Manual Therapy, Posturology & Rehabilitation Journal
ISSN: 2236-5435

RESEARCH ARTICLE

Safety in the application of high-velocity low-amplitude technique in upper cervical in elderly: Preliminary study

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Abstract

Background: The literature is still controversial regarding the safety of applying high-velocity, low-amplitude (HVLA) techniques to the upper cervical spine, as well as the effects on heart rate variability (HRV) in the elderly. To date, there are no studies reporting the safety of applying these techniques to elderly. **Objective:** To verify the safety and immediate effects on HRV after applying an HVLA technique to elderly, for the purpose of conducting a future clinical trial. **Materials and Methods:** This is a preliminary, randomized, crossover study. Six physically active elderly individuals without cardiovascular disease were recruited. The subjects underwent two interventions, with a seven-day interval between them: intervention one consisted of an HVLA technique to the upper cervical spine, while intervention two was a simulated (sham) technique. Data on self-reported symptoms after applying the techniques were collected, in addition to HRV, to assess autonomic function. **Results:** There were no records of immediate adverse effects after applying the intervention techniques. However, a significant increase in the root means square difference between adjacent normal RR intervals over a time interval (RMSSD) and in the instantaneous beat-to-beat heart rate recording (SD1) was observed in the HVLA group when compared to the sham group. **Conclusion:** The application of the HVLA technique in the upper cervical spine did not produce self-reported adverse effects in elderly. The HVLA technique increased the activity of the parasympathetic nervous system, producing adjustments in HRV, thus indicating that there may be a significant parasympathetic stimulation in elderly.

Keywords: Musculoskeletal manipulations; autonomic nervous system; safety; elderly.

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Received: 26 Jul, 2024.
Accepted: 11 Sept, 2024.
Published: 14 Oct, 2024.

BACKGROUND

Weight gain is a common concern for midlife women and has been reported in several studies. In the Study of Women Across the Nation (SWAN), midlife women (n=3064) gained an average of 0.7 kg per year, independent of age at baseline or menopause status[1]. Although racial and socioeconomic disparities impacted body weight at baseline (i.e., non-white and lower socioeconomic status are associated with higher baseline weight), subsequent studies showed that weight gain occurred across all midlife women, suggesting the uniformity of this trend[2]. However, weight gain is not limited to midlife; numerous studies have documented an average yearly weight gain of 0.5 kg to 1 kg in US adults[3,4]. Obesity is a critical condition characterized by an accumulation of body fat resulting in body weight that is at least 20% more than the optimum weight[5].

HVLA techniques are commonly used to increase joint range of motion (ROM)[1]. However, secondary effects to increased ROM may occur, such as increased muscle tension and reduced ROM, which are sometimes not reported as unwanted events[2]. Serious injuries to cervical arteries have been reported after cervical manipulations, but are extremely rare[3]. Furthermore, biomechanical studies have shown that angular displacements of the head and changes in vertebral artery length are small during HVLA maneuvers and that the vertebral artery does not experience longitudinal force during manipulation of the cervical spine[4]. However, these findings are not reported in the elderly population who are physiologically predisposed to spinal osteoarthritis[5] in addition to autonomic imbalances[6].

During the development process of physiological changes such as sympathetic tone, which is due to the increase in the concentration of noradrenaline in the blood plasma and impairment of cardiac-vagal neurons, changing the neurohormonal mechanism[7]. Furthermore, the decrease in the number of muscle fibers, especially type II fibers, are responsible for modifying muscle physiology during the aging process[8,9]. The change in autonomic function, due to aging, is reflected in an imbalance of HRV and can damage the cardiovascular system[10]. Healthy older adults have lower resting HRV, and, consequently, greater sympathovagal balance, with the decrease in HRV being an important indicator of cardiovascular events in middle age[11,12].

There are some therapeutic strategies capable of modulating the autonomic nervous system (ANS), reflecting changes in HRV. Studies demonstrate that the application of HVLA techniques on the spine may be able to modulate HRV[13,14]. The likely mechanism of HRV attenuation may be the increase in parasympathetic tone after application of HVLA techniques, which can lead to a modulation of the ANS, promoting hemodynamic heart rate adjustments, blood pressure e HRV[14,15]. But, on the other hand, there is still a gap about the effects of HVLA on HRV and HR in elderly subjects. Thus, the objective of this preliminary study is to evaluate the safety, through the reporting of unwanted effects, and possible immediate effects of HVLA on autonomic function in elderly. Furthermore, this preliminary study aims to establish a protocol for a future randomized clinical trial.

METHODS

This is a randomized preliminary study with a crossover design and followed the recommendations of the Consolidated Standards of Reporting Trials (CONSORT) for pilot study[16]. The sample was composed of six elderly individuals of both sexes, physically active, who were recruited from a list generated in the Study and Research Group on Physical Activity for the Elderly at University of Brasilia, Brazil (GEPAFI – UnB). This research was approved by the ethics and research committee (CAAE 10146913.2.0000.0030) and performed in October 2013 at University of Brasilia, Brazil. The protocol of this study was registered in the Brazilian Registry of Clinical Trials (ReBEC) under the code RBR-7f4jy8j. All subjects who agreed to participate signed an informed consent form, and their data were stored and protected through codes. Subjects aged 60 years or older, no history of cervical disc herniation and vertigo, normotensive and physically active were included in the study. On the other hand, subjects unable to maintain the orthostatic position for at least 10 minutes, with rheumatological diseases, acute and /or chronic cervical pain were excluded from the study.

The subjects included in the study underwent an assessment of their physical activity level, carried out through the International Physical Activity Questionnaire (IPAQ), short version. After applying the questionnaire, anthropometric data were collected using a digital scale (Digital Scale Welmy® W300A, Santa Bárbara D'Oeste, SP, Brazil). To calculate the body mass index, body weight data were used, in kilograms (Kg) and height, in centimeters (cm). Measurements of waist and hip circumferences were taken with a tape measure, midway between the last rib and the iliac crest, two centimeters above the umbilicus and with the subject standing. The hip circumference was performed with a tape measure at the largest point of circumference of the buttocks, to rate the risk of waist/hip ratio.

Randomization and blinding

Randomization was performed with a computerized random number generator (http://www.random.org). Numbers 1 and 2 were randomly organized into a list of 18 to define the allocation sequence of subjects. Random number list was concealed by the investigator who was not in charge of evaluations. As subjects received both interventions, randomization was performed to determine the order of interventions that patients would receive, HVLA group or sham group (Figure 1). Subjects could not distinguish which group they were allocated to, given the similarity of the interventions. To ensure the blinding of the study, each step (randomization, assessments, application of interventions and data analysis) was performed by a different researcher.

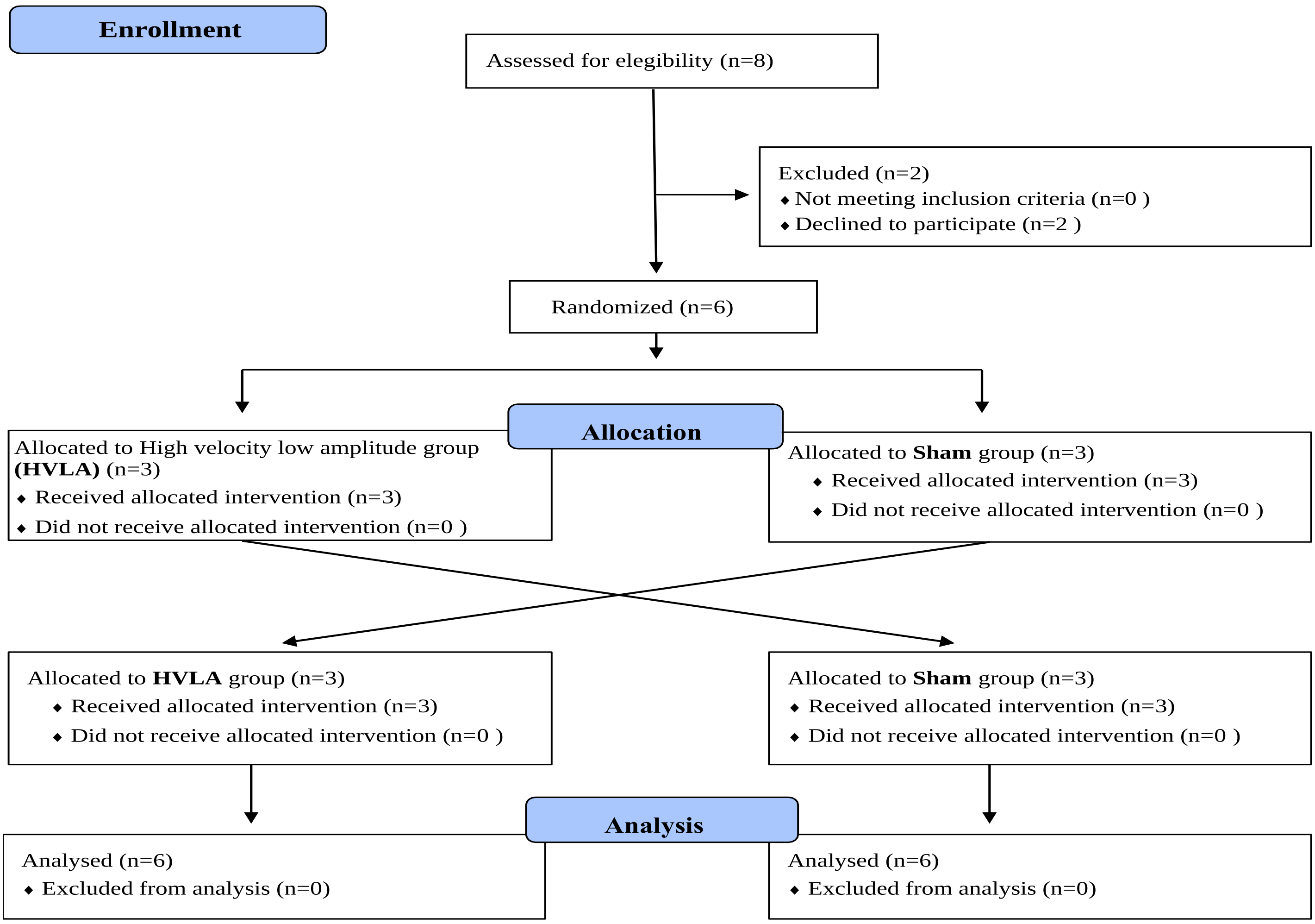

Figure 1. Flow diagram of allocation of the subjects. CONSORT, 2010

Assessment protocol

Data collection consisted of two visits by the subjects to the laboratory, lasting two hours each, where the subjects were submitted to safety and HVR measurement. To evaluate the safety of the HVLA technique, we took an anamnesis with the subject. Where, pre and post manipulation symptoms were recorded. We considered adverse or unwanted effects after applying the HVLA technique: pain in the cervical region, dizziness, nausea, vertigo, reduced cervical ROM. A researcher blinded to the interventions collected this information immediately before and after the interventions were administered. The HRV analysis was performed using a heart rate monitor (Polar RS-800, SP, Brazil) positioned at the level of the xiphoid process of the subjects. HRV monitoring was performed continuously. HRV data were recorded with the aid of a digital heart monitor (Modelo S810, Polar® Electro Oy, Kempele, Finlândia). RR interval data was recorded by a transmitter attached to the chest and transmitted in real time to a portable computer to calculate the HRV power spectrum by Fast Fourier Transform, through the Kubios HRV® software (version 1.1, Kuopio, Finland). The larger stability section of RR intervals, which included a single line composed of 256 points, was selected by visual inspection according to criteria established by the Task Force of the European Society of Cardiology and the North American Society for Pacing and Electrophysiology. The total potency and power of user-defined frequency bands were computed. The standards were established for three bands: 1) LF band between 0 and 0.05 Hz; 2) LF band between 0.05 and 0;17 Hz; e 3) high frequency (HF) between 0.17 and 0.40 Hz. The power density of each spectral component was calculated in absolute values. In the time domain analysis, the square root of the mean sum of squares of the difference between the adjacent normal RR interval within a given time minus one was analyzed. The HRV measure has intraclass correlation coeficiente (ICC) between 0.70 and 0.98[17].

Intervention protocol

The intervention applied was a bilateral HVLA technique on the C1 and C2 vertebrae. The technique was applied by a physical therapist, osteopath and with 10 years of experience. Initially, the osteopath performed the palpation and localization of the transverse process of the C1 and C2 vertebrae of the subjects and performed an analytical mobility test to detect possible biomechanical changes. Immediately after, the HVLA technique was performed, with the subject in the supine position and the osteopath standing towards the subject's head. The osteopath's hand was positioned, with indexical contact, on the vertebral lamina and the forearm was positioned following the axis of manual contact. The HVLA technique was performed by doing a backward translation causing a vertebral rotation[15]. For the application of the sham technique, the same evaluation and positioning procedures of the subject were performed, however, instead of performing an HVLA technique, the osteopath applied the technique with an activator (LIVTA®, Confort, São Paulo – SP, Brazil) unloaded, bilaterally in the transverse processes of the C2-C1 vertebrae. A seven days of washout was given between interventions. All interventions were performed in an appropriate room, with a temperature of 22^{0}C and on a stretcher suitable for carrying out the interventions. The total time of the intervention protocol was around 80 minutes for both groups. The summary of the study protocol and interventions is in figure 2.

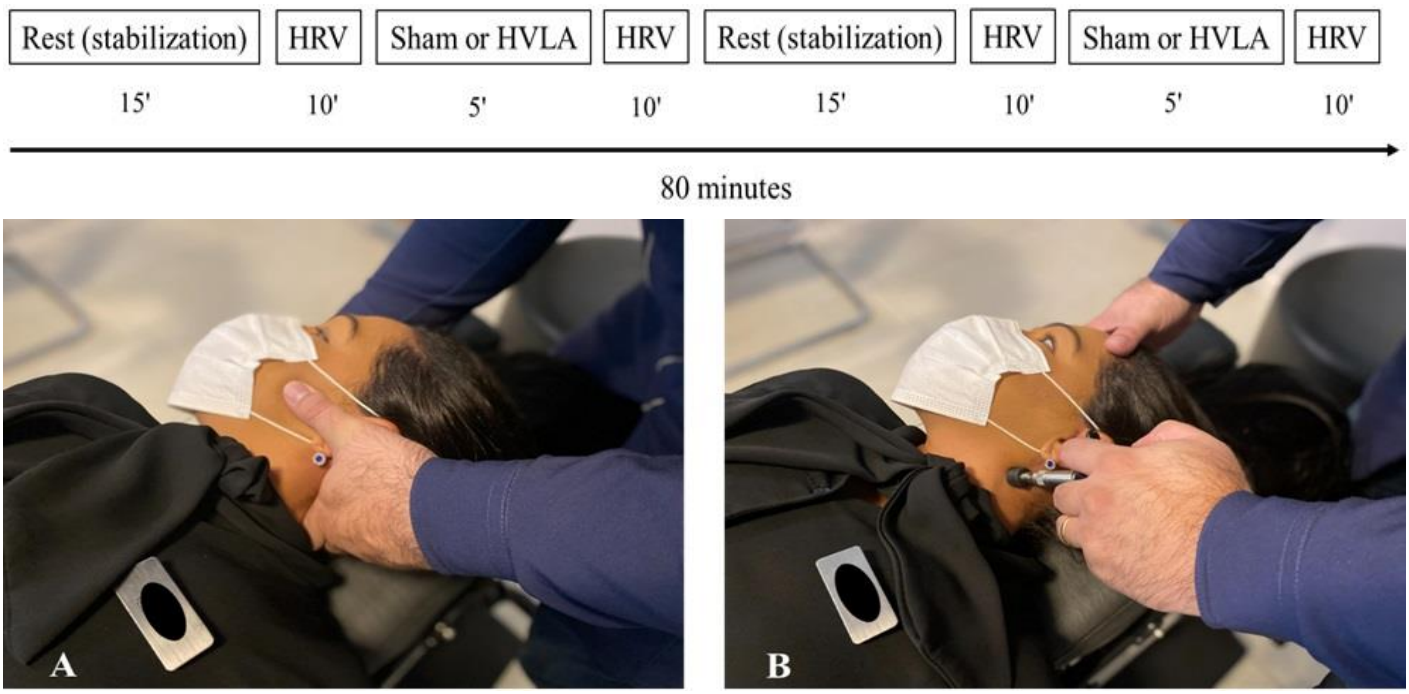

Figure 2. Study protocol illustration.

Note: A, HVLA technique; B, sham technique. HVLA, high velocity low amplitude technique.

Data analysis

Initially, the data were submitted to the Shapiro-Wilk normality and presented a normal distribution. Data comparison was performed over time using analysis of variance for repeated measures, with a Bonferroni post-test. All files were coded and analyzed by a researcher blinded to interventions and assessments. A $p<0.05$ was considered statistically significant for all tests. The Graphpad Prism software version 8.0 was used for the analysis. All the analysis followed the principles of Intention-to-treat (i.e. patients were analyzed into the groups they were originally allocated to)[18].

RESULTS

A total of six elderly finished this study. The sample characterization data are shown in table 1. There were no reports of side or unwanted effects in the elderly, in any of the interventions (table 2). However, regarding HRV, an increase in RR intervals was observed in the HVLA group [p=0.029], when compared with pre-intervention values [p=0.049]. A significant increase in the variable RMSSD and SD1 was also observed in the HVLA group, when compared to pre-intervention values [p=0.027] and when compared to the sham group [p=0.010]. HRV data are shown in table 3.

Table 1. Baseline data sample of subjects.

	n = 6
Demographic data	
Age (years)	73 ± 7.24
Body weight (kg)	62 ± 10.9
Height (m)	1.56 ± 0.05
BMI (kg/m^2)	25.6 ± 5.04

Waist circumference (cm)	89.5 ± 12.82
Hip circumference (cm)	100 ± 7.42
Waist-Hip Ratio	0.89 ± 0.09
IPAQ (active/very active)	3/3

Note: Data are mean ± SD. Kg, kilograms; m, meters; BMI = body mass index; Kg/m^2, kilogram per square meter; cm, centimeters; IPAQ, international physical activity questionnaire. IPAQ data are in proportion. No differences in demographic variables.

Table 2. Self-report of effects after applying the techniques.

	HVLA			Sham		
	Neck pain	D/N/V	ROM decrease	Neck pain	D/N/V	ROM decrease
P 1	X	X	X	X	X	X
P 2	X	X	X	X	X	X
P 3	X	X	X	X	X	X
P 4	X	X	X	X	X	X
P 5	X	X	X	X	X	X
P 6	X	X	X	X	X	X

Note: HVLA, high-velocity low-amplitude technique; D, dizziness; N, náusea; V, vertigo; ROM, range of motion; P, patient; **X**, unreported event.

Table 3. Heart rate variability data.

	Pre mean ± SD	Sham mean ± SD	HVLA mean ± SD	F test	*p*	Post-hoc Pre vs Sham	Post-hoc Pre vs HVLA	Post-hoc Sham vs HVLA
HR (bpm)	60.22 ± 7.01	58.46 ± 6.73	57.7 ± 6.71	7.42	0.067	0.081	0.099	0.853
RR (ms)	1007.93 ± 109.1	1041.76 ± 116.46	1052.98 ± 118.16	6.81	0.059	0.109	0.120	0.990
SDNN (ms)	33.94 ± 11.02	49.74 ± 9.76	43.21 ± 10.91	2.173	0.185	0.170	0.337	0.990
RMSSD (ms)	22.88 ± 13.35	25.64 ± 16.18	29.15 ± 17	8.542	0.027*	0.410	0.078	0.010*
pNN50 (%)	5.81 ± 10.38	10.06 ± 17.86	12.76 ± 19.43	2.925	0.143	0.696	0.374	0.175
LF (Hz)	309.97 ± 241.84	306.29 ± 203.53	496.68 ± 375.25	2.11	0.200	0.990	0.718	0.383
HF (Hz)	198.3 ± 274.83	274.86 ± 327.58	303.81 ± 334.73	3.34	0.108	0.512	0.268	0.784
LF/HF (%)	2.35 ± 1.72	2.59 ± 2.19	3.22 ± 2.48	0.76	0.433	0.990	0.980	0.990
LFnu (nu)	63.63 ± 17.28	61.16 ± 23.96	66.96 ± 22.21	0.574	0.559	0.990	0.990	0.975
HFnu (nu)	36.33 ± 17.27	39.57 ± 25.07	33.3 ± 22.26	0.7	0.504	0.990	0.990	0.980
SD1 (ms)	16.19 ± 9.46	18.14 ± 11.45	60.64 ± 12.03	8.597	0.027*	0.418	0.077	0.010*
SD2 (ms)	44.93 ± 13.28	58.22 ± 13.56	56.51 ± 14.43	1.705	0.240	0.247	0.528	0.990

Note: SD, standard deviation; HVLA, high velocity low amplitude technique; HR, heart rate; bpm; beat per minute; RR, interval between beats R to R wave; ms; millisecond; SDNN; standard deviation of all normal RR intervals recorded in a time interval; RMSSD, square root of the mean square of the differences between adjacent normal RR intervals over a time interval; pNN50, percentage of adjacent RR intervals with duration difference greater than 50ms; %, percent; LF, low frequency; Hz, hertz; HF, high frequency; LF/HF, low frequency to high frequency ratio; LFnu, normalized low frequency; nu, normal units; HFnu, normalized high frequency; SD1, instant beat-to-beat heart rate recording; SD2, beat-to-beat heart rate recording over time. One-way ANOVA. *p<0.05.

DISCUSSION

This preliminary study evaluated the safety and effects on HRV in healthy elderly after application of HVLA technique in Upper cervical spine. No patient reported the presence of neck pain, dizziness, nausea or vertigo after applying the interventions. Furthermore, we found that the HVLA technique increased parasympathetic activity. Regarding reports of adverse effects after the application of HVLA techniques in clinical trials, it remains insufficient[19].A recent systematic review evaluated 154 studies, 94 of which reported adverse events, of which 94 studies, 36 reported directly adverse events. In studies where the HVLA technique was performed by a chiropractor these reports occurred more frequently. Indirect reporting occurred in 58 studies, the most frequent being when the HVLA technique was performed by a physical therapist. Our hypothesis is that conceptual differences in the application of techniques, classification of adverse events, the training of the professional who performed the HVLA technique, as well as the region where the technique was applied may justify the low or even non-reporting of adverse events.

Regarding the modulation of the sympathetic nervous system, after the application of HVLA techniques, Giles et al. verified the performance of HVLA techniques applied to the cervical spine in the vagal function of adults, who underwent three interventions: HVLA, soft tissue mobilization in the upper cervical spine and suboccipital decompression; sham manipulation; and control (no physical contact). HRV was evaluated in the time and frequency domains. As a result, the group that received HVLA and soft tissue mobilization in the upper cervical spine had increased standard deviation ($p < 0.01$) and high frequency spectral power ($p = 0.03$), suggesting the hypothesis that HVLA in the upper cervical spine may acutely affect HRV measurements in healthy individuals and generate changes in cardiac control by the parasympathetic nervous system[20].

Another study conducted by Henley et. al, showed the relationship of HVLA techniques with the ANS in sixteen healthy subjects. In this study, we compared the application of: HVLA technique associated with myofascial release in the cervical spine; simulated treatment, with placement of hands in the cervical region; and control (no intervention). The protocol lasted 30 minutes and involved changing the horizontal position and tilting the head at 50° and as a result there was a predominance of parasympathetic responses in subjects in the horizontal position, while the tilting at 50° showed increased sympathetic responses. An increase in HR was also observed in all individuals and vagal activity was also obtained when HVLA was applied, sufficient to overcome the sympathetic tone[21].

Limitations

Our study had some limitations that may have compromised the results. Even being a preliminary study, we consider the sample small. Another limitation was the subjectivity of palpation to locate the C1 and C2 vertebrae, so it is not known for sure whether the HVLA techniques were actually applied to the desired vertebrae. Patients were also not followed for any period after the end of the study.

CONCLUSION

This study showed that the high-velocity and low-amplitude technique applied to the C1 and C2 vertebrae did not produce adverse effects, in addition, increased the parasympathetic activity, through the modulation of the autonomic nervous system, resulting in changes in the HRV variables. Therefore, we believe it is safe and feasible to conduct a clinical trial based on the results of this preliminary study.

Author Contributions: J.Z., A.P.X. and F.A. conceived the idea for the study. J.Z., G.C., L.N. and R.Q. contributed to the design and planning of the research. All authors were involved in data collection. T.R. analysed the data. J.Z., A.P.X., T.R. and G.C. wrote the first draft of the manuscript. J.Z., T.R. and L.N. coordinated funding for the project. All authors edited and approved the final version of the manuscript.

Financial Support: This research did not receive any financial support.

Conflict of interest: No conflict of interest has been declared by the authors.

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