IMPACT OF A MULTI-SESSION LPG®

CELLU M6 ALLIANCE®

Effects on cognitive performance, sleep quality, stress levels and immunity in stressed individuals.

Prof. Christophe Hausswirth, PhD[1,2,3], Dr. Alexandre Coste, PhD[1], Dr. Vincent Raimondi, MD, PhD[4], Dr. Cyril Schmit, PhD[1], Dr. Anis Aloulou, PhD[5], Dr. François Duforez, MD[5], Nathalie Paradis[6] & Prof. Damien Léger, MD, PhD[7]

[1] Institut beScored, Sophia-Antipolis (France) ; [2] Université Côte d'Azur, Nice (France) ;
[3] University of Technology, Sydney (Australia); [4] Cerballiance Côte d'Azur, Cagnes-sur-Mer (France);
[5] European Sleep Center, Paris (France);[6] Medical Esthetic LPG® Expert, Sophia-Antipolis (France)
[7] Centre du Sommeil et de la Vigilance, Hôtel Dieu, Paris (France)

1. INTRODUCTION

While physical health and healthy life expectancy areincreasing steadily every year in Europe, this is not the case when it comes to mental health. According to the World Health Organisation (WHO), our mental health contributes directly to our overall health. This corresponds to "a state of mental well-being that enables people tocope with stresses of life, realise their abilities, learn well and work well, and contribute to their community" (WHO, 2005). It has been observed that stress-related illnesses such as burnout, sleep disorders, nervous tension, anxiety and vulnerability to various infections have increased considerably. These illnesses very often lead to type 2 diabetes, reduced immune function or cognitive problems; they develop over a long period, resulting in a real inability to work. It is also recognised that people with high levels of stress are more prone to injury, illness and even insomnia (Mirchandaney et al. 2022). Stress is known to increase our heart rate, raise cortisol and blood pressure, cause headaches, digestive problems, sleep problems, heart disease, and problems with memory and concentration.
All this affects our immune system and makes people physically more vulnerable to infections (Jarron et al. 2018; Mirchandaney et al. 2022; Segerstrom and Miller 2004).

In this context, various non-pharmacological options have been researched with the aim of reducing stress levels in people who are overworked or have sleep disorders (Hausswirth et al. 2022). Among these therapies, massage is often put forward as being of proven effectiveness; in fact, it has been shown that a relaxing massage can significantly reduce cortisol levels and increase serotonin and dopamine levels, considered the ‘happy hormones’ as they increase positive moods and emotions (Field et al. 2005). To confirm these data, several studies carried out on stress at work have shown that a 15-minute 'chair massage' per day for 1 month (back, shoulders, neck and head) resulted in improved concentration (visible on the electroencephalograph, EEG), reduced stress (i.e., cortisol), improved cognitive performance (faster, more accurate calculations), boosted team spirit, increased attention, improved creativity, reduced absenteeism from work and increased motivation (De Souza et al. 2021). In addition, Garner et al (2008) examined the effectiveness of massage in reducing stress, anxiety and aggression in young adults. This study was conducted by comparing treatment as usual (TAU) with TAU plus massage therapy intervention (MT) over a period of seven consecutive weeks. The study demonstrated a significant reduction in anxiety, resting heart rate and cortisol levels, while significant improvements in hostility and depression scores were observed in both treatment group.

Another more recent study found that massage had immediate positive effects on anxiety-related measures and reduced stress in hospitalised patients with cognitive impairment (Nazari et al. 2015). As well as reducing stress, massage is also known to improve the quality of sleep in people suffering from temporary insomnia.

Insomnia is determined by a lack of time spent in bed, a reduction in sleep quality and interrupted sleep that can significantly affect our daytime activities (American Psychiatric Association, 2000). In addition, with the steady increase in the pace of our lives, and due to ever-increasing work pressure, the incidence of insomnia has gradually risen and patients may have difficulty falling asleep, thus presenting not only with sleep disorders, but also mood disorders, chronic fatigue, increased irritability, all of which lead to a reduction in work efficiency (Feige et al. 2023). These changes can lead to states of intense stress, and could cause chronic cardiovascular diseases and even diseases of the nervous system. Currently, the main therapeutic option to treat insomnia is medication or behavioural therapy. Thus, the potential mechanisms by which massage could reduce insomnia are essentially the nervous axes (stimulation of the vagus nerve) and the endocrine system [hypothalamic-pituitary-adrenal (HPA) axis]. These two systems should be taken into consideration in the management of insomnia (He, 2019).

In this context, abdominal vibration therapy has recently been introduced. massage that uses the meridians to facilitate the efficiency of our organs in the body (Zhang et al. 2014). This technique is based on visceral massage, combining modern brain-gut interaction theory. This could gradually lead to the conception of a technique to improve the functionality of the brain by treating our intestines (Zhang et al. 2021). In addition, based on the results of several studies, it has been confirmed that abdominal vibration can significantly improve the symptoms of patients suffering from insomnia, and thus enhance neuronal activity. It has thus been shown that there is probably a brain-gut interaction in the treatment of insomnia. However, due to various limitations in clinical diagnosis, treatment standards and medical ethics, there is still a lack of research into the specific mechanism of brain-gut interaction in the treatment of insomnia by abdominal massage (Zhang et al. 2020). Treating insomnia therefore undoubtedly involves understanding the various stress factors that could induce prolonged periods of insomnia while modifying some of our immune defences.

The use of massage as an effective way of boosting our immune defences has recently been highlighted. Indeed, one study suggests that regular massage naturally increases the healthy immune system's ability to kill off certain cells to improve

the body's overall immune function (Poland et al. 2013). In particular, the participants in this study showed a joint increase in serotonin and in the cells that make up the immune system's initial defence against infection and disease. Another, more recent study was conducted on a population of healthy pregnant women and the hypothesis was to show the immune benefits of massage (Chen et al. 2017). These researchers found that the group receiving oil massage showed a significant reduction in cortisol levels and an improvement in levels of other immune markers such as immunoglobulin A. This study provides clear evidence that massage could significantly reduce stress and improve immune function in pregnant women. To support these results, a study has shown that people who have had a single massage session also experience significant changes in their immune and hormonal responses (Rapaport et al. 2010). They compared the effects of a 45-minute Swedish massage session with those of a simple effleurage massage of the same duration (Rapaport et al. 2010, 2012). The researchers found that people who received a Swedish massage experienced significant changes in their lymphocyte count, which plays an important role in a healthy immune system. The same results were demonstrated for certain regulatory T lymphocytes (CD8+ and CD56+).

At this stage, the study of the cumulative effects of massage presents a real challenge; it is possible that a dose-response effect exists and that several massage sessions can produce more effects, particularly on the immune system.

2. OBJECTIVE OF THE STUDY

This study examined the effects of a ten-session program of mechanised massage on immune, sleep and stress parameters in stressed individuals with sleep disorders. We hypothesised that a five-week program of mechanised massage would improve sleep quality in all participants, normalise their stress-related symptoms and increase immunity-related parameters. We also hypothesised that repeated use of mechanised massage would improve certain cognitive factors in all participants compared with a placebo group.

3. MATERIALS AND METHODS

3.1. Ethical approval

This clinical investigation (n° 2022-A01741-42) was approved by the french ethics committee "CPP Sud-Est I" on 12/09/2022 and was carried out in accordance with current good clinical practice at the beScored institute in Valbonne and the Cerballiance Saint-Jean medical biology laboratory in Cagnes-sur-Mer from 12/01/2023 to 14/06/2023. After receiving clear explanations of the nature of the study, its objectives, the way it was conducted and the associated risks, all participants gave their written informed consent.

3.2. Participants

A total of 32 participants aged between 22 and 57 voluntarily took part in the study, 29 of whom completed the entire program and were therefore included in the analysis (see figure 1). They were randomised into 2 groups: an experimental group (G-EXP) and a placebo group (G-PLA). Participants in the G-EXP completed a program of 10 sessions of massages using the Cellu M6 Alliance® according to the protocol defined below. The G-PLA participants carried out a program of 10 Cellu M6 massage sessions but with the lowest intensity, i.e. without aspiration or mobilisation of the skin fold, unlike a classic endermologie session .®
The inclusion and non-inclusion criteria for this study were as follows:

3.2.1. Inclusion criteria

- Volunteers in good health,
- Male or female,
- With a level of weekly physical activity below the level recommended by the World Health Organisation (i.e. less than 300 minutes of moderate-intensity physical activity or less than 150 minutes of sustained-intensity physical activity),
- With a score strictly greater than 7 on the *Insomnia Severity Index* (*ISI)* questionnaire, and a score of strictly greater than 13 on the *Perceived Stress Scale* (*PSS*),
- For women of childbearing age who are sexually active, it is necessary to use an effective contraceptive method (i.e. *Pearl* index < 1) for the duration of the study.

3.2.2. Non-inclusion criteria

- People with one or more known contraindications to endermologie® treatments,
- Vulnerable persons as defined in articles L. 1121-5 to L.1121-8 and L.1122-1-2 of the French Public Health Code (e.g. persons deprived of their liberty, minors, protected adults, etc.),
- People who have already had one or more endermologie sessions® ,
- Absence of affiliation to a social security scheme,
- Absence of consent / refusal to cooperate.

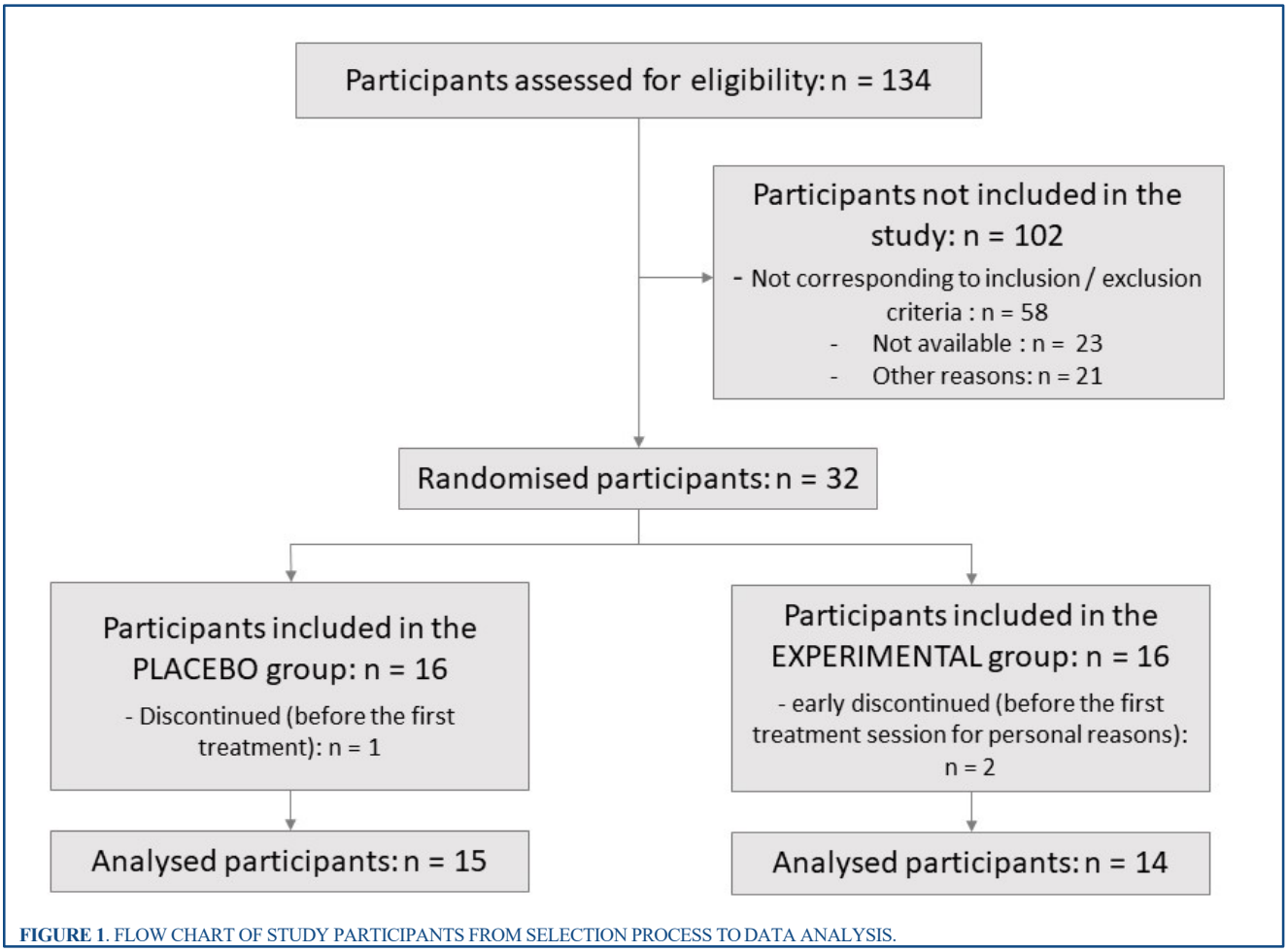


FIGURE 1. FLOW CHART OF STUDY PARTICIPANTS FROM SELECTION PROCESS TO DATA ANALYSIS.

3.3. Experimental design

The present study is an interventional, bi-centric, randomised, single-blind study in which participants in both groups (G-EXP and G-PLA) underwent a program of 10x 40-minute sessions of mechanised massage using the Cellu M6 Alliance® with a qualified, LPG-certified therapist® (Nathalie Paradis, osteopath and physiotherapist). The comparison between the experimental group and the placebo group made it possible to evaluate the specific action of mechanised massage on cognitive performance, sleep quality, stress levels and immunity, independently of potential psychological effects.The program took place over a period of 5 weeks, at a rate of 2 weekly sessions separated by at least 48 hours.

Various measurements, presented in Figure 2 and detailed below, were taken before, during and after the program for participants in both groups (G-EXP and G-PLA).

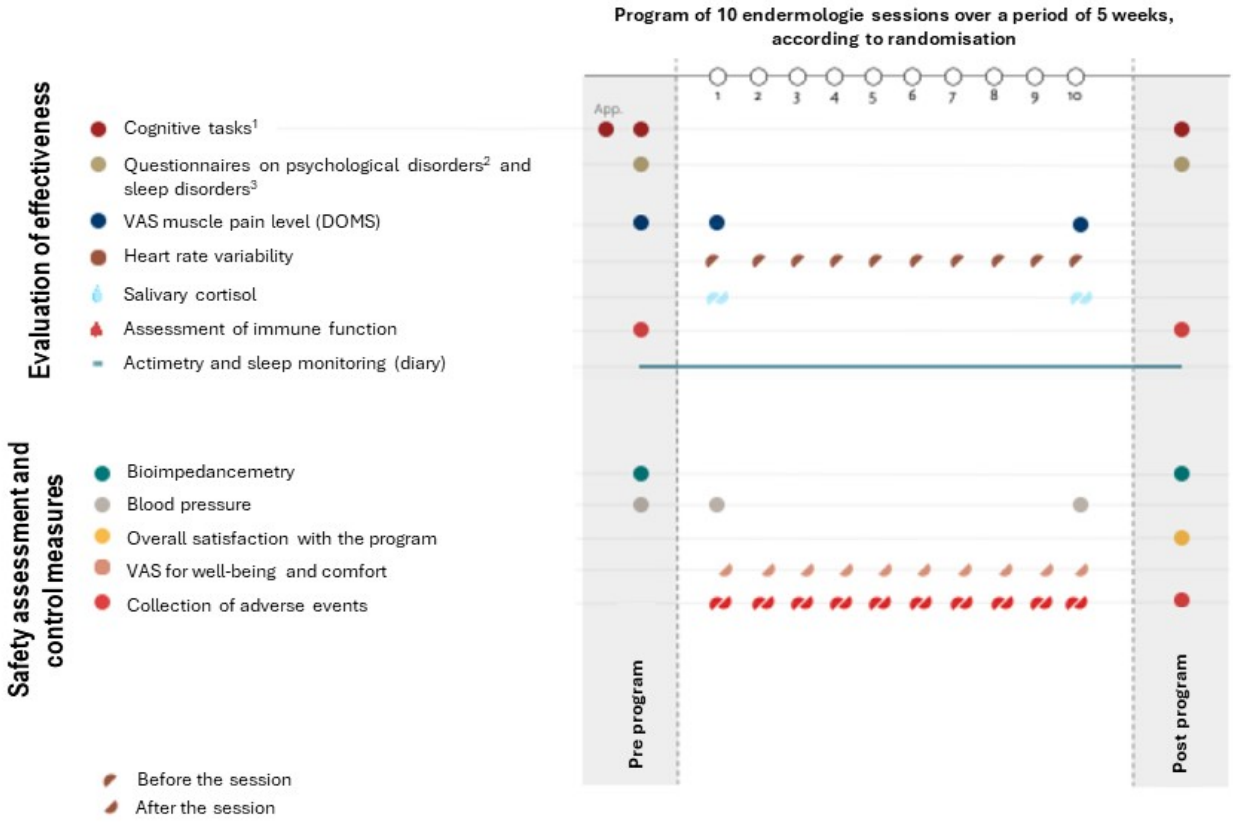


FIGURE 2: SCHEMATIC REPRESENTATION OF THE EXPERIMENTAL DESIGN AND THE VARIOUS MEASUREMENTS CARRIED OUT DURING THE STUDY FOR THE EXPERIMENTAL GROUP (G-EXP) AND THE PLACEBO GROUP (G-PLA).

To avoid any bias, all the measurements were carried out by the same experimenter, and participants were asked not to apply any body creams or treatments for the duration of the study. In addition, no exposure to the sun or infrared rays was permitted during this period, nor were massage, cryotherapy, sauna or hammam sessions allowed. Finally, the participants were asked not to change their lifestyle, either in terms of physical activity, sport or diet.

3.3.1. Course of sessions

The endermologie® sessions lasted 45 minutes each, comprising 5 minutes of set-up and 40 minutes of treatment. After giving an individual suit specially designed for endermologie® treatments, participants were asked to lie on a massage table, initially on the dorsal decubitus position (i.e. on their back), allowing the therapist to work on the front of the body for 10 minutes, then in the ventral decubitus position (i.e. on their stomach) for work on the back for 30 minutes (see figure 3 below for an overview of the body areas treated and the time breakdown).

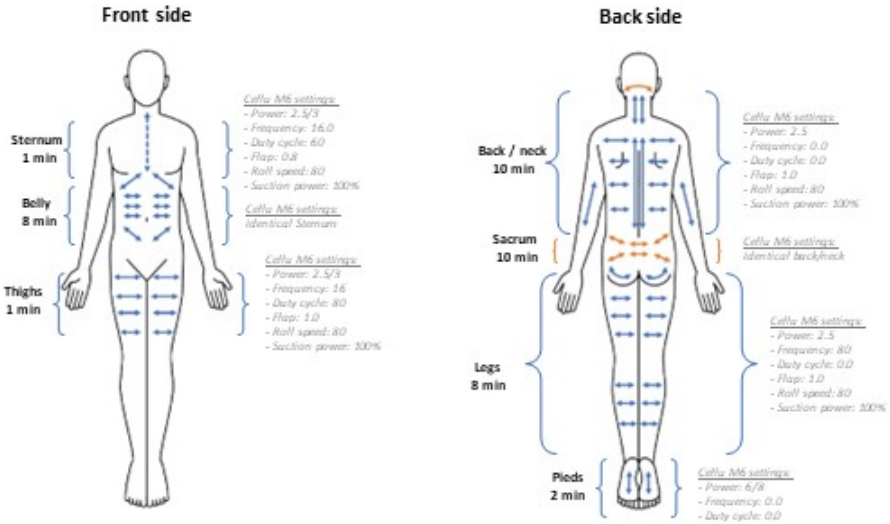


FIGURE 3. SCHEMATIC REPRESENTATION OF THE DIFFERENT BODY ZONES TARGETED AND THE MOVEMENTS AND DURATIONS OF THE CELLU M6 TREATMENT HEAD FOR PARTICIPANTS IN BOTH GROUPS (G-EXP AND G-PLA). PLEASE NOTE THAT THE SYSTEM SETTINGS, SHOWN IN GREY, ARE FOR THE EXPERIMENTAL GROUP ONLY. REFER TO THE BODY OF THE TEXT FOR MORE DETAILS ON THE SETTINGS OF THE PLACEBO GROUP.

The device used was the Cellu M6 (LPG Systems, Valence). This is a class IIa medical device (certificate no. 20M00111CRT01) enabling various skin mobilisation manoeuvres to be performed using a treatment head equipped with a suction force enabling a skin fold to be grasped. Skin and subcutaneous tissue are mobilised by rollers and valves inside the treatment head. Numerous settings are possible for action of varying depth and intensity. Figure 3 shows the Cellu M6 settings, depending on the body zones treated, for the G-EXP. For the G-PLA, the movements of the treatment head and the application times were strictly the same as for the G-EXP (as shown in Figure 3), but the settings of the Cellu M6 differed: Power: 0, Frequency: 0.0, Duty cycle: 0.0, Flap: 1.0, Roll speed: 100, Suction power: 100% for the whole body.

3.4. Tools and measurements

3.4.1. Stress, anxiety and mood assessment

The participants' stress levels were assessed objectively using two separate methods: measurement of salivary cortisol and measurement of heart rate variability (HRV). For the cortisol measurement, saliva samples were collected

using specal tube (Sarstedt-Salivette) immediately before treatment and 15 min after the end of treatment at the first (S1) and last (S10) treatment sessions. In order to guarantee the reliability of the results, the sessions were scheduled at the same time slot, and participants were asked to refrain from smoking for 4 hours prior to sampling, and not to eat or drink any hot beverages (e.g. tea, coffee) or sweetened beverages for 30 minutes prior to sampling. Saliva samples were then immediately frozen and stored at -20°C before being analysed according to the methodology described by Vandeputte et al (2023). HRV was measured throughout the program, at the start of each session, using a chest heart rate sensor (Polar H9, Kempele, Finland) connected via Bluetooth to the *Elite HRV* application (https://elitehrv.com/). Participants were asked to lie on their backs in a quiet room for a period of 5 minutes. Participants were required to wear a black-out mask and earplugs. No specific breathing frequency was imposed. For data analysis, only RR intervals between 1 min 30 and 4 min 30 from recordings of the first session (pre-program), sessions 2 to 4 (start of program), sessions 5 to 7 (middle of program), and sessions 8 to 10 (end of program) were used to calculate temporal indices of HRV, namely the root mean square of successive R-R intervals (*RMSSD*; Pereira et al. 2017).

In addition to objective measures, participants' levels of stress, anxiety and psychological well-being (mood states) were assessed subjectively using self-questionnaires administered before and after the 10-session program: *Perceived Stress Scale (PSS-10), Hospital Anxiety and Depression Scale (HADS) and Abbreviated Profile of Mood States (abbreviated POMS).*

Perceived Stress Scale (PSS-10)

First, the participants were asked to complete the French version of the *PSS-10* questionnaire, originally developed in 1983 by Cohen et al. to assess people's perceived stress levels. Of the ten questions that make up the *PPS-10*, six are negative and four are positive. A Likert scale ranging from 0 points (never) to 4 points (very often) is used to calculate the score, the scale being inverted for the negative questions. Thus, the total score is between 0 and 40, with the following interpretation of the level of stress: "low" from 0 to 13 points, "moderate" from 14 to 26 points, and "high" from 27 to 40 points.

Hospital Anxiety and Depression Scale (HADS)

Secondly, the participants answered the French version of the *HADS* questionnaire (Zigmond & Snaith, 1983) proposed by the Haute Autorité de Santé in 2021. This consists of 14 items graded from 0 to 3 points to measure the severity of symptoms related to anxiety and depression. The score for each psychological disorder ranges from 0 to 21. A score between 0 and 7 is considered 'normal', between 8 and 10 'borderline abnormal', and between 11 and 21 'abnormal'.

Abbreviated Profile of Mood States (abbreviated POMS)

Finally, the participants answered the short version of the *POMS* (Grove and Prapavessis, 1992). This psychometric test is a self-assessment of mood profile in which participants rate themselves on 40 adjectives using a Likert scale ranging from 1 to 5 points.

These 40 responses are used to define 6 mood states (i.e. anger, vigour, depression, fatigue, tension, self-esteem and confusion). In addition, the Total Mood *Disturbance* (*TMD)* is calculated by adding the totals of the negative subscales, then subtracting the totals of the positive subscales (i.e., *TMD* = [Anger + Depression + Fatigue + Tension + Confusion] - [Vigour + Self-Esteem]).

3.4.2. Assessment of immune function

To assess the participants' immune function, blood samples were taken the week before the start of the treatment program and the week after the last session (S10). These samples were used to determine the levels of lymphocytes and lymphocyte regulators (i.e. T lymphocytes, CD3, CD4, CD8) per cubic millimetre of blood.

3.4.3. Assessment of sleep-related parameters

Participants' sleep was also monitored throughout the program using an actimeter (*Motionwatch 8*, Cambridge Neurotechnology Ltd., Cambridge, UK) worn only at night on the non-dominant wrist (i.e. on the left for right-handers and on the right for left-handers). Actimetry data, sampled at 50Hz and processed over 30-second time windows, were used to express various parameters:

- the time spent in bed (i.e. the total time elapsed between the 'going to bed' and 'getting up' moments corresponding to the time markers set by the participants when they pressed the button on the actimeter);
- actual sleep time (i.e., the total time spent 'asleep', calculated from actigraphic activity);
- Sleep efficiency (actual sleep time expressed as a percentage of time spent in bed) ;
- time to fall asleep sleep or sleep latency (i.e. the time between going to bed and falling asleep);
- time spent still;
- the fragmentation index (i.e., an indicator of sleep quality).

As with HRV, these actimetric indices were averaged over periods of 4 nights before the program (pre-program), after the 1st session (start of program), after the 5th session (middle of program) and after the 10th session (end of program).

In addition, participants completed various questionnaires, before and after the program, on sleep quality and sleep disorders: *Insomnia Severity Index (ISI), Ford Insomnia Response to Stress Test (FIRST), Spiegel Sleep Quality (SSQ).*

Insomnia Severity Index (ISI)

This is a self-assessment questionnaire consisting of 7 items assessing the nature, severity and impact of insomnia (Bastien et al. 2001). A 5-point Likert scale is used to evaluate each item (from 0 = no problem to 4 = very serious problem), giving a total score ranging from 0 to 28 points. The total score is interpreted as follows: no insomnia (score between 0 and 7 points); sub-threshold insomnia (score between 8 and 14); moderate insomnia (score between 15 and 21 points); severe insomnia (score between 22 and 28 points).

Ford Insomnia Response to Stress Test (FIRST)

Sleep reactivity was assessed using the French version of the *FIRST* test validated by Chen et al. (2015). This is a 9-item questionnaire designed to assess the likelihood of an individual experiencing difficulty falling asleep in response to common stressful situations. Each item is self-assessed on a 4-point Likert scale and summed to give a total score of between 9 and 36 points. A high score indicates that sleep reactivity is important, and vice versa.

Spiegel Sleep Quality (SSQ)

Finally, in order to assess perceived sleep quality, participants completed the French version of the *Spiegel Sleep Quality* questionnaire (Spiegel, 1981). This consists of six items scored from 0 to 5 points. The maximum score is 30 points, and sleep disorders are identified when the score is strictly below 24 points. If the score is strictly below 15 points, it is generally accepted that the participant has a sleep-related pathological condition.

3.4.4. Assessment of cognitive performance

Three cognitive tasks, implemented in Matlab/PsychToolbox and carried out in sequence on the computer, were used to assess the effects of the program on the participants' cognitive performance.

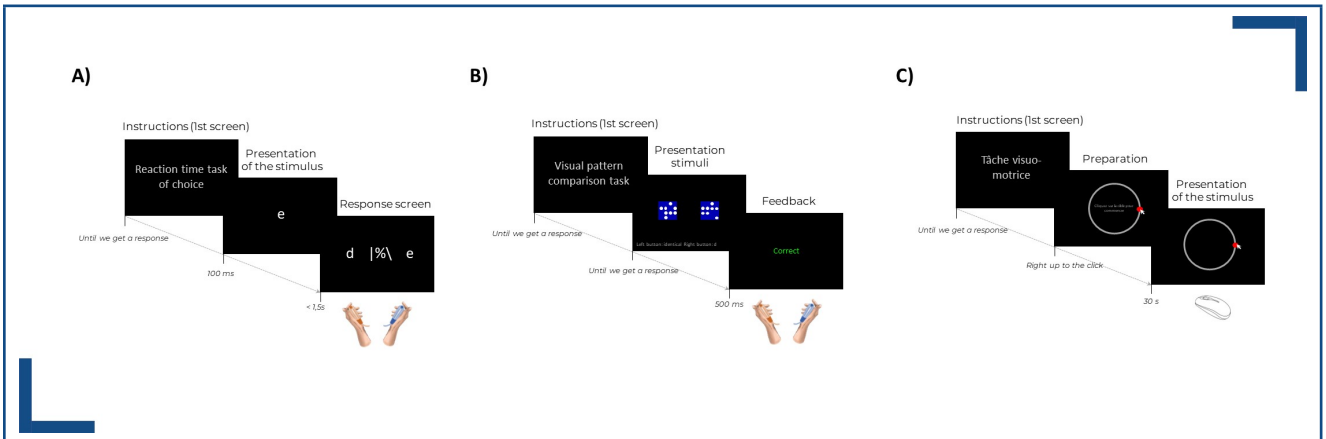


FIGURE 3. ILLUSTRATION OF THE 3 COGNITIVE TASKS (AND THEIR TEMPORAL BREAKDOWN) USED TO ASSESS PARTICIPANTS' COGNITIVE PERFORMANCE: **A)** CHOICE REACTION TIME TASK, **B)** VISUAL PATTERN COMPARISON TASK, **C)** VISUOMOTOR TASK. CF. BODY TEXT FOR MORE DETAILS.

Choice Reaction Time (CRT) task

First, participants performed a choice reaction time (*CRT*) task to assess reaction time, selective response inhibition and the speed of processing psychomotor information (Mueller and Piper, 2014; Burle et al. 2004). As its name suggests, the choice reaction time task is an elementary task in which a fixation cross appears in the centre of the computer screen for 1,250 ms, before giving way to a target stimulus (a letter chosen randomly from the letters: a, d, c, e, o, n, b, g, s) for a duration of 100 ms.

The target letter (e.g. the letter 'a') is then briefly masked by three non-alphabetic characters (3 symbols chosen at random from the following symbols: & # @ $ % *| ?/ \) before reappearing either to the right or to the left, alongside a distracting stimulus (a letter other than the target letter, e.g. the letter 'e'). As quickly and correctly as possible, participants then had to press a push button (left or right) to indicate which side of the screen the target stimulus ('a') appeared on. It should be noted that a time constraint of 1.5 seconds was applied, i.e. if no response was received from the participant within this time, the response screen disappeared and a new trial began. A learning phase, consisting of at least 7 blocks of 30 trials (depending on the participants' learning curve, with stopping criteria of accuracy in performing the task strictly greater than 85% and inter-block variability strictly less than 5%), was carried out one week before the test phase and the start of the program. A total of 216 trials (9 target stimuli: a, d, c, e, o, n, b, g, s x 24 repetitions) were performed a few days before the first treatment session for pre-program evaluation, and a further 216 trials were performed a few days after the last session for post-program evaluation. Mean reaction time (expressed in milliseconds) and response accuracy (i.e. the rate of correct responses) were used as performance indicators for this task.

Visual Pattern Comparison (VPC) task

In a second step, participants performed a visual pattern comparison task (*VPC*, Mueller and Piper, 2014). Like the *CRT*, the visual pattern comparison task measures reaction time and psychomotor information processing speed, with the difference that participants are not primed by subliminal information. In this task, participants are simultaneously presented with two visual stimuli (grids), one next to the other, and must determine as quickly as possible whether they are identical or different by pressing one of the push buttons. A learning phase of at least 7 blocks of 40 trials under the same conditions as above, preceded by two evaluation phases, pre- and post-program. These included 400 trials each (200 congruent trials, i.e. when the pair of stimuli was identical, and 200 incongruent trials, i.e. when the pair of stimuli was different). Both mean reaction time (in ms) and response accuracy were the measures of interest in this task.

Pursuit Rotor Task (PRT)

Finally, in the third and last stage, participants performed a visuomotor task (*PRT*, Mueller and Piper, 2014) in which they had to track, using the computer mouse, a moving target moving along a circular trajectory. The mean time spent on the target as well as the mean deviation between the cursor and the centre of the target (i.e., spatial accuracy in pixels) were the dependent variables. A minimum of 7 blocks of 30 seconds were performed to familiarise the participants with the task, with the stopping criteria being time spent on target strictly greater than 70% of the total trial duration, inter-block variability strictly less than 10% and mean cursor-target deviation strictly less than 25 pixels. The pre- and post-program evaluation sessions comprised four trials of two minutes each, i.e. 4 x 16 revolutions (the speed of rotation was set at one complete revolution every 7.5 s).

3.4.5. Ancillary measurements

Blood pressure

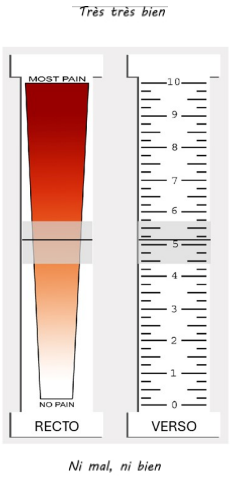
In order to characterise our population, systolic blood pressure (SBP), diastolic blood pressure (DBP) and heart rate at rest were measured before the program using an electronic upper arm blood pressure monitor (HBP 1120, Omron, Kyoto, Japan).

Bioimpedancemetry

Participants' body mass was also assessed before the start of the program using an impedance-meter scale (MC 780 MA; Tanita Europe BV, Amsterdam, Netherlands). Measurements were taken in underwear and bare feet.

Assessment of muscular pain levels and general well-being Muscular pain levels (*Delayed Onset of Muscle Soreness, DOMS; Mattacola et al. 1997)*

The participants muscular pain, muscle soreness and general well-being (Masa et al. 2011) were assessed at different measurement times (before the program, after the first and last session for muscular pain and at the end of each session for well-being) using 100 mm visual analogue scales (VAS) fitted with a sliding indicator. The questions asked were as follows.



The following questions were asked: "How do you rate your level of muscular pain at the moment? and "How do you rate your level of well-being at the moment? Only the front of the scale was presented to the participants. This showed the title of the question and a linear gauge with two marks at the ends (bottom: "No pain"; top: "Very very painful").
"On the reverse side, the experimenter could record the score between 0 and 10 (corresponding to the position in millimetres of the indicator sliding between the two ends) without the participant being aware of it. On the reverse side, the experimenter could record the score between 0 and 10 (corresponding to the position in millimetres of the indicator sliding between the two extremities) without the participant's knowledge.

Questionnaire on overall satisfaction with the program

Finally, at the end of the program, a satisfaction questionnaire (*Client Satisfaction Questionnaire*, *CSQ-8*; Attkisson & Zwick, 1982) was administered to participants in both groups. The *CSQ-8* is an 8-item questionnaire designed to score the satisfaction of users of different products or services. Each *CSQ-8* item is scored from 1 to 4.

The total CSQ-8 score, corresponding to the sum of the responses to each item, is therefore between 8 and 32. On the basis of this total score and the 'Net Promoter Score' (NPS) methodology, participants were classified into 3 categories: detractors (score ≤ 22), passives (22 < score ≤ 27) and promoters (27 < score ≤ 32). The NPS is therefore the difference between the proportion of promoters minus the proportion of detractors, and is between -100 and +100.

3.5. Data analysis

All data were recorded on an electronic notebook, then pre-processed and analysed using Matlab software (Version 2023a, The MathWorks, Natick, MA, USA) and JAMOVI statistical analysis software (Version 2.4.7.0, Sydney, Australia). One-way analyses of variance (ANOVAs) (G-EXP vs. G-PLA group) with repeated measures (time points: Before vs. After program or Before vs. Beginning vs. Middle vs. End of program), and where necessary, post-hoc analyses (Tukey HSD), were conducted on all the variables of interest. Beforehand, normality, homogeneity of variances and the sphericity hypothesis were verified using the Shapiro-Wilk test, the Levene test and the Mauchly test, respectively.

4. RESULTS

4.1. General characteristics of participants

The initial characteristics of our population are presented in Table 1 below. As shown, the sample was predominantly female (86% and 87% respectively for the experimental and placebo groups) and had stress levels and sleep disorders judged to be moderate to severe. For all the initial characteristics, there was no statistical difference between the two groups, indicating good randomisation, an essential step for further analysis.

Features	Experimental group G-Exp (n = 14)	Placebo group G-Pla (n = 15)	Meaning statistics
Demographic and anthropometric data			
Gender, No. (%)			
Women	12 (86%)	13 (87%)	
Men	2 (14%)	2 (13%)	
Average age (years)	43,9 ± 8,6	37,5 ± 10,1	*ns* (p =0.08)
Weight (kg)	71,0 ± 12,8	72,5 ± 18,4	*ns* (p =0.80)
Height (cm)	166,5 ± 6,7	166,1 ± 8,0	*ns* (p =0.88)
BMI ($^{kg/m2}$)	25,6 ± 4,6	26,3 ± 6,6	*ns* (p =0.75)
Level of physical activity (min/week)			
Moderate intensity	79,3 ± 92,2	28 ± 53,7	*ns* (p =0.08)
Sustained intensity	0 ± 0	3 ± 11,6	*ns* (p =0.37)
Cardiovascular factors			
Blood pressure (mmHg)			
Systolic	125,8 ± 14,8	126,5 ± 16	*ns* (p =0.91)
Diastolic	77,6 ± 10,3	77,5 ± 8,5	*ns* (p =0.96)
Resting heart rate (bpm)	64,8 ± 8,5	70,5 ± 12,8	*ns* (p =0.17)

Questionnaire scores			
Anxiety (HADS)	12,2 ± 3,8	10,4 ± 2,2	*ns* (p =0.47)
Depression (HADS)	7,6 ± 3,8	6,7 ± 2,5	*ns* (p =0.64)
Perceived stress (PSS)	25,3 ± 6,5	23,3 ± 4,2	*ns* (p =0.59)
Sleep quality (SSQ)	15,6 ± 3,6	16,5 ± 3,0	*ns* (p =0.83)
Insomnia Severity Index (ISI)	19,9 ± 3,3	18,1 ± 4,0	*ns* (p =0.20)

Notes :
PSA: Physical Activity and Sport; HADS: Hospital Anxiety and Depression Scale
PSS: Perceived Stress Scale; SSQ: Spiegel Sleep Questionnaire; ISI: Insomnia Severity Index

TABLE 1. CHARACTERISTICS OF PARTICIPANTS AT THE INCLUSION VISIT. VALUES ARE PRESENTED AS MEAN ± STANDARD DEVIATION.

4.2. Effects of endermologie essions on stress

Figure 4 shows the results of the two objective measures of participants' stress levels, namely heart rate variability (Figure 4A) and salivary cortisol levels (Figure 4B). A significant increase in the *RMSSD* indicator of HRV was found for the experimental group only (+76.6% between the pre-program measurement and the measurement taken at the end of the program $p < 0.05$), indicating a higher level of vitality for the G-EXP participants compared with the placebo group, where the increase was only 7.5% (not significant). This result is consistent with the measurement of salivary cortisol - the stress hormone - showing a significant decrease ($p < 0.01$) for the experimental group only. Interestingly, this effect was observable from the first endermologie session, with a significant 19% reduction in salivary cortisol concentration between the Pre and Post S1 measurements (compared with a non-significant -4.8% for G- PLA).

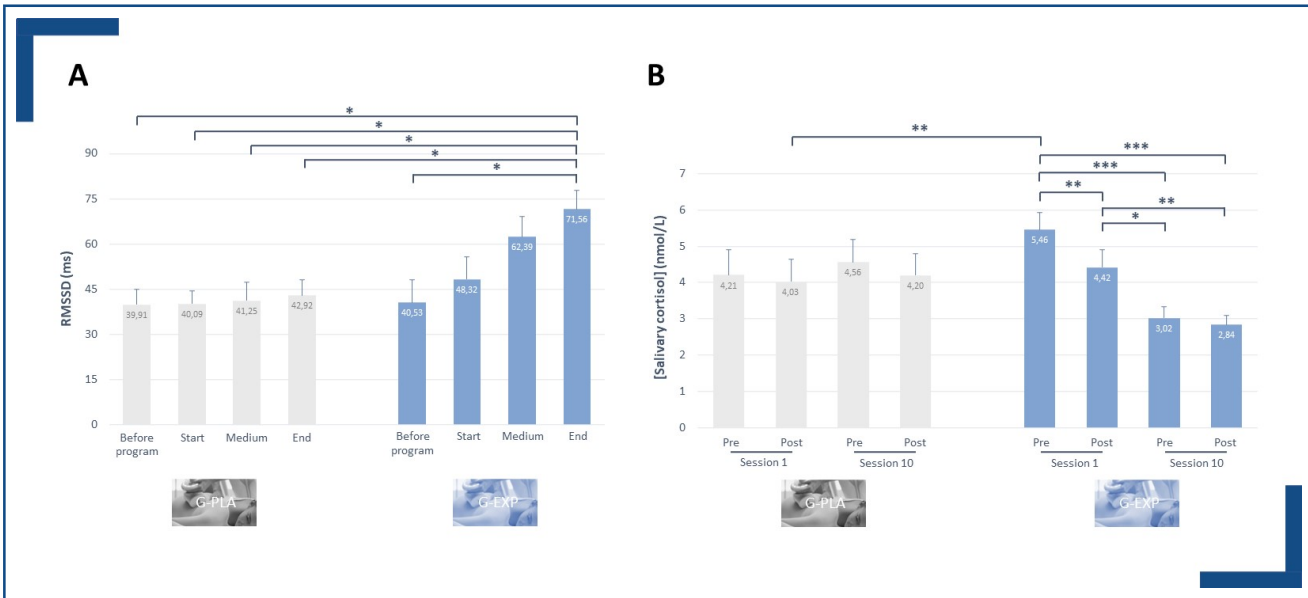


FIGURE 4. **A)** CHANGES IN HEART RATE VARIABILITY (RMSSD) OVER THE COURSE OF THE program FOR THE PARTICIPANTS IN THE EXPERIMENTAL AND PLACEBO GROUPS. **B)** CHANGES IN SALIVARY CORTISOL LEVELS BEFORE AND AFTER THE FIRST AND LAST ENDERMOLOGIE® SESSIONS. NOTE: ASTERISKS INDICATE SIGNIFICANT MEAN DIFFERENCES (* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$).

Psychometric measures (i.e., self-questionnaires; Table 2) corroborate these objective measures, although significant differences were noted in the placebo group for two of the three questionnaires relating to stress, anxiety and mood states (PSS and POMS).

Statistical analysis revealed a significant reduction in perceived stress among participants in both groups between pre- and post-program measurements (-49.4% *p<0*.001 for G-EXP and -29.2% *p<0*.01 for G-PLA), as well as a significant reduction in total mood disturbance (-71.4% *p<0*.001 for G-EXP and -64% *p<0*.001 for G-PLA). It should be kept in mind, however, that the perceptual effects observed in the placebo group do not appear to result exclusively from a simple placebo effect, but could also be due to a relaxing effect inherent in the lying position maintained for almost forty minutes, twice a week, for five consecutive weeks, as well as to skin stimulation of the effleurage type. In addition, it should be noted that only the participants in the experimental group recorded a significant reduction in their levels of anxiety (-37.4%, $p < 0.01$ *vs.* 23.1%, *ns* for G-PLA) and depressive disorders (-50.9%, $p < 0.001$ vs. -20%, *ns* for G-PLA).

Questionnaire	Size (min-max score)	Group	Before program	After program	Rate of change $_{before/after}$ (%)
HADS	Anxiety (0–21)	G-PLA	10,4 ± 2,2	8,0 ± 3,4	-23,1
		G-EXP	12,2 ± 3,8	**7,6 ± 3,5****	-37,4
	Depression (0–21)††	G-PLA	6,7 ± 2,5	5,3 ± 3,2	-20,0
		G-EXP	7,6 ± 3,8	**3,7 ± 2,8*****	-50,9
PSS	Perceived stress (0–40)†	G-PLA	23,3 ± 4,2	**16,5 ± 5,8****	-29,2
		G-EXP	25,3 ± 6,5	**12,8 ± 5,3*****	-49,4
ISI	Severity of insomnia (0–28)††	G-PLA	18,1 ± 4,0	**13,2 ± 4,0****	-26,9
		G-EXP	19,9 ± 3,3	**9,0 ± 4,9*****	-54,7
FIRST	Sleep reactivity (9–36)	G-PLA	30,4 ± 3,1	25,9 ± 6,1	-14,9
		G-EXP	29,5 ± 4,1	26,6 ± 5,9	-9,7
SSQ	Quality of sleep (0–30)	G-PLA	16,5 ± 3,0	**21,5 ± 3,6*****	30,8
		G-EXP	15,6 ± 3,6	**22,0 ± 3,3*****	41,3
POMS	Tension (0–24)	G-PLA	18,1 ± 3,7	**11,9 ± 4,7*****	-34,3
		G-EXP	16,9 ± 4,2	**11,3 ± 4,7*****	-33,1
	Depression (0–28)	G-PLA	14,7 ± 5,0	**9,6 ± 2,5*****	-34,7
		G-EXP	14,7 ± 4,3	**9,9 ± 4,1*****	-32,7
	Anger (0–24)	G-PLA	14,1 ± 4,3	**9,2 ± 3,0*****	-34,8
		G-EXP	13,6 ± 4,6	**8,7 ± 4,6*****	-36,0
	Vigour (0–20)	G-PLA	13,5 ± 3,0	**14,4 ± 3,9****	6,7
		G-EXP	14,0 ± 4,3	**16,9 ± 4,5****	20,7
	Tiredness (0–20)	G-PLA	17,7 ± 3,2	**11,3 ± 2,8*****	-36,2
		G-EXP	16,9 ± 3,1	**9,8 ± 4,2*****	-42,0
	Confusion (0–24)	G-PLA	12,7 ± 3,0	**9,3 ± 3,6*****	-26,8
		G-EXP	14,5 ± 2,6	**9,6 ± 3,6*****	-33,8
	Total mood disturbance (-44–76)	G-PLA	48,1 ± 15,3	**17,3 ± 17,7*****	-64,0
		G-EXP	46,8 ± 18,4	**13,4 ± 25,3*****	-71,4
CSQ-8	Overall satisfaction (8–32)	G-PLA	NA	26,2 ± 3,3	NA
		G-EXP	NA	**28,4 ± 2,3**	NA
	Net Promoter Score (-100–100)	G-PLA	NA	26,7	NA
		G-EXP	NA	**64,3**	NA

Notes:

PSS : Perceived Stress Scale ; HADS : Hospital Anxiety and Depression Scale ; ISI : Insomnia Severity Index ; FIRST : Ford Insomnia Response to Stress Test ; SSQ : Spiegel Sleep Questionnaire; POMS : Abbreviated Profile Of Mood States

CSQ-8 : Customer satisfaction Questionnaire-8

†Significant Time-Group Interaction ($p < 0.05$), ††Significant Time-Group Interaction ($p < 0.01$), †††Significant Time-Group Interaction ($p < 0.001$)

*Significantly different from the pre-programme measurement ($p < 0.05$), **Significantly different from the pre-programme measurement ($p < 0.01$), ***Significantly different from the pre-programme measurement ($p < 0.001$)

TABLE 2. SUMMARY OF PSYCHOMETRIC ASSESSMENTS (SELF-QUESTIONNAIRES) BEFORE AND AFTER THE program FOR PARTICIPANTS IN THE EXPERIMENTAL (G-EXP) AND PLACEBO (G-PLA) GROUPS. THE VALUES PRESENTED ABOVE A R E THE MEAN ± STANDARD DEVIATION.

4.3. Effects of endermologie sessions on immunity

There were distinct trends in immune function between the G-PLA and G-EXP groups. While participants in the G-PLA group showed a non-significant decrease in their T lymphocytes (-5%), and CD3 (-6.3%), CD4 (-4.4%) and CD8 (-1.9%) lymphocyte regulators, those in the G-EXP group showed a significant increase in their

T lymphocytes (+9.6%, *p<0*.05), and CD8 (+9.4%, *p<0*.05) as well as a non-significant increase in CD3 (+1.3%) and CD4 (-5.5%) regulators. Taken together, these results suggest a boost in the immune status of participants who had received mechanised massage sessions.

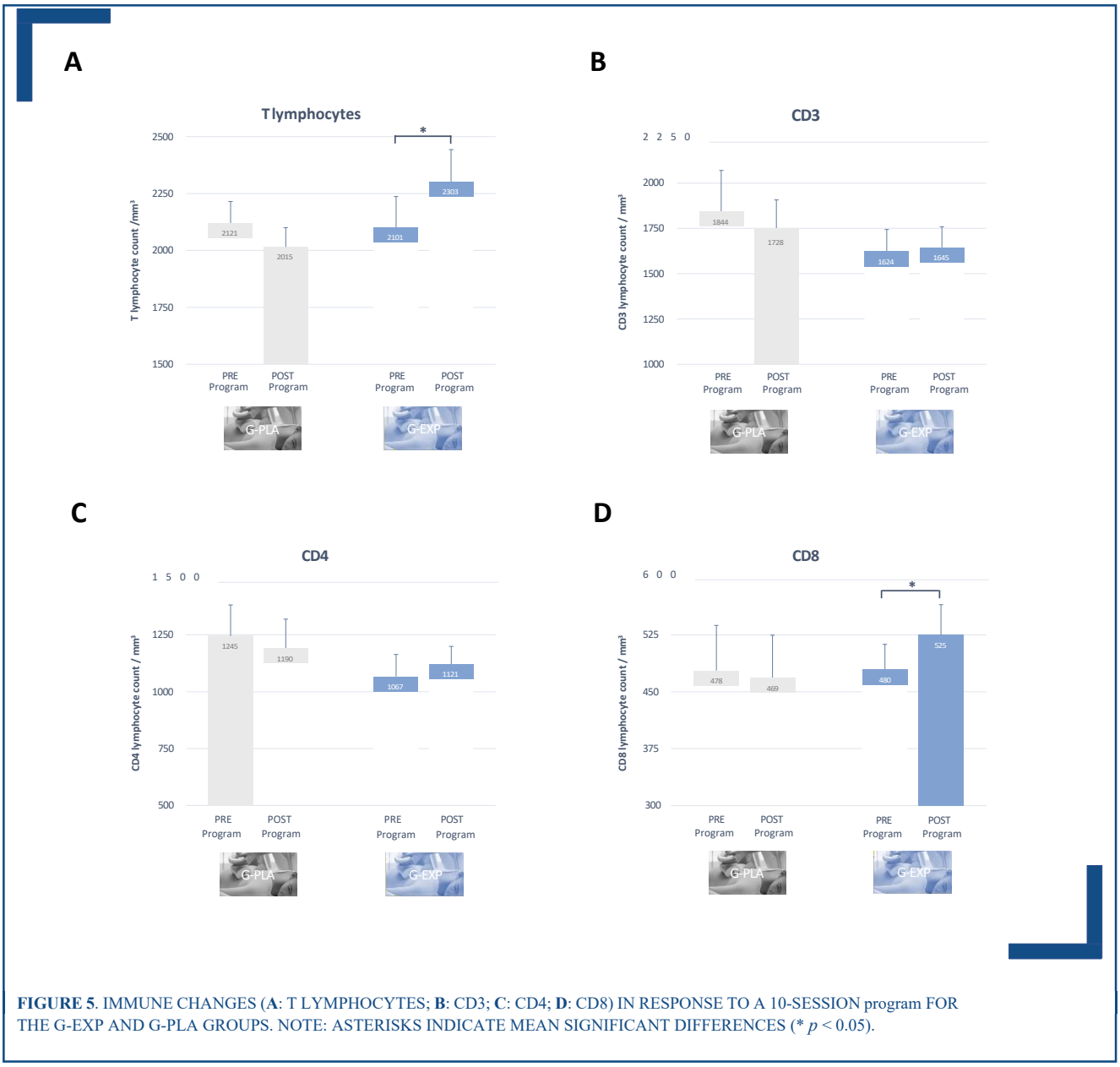


FIGURE 5. IMMUNE CHANGES (**A**: T LYMPHOCYTES; **B**: CD3; **C**: CD4; **D**: CD8) IN RESPONSE TO A 10-SESSION program FOR THE G-EXP AND G-PLA GROUPS. NOTE: ASTERISKS INDICATE MEAN SIGNIFICANT DIFFERENCES (* $p < 0.05$).

4.4. Effects of endermologie essions on sleep quality

With regard to sleep, the actimetry data (table 3) show a significant increase in time spent immobile (+3.9%, *p<0*.05 for G-EXP *vs*. 0.5%, *ns* for G-PLA) and a significant reduction in the fragmentation index (-19.2% between measurements before and at the end of the program, *p<0*.001 *vs.* -8.2%, *ns* for G-PLA) for the experimental group only. This indicates a significant improvement in sleep continuity and quality in the G-EXP participants compared with those in the placebo group. With regard to perceptual aspects (cf. table 2), as with the stress-related questionnaires, there was a significant increase in perceived sleep quality (i.e., on the *SSQ* questionnaire, +41.3%, *p<0*.001 for G-EXP *vs.* +30.7%, *p<0*.001 for G-PLA) as well as a decrease in perceived sleep quality (i.e., on the SSQ questionnaire, +41.3%, *p<0.001 for G-EXP vs.* +30.7%, *p<0.001 for* G-PLA) and also a

significant decrease in the insomnia severity index (-54.7%, *p<0*.001 for G-EXP *vs.* -26.9%, *p<0*.01 for G-PLA) for both groups, although these variations were greater for G-EXP. On the other hand, for sleep reactivity (*FIRST* questionnaire) the decreases were comparable in the two groups, i.e. -14.9% for G-PLA and -9.7% for G-EXP.

Parameters	Group	Before	Start	Medium	End
Time spent in bed (hh:mm)	G-PLA	08:05 ± 01:17	07:49 ± 00:55	07:33 ± 01:00	07:44 ± 00:39
	G-EXP	08:06 ± 00:58	07:56 ± 00:41	08:05 ± 00:48	07:51 ± 00:47
Real sleep time (hh:mm)	G-PLA	06:41 ± 01:04	06:28 ± 00:52	06:13 ± 00:54	06:21 ± 00:44
	G-EXP	06:42 ± 00:42	06:28 ± 00:38	06:39 ± 00:32	06:27 ± 00:31
Sleep efficiency (%)	G-PLA	83,3 ± 5,9	82,9 ± 6,1	82,5 ± 6,7	82,2 ± 7,4
	G-EXP	83,1 ± 3,9	82,1 ± 7,6	82,6 ± 5,9	83,6 ± 6,2
Time to fall asleep (min)	G-PLA	19 ± 13	16 ± 11	16 ± 11	18 ± 13
	G-EXP	19 ± 12	25 ± 22	24 ± 19	23 ± 21
Still time (min)	G-PLA	412 ± 45	407 ± 38	399 ± 39	414 ± 32
	G-EXP	410 ± 41	416 ± 44	424 ± 36	**426 ± 33***
Fragmentation index †	G-PLA	28,1 ± 5,2	27,3 ± 5,2	26,5 ± 5,5	25,8 ± 4,9 $^{p = 0.17}$
	G-EXP	28,7 ± 4,0	26,6 ± 4,6	25,2 ± 3,9	**23,2 ± 4,4*****

Notes :

†Significant Time-Group Interaction ($p < 0.05$)

*Significantly different from the pre-programme measurement ($p < 0.05$), ***Significantly different from the pre-programme measurement ($p < 0.001$)

TABLE 3. MAIN RESULTS OF THE SLEEP ANALYSIS BASED ON ACTIMETRY DATA AT DIFFERENT TIMES DURING THE PROGRAMME (BEFORE, START, MIDDLE, END) FOR THE EXPERIMENTAL (G-EXP) AND PLACEBO (G-PLA) GROUPS. VALUES ARE PRESENTED AS MEAN ± STANDARD DEVIATION.

4.5. Effects of endermologie sessions on cognitive performance

The results of the three cognitive tasks performed before and after the program of 10 endermologie® sessions are presented in Table 4 below. Although the G-EXP intervention resulted in visible improvements on all tasks (e.g., +6.1% time on target, -7.9% mean deviation, -6.8% response time for congruent trials in the visual pattern matching task), only the task requiring high time pressure, namely the choice reaction time task, showed a significant improvement in response accuracy (+2.5%, p<0.01 for G-EXP vs. +0.1%, ns for G- PLA). This result suggests a specific effect of the intervention. Indeed, it seems that the more an individual is confronted with decisions requiring a rapid decision, the more beneficial the intervention could be. Thus, for cognitive functions requiring longer information processing times, the positive effect observed seems to fade. In practical terms, the benefits observed here could be seen in everyday life during social interactions (improved detection of social signals, better understanding of others/emotional intelligence) or in situations where it is necessary to adapt quickly to one's environment (e.g. driving or taking part in physical and sporting activities). On the other hand, for more complex tasks, which require the individual to take the time to analyse, compare and consider different scenarios (for example, activities such as comparing routes or drawing up a shopping list seem to be less affected by these results), appear to be less impacted by the intervention.

Cognitive tasks	Parameters	Group	Pre-program	After program	Rate of change $_{before/after}$ (%)
Choice reaction task (CRT)	Precision (%)††	G-PLA	97,6 ± 1,6	97,7 ± 2,0	0,1
		G-EXP	95,7 ± 3,2	**98,1 ± 1,6****	2,5
	Response time (ms)	G-PLA	514 ± 59	497 ± 52	-3,3
		G-EXP	540 ± 56	515 ± 55	-4,6
Pattern comparison task	Precision CO (%)	G-PLA	97,3 ± 1,3	97,2 ± 1,8	-0,1
		G-EXP	97,1 ± 1,9	98 ± 2,1	0,9
	Response time CO (ms)	G-PLA	1028 ± 213	1039 ± 288	1,1
		G-EXP	1159 ± 287	1080 ± 227	-6,8
	Precision IN (%)	G-PLA	97,5 ± 2,0	97,5 ± 2,0	0
		G-EXP	96,7 ± 2,1	97,4 ± 2,3	0,7
	Response time IN (ms)	G-PLA	986 ± 161	1030 ± 232	4,3
		G-EXP	1126 ± 222	1099 ± 207	-2,4
Visuo-motor task	Time on target (%)	G-PLA	65 ± 7	64 ± 8	-1,5
		G-EXP	66 ± 9	70 ± 4	6,1
	Average cursor/target deviation (pixels)	G-PLA	19,7 ± 5,3	21,6 ± 8,6	9,6
		G-EXP	17,8 ± 3,9	16,4 ± 2,1	-7,9

Notes:

CO : congruent tests ; IN : incongruous tests

††Significant Time-Group Interaction ($p < 0.01$)

**Significantly different from the pre-programme measurement ($p < 0.01$)

TABLE 4. SUMMARY OF COGNITIVE TASK RESULTS FOR PARTICIPANTS IN THE EXPERIMENTAL (G-EXP) AND PLACEBO (G-PLA) GROUPS. VALUES PRESENTED ARE MEAN ± STANDARD DEVIATION.

4.6. Subjective reports and overall satisfaction

The results concerning subjective reports (cf. figure 6), whether it be the sensation of muscular pain, general well-being or the participants' overall satisfaction with the program, are also very instructive. In fact, the results show a significant reduction in levels of muscular pain (*DOMS*) between the pre-program and post-S10 measurements in the experimental group only (-69.2%, $p<0.01$ *vs.* -17.1, *ns*, for the G-PLA). It should be noted that a significant reduction in muscle soreness was observed from the first session (-38.1%, $p<0.05$ *vs*. +9.6%, *ns*, for G-PLA).

In terms of well-being, participants in the G-EXP had higher levels than those in the G-PLA (on average +15.5%, $p<0.001$).

Finally, an analysis of participants' satisfaction with the program, using the *Net Promoter* Score (*NPS)* methodology, revealed a higher percentage of "satisfied" participants.
"There was a higher percentage of 'promoters' in the G-EXP than in the placebo group (64% *vs.* 40%), and a lower percentage of 'passives' in the G-EXP than in the placebo group (36% *vs.* 40%). But the most convincing result overall was the total absence of 'detractors' in the experimental group, compared with 13% of participants (or just over one in ten) in the placebo group. These differences are naturally reflected in the overall *NPS* score, with the experimental group showing much higher satisfaction (*NPS* = 64.3) than the placebo group (*NPS* = 26.7).

4.7. Adverse events

No adverse events or side effects have been reported.

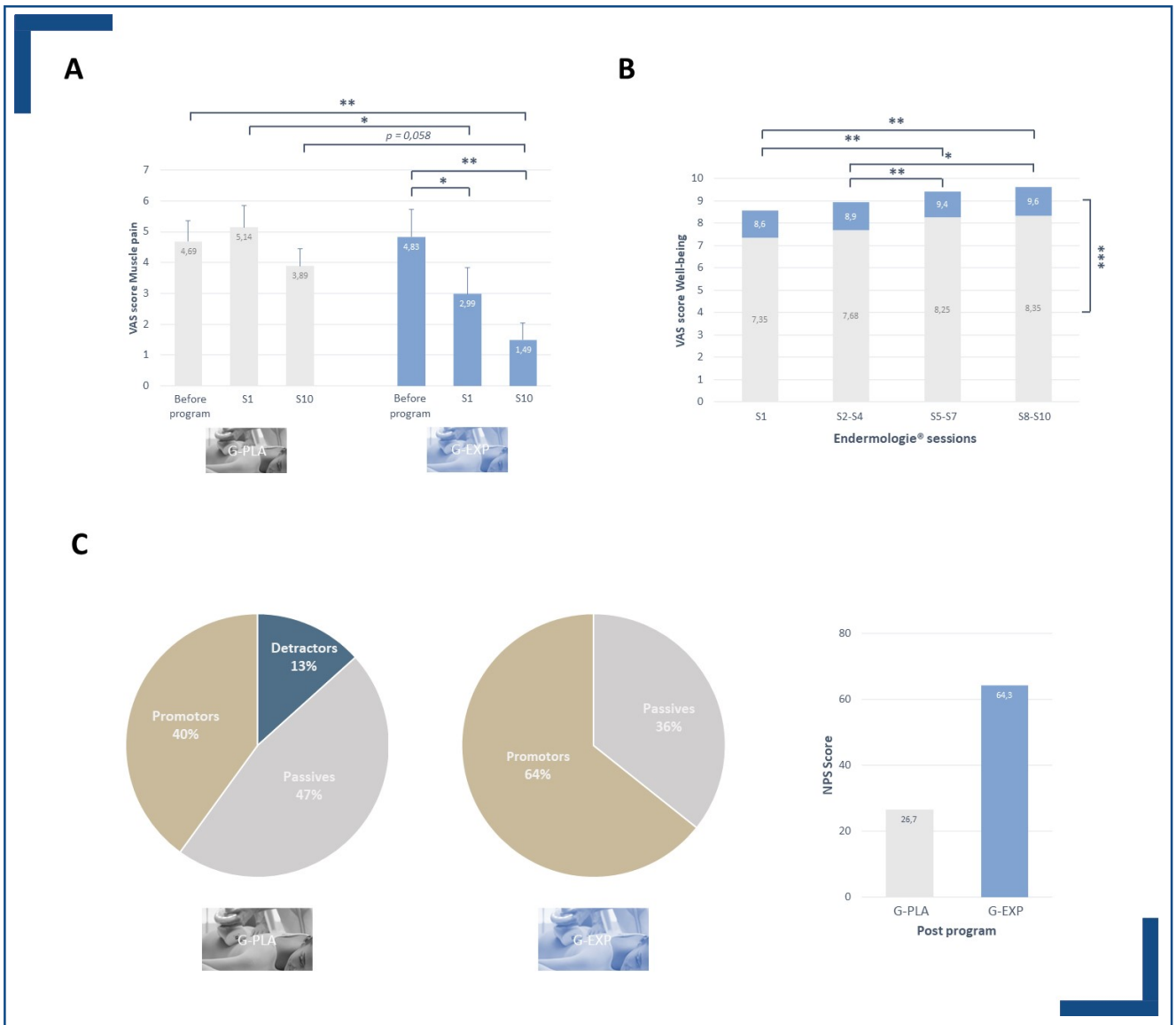


FIGURE 6. A) CHANGES IN SCORES RELATING TO LEVELS OF MUSCLE PAIN PERCEIVED BY PARTICIPANTS IN THE TWO GROUPS (G-PLA AND G-EXP) DURING THE DIFFERENT MEASUREMENT PERIODS: BEFORE THE START OF THE program, AFTER THE FIRST SESSION AND AFTER THE LAST ENDERMOLOGIE SESSION. **B)** CHANGES IN SCORES RELATING TO PARTICIPANTS' GENERAL LEVEL OF WELL-BEING. **C)** SUMMARY OF THE RESULTS ON THE OVERALL SATISFACTION OF PARTICIPANTS IN BOTH GROUPS WITH THE program THEY FOLLOWED, USING THE NET PROMOTER SCORE METHODOLOGY (SEE MAIN TEXT). NOTE: ASTERISKS INDICATE SIGNIFICANT AVERAGE DIFFERENCES (* $p < 0.05$, ** $p < 0.01$).

5. SUMMARY

The aim of this study was to evaluate the effects of a program of 10 mechanised massage sessions using the Cellu M6 from LPG Systems on people suffering from stress and sleep disorders. The main results of this study are as follows:

STRESS LEVELS REDUCED FROM THE VERY FIRST ENDERMOLOGIE® SESSION

- 19% reduction in salivary cortisol after a 40-minute session of mechanised massage and 45% reduction in salivary cortisol after a 40-minute session of mechanised massage after 10 sessions.

Note: Cortisol is our stress hormone. Controlling cortisol levels can help us strengthen our immune system and combat chronic fatigue. It also plays an important role in regulating sleep and stabilising blood pressure.

- 76.6% increase in the RMSSD indicator of heart rate variability after 10 sessions.

Note: Heart rate variability (HRV) is the variation over time between two successive R-R intervals. It is a measure of the autonomic nervous system and is widely recognised as a relevant biomarker for monitoring various states of fatigue and stress. RMSSD is a standard statistical measure of VFC. It represents the root mean square of successive differences between normal heartbeats for a specific set of heart rate data.

- 49.4% reduction in perceived stress, 71.4% reduction in total mood disturbance, 37.4% reduction in mood levels anxiety and 50.9% of depressive disorders after 10 sessions of mechanised massage.

THE NATURAL DEFENCES ARE REINFORCED AFTER 10 SESSIONS ENDERMOLOGIE® TREATMENT

- 9.6% increase in T lymphocytes.

Note: T lymphocytes are a type of white blood cell that play a key role in the adaptive immune response.

- 9.4% increase in CD8 lymphocytes.

Note: CD4+, CD8+ regulatory T lymphocytes (Treg) are involved in maintaining peripheral tolerance and preventing autoimmune diseases. They also regulate the immune responses observed in allergies, transplants, cancers and infectious diseases.

IMPROVED SLEEP AFTER A FEW ENDERMOLOGIE® SESSIONS

- 3.9% increase in time spent immobile and 19.2% reduction in sleep fragmentation after 9 months mechanised massage sessions.

Note: Sleep is a physiological state necessary for a good state of health, corresponding to a drop in consciousness and muscle tone that separates two periods of wakefulness. The time spent immobile during the night and the fragmentation of sleep refer to the notion of nocturnal movement. When these parameters evolve (increase in time spent motionless and decrease in fragmentation), this implies a better overall continuity of sleep and therefore deep slow wave sleep, which could also be improved (hypothesis).

- 41.3% increase in perceived sleep quality and 54.7% reduction in the severity of insomnia.

Note: Insomnia is a lack or poor quality of sleep that affects physical, mental and social activities during the day. The main causes of insomnia in adults are stress, anxiety and depression.

IMPROVED COGNITIVE PERFORMANCE AFTER 10 SESSIONS ENDERMOLOGIE® TREATMENT

- 2.5% increase in response accuracy in a high - pressure decision-making task time.

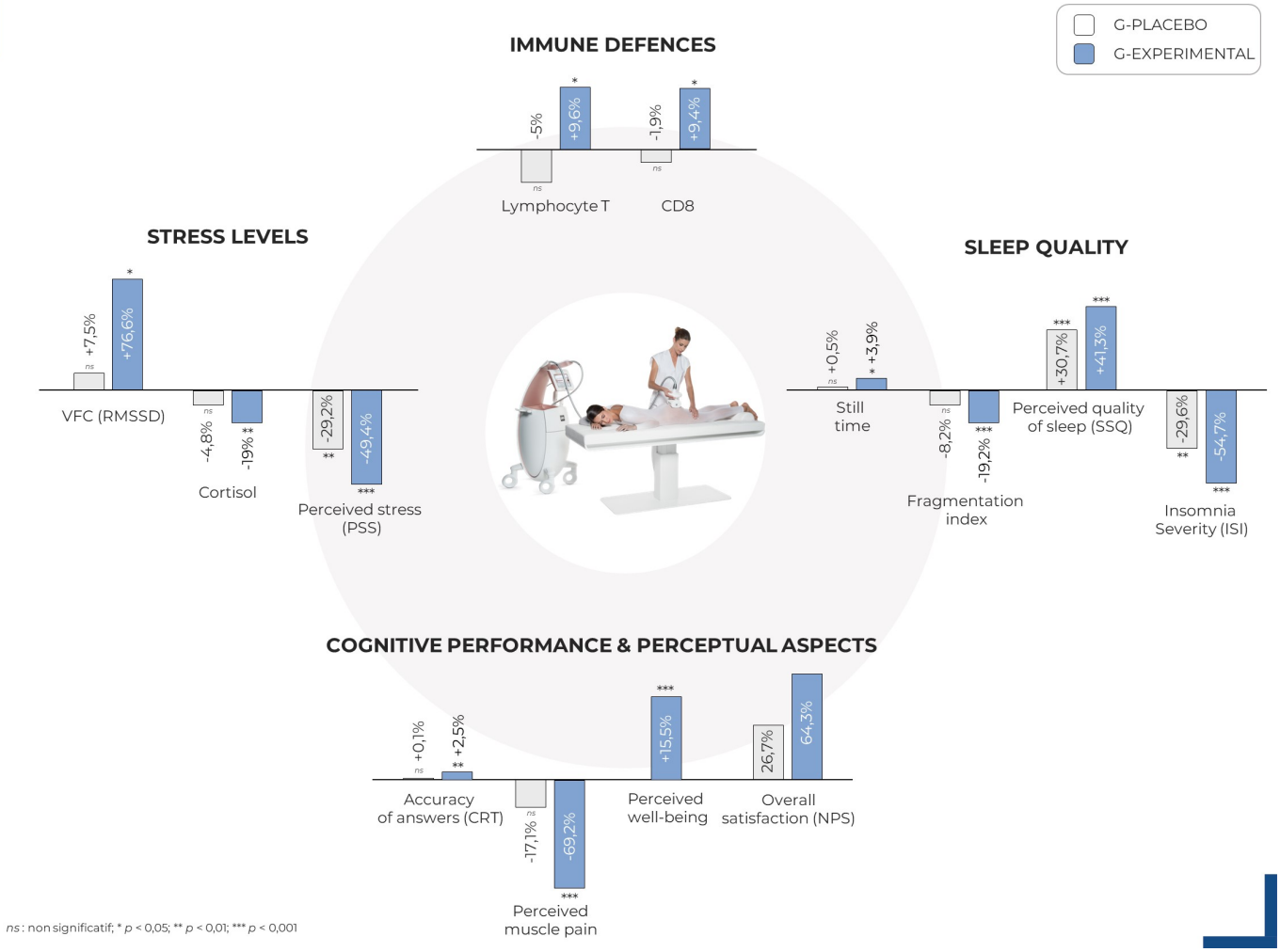
Note: Cognitive functions represent all the capacities of our brain that enable us, on a daily basis, to analyse and adapt to interact as effectively as possible with our environment. Cognitive functions include memory, attention, executive functions, visual-spatial functions and social cognition. Cognitive performance is our brain's ability to use our brain functions to identify information in our environment, analyse it, prioritise it and solve problems in the most appropriate and efficient way possible.

REDUCED MUSCULAR PAIN AND A GREATER SENSE OF WELL-BEING AS EARLY AS THE FIRST ENDERMOLOGIE® SESSION

- 38.1% reduction in muscle aches and pains after the first session of mechanised massages and 69.2% after a program of 10 sessions.

- A greater feeling of well-being (+15.5% on average) after a session of mechanised massage endermologie, compared with a procedure of the same duration with no mechanical action on the skin.

KEY FIGURES:



ns : non significatif; * $p < 0,05$; ** $p < 0,01$; *** $p < 0,001$

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beScored

Institute

Prof. Christophe **HAUSSWIRTH**

Founder beScored Institute

christophe@bescored.fr

+33.6.86.58.46.93

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