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Pilot randomized single-blind clinical trial, craniosacral therapy vs control on physiological reaction to math task in male athletes

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ABSTRACT

Objectives: The purpose of this study was to explore how osteopathic treatments influence certain measurable aspects of stress performance in male athletes.
Design and participants: Twenty-two (22) healthy male athletes (21,63 ± 1,41 years), participated in the study and were randomly allocated to either a craniosacral therapy or placebo group with 11 participants receiving a craniosacral therapy session, and the other 11 a placebo session. Pre- and post-intervention psychophysiological correlates of stress reaction (skin conductance - SC, heart rate – HR and respiratory rate – RR) were measured.
Results: Stress induced from an arithmetic task resulted in a significant increase in physiological stress markers such as SC, HR and RR in both groups. Over the short term, craniosacral therapy was associated with a physiological relaxation response (a decrease in HR and SC) and an altered HR and SC response during the math task in comparison to the placebo group.
Conclusions: At least over the short term, the results of this study indicate that participating in 20-min exposure to craniosacral treatment may benefit participants by decreasing heart rate reactivity and skin conductance reactivity. Further research, with some modifications, using a larger sample is required to determine the effectiveness of craniosacral therapy for immediate stress reduction of athletes.

Implications for practice

Athletes are often expected to perform well under high pressure.

Athlete's physiological parameters must return quickly to the baseline after stress.

Osteopathic treatment may influence athlete's autonomic nervous system during stress.

Further studies are required to prove the immediate effect of osteopathic treatment.

Introduction

When faced with intense demands, athletes of competitive sports must be able to perform well both physically and psychologically. Performance of high levels of exercise requires great mental fortitude and motivation and can be stress inducing. This competition-related stress can be traced to various sources such as - ineffective coping strategies, overtraining, and interactions with leaders or peers, all of which may be considered potential causes of generating stress [1–3].

Stress is a physiological response to the mental, emotional, or physical challenges that people encounter. Immediate threats provoke the body's “fight-or-flight” response or an acute stress response [4]. Biological effects of stress are characterized by autonomic arousal and metabolic changes [4]. Reactions to stress are also associated with enhanced secretion of numerous hormones including; glucocorticoids, catecholamines, growth hormone and prolactin, the effect of which is an increased mobilization of energy resources and improved adaptation of an individual to their new circumstances [5].

The stress response is regulated by the autonomic nervous system (ANS), which consists of two branches that respond to antagonistic activity. The sympathetic branch is responsible for quick and automatic mobilization of the organism in moments that require immediate, determined action for an effort generally associated with the fight-or-flight response. Among other effects, sympathetic nerve fibers can cause pupil dilation, hand sweating and increased heart rate, while the parasympathetic branch of the ANS is responsible for returning the

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body to a state of physiological balance, usually after the danger or trigger is passed [4].

The stress mechanism supporting adaptation is based on stimulation of the body to action. Feelings of excitement and tension rise with further increase in the intensity of stress. At this point, stress shifts its effect into either feelings of anxiety or enthusiasm. Strong emotions (both positive and negative) are not conducive to an accurate and fluid response, leading to errors and lowering of an athlete's performance [6,7 8]. Knowledge of ways to effectively deal with stress are therefore highly relevant to athletes.

Osteopathy is based primarily on the holistic belief that the human body is a whole, not the sum of organs operating independently of each other. Instead of focusing on isolated symptoms, osteopathy considers the human condition as a psychophysical whole, with special emphasis on the nervous system [9,10].

Traditionally osteopathy was considered to influence tissue and biomechanical mechanisms, but there is not enough clinical evidence supporting this thesis. More modern theories indicate that therapeutic effect of osteopathic treatment may originate from both biological and psychosocial therapeutic mechanisms [11]. Recent reports also indicate that osteopathic methods can be useful in building self-awareness [12] as well as inducing stress reduction [13-16], however these data are scarce and inconsistent [17]. Importantly, no previous studies have analyzed psychophysiological performance.

The current study was designed to determine whether volunteers were indeed more relaxed regarding their psychophysiological response to stress after experiencing the same osteopathic procedure.

Methods

The study was conducted in two phases: pre- and post-osteopathic technique application. All participants were briefed about the study protocol using an information sheet, and their informed written consent for participation in the study was obtained. The local Bioethics Committee approved the study protocol (Permit No. KB/99/2016). No changes to methods after trial commencement were made.

Participants

Twenty-two men, 18–24 years (21.63 ± 1.41), with a Body Mass Index of 24.44 ± 3.05 kg/m2, voluntarily participated in the study. All participants were provided with the full information about the study design. Sample size was calculated according to Henley et al's [18] method of data collection and based on heart rate data collected in male athletes taken from our previous study [19]. As female stress reactivity depends on the phase of menstrual cycle, only male volunteers were considered [20]. Participants were recruited from a local soccer clubs through leaflets and posters over a period of 4 months. All participants were competitive soccer players (7.54 ± 2.08 h of sport per week). Interested candidates were screened by telephone interview to check their eligibility according to the inclusion and exclusion criteria. Additional exclusion criteria were: any history of osteopathic treatment, daily smoking, alcohol abuse, heavy caffeine use (> 300 mg/day), medication intake, drug abuse, reported medical illness, history of endocrine disorder and cardiovascular disease. Out of 54 interested candidates, 31 met the above mentioned eligibility criteria. Finally, 9 candidates decided not to take part in the study.

Randomization

To allocate participants in groups, a block randomization was performed using an Excel file. Firstly, a block to assign sample numbers equally to each group was generated. The block size was randomly generated (2-, 4- or 6-letter combination of A and B). Then each block was assigned to a group. Each participant was provided with the printed number, so the therapist could not predict which treatment (placebo or craniosacral therapy) would be performed until the participant came.

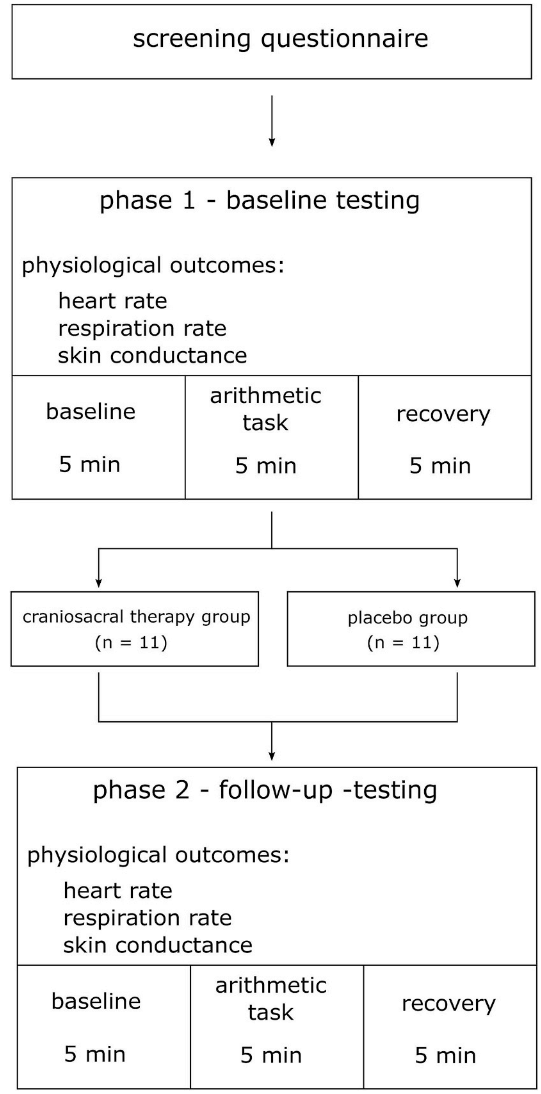

Fig. 1. Flow chart describing the participant's flow through the study. Phase 1 and phase 2.

Design

Experimental sessions were conducted between 9:30 and 13:00 h, lasted about 50 min and consisted of 3 parts: Phase 1 - participants were exposed to a mental stressor and an osteopathic or placebo session of 20 min. Phase 2 was homologous to Phase 1. Both Phases incorporated baseline (first 5 min), arithmetic task (5 min) and post-stress (5 min) intervals. To determine the effects of stress on the participant's heart rate (HR), respiration rate (RR) and skin conductance (SC), values were continuously recorded during phase 1 and phase 2. The full procedure is presented in Fig. 1.

After 5 minutes at baseline, an arithmetic test was administered to induce mental workload and psychological stress. For the math stressor, participants performed a series of subtraction problems aloud, continuously for 5 min and were asked to give answers aloud as fast as possible. They were instructed that the experimenter would correct any errors they made and that they should then continue from the correct number to maintain maximal stress from task involvement and moderate stress task difficulty (approximately 10 correct answers per minute [21]. Better performance led to more difficult math problems in the subsequent minute. Following the arithmetic task, participants were asked to sit still for a 5-min recovery period.

Craniosacral therapy

Prior to application of the osteopathic craniosacral techniques all participants of the group were acquainted with its methodology. Techniques were performed in a quiet and warm room. The participants lay supine and therapy was administered by a female therapist with 4-years of experience in osteopathy. Following the "release of mobilized structures", the therapist applied the following individual phases of osteopathic craniosacral techniques described by Ref. [22] sacrum compression and traction, mobilization of the frontal bone, parietal bones, sphlenoid bone and temporal bones. The final step was the CV4 technique (for full description of the procedure see: [22].

For the placebo group, the therapist only held the subject's head (while the subject was in the supine position) and did not use her hands for the application of any osteopathic techniques. The treatment time for both groups' individual subjects was 20 min, which was ensured by using a stopwatch.

Outcomes

Primary outcomes of the current study were changes in indicators of autonomic stimulation: skin conductivity, frequency of heart contractions and respiratory rate in response to the math task and during recovery following craniosacral/placebo therapy.

Electrodermal activity is an indicator of sympathetic stimulation. Skin conductivity varies depending on the activity of the eccrine sweat glands which are found primarily on the surface of the palms and on the soles of the feet. Eccrine sweat glands' main role is thermoregulation, however, their increased activity on the hands and feet is most often associated with sweating stemming from the emotions experienced. Skin conductance (SC) is a relatively reliable index of sweat-gland activity and changes in the activation level of the sympathetic nervous system. Stress response is also connected with acceleration and shortness of breath which leads to increased heart rate [23,24].

For measuring multisensory data, a ProComp Infinity 5 (Thought Technology Ltd) device was used. The device is designed to measure up to 8 biosensors. For the current experiment, 3 channels were used, including blood volume pulse (BVP) -a photoplethysmographic sensor measured on finger, with a sampling rate at 256 per sec), skin conductance (SC) - two sensors measured on finger, with a sampling rate at 256 per sec, (3) respiration rate (RR) -measured at abdomen with a sampling rate at 256 per sec. The device was calibrated by the manufacturer and met the current guidelines of the psychophysiological measurements [22-25].

On the participant's non-dominant hand, a BVP optical pulse sensor was placed on the palmar surface of the little finger to measure heart rate (HR), and two Ag/AgCl electrodes were placed on the palmar surface of the middle and index fingers to acquire an SC signal. The respiratory transducer records respiratory frequency using a belt which measures the force of chest expansion during each inhalation and exhalation.

SC, together with HR and RR can provide useful information about the activity of the sympathetic nervous system – namely: greater values represent greater sympathetic activity [22-25]. For each parameter Δ, defined as [mean recovery value] – [mean baseline value] was calculated, to describe self-regulation.

In addition to the measurement of autonomic stress response and recovery following math stress, secondary outcomes included the baseline HR, SC and RR levels following the craniosacral/placebo intervention.

Treatment blinding

None of the participants had received any osteopathic treatment prior to the study nor had they any knowledge about osteopathic procedures. To ensure blinding, participants did not contact one another until all measurements were collected. The randomization code was kept by the therapist and only revealed once the final results were collected. Participants remained blinded to treatment allocations until all participants had completed the study. At the end of the intervention, participants were asked to guess which treatment they underwent.

Measurements were recorded by a psychologist who was blinded to intervention. Statistical analysis was carried out blind to group allocation.

Statistical analysis

Statistical analysis was performed using STATISTICA 13.1 (Statsoft, Poland). As the presented study is a pilot trial, descriptive analysis was performed in accordance with [26]. To describe results, mean (M) values with 95% confidence intervals (95% CI) were presented. Median values with interquartile range presented as: lower quartile (Q_1) – upper quartile (Q_3) were presented in graphs to illustrate the results. A calculated sample size using power = 0.8 was obtained.

Results

Group characteristics are presented in Table 1.

The arithmetic task induced a rise in HR, SC and RR in both groups in Phase 1 of the study. RR increased. In Phase 2, the arithmetic task induced a significant rise in HR in both the experimental and placebo group, but SC increased during the recovery period only in the control group. Also, the differences between baseline and recovery values of HR and SC seemed to be smaller in the experimental group. Compared to the placebo group, participants who received a craniosacral therapy session showed decreased HR and SC during all phases (baseline, math task and recovery) and decreased respiratory rate in baseline and recovery, but not during the arithmetic task as presented in Table 2 and Figs. 2–4.

Required sample size for an adequately powered study

Power calculations were conducted to determine sample size for a future adequately powered study. Based on the HR results, 88 participants should be required in each (placebo and control) group. Based on the SC results, 31 participants should be required in each (placebo and control) group. Based on the RR results, 156 participants should be required in each (placebo and control) group.

Participants' guesses

Of the 11 participants receiving craniosacral therapy, 7 (64%) correctly guessed they were in the treatment group. Of the 11

Table 1
Group characteristic for the experimental (n = 11) and control (n = 11) group.

Variable	whole group		experimental		control	
	N = 22		*N = 11*		*N = 11*	
	Me	*IQR*	*Me*	*IQR*	*Me*	*IQR*
age	22.0	4.0	22.5	5.0	22.0	3.0
BMI	24.96	2.13	24.40	2.09	24.39	2.30
education (years)	15.0	3.0	15.0	4.0	15.0	2.0
employment						
full-time	*N = 10*		*N = 5*		*N = 6*	
student	*N = 12*		*N = 6*		*N = 5*	

Table 2
Mean values with 95% Confidence Intervals of heart rate, respriration rate and skin conductance *for* the experimental (n = 11) and control (n = 11) group.

phase	parameter	Group	Baseline mean (95%CI)	Math task mean (95%CI)	Recovery mean (95%CI)
1	HR (beats/min)	*E*	65.29 (82.11–74.71)	74.71 (49.91–99.50)	67.62 (47.57–87.66)
		C	69.83 (47.75–82.99)	78.18 (51.69–104.66)	72.49 (48.19–96.78)
	RR (br/min)	*E*	10.91 (3.49–18.32)	12.93 (7,59–18.26)	10.75 (4.32–17.18)
		C	10.81 (2.37–19.34)	14.98 (8.55–21.41)	11.70 (5.99–17.41)
	SC (μS)	*E*	6.39 (1.67–11.10)	9.43 (3.95–14.91)	8.15 (3.73–12.57)
		C	4.71 (0.53–8.89)	8.06 (3.32–12.79)	6.21 (1.56–10.86)
2	HR (beats/min)	*E*	61.85 (44.59–79.10)	70.35 (60.45–80.25)	63.28 (45.39–81.17)
		C	70.81 (50.78–90.83)	81.68 (63.22–100.14)	74.55 (63.99–85.11)
	RR (br/min)	*E*	11.45 (4.03–18.87)	12.29 (4.92–19.66)	11.13 (3.98–18.28)
		C	10.57 (4.75–16.39)	13.33 (7.35–19.30)	10.51 (4.99–16.02)
	SC (μS)	*E*	5.00 (1.44–8.56)	6.82 (1.60–12.04)	6.11 (1.91–10.31)
		C	8.63 (2.82–14.44)	13.57 (5.05–20.08)	11.42 (4.99–17.84)

AbbreviationsHR-heart rate; RR – respiration rate; SC-skin conductance; E – experimental group, C – control group, CI – confidence interval.

participants receiving placebo therapy, 6 participants (55%) correctly guessed that they were allocated to the placebo group. The number of correct guesses of mode of treatment between the groups did not differ significantly (p = 0.66).

Discussion

Feasibility of study design and method

The method of collecting data by psychophysiological measurement was well designed. The athletes willingly participated in the study and focused on the body processes requiring their active participation. However, there is a need to recruit at least twice as many eligible participants as needed, due to the high risk of reassignment.

In the future, the authors recommend that instead of a finger optic sensor, a chest strap heart rate monitor or electrode pads should be used to measure heart rate. This change should deliver a more reliable measurement of heart rhythm and allow analysis of a wider spectrum of heart rate variability parameters [24]. Furthermore, we recommend that a self-reported questionnaire, i.e. state-anxiety level should be used for monitoring participants' psychological response to treatment. Including female athletes in a future study would also be beneficial, however the women's menstrual cycle phase should be taken into consideration.

Effects of craniosacral therapy

Previous studies suggest potential benefits of osteopathic manipulation for inflammatory diseases such as chronic obstructive pulmonary disease, asthma, irritable bowel syndrome, and peripheral arterial disease [27]. Osteopathic treatment has also been shown to be valuable for treating behavioural conditions. For example [28], preliminary findings showed that compression of the fourth ventricle (CV4) may decrease sleep latency [29]. and Grill [30] also suggested that CV4 technique may have particular influence on the functioning of the autonomic nervous system. Noteworthy not all studies claim such a result – for example preliminary findings of [14,31] found no effect of the CV4 on autonomic nervous system. However, caution is needed when drawing any “strong” conclusions, as all these studies seem to be underpowered, examined small groups of patients and might have been affected by uncontrolled factors (i.e. menstrual cycle phase of females).

Athletes, who received osteopathic manipulation showed lower heart and respiratory rates and accelerated autonomic recovery (lower skin conductance, heart rate and respiratory rate in recovery phase) when compared to the placebo group. Such changes are attributed to the parasympathetic nervous system – namely modulation of the vagus nerve during osteopathic manipulation [32]. Decreased activity of the vagus nerve is reflected in decreased heart rate, respiratory rate, and SC [33]. The state of well-being experienced following application of the technique may be explained by improved brain tissue oxygenation [34]. This seems to be beneficial for performance during a stressful event, at

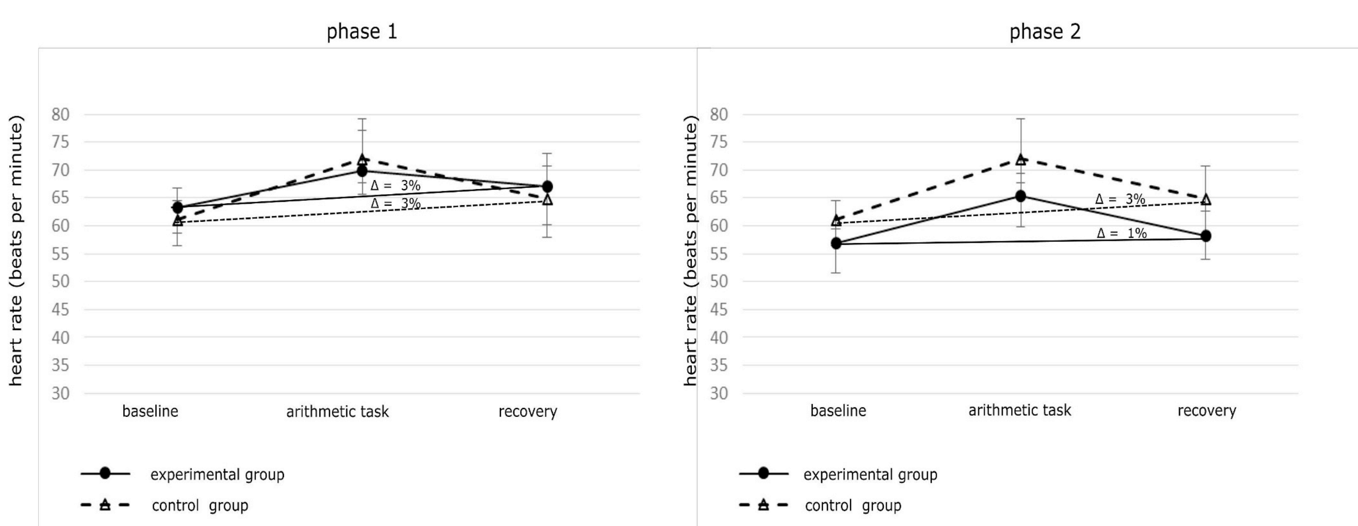

Fig. 2. Median (Q1-Q3) values of heart rate during stress test for the experimental (n = 11) and control (n = 11) group. Δ denotes the differences between recovery and baseline; smaller differences indicate more efficient self-regulation.

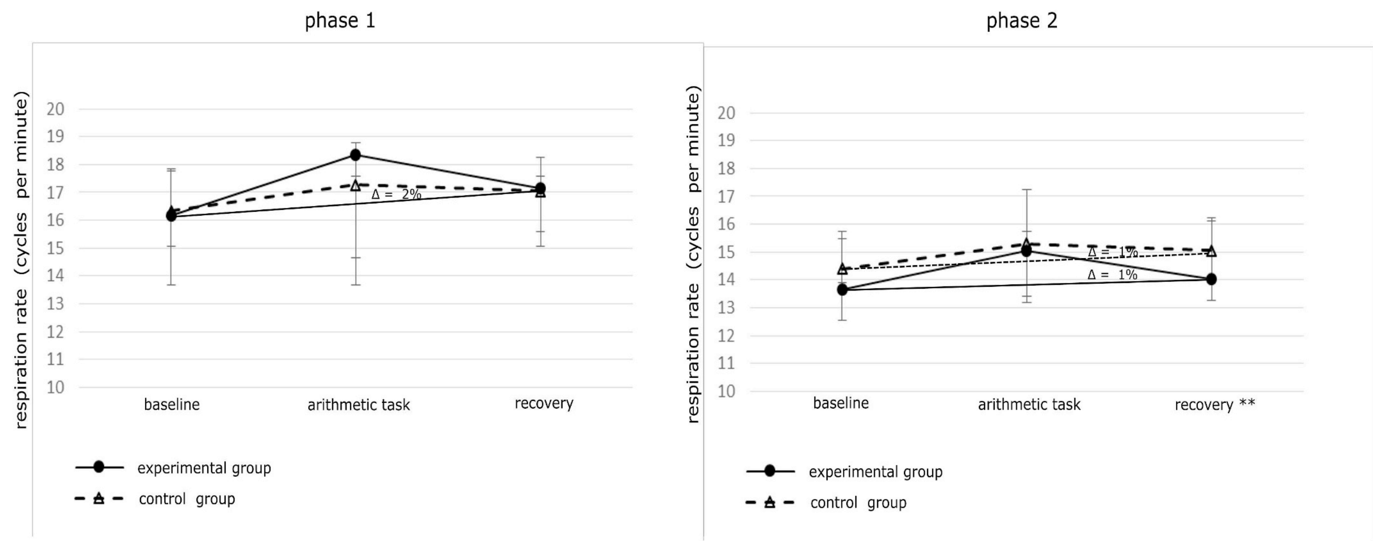

Fig. 3. Median (Q_1-Q_3) values of respiration rate during stress test for the experimental (n = 11) and control (n = 11) group. Δ denotes the differences between recovery and baseline; smaller differences indicate more efficient self-regulation.

least experienced immediately after the therapy. In practice, if further trials show the intervention to effect performance, this kind of therapy may be then applied before sport competitions to enhance athlete's performance.

Moreover, the experimental group's baseline heart rate and respiratory rate were lower, which reflects a more relaxed state and increased vagal tone. It has been proven that enhanced vagal tone (regulation of body at rest) allows individuals to achieve mindfulness – that is, to be more aware and acceptant of their current environments and thus respond to situations with less stress [35]. This means greater autonomic self-regulation and response to environmental conditions in an adaptive way. Thus, these findings suggest that after craniosacral therapy individuals may not only feel more relaxed, but also experience decreased cardiovascular reactivity and may be able to recover more quickly following a stressor. The results of the current study indicate that athletes who participate in 20-min craniosacral therapy training may benefit from greater autonomic cohesion, at least over the short term. However, further testing is required to prove this finding.

Limitations of the study

The relatively small size, convenience and homogeneity of the sample limit generalizations of this study. The intervention was delivered by one practitioner, which might enhance the observed effect of craniosacral therapy. Furthermore, the study examined only short-term effect of craniosacral therapy. Thus, the therapy may be beneficial for stressful event experienced immediately after the procedure, but no assumptions can be made regarding long term influence on performance. Nonetheless, we believe our findings are substantially thought provoking and should be further developed on larger samples. When considering female participants, such variables as: menstrual cycle phase, using contraception and pregnancy/lactation period should be taken into account. We suggest that ECG sensor, instead of BVP should be used to enhance signal detection and not heart rate variability analysis [24]. Also we suggest that to meet current guidelines in psychophysiology Trier Social Stress Test (TSST) protocol should be adapted instead of a simple math task [36]. In addition, there is a need to assess not only the physiological reaction, but also athletes' performance.

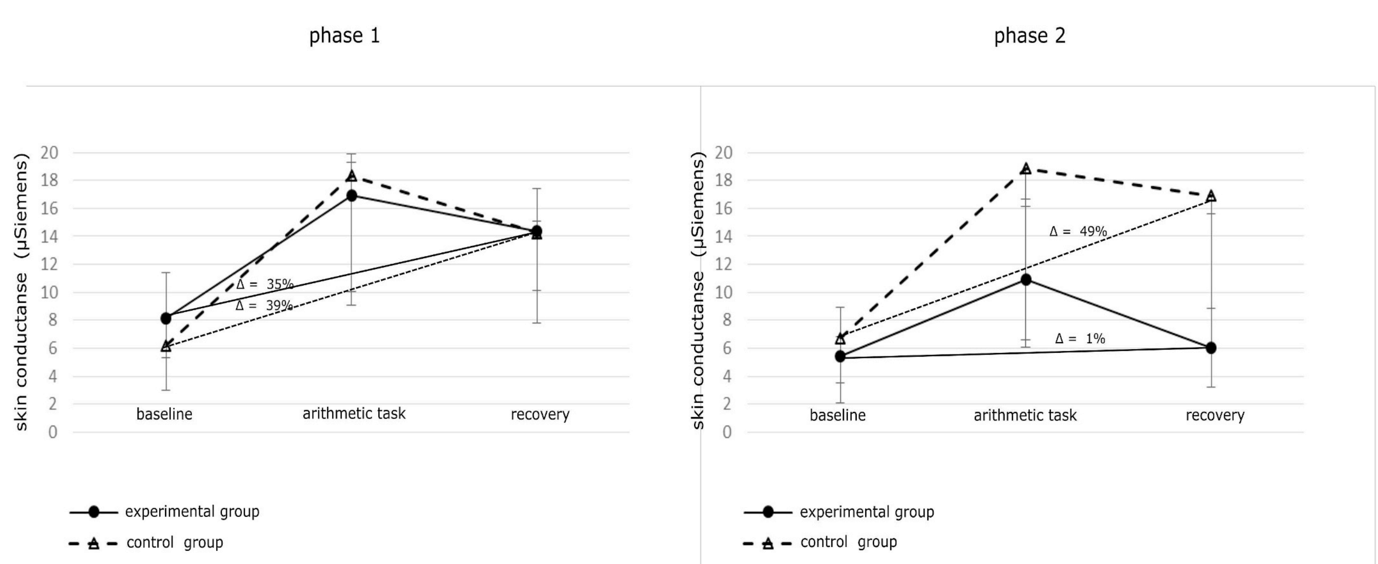

Fig. 4. Median (Q_1-Q_3) values of skin conductance during stress test for the experimental (n = 11) and control (n = 11) group. Δ denotes the differences between recovery and baseline; smaller differences indicate more efficient self-regulation.

Conclusion

The results of this study indicate that athletes who were exposed to 20-min craniosacral treatment may benefit by having a more blunted autonomic reaction to stressors, at least in the short term. Further research, with some modifications, using Trier Social Stress Test and a larger sample of approximately 31–88 participants in each group is required to determine the effectiveness of craniosacral therapy for psychophysiological reactions in athletes. Further work is needed to determine whether or not the intervention effects athlete's performance.

Conflict of interest

Dr. Małgorzata Wójcik declares that she has no conflict of interest.
Dr. Inga Dziembowska declares that she has no conflict of interest.
Dr. Paweł Izdebski declares that he has no conflict of interest.
Prof. Ewa Żekanowska declares that she has no conflict of interest.

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Ethical statements

This material has not been published in whole or in part elsewhere. The manuscript is not currently being considered for publication in another journal. All authors have been personally and actively involved in substantive work leading to the manuscript, and will hold themselves jointly and individually responsible for its content.

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. All participants were briefed of the study protocol using an information sheet, and their informed written consent for participating in the study was obtained. The study protocol was approved by the Bioethics Committee of the Nicolaus Copernicus University in Toruń functioning at Collegium Medicum in Bydgoszcz (permit No. KB/99/2016).

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