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• Research Article

Heart rate variability and the influence of craniosacral therapy on autonomous nervous system regulation in persons with subjective discomforts: a pilot study

Wanda Girsberger[1,2], Ulricke Bänziger[1], Gerhard Lingg[1], Harald Lothaller[1], Peter-Christian Endler[1]
1. Interuniversity College for Health and Development, Castle of Seggau, 8042 Graz, Austria
2. Practice for Craniosacral Therapy, Kronenstrasse 48, 8006 Zurich, Switzerland

BACKGROUND: Subjective discomforts in a preclinical range are often due to imbalanced autonomic nervous system activity, which is a focus of craniosacral therapy.
OBJECTIVE: The aim of this work was to determine any changes in heart rate variability (HRV) in a study on craniosacral therapy.
DESIGN, SETTING, PARTICIPANTS AND INTERVENTIONS: This is a quasi-experimental (controlled) study with cross-over design. In a private practice, measurements were performed on 31 patients with subjective discomforts before and after a control and an intervention period. HRV was determined using a device that requires a measuring time of 140 s and electrode contact only with the fingertips.
Main PRIMARY OUTCOME MEASURES: HRV change under the influence of a defined one-time intervention (test intervention) with craniosacral therapy versus control (defined rest period).
RESULTS: Standard deviation of all RR-intervals (ms) and total power of RR-interval variability in the frequency range (ms^2) were together interpreted as an indicator of test subjects' autonomic nervous activity and as a measure of their ability to cope with demands on their health. Neither of these parameters increased during the control period ($P>0.05$), whereas during the test intervention period there was an increase in both ($P<0.05$, $P<0.01$). Nevertheless, interactions between treatment and the increase were statistically not significant ($P>0.05$). No changes were observed in the low frequency/high frequency ratio (sympathetic-vagal balance) in the course of the control or the test intervention period ($P>0.05$).
CONCLUSION: Craniosacral treatment had a favourable effect on autonomic nervous activity. This in itself is an interesting result, but further research will be needed to distinguish specific effects of craniosacral therapy technique from less specific therapist-client interaction effects.
KEYWORDS: massage; autonomic nervous system; electrocardiography; adult; complementary therapies; pilot projects

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Correspondence: Wanda Girsberger; Tel: +41-78-791-90-20; E-mail: wanda.girsberger@hispeed.ch

1 Introduction

Craniosacral therapy (CST) is a non-invasive method, derived from osteopathy, developed in the 1970s by J. Upledger, MD[1]. It is based on the assumption that there is a fine rhythmic movement, which pervades the body and can be discerned by practised therapists under their palpating hands. This movement can be utilised for diagnostic as well as therapeutic purposes by regulating the flow of cerebrospinal fluid[2,3]. The focus of craniosacral examination and treatment lies on the craniosacral structures; these include the bones and connective tissues (membranes of the brain and spinal cord) of the skull and spine and the cerebrospinal fluid. Anatomically surrounding and physiologically sustaining the central nervous system, these structures have a direct influence on functioning of the autonomic nervous system[2,4]. The effects which can be brought about through CST are achieved through gentle touch in the areas of the skull, face, spine and pelvis[5]. Treatment is not primarily aimed at symptoms, but determined by priorities established by the therapist during each patient examination[2].

Studies on the use of CST to treat migraine[6], fibromyalgia[7,8] and asthma[9] showed encouraging results. In a review performed by Jaekel and von Hauenschild[10], positive clinical outcomes were reported for pain reduction and improvement in general well-being of patients in randomized clinical trials; as the quality of other trials was low, the authors stated that currently available evidence was insufficient to draw definite conclusions on the general efficacy of this treatment modality. A review by Ernst[11] was less optimistic, and concluded that "the notion that CST is associated with more than non-specific effects is not based on evidence from rigorous randomized clinical trials".

Working from the observation that changes in autonomic balance are one of the fundamental causes of bodily discomforts, the question of whether CST has a harmonizing influence on the regulation of autonomic nervous processes has been raised. Heart rate variability (HRV) is a non-invasively measurable indicator of such processes, which has been used for diagnostic purposes since the mid-1960s. Its range of application extends from obstetrics to stress and regeneration research as well as sports. Determination of HRV is regarded as a method of assessing health and coping status[12]. It is therefore also used in therapy evaluation[13-18]. A randomized controlled trial showed positive effects of CST on sensitive, tender points and HRV in patients with fibromyalgia[8]. To date there have been no studies on the effects of CST on the regulation of the autonomic nervous system in subjects with subjective discomforts but without clinical diagnosis.

The following research questions were pursued in this study: does HRV change under the influence of a defined rest period (control rest)? does HRV change under the influence of a defined one-time intervention (test intervention)? are there differences between treatment periods?

2 Materials and methods

2.1 Design

This pilot study was a quasi-experimental (controlled) study with cross-over design. The design and methods of the study were approved by the ethics committee of the Interuniversity College, Graz, Austria. Informed written consent was obtained from each participant, and all data were made anonymous before analysis.

2.2 Test subjects

Thirty-one volunteers (16 females, 15 males, average age 46.2 years) were enrolled on the basis of the following inclusion criteria: age 19-60 years; subjective discomforts such as prolonged sleep latency, feeling stressed, nervous, weak or restless as found typical for patients of complementary therapy practices in Switzerland[19]. These symptoms are typical of persons seen by a craniosacral therapist, their prime motive for seeking treatment being more often a lack of feeling completely healthy than a clinically diagnosed disease.

The following were exclusion criteria: cardiovascular disease; pacemaker; diabetes with neural involvement; acute infection; medication with β-blockers, antidepressants, psychotropic drugs, atropine or phenylephrine. There were no dropouts. All volunteers included in the study completed all pre- and post-measurements.

2.3 Treatment allocation

The study was carried out in a practice for CST in Zurich, Switzerland. Each test subject was given two appointments, each between 10 am and 11 am on two consecutive days. Upon their arrival on day 1, test subjects were randomly assigned by dice either to a 30-minute session (intervention period) or to a 30-minute control rest period for that day (t1). Each patient was assigned to the other of the two alternatives for the following day (t2) (Figure 1). In both cases they underwent a 10-minute rest period of sitting prior to the first measurement (t1_1 or t2_1, see below). The study was carried out as an open study, *i.e.*, neither participants nor therapist were blinded to group assignment.

2.4 Intervention and control rest

A trained Swiss craniosacral therapist, with 20 years of professional experience, gave 30-minute sessions in CST following the 10-step protocol developed by Upledger *et al*[5], proceeding in each case according to her observations in the individual subject. The treatment involved gentle touch of different parts of the fully clothed patient's body with the intent of resolving structural or energy restrictions. This included techniques on the patient's feet, sacrum,

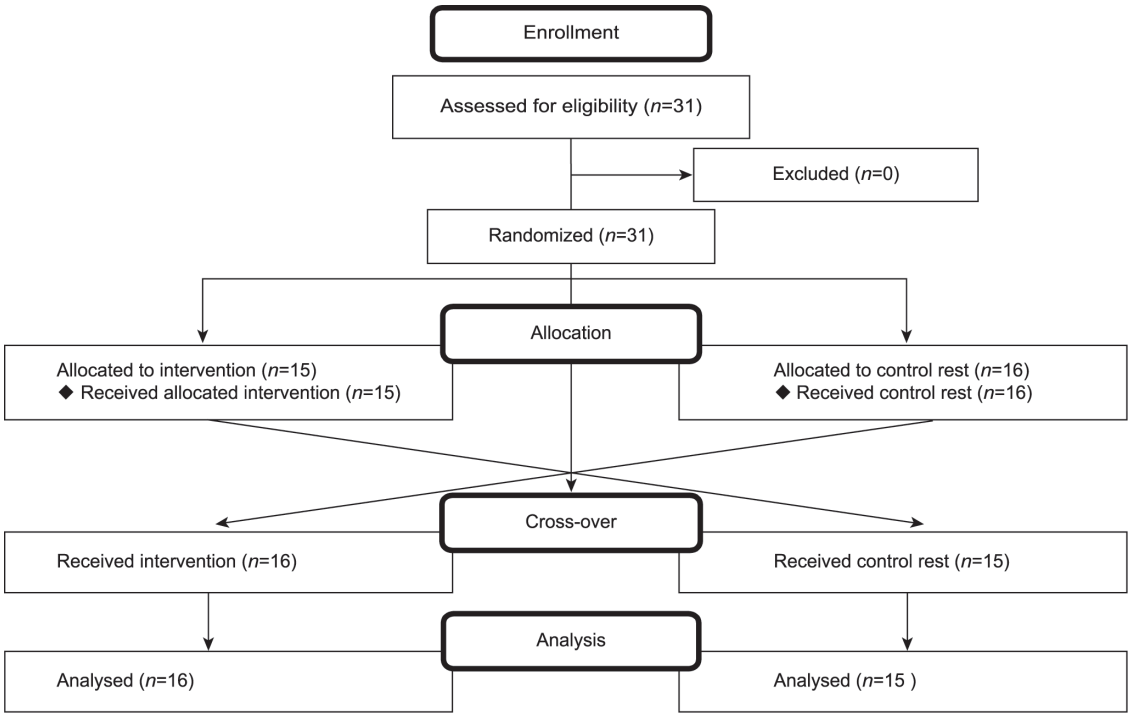

Figure 1 Flow of participants of the study

thoracic inlet, occiput (CV4) and parietal bones (parietal lift)[2,5]. The expectation was that these treatments would have an influence on HRV.

A 30-minute rest, under otherwise identical circumstances (same participants, same time of the day, same room, same supine position), served as a control without intervention.

2.5 Measurements

The required electrocardiogram (ECG) sequences were recorded using a Universal Bodywave Mobile Wellness cell phone (IMI-Health AG Co., Liechtenstein). This is a special cell phone model with an integrated electronic single-channel ECG recorder. Recordings are performed via three integrated silver/silver chloride dry electrodes connected to the tips of the index and middle fingers of both hands. With a sampling rate of 500 Hz, common mode rejection > 100 dB and a resolution < 2.7 μV/bit (19 bit), this system conforms to current standards of good clinical practice.

Raw ECG data are transmitted in realtime to the cell phone's main memory, where they are provisionally stored for quality control purposes, and are shown on the cell phone display.

The cell phone is equipped with an application which calculates all required HRV parameters in both the time and the frequency domain. Calculation of HRV parameters in the frequency domain involves the following calculations: QRS detection based on a modified Pan-Tompkins algorithm; correction of erroneous inter-beat intervals by interpolation; dynamic resampling to 2^n to avoid discontinuities attributable to zero-padding which are beyond the influence of the window function; second-order detrending; application of a $\cos^2$ window function; integration of frequency bands.

Measurements were performed with test subjects seated while resting the tips of both index and both middle fingers on the device electrode over a 140-second interval. If the device indicated insufficient electrode contact, the test subject's finger tips were wetted prior to measurement. The data delivered by the device used were cross-checked against and found to be compatible with the output of a standard HRV device. A mock measurement was performed on every test subject to allow them to become familiar with the device and was not evaluated. On each study day, a measurement was taken before and after the "treatment". We refer to these measurements on day one as t1_1 and t1_2 respectively; similarly, on the second day of the study we refer to the measurements as t2_1 and t2_2. See Figure 2.

2.6 Parameters and data analysis

The following parameters were used to describe the status of test subjects' autonomic nervous activity:

(1) SDNN, the standard deviation (*i.e.*, the square root of the variance) of all RR-intervals in ms, used as an overall measure of HRV across all frequency ranges;

(2) TP, total power of RR-interval variability in the frequency range 0.003-0.4 Hz in ms^2, used as a supplementary measure

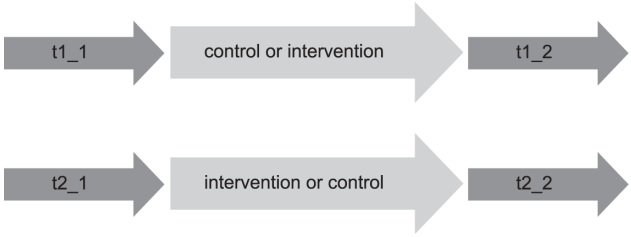

Figure 2 Sequence of heart rate variability measurements (dark-shaded arrows) and control or test period (light-shaded arrows) on day 1 (t1_1 and t1_2) and day 2 (t2_1 and t2_2)

(which necessarily correlates strongly with SDNN).

Parameters used to measure parasympathetic activation:

(1) HF (high-frequency power, 0.15-0.4 Hz, in ms^2);

(2) HF% (proportion of HF in relation to TP).

Parameters reflecting sympathetic activation (amongst other processes):

(1) LF (low-frequency power, 0.04-0.15 Hz, in ms^2);

(2) LF% (proportion of LF in relation to TP).

Parameter of sympathetic-vagal balance: LF/HF ratio.

Furthermore, heart rate (HR, in beats per minute) was measured. No attempt was made to calculate the power of very low frequency (0.003-0.04 Hz) from the data of this short-term ECG.

Average freedom from artifacts was 97%.

2.7 Statistical analysis

IBM SPSS Statistics 20 was used for all statistical analyses. Data were evaluated with analysis of variance with repeated measures of the parameters in a pre-post design and the treatments as independent variables. This procedure can identify whether experimental parameters change over the course of a treatment by comparing before and after measurements. It can also determine whether the magnitude of change in measured parameters is statistically different among experimental groups.

LF/HF ratios were calculated on the basis of the individual measurements and not on the basis of LF and HF means. Results with an error probability $P < 0.05$ were considered significant.

3 Results

3.1 Basic characteristics of the patients

Thirty-one volunteers (16 females, 15 males, average 46.2 years) were enrolled. Baseline measures for all parameters did not differ between the groups ($P > 0.05$).

3.2 SDNN and TP

Both control rest and the intervention gave significant increase of SDNN, but while the increase was +15% ($P < 0.05$) in the control period, it was +32% ($P < 0.05$) in the test period. TP value did not increase significantly in the control period (+19%; $P > 0.05$), but showed high significance in the test intervention period (+126%; $P < 0.01$).

Although interactions were not statistically significant, the increase was more marked in the test than in the control rest period. With regard to SDNN, this statistical finding might be due to the data characteristics. The interaction between treatment and increase of TP was only marginally above the level of significance ($P = 0.057$). The measured values showed remarkably high variability. Further analysis revealed that this was not attributable to measurement quality (freedom from artifacts) but to the values obtained from test subjects with SDNN > 100 ms. SDNN values in this range may result from above-average physical fitness, amongst other causes.

3.3 LF/HF ratio

No changes in the LF/HF ratio (sympathetic-vagal balance) were observed in the course of the control or the test intervention period ($P > 0.05$).

3.4 Heart rate

A highly significant decrease in heart rate ($P < 0.01$) was observed after the CST as compared to that after the rest period.

No significant adverse events or side effects were reported.

Table 1 shows the values for the parameters for pre-measurement points t1_1/t2_1 (immediately before – upper line) and post-measurement points t1_2/t2_2 (immediately after – lower line) for the control rest period and the test intervention period. Significant P value obtained in the control rest period was change in HR (beats per minute). In the test intervention period SDNN (ms), TP (ms^2), HF (ms^2), LF (ms^2) and HR (beats per minute) showed significant change.

4 Discussion

In this study on CST given to test subjects with subjective discomforts, SDNN and TP were used as a global measure of autonomic nervous activity and as an indicator of test subjects' ability to cope with demands on their health (regulatory capacity)[12]. Before the control rest and before the test intervention period, mean values (65.95 ms/2 161.3 ms^2 and 55.2 ms/1 375.7 ms^2, respectively) were within the range expected from the literature[13,20]. SDNN and TP values both did not increase significantly in the control period (+15%/+19%; $P > 0.05$), but increased significantly in the test intervention period (+32%/+126%; $P < 0.05$/$P < 0.01$).

In preliminary studies performed by the team, a rest period of several minutes led to no changes or to an increase in SDNN (range about 0 to 10 ms difference) and TP (range 0 to 400 ms^2)[18].

Further studies using the device compared the HRV parameters on two subsequent days at identical times of day for each participant. No significant differences between SDNN, TP or LF/HF values were found ($P > 0.05$)[18].

Table 1 The values for the parameters for pre-measurement points t1_1/t2_1 and post-measurement points t1_2/t2_2

(Mean ± standard deviation)

Group	*n*	Measurement point	SDNN (ms)	TP (ms^2)	HF (ms^2)	HF (%)
Control rest period	31	Pre	65.95±45.32	2 161.26±2 680.72	599.33±952.06	26.97±17.26
		Post	75.92±50.52*#	2 575.48±2 555.28	556.12±807.00	23.23±18.88
Test intervention period	31	Pre	55.21±43.34	1 375.70±1 756.80	414.25±899.22	26.10±15.37
		Post	72.97±40.01*	3 113.29±3 526.84**	754.84±1 431.92 **	23.81±16.17
Group	*n*	Measurement point	LF (ms^2)	LF (%)	LF/HF	HR (beats/min)
Control rest period	31	Pre	677.03±936.50	32.55±17.13	3.55±8.43	67.45±10.13
		Post	1 006.05±1 183.89	37.81±18.39	3.59±4.08	65.26±9.28*
Test intervention period	31	Pre	480.48±596.20	34.03±18.03	2.25±2.41	68.45±11.22
		Post	1 143.33±1 239.16 **	36.39±15.70	3.06±4.08	64.52±9.45**

*$P< 0.05$, **$P< 0.01$, *vs* pre-measurement point.

#An additional non-parametric Wilcoxon-test, executed due to a non-normal distribution of data, shows a slightly significant difference ($P = 0.044$).

SDNN: the standard deviation of all RR-intervals; TP: total power of RR-interval variability; HF: high-frequency power; LF: low-frequency power; HR: heart rate.

Conditions during the control rest period and the test intervention period were otherwise identical, so that it can be assumed that if there were any nonspecific influences, relating for example, to the person conducting the experiment or her relationship with the test subject, they cancelled each other out. Thus, any differences observed between the control regimen and the test intervention in the degree of change occurring during the experiment should be attributed to the test intervention.

The LF/HF ratio (sympathetic-vagal balance) in this study was interpreted as a measure of the balance between activation and relaxation[12]. Mean baseline values (3.6 in the control group, 2.3 in the test group) were classified as sympathicotonia according to literature data. No significant changes in the LF/HF ratio were observed in the course of the control or the test intervention period ($P > 0.05$). In preparatory studies performed by the team, mean LF/HF ratio ranged about 1.0 to 2.0 in various groups of healthy volunteers. A rest period led to no changes or to a decrease in the LF/HF ratio (ranged about 0 to 0.5).

The dropout rate of zero has strengthened the study. It might be due to the applied therapy that was not invasive and without any reported adverse effects. On the other hand the weakness of this study is the lack of blinding, which sets the standard for experimental design in the clinical setting. Taking this into consideration, each participant received both an intervention and a control rest, on two consecutive days.

In order to reflect the everyday routine of a CST practice, it had been decided to admit test subjects across a wide age range and of very different levels of fitness. This brought with it a high variability in measured parameters. For follow-on studies it could be of interest to define more limiting inclusion criteria for test subjects' age and physical fitness, and to include matched instead of randomised participants in the cross-over design. Furthermore, the criteria for freedom from artifacts should be tightened.

The results are in line with the literature, in that they indicate that HRV may be a useful tool to determine effects of interventions, including complementary and alternative medicine[13-18]. The measurement device used seems to be a promising tool for practical application studies of this kind.

5 Conclusion

In this pilot study on test subjects with subjective discomforts, CST had a favourable effect on autonomic nervous activity. This, in itself, is an interesting result, considering the frequency persons with subjective discomforts electing to be treated by a craniosacral therapist in Switzerland. Nevertheless, further research will be needed to distinguish specific effects of CST technique from less specific therapist/client-interaction effects.

6 Acknowledgements

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7 Competing interests

The authors declare that there are no competing interests.

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