Dome program.



Picture 1. The Tango M2 is a reliable, automated blood pressure monitor for cardiac stress and exercise testing.

For Gexp only

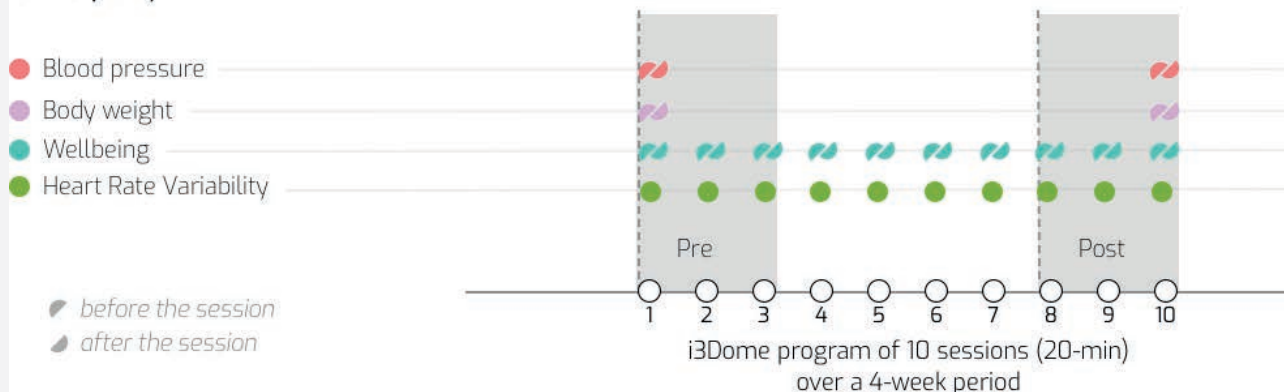


Figure 2. Schematic representation of the experimental design displaying the measurements completed throughout the study only in Gexp.

Muscular and joint soreness level

Prior to the first session and in the 2 days following the last session, muscular and joint pain soreness was evaluated from a visual analog scale with a sliding mark. The front side of the scale displayed the question “How is your level of muscle and joint soreness at this moment?” and a linear gauge with two items at extremities (bottom: “None”; top: “Maximal”). From the bottom, the participants slid the mark along the scale in order to rate their feeling of soreness. On the back side, a numerical scale from 0 (corresponding to the level “None”) to 10 (“Maximal”) displayed the DOMS value.

Psychological disturbances questionnaires

Abbreviated Profile of Mood State (POMS)

This psychometric test is a self-report measure in which subjects rate themselves on each of 48 adjectives using a 1-5 scale. These 48 responses yield 6 mood state scales which are: Anger, Vigor, Depression, Fatigue, Tension, Esteem and Confusion. Moreover, Total Mood Disturbance (TMD) is calculated by summing the totals for the negative subscales and then subtracting the totals for the positive subscales (i.e. $TMD = [Anger + Depression + Fatigue + Tension + Confusion] - [Vigor + Esteem]$)

Hospital Anxiety and Depression Scale (HADS)

The HADS (Zigmond & Snaith, 1983) consists of 14 items measuring symptom severity on a scale of 0 to 3 with subscales for anxiety (HADS_A) and depression (HADS_D), and a range of possible scores for each subscale of 0 to 21. For HADS-A and HADS_D, a score between 0 and 7 is ‘Normal’, between 8 and 10 is ‘Borderline abnormal’, and between 11 and 21 is ‘Abnormal’.

Sleep evaluation scales

Insomnia Severity Index (ISI)

The ISI is a self-assessment questionnaire evaluating the nature, severity, and impact of insomnia. A 5-point Likert scale is used to rate each item (from 0 = no problem to 4 = very severe problem) yielding a total score ranging from 0 to 28.

The total score is interpreted as follows: absence of insomnia (scores 0-7); sub-threshold insomnia (scores 8-14); moderate insomnia (scores 15-21); and severe insomnia (scores 22-28).

Ford Insomnia Response to Stress Test (FIRST)

Sleep reactivity was measured using FIRST. The FIRST is a 9-item scale used to assess an individual’s likelihood of experiencing sleep difficulties in response to common stressful situations. Each item is self-rated on a 4-point Likert scale and summed to yield a total score (range: 9-36); higher scores indicate higher levels of sleep reactivity.

Spiegel Sleep Quality (SSQ)

The SSQ is comprised of six questions scored from 0 to 5, and designed to assess sleep quality. The maximum score is 30 and impaired sleep is defined as a score < 24; a pathological sleep pattern exists if the score is < 15.

Sleep monitoring

During the 4 days preceding the MLX i³Dome program until the night of the 10th session, sleep monitoring was completed using Actiwatch (Cambridge Neurotechnology Ltd., Cambridge, UK - Picture 2) worn on the nondominant wrist and a daily sleep diary. In the evening, the participants were asked to record the time of going to bed and to rate the perceived energy of the

day on a Likert scale (0: very low energy; 10: very high energy); in the morning, they were asked to record the time of waking up and to rate the perceived sleep quality on a Likert scale (0: very bad sleep; 10: very good sleep). In addition, the subjects were asked to mark the time of switching off the light to sleep and wake-up time with a push of the button on the face of the Actiwatch. Individual nights of sleep (Picture 3) were analyzed for :

- ▶ Time in bed (the total elapsed time between the 'Lights Out' and 'Got Up' times)
- ▶ Sleep latency (the time between 'Lights Out' and 'Fell Asleep')
- ▶ Assumed sleep (the total elapsed time between the 'Fell Asleep' and 'Woke Up' times)
- ▶ Actual sleep time (the total time spent in sleep)
- ▶ Sleep efficiency (actual sleep time expressed as a percentage of the assumed sleep time)
- ▶ Fragmentation Index (an indication of sleep quality)

As displayed on Figure1, these measurements, and values recorded for perceived energy of the day and perceived sleep quality were averaged over 4 nights before the program (Baseline), after session 1 (Pre), after session 5 (Intra) and after session 9 (Post).

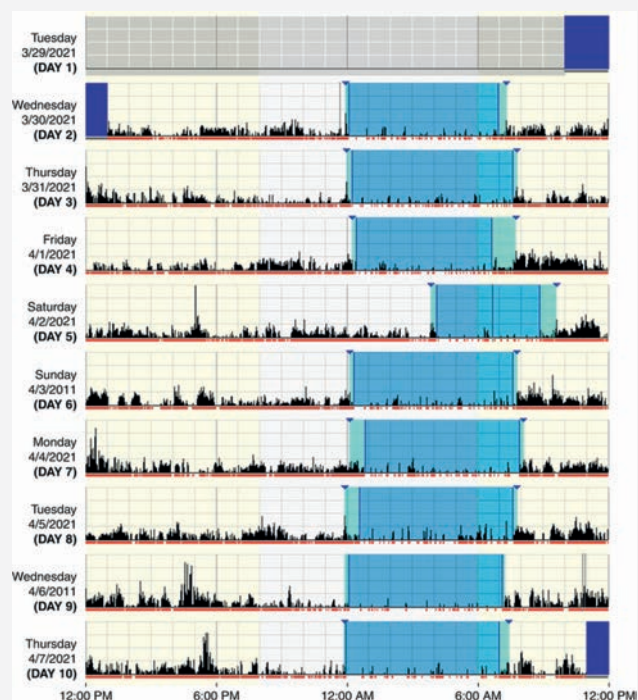
Heart Rate Variability (HRV)

HRV indexes were evaluated throughout the program, at the beginning of each session in the Gexp. RR intervals (Picture 4) were collected using a chest strap heart rate monitor (Polar H9, Kempele, Finland) connected via Bluetooth to a mobile web app (Elite HRV). The participant was lying quietly for a 4-min period to allow the heart rate to stabilize. No particular breathing frequency was imposed. The RR intervals recorded over the last 3 min were used to compute the resting heart rate (HR_{rest}) and HRV indexes (i.e., SDNN and RMSSD).

In order to reduce the inter-individual variability in data, HR_{rest}, SDNN and RMSSD values were normalized from a standard scaler (i.e., by removing the mean and scaling to unit variance) fitted on the recorded HR on session 1.



Picture 2. The MotionWatch 8 is the next generation of medical-grade actigraphy watch for the monitoring of sleep, circadian rhythm and physical activity.



Picture 3. Example of actimetry over few days. Nights are represented by blue periods and sleep indices are calculated from this data.

Wellbeing

Just before and 5-min after each session, the level of wellbeing was evaluated using a visual analog scale with a sliding indicator. The front side of the scale displayed the question “How are you feeling right now?” and a linear gauge with two items at extremities (bottom: “Neutral”; top: “Very well”). Starting from the bottom, the participants slid the indicator up the scale to rate their feeling of wellbeing. On the back side, a numerical scale from 0 (corresponding to the level “Neutral”) to 10 (“Very well”) made it possible to read the value of wellbeing.



Picture 4. Illustration of the heart rate variability (HRV) and RR intervals expressed in ms.

Statistical Analysis

All data was stored in an electronic database and analyzed using Jupyter Notebook and Python programming language. Results are expressed as mean \pm standard deviation (SD). The criteria to interpret the magnitude of effect size (ES) was > 0.2 small, > 0.5 moderate, > 0.8 large, and > 1.3 very large (Cohen, 1988). Statistical significance was accepted at $P < 0.05$.

Results

Blood parameters

In response to the 4-week period, the changes in zinc, copper, mercury, cortisol and lymphocytes were significantly different in Gexp compared to Gcon.

Trace elements

Zinc and copper blood concentrations significantly increased in response to MLX i³Dome program in Gexp ($P < 0.05$), with no change in Gcon (Figure 5). In Gexp, the changes were of $+19.4 \pm 20.3\%$ (ES = 0.97, large) and $+20.1 \pm 23.8\%$ (ES = 0.93, large) in zinc and copper respectively. For Gcon, the change for zinc was $-1.8 \pm 22.7\%$ (ES = 0.33, small) and the change for copper was $-3.2 \pm 7.4\%$ (ES = 0.13, no effect).

For the other trace elements (Selenium, Magnesium, Magnesium in red blood cells), no change in relation to the group (Gexp vs Gcon) was reported after the 4-week period.

Toxic metals

As illustrated by Figure 4, mercury and lead concentrations presented a trend to decrease in Gexp (mercury: $-16.8 \pm 42.1\%$, ES = 0.52, moderate; lead: $-8.2 \pm 15.7\%$, ES = 0.29, small), compared to Gcon (mercury: $9.9 \pm 23.4\%$, ES = 0.19,

no effect; lead: $1.7 \pm 11.9\%$, ES = 0.06, no effect).

For the other toxic metals (Chromium, Nickel, Manganese, Cobalt, Aluminium, Cadmium), no change in relation to the group (Gexp vs Gcon) was reported after the 4-week period.

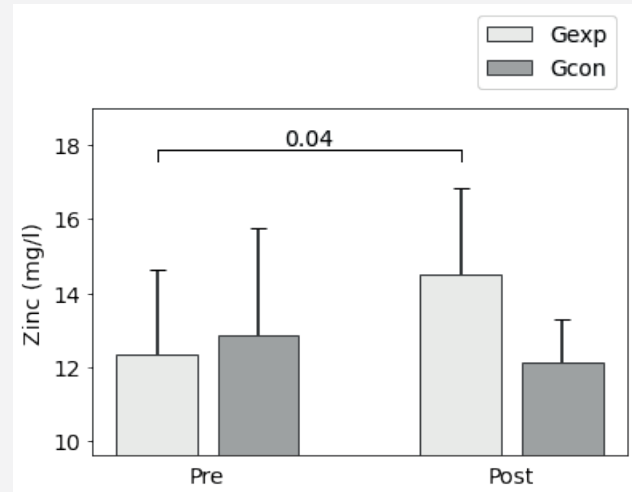


Figure 3. Changes in zinc blood concentrations in Gexp and Gcon before and after the 4-week period (Pre and Post, respectively).

Cortisol

For the Gexp, the cortisol blood concentration showed a trend to decrease in response to the MLX i³Dome exposure ($-17.3 \pm 33.7\%$; ES = 0.62, moderate), whereas the variation was $+5.6 \pm 17.5\%$ (ES = 0.17, no effect) in Gcon after the 4-week period (Figure 5).

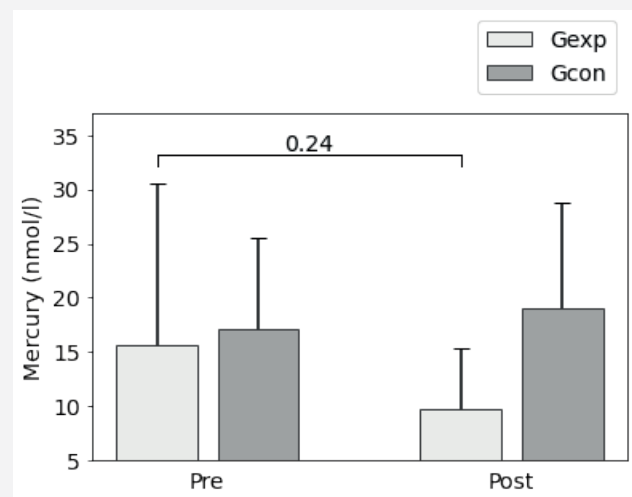


Figure 4. Changes in mercury blood concentrations in Gexp and Gcon before and after the 4-week period (Pre and Post, respectively).

Complete blood count

No change was observed in red blood cells, hematocrit and hemoglobin after the 4-week period in both groups. However, positive variations were reported in Gexp for white blood cells in

response to the MLX i³Dome program (lymphocytes: $15.9 \pm 17.4\%$, ES = 0.51, moderate; monocytes: $11.3 \pm 18.2\%$; ES = 0.20, small). In Gcon, these variations were $-5.1 \pm 17.7\%$ for lymphocytes (ES = 0.20, small) and $-1.8 \pm 13.7\%$ for monocytes (ES = 0.09, no effect).

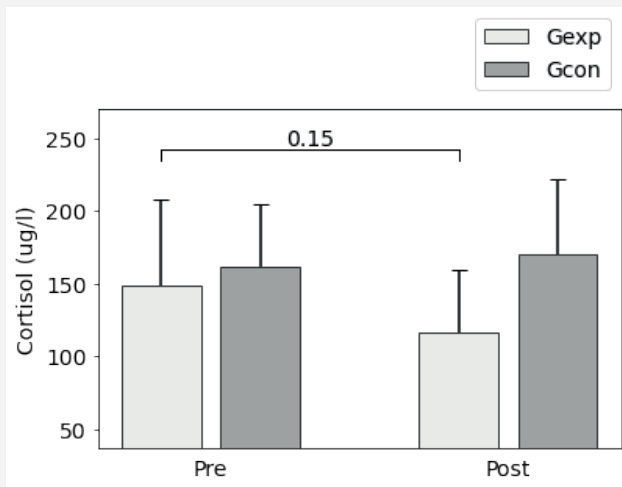


Figure 5. Changes in cortisol blood concentrations in Gexp and Gcon before and after the 4-week period (Pre and Post, respectively).

Blood pressure and body weight

The blood pressure measured before the first session was higher than the ideal value (i.e. 120 / 80 mmHg for SBP and DBP respectively). SBP was 126 ± 18 mmHg and DBP was 76 ± 18 mmHg. In response to the first session, a significant decrease was observed in SBP and DBP, as shown in Figure 7 (-9.4 ± 14.4 mmHg) and in Figure 8 (-8.9 ± 11.2 mmHg). Moreover, the SBP measured at rest presented a significant decrease following the MLX i³Dome program carried out in 1 month (-6.4 ± 9.4 mmHg). As in session 1, DBP also decreased significantly during the last session of the program (-6.3 ± 4.3 mmHg).

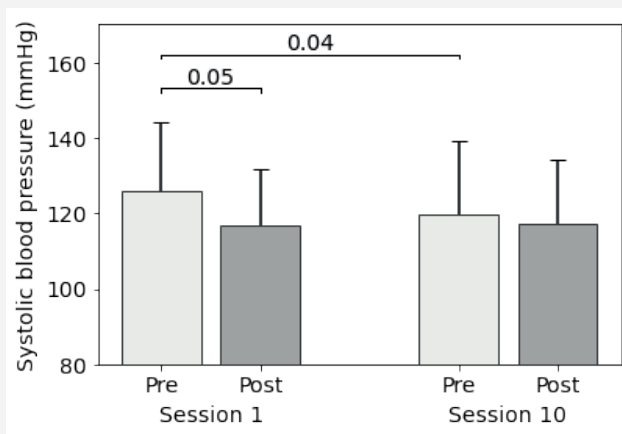


Figure 6. Changes in systolic blood pressure during session 1 and session 10 of the MLX i³Dome program.

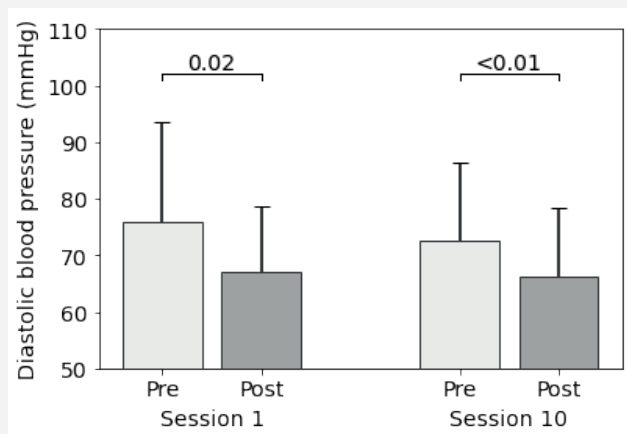


Figure 7. Changes in diastolic blood pressure during session 1 and session 10 of the MLX i³Dome program.

We observed a significant decrease in body weight after the first session (-0.10 ± 0.06 kg; $P < 0.01$). On the last session, body weight showed a trend to decrease in response to a 20-min MLX i³Dome session (-0.19 ± 0.32 kg; $P = 0.07$). However, no significant change in body weight was observed between the first and last session, at rest or after a 20-min MLX i³Dome session (Figure 8).

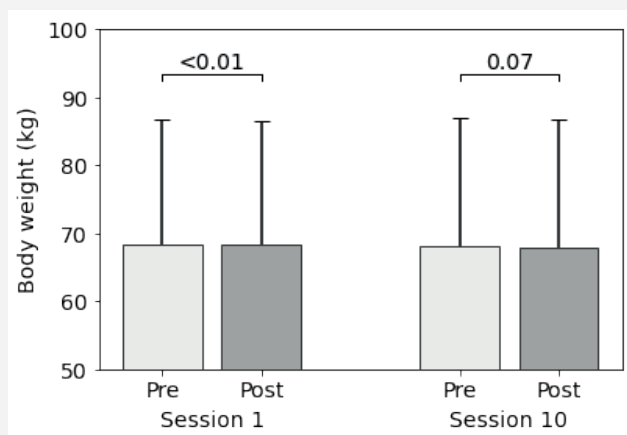


Figure 8. Changes in body weight during session 1 and session 10 of the MLX i³Dome program.

Muscular and joint soreness level (DOMS)

For Gexp and Gcon, the muscular and joint soreness level (DOMS) was relatively high (5.3 ± 2.0 vs. 6.0 ± 2.8) at the start of the program, and not significantly different between the 2 groups. For Gcon, DOMS didn't change over the 4-week period whereas soreness level tended to decrease in Gexp after the 10 MLX i³Dome sessions (Figure 9). After the 4-week period, DOMS values were not significantly different between Gexp and Gcon ($P = 0.16$).

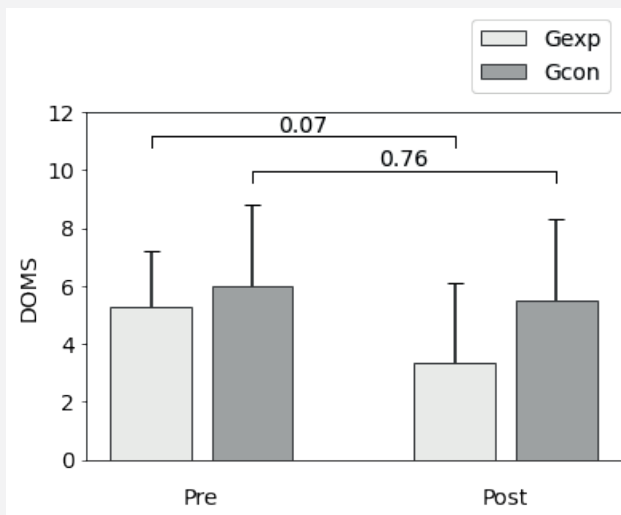


Figure9. Changes in DOMS values before and after the 4-week period in Gexp and Gcon.

Psychological disturbances questionnaires

Abbreviated Profile of Mood State (POMS)

The Total Mood Disturbance score computed was not significantly different between Gexp and Gcon before or after the 4-week period. As shown in Figure10, a significant decrease in TMD was observed in Gexp (-31.5 ± 36.5 pts) while the change was not significant in Gcon (-14.8 ± 28.7 pts). In the same way, Anger, Depression, Fatigue, Tension and Confusion tended to decrease while Vigor and Esteem tended to increase after the 4-week period, with a larger change in Gexp compared to Gcon.

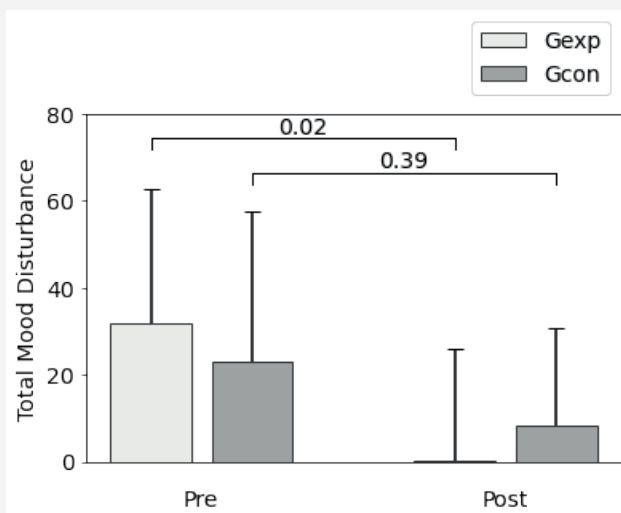


Figure10. Changes in TMD scores before and after the 4-week period in Gexp and Gcon.

Hospital Anxiety and Depression Scale (HADS)

The anxiety and depression scores evaluated from HADS were not different between Gexp

and Gcon at the start of the program (Figure11). In the same way, no significant difference was reported between the 2 groups after the 4-week period. However, the decreases in anxiety and depression scores observed (-4.0 ± 2.1 pts and -3.5 ± 1.9 pts) were only significant in Gexp.

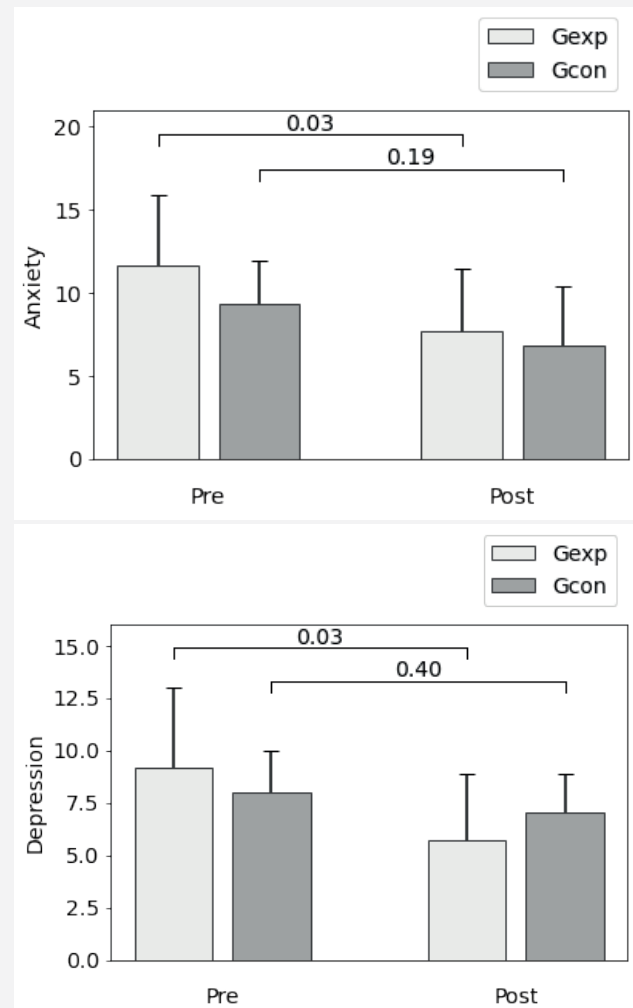


Figure11. Changes in HADS scores (top: Anxiety ; bottom: Depression) before and after the 4-week period in Gexp and Gcon.

Sleep evaluation scales

In Gexp, significant changes in sleep scores were observed in response to the program: the quality of sleep has improved ($+3.4 \pm 5.1$ pts) while insomnia index has decreased (-4.6 ± 3.8 pts) after the 10 MLX i³Dome sessions (Figure12). However, no change was reported in the Ford Insomnia Response to Stress Test in Gexp in relation to the program. As illustrated by Figure12 for Spiegel Sleep Quality, the sleep indexes calculated in Gcon did not change at the end of the 4-week period.

Sleep monitoring

The variations in perceived energy of the day, perceived sleep quality and actimetry indexes were not significantly different over the 4 periods (i.e. Baseline, Pre, Intra and Post) between the Gexp and the Gcon. As illustrated by Figure 13, similar changes in perceived energy of the day were observed during the study period for the 2 groups. In the same way, actimetry indexes presented some non-significant change between the 4 periods. The calculated data over each period for Gexp and Gcon are displayed in Table 1.

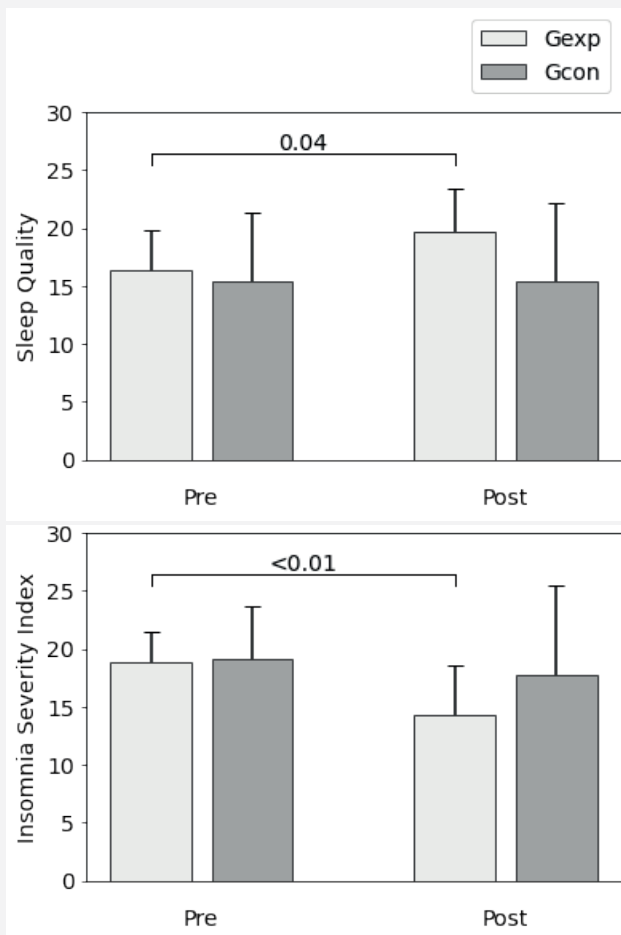


Figure 12. Changes in Spiegel Sleep Quality and Insomnia Severity Index scores before and after the 4-week period in Gexp and Gcon.

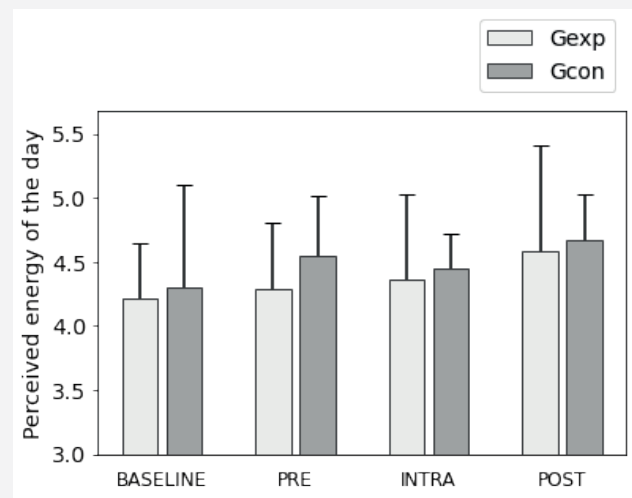


Figure 13. Changes in perceived energy of the day recorded during baseline and the 4-week period in Gexp and Gcon.

Table 1. Mean \pm SD values of sleep actimetry data during the baseline and the 4 nights following the first, fifth and ninth MLX i³Dome sessions (Pre, Intra and Post, respectively) in Gexp and Gcon.

| Parameters | Group | Baseline | Pre | Intra | Post |
|--------------------------|-------|-----------------|-----------------|-----------------|-----------------|
| Time in bed (h:mm) | Gcon | 7:42 \pm 0:49 | 8:14 \pm 0:50 | 7:54 \pm 1:20 | 7:45 \pm 0:36 |
| | Gexp | 7:57 \pm 0:38 | 8:15 \pm 0:54 | 7:54 \pm 1:01 | 8:00 \pm 1:02 |
| Sleep latency (h:mm) | Gcon | 0:12 \pm 0:05 | 0:12 \pm 0:07 | 0:14 \pm 0:06 | 0:17 \pm 0:08 |
| | Gexp | 0:12 \pm 0:07 | 0:17 \pm 0:12 | 0:17 \pm 0:10 | 0:17 \pm 0:14 |
| Assumed sleep (h:mm) | Gcon | 7:21 \pm 0:53 | 7:54 \pm 0:47 | 7:28 \pm 1:15 | 7:17 \pm 0:34 |
| | Gexp | 7:37 \pm 0:39 | 7:46 \pm 1:00 | 7:26 \pm 0:59 | 7:34 \pm 0:58 |
| Actual sleep time (h:mm) | Gcon | 6:31 \pm 0:46 | 6:56 \pm 0:34 | 6:35 \pm 0:59 | 6:30 \pm 0:27 |
| | Gexp | 6:38 \pm 0:44 | 6:47 \pm 1:02 | 6:23 \pm 0:53 | 6:36 \pm 1:03 |
| Sleep efficiency (%) | Gcon | 88.8 \pm 1.9 | 88.0 \pm 3.4 | 88.4 \pm 2.9 | 89.5 \pm 3.5 |
| | Gexp | 87.1 \pm 3.8 | 87.2 \pm 3.4 | 86.0 \pm 4.2 | 87.3 \pm 3.6 |
| Immobile time (%) | Gcon | 92.3 \pm 1.9 | 91.5 \pm 2.7 | 92.2 \pm 2.6 | 92.7 \pm 2.7 |
| | Gexp | 91.8 \pm 2.4 | 91.7 \pm 1.8 | 90.9 \pm 2.8 | 91.5 \pm 3.2 |
| Fragmentation index | Gcon | 25.3 \pm 5.2 | 28.8 \pm 7.8 | 25.6 \pm 5.5 | 26.8 \pm 9.3 |
| | Gexp | 27.3 \pm 8.5 | 28.1 \pm 8.2 | 30.1 \pm 9.6 | 27.5 \pm 10.3 |

Heart Rate Variability (HRV)

In Gexp, the HR_{rest} and HRV computed during each session did not change over the 4-week period. As illustrated in Figure 14 with normalised RMSSD, some variations were observed in the HRV indices between sessions but no significant change was found in response to the MLX i³Dome program.

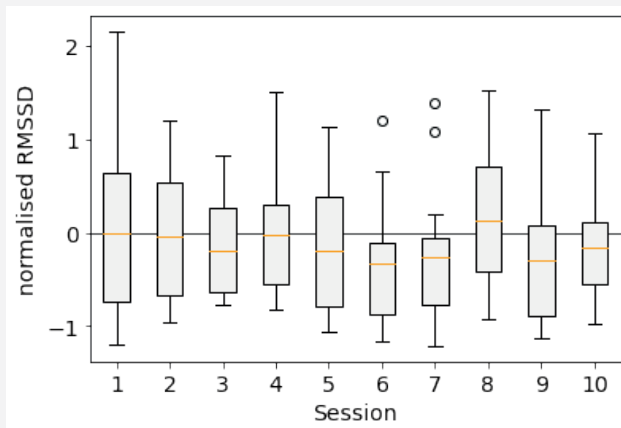


Figure 14. Heart Rate Variability expressed as normalised RMSSD computed during each session of the MLX i³Dome program.

Wellbeing

The effect of MLX i³Dome sessions on the level of wellbeing was presented in Figure 15. For half of the sessions of the program, the participants of Gexp show a significant improvement of the level of wellbeing in response to MLX i³Dome exposure. On average, the increase in wellbeing level was $+1.02 \pm 1.18$ pts during the program.

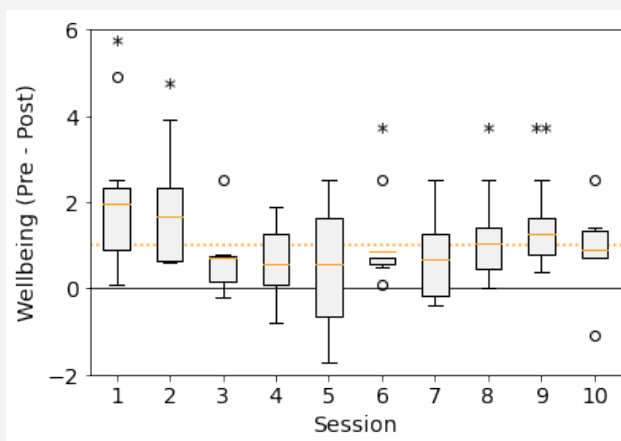


Figure 15. Change in wellbeing computed between (Pre) and after (Post) each session of the MLX i³Dome program. Orange dashed line represents the mean improvement of wellbeing computed on the 10 sessions. * and ** correspond to a significant change in wellbeing in response to the session ($P < 0.05$ and $P < 0.01$, respectively)

Take-home messages

This study aims to evaluate the effects of 10-session of MLX i³Dome as a body detoxification method on wellbeing-related data compared to a control group. The main results to remember from the present study are:

IMMUNE FUNCTION is higher when MLX i³Dome is used during a 10-session program:

- ▶ Lymphocytes increased by 15.9% after the one-month program.

Rem: Lymphocytes are white blood cells (leukocytes) that play an important role in the immune system. They identify and neutralize pathogens present in the body.

- ▶ Zinc concentrations augment by 19.4% after the MLX i³Dome program but no changes were reported in control condition.

Rem: The role of zinc in the antiviral response can be summarized in 2 modes of action:

- *Improvement of the immune response (activation of T cells),*
- *Inhibition of viral replication and multiplication in the body.*

BODY DETOXIFICATION is increased when MLX i³Dome is used as a detox program for 10 sessions:

- ▶ Toxic metals concentrations are lower for the MLX i³Dome by 16.8% and 8.2%, for mercury and lead, respectively; no variation was recorded for the control group.

Rem: These toxic metals pass mainly in our system through our food, tap water, pollution, certain drugs or even cosmetics or daily hygiene products like deodorants. We need to find ways to detoxify our bodies, and 10 sessions of MLX i³Dome seem to be appropriate in this context.

- ▶ Antioxidant status is increased - as represented by the 20.1% augmentation of the copper concentration.

Rem: Copper acts as an antioxidant as it helps protect cells from oxidative stress.

STRESS LEVEL is decreased globally after a 10-session program of MLX i³Dome exposure compared to the control group:

- ▶ Blood pressure is lower by -9.4mmHg for systolic and -8.9mmHg for diastolic after only one session. The decreases in blood pressure (diastolic and systolic) observed after an one-month program of MLX i³Dome are almost the same compared with only one

isolated session, meaning that the effects last over time.

Rem: Blood pressure is relevant in terms of cardio-vascular health. In this context, sessions of MLX i³Dome could prevent the risk of high blood pressure in people.

- ▶ Cortisol levels - often associated to stress levels - are lower by -17.3% at session 10, in comparison with the control group.

Rem : Cortisol is our stress hormone. Controlling our cortisol levels can help us in boosting our immune system and fighting chronic fatigue. It also has a role in regulating sleep and stabilizing blood pressure.

- ▶ Anxiety and depression scores are lower by -4.0 pts and -3.5 pts, for anxiety and depression, respectively, after an one-month program of MLX i³Dome.

Rem: The HADS (Hospital Anxiety and Depression Scale) is often used to appreciate the level of stress (anxiety and depression) in patients. The HADS score is then modified positively (i.e., decrease) after 10 sessions of MLX i³Dome.

GLOBAL WELLBEING is improved after one month of MLX i³Dome exposure:

- ▶ Wellbeing ratings are highly elevated (average: +1.02 pts) for half of the sessions of the program and in response to the session,

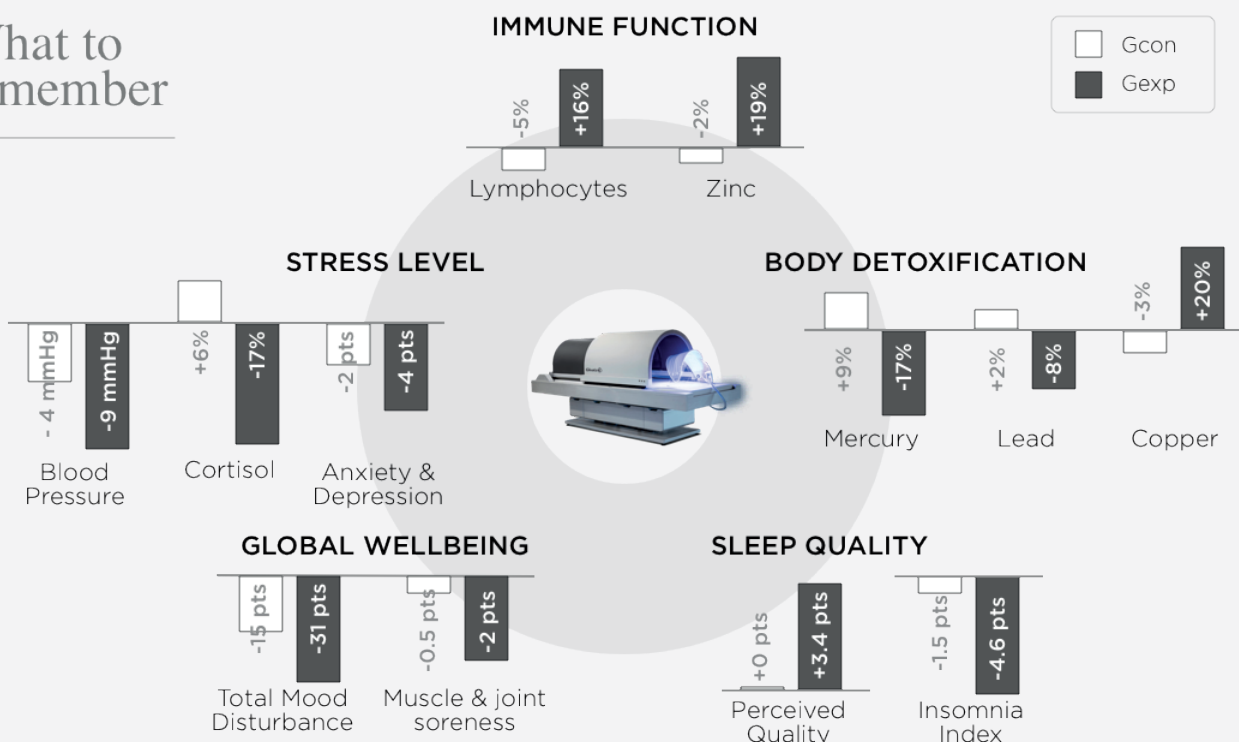
meaning that MLX i³Dome provides essential and relevant wellbeing for all subjects.

- ▶ The Total Mood Disturbance (TMD) - represented by the abbreviated Profile of Mood State scale (POMS) - is decreased by 16.7 more points after the 10-session of MLX i³Dome compared to the control group.
- ▶ Muscle and joint soreness - represented by the Delayed Onset of Muscle Soreness (DOMS) score - was high at the start of the program but decreased from 5.4 to 3.4 at the end of the MLX i³Dome program.

SLEEP QUALITY is improved after the 10-session of MLX i³Dome people under stress:

- ▶ Subjective quality of sleep - evaluated by Spiegel Sleep Quality questionnaire - is more elevated after the program than the control group, meaning that 10 sessions of MLX i³Dome have induced a better quality of sleep (from 16.4 pts to 19.8 pts, on a maximal of 30 pts) even appreciated subjectively: this result could be helpful to reduce stress level in people.
- ▶ Insomnia index - represented by the Insomnia Severity Index - decreased by -4.6 pts (from 18.8 pts to 14.2 pts) from the start to the end of program. The decrease in insomnia phases for the test persons is an indicator of a lower stress level obtained for these same persons.

What to remember



References

- Charry, J.M. and Hawkinshire, F.B. (1981) 'Effects of atmospheric activity on some substrates of disordered social behaviour', *Journal of Personality and Social Psychology*, Vol. 41, pp.185-197.
- Faulkner SM, Bee PE, Meyer N, Dijk DJ, Drake RJ. Light therapies to improve sleep in intrinsic circadian rhythm sleep disorders and neuro-psychiatric illness: A systematic review and meta-analysis. *Sleep Med Rev*. 2019;46:108e123.
- Genuis SJ, Sears ME, Schwalfenberg G, Hope J, Bernhoft R. Clinical detoxification: elimination of persistent toxicants from the human body. *ScientificWorldJournal*. 2013 Jun 6;2013:238347.
- Giannini, A.J., Castellani, S. and Dvoredsky, A.E. (1983) 'Anxiety states: relationship to atmospheric cations and serotonin', *Journal of Clinical Psychiatry*, Vol. 44, pp.262-264.
- Hauswirth C. and Mujika I. (2013). Recovery for performance in sport. Eds *Human Kinetics*. pp 377.
- Hawkins LH and Baker T. (2008) Air ions and human performance. *Ergonomics*, 21, 273
- Iwama, H. (2004) 'Negative air ions created by water shearing improve erythrocyte deformity and aerobic metabolism', *Indoor Air*, Vol. 14, pp.293-297.
- Johns D.P. et al. (2006) Effect of long-term ionized air treatment on patients with bronchial asthma". *Thorax*, 31, 428.
- Jung, S.J., Kim, W.L., Park, B.H. et al. Effect of toxic trace element detoxification, body fat reduction following four-week intake of the Wellnessup diet: a three-arm, randomized clinical trial. *Nutr Metab (Lond)* 17, 47 (2020)
- Kondrashova, M.N., Grigorenko, E.V., Tikhonov, A.N., Sirota, T.V., Temnov, A.V., Stavrovskaja, I.G., Kosyakova, N.I., Lange, N.V. and Tikhonov, V.P. (2000) 'The primary physico-chemical mechanism for the beneficial biological/medical effects of negative air ions', *IEEE Transactions on Plasma Science*, Vol. 28, pp.230-237.
- Krueger, J.A. and Reed, A.J. (1976) 'Biological impact of small air ions', *Science*, Vol. 193, pp.1209-1213.
- Lin CC, Chang CF, Lai MY, Chen TW, Lee PC, et al. (2007) Far-infrared therapy: a novel treatment to improve access blood flow and unassisted patency of arteriovenous fistula in hemodialysis patients. *J Am Soc Nephrol* 18: 985-992.
- Livanova, L.M., Levshina, I.P., Nozdracheva, L.V., Elbakidze, M.G. and Airapetyants, M.G. (1999) 'The protective effects of negative air ions in acute stress in rats. *Neurosci Behav Physiol* . Jul-Aug 1999;29(4):393-5.
- Lucas RJ, Peirson SN, Berson DM, et al. Measuring and using light in themelanopsin age. *Trends Neurosci*. 2014;37(1):1e9.
- Masuda A, Kihara T, Fukudome T, Shinsato T, Minagoe S, et al. (2005) The effects of repeated thermal therapy for two patients with chronic fatigue syndrome. *J Psychosom Res* 58: 383-387.
- Masuda A, Kihara T, Fukudome T, Shinsato T, Minagoe S, et al. (2005a) The effects of repeated thermal therapy for two patients with chronic fatigue syndrome. *J Psychosom Res* 58: 383-387.
- Masuda A, Koga Y, Hattanmaru M, Minagoe S, Tei C (2005b) The effects of repeated thermal therapy for patients with chronic pain. *Psychother Psychosom* 74: 288-294
- Nakane H. (2003) Stress-reducing effect of negative air ions. *R&D review*, vol.38, N2, 50-54.
- Tyagi, A.K., Kumar, B.N., Malik, A. and Singh, K (2008) 'The effect of negative air ion exposure on *Escherichia coli* and *Pseudomonas fluorescens*', *Journal of Environmental Science and Health Part A*, Vol. 43, pp.694-699.
- World Health Organization and United Nations Environment Program, *State of the Science of Endocrine Disrupting Chemicals*, 2013.
- Zajac J, Bojar I, Helbin J, Kolarzyk E, Owoc A. Salt caves as simulation of natural environment and significance of halotherapy. *Ann Agric Environ Med*. 2014;21(1):124-7. PMID: 24738510.
- Zambotti M De, Goldstone A, Colrain IM, Baker FC. Insomnia disorder in adolescence: diagnosis, impact, and treatment. *Sleep Med Rev*. 2018;39(June): 12e24.

beScored

Institute



Pr. Christophe **HAUSSWIRTH**

Founder beScored Institute

christophe@bescored.institute

+33.6.86.58.46.93