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Study Identification

Unique Protocol ID: TUN IRB4-10-13A

Brief Title: Physiological Responses to Osteopathic Manipulative Techniques in Healthy Young Adults

Official Title: Physiological Responses to Osteopathic Manipulative Techniques in Healthy Young Adults

Secondary IDs:

Study Status

Record Verification: April 2022

Overall Status: Completed

Study Start: October 4, 2013 [Actual]

Primary Completion: August 7, 2019 [Actual]

Study Completion: August 7, 2019 [Actual]

Sponsor/Collaborators

Sponsor: Touro University Nevada

Responsible Party: Principal Investigator

Investigator: Marina loudina [mioudina]

Official Title: Assistant Professor

Affiliation: Touro University Nevada

Collaborators:

Oversight

U.S. FDA-regulated Drug: No

U.S. FDA-regulated Device: No

U.S. FDA IND/IDE: No

Human Subjects Review: Board Status: Approved

Approval Number: IRB4-10-13A, IRB 8-09-17A

Board Name: Touro University Nevada IRB

Board Affiliation: Touro University Nevada

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Data Monitoring: No
FDA Regulated Intervention: No

Study Description

Brief Summary: This study was designed to investigate the effect of selected osteopathic manipulative techniques (OMT) on cardiovascular functions in healthy young men and women.

This work addressed questions regarding physiological responses to OMT in maintaining the cardiovascular homeostasis by (1) measuring changes in the cardiac autonomic nerves activity, (2) measuring changes in cardiovascular parameters such as blood pressure, cardiac contractility, and heart rate, and (3) investigating if changes in the cardiac autonomic nerves activity were related to changes in blood pressure, cardiac contractility, or heart rate.

This controlled not-randomized pilot study with repeated measures was conducted at the Touro University Nevada College of Osteopathic Medicine. Healthy 21-35 years old students and employees volunteered in the study. The experimental group received the three cranial osteopathic manipulative techniques, namely, occipital-atlantal decompression, occipital-mastoid decompression, and compression of the fourth ventricle, consecutively applied. This study included two control groups; one group received sham manipulations, and the second group did not receive any manipulations and was the non-touch group.

The computerized MP150 BIOPAC System was used for data collection and analysis. The skin electrodes were used for the one-lead ECG and impedance cardiography. Digital data were recorded during the entire experimental protocol. The blood pressure was measured manually before and after the experimental procedure using blood pressure cuff and stethoscope. Cardiovascular responses to OMT were evaluated by using the heart rate variability test (HRV), calculating changes in cardiac contractility, and comparing changes in pre- and post- blood pressure readings.

An analysis of variance (ANOVA) with a Bonferroni post-hoc test was used to evaluate treatment effects. The type I error rate (alpha) was set at 0.05.

Detailed Description: Healthy, 21-35 years old, male and female volunteers were recruited from Touro University students, faculty and staff using a brochure, poster, e-mail and personal conversation. Each participant signed an informed consent form. Participants were allowed to participate in multiple experiments (in the experimental and control groups) at least 7 days after the last experiment.

Each subject's weight and height were measured before the procedure. Anthropometric measures were used in cardiac impedance analysis, and as descriptive statistics of the studied population. All cardiovascular parameters were recorded by using a non-invasive method. We used disposable skin electrodes for impedance cardiography and a one-lead ECG.

The subjects were lying in the supine position and were asked to relax. All surface electrodes were connected to the computerized MP150 BIOPAC System for data recording. The duration of experimental protocol was about 30 minutes, and included three intervals: 10 minutes, pre-OMT rest phase (Rest); 8 to 12 minutes (about 10 minutes) of the OMT/Sham (Manipulations); and 10 minutes post-OMT recovery phase (Recovery).

OMT and sham manipulations were administered by an osteopathic physician. The participant lied supine with physician seated at the side of the table facing the participant. Cranial OMT included three techniques and was administered in the following sequence: occipital-atlantal decompression, occipital-mastoid joint, and compression of the fourth ventricle. Control subjects received the sham manipulative procedure or relaxed in supine position (non-touch control). The total duration of OMT was controlled by an osteopathic physician and was

about 10 minutes.

Occipital-atlantal decompression: Patient is in the supine position. The operator places the tip of a finger against the posterior tubercle of the atlas and holds that bone anteriorly, preventing it from moving posteriorly with the condyles as the patient nods or tips the head forward. This will release tension between the occipital condyles and the first cervical vertebrae.

Occipital-mastoid joint decompression: The occipital squama is gently moved forward and upward (anteriorly and superiorly) with the pads of the long finger, and the mastoid process of the temporal bone is lifted anterolaterally with the pads of the index fingers. This technique decompresses the jugular foramen, which the vagus nerve passes through.

Compression of the fourth ventricle: Manipulation is accomplished by having the operator's hands cupped to receive the lateral angles and supra-occiput on their thenar eminences. Gentle compression medially is maintained (generally 2 to 3 minutes) until tissue changes, such as a softening or increased motion, are noted in the supraoccipital area.

Sham: The osteopathic physician placed his hands on the skull of the subject but did not influence cranial motion. The sham manipulative procedure (SMP) was administered for 10 minutes.

All manipulations were administered by the osteopathic physician; experiments were conducted at Touro University Nevada. Data were collected by a non-invasive method using BIOPAC Systems, Inc. Equipment MP150 for data acquisition and analysis. The protocol consisted of three phases: rest before manipulations (10 min), manipulations (OMT) (approximately 10 min), and recovery after manipulations (10 min).

Data analysis: Most cardiovascular response variables were measured at baseline, immediately after manipulation ("immediate response"), and at the end of protocol ("after rest"). The immediate responses and at the end of protocol were calculated on a percentage basis relative to baseline to control some individual variations.

The percent response variables were each analyzed in a three-way analysis of variance (ANOVA) which included time ("Immediate response", "after rest"), treatment (cranial manipulation, sham), and sex (male, female) as fixed effects. For significant interactions in the ANOVA, a Bonferroni post-hoc test was used to compare treatment effects within time, sex, or both. The type I error rate (alpha) was set at 0.05. The relationships among dependent variables were described with Spearman correlations between percent response variables within. Analyses were done in Rv3.5.1 (R Core Team 2018).

Conditions

Conditions: Healthy Young Adults

Keywords: Osteopathic manipulations,
autonomic,
cardiovascular

Study Design

Study Type: Interventional

Primary Purpose: Basic Science

Study Phase: N/A

Interventional Study Model: Parallel Assignment

Number of Arms: 3

Masking: None (Open Label)

Allocation: Non-Randomized

Enrollment: 51 [Actual]

Arms and Interventions

Arms	Assigned Interventions
<p>Experimental: Cranial OMT The experimental group received the three cranial osteopathic manipulative techniques, occipital-atlantal decompression (OAD), occipital-mastoid decompression (OMD), and compression of the fourth ventricle (CV4), consecutively applied.</p>	<p>Procedure/Surgery: Cranial manipulation group, or cranial osteopathic techniques (OMM) Cranial OMT procedure: Subjects were relaxed lying on the back for entire time of the research protocol (approximately 30 min). Osteopathic physician performed the osteopathic manipulations using his hands. The physician gently applied a small amount of force to the neck and head to release tissue tension until feeling a softening and warmth of tissues. Subjects experienced a sensation of slight pulling, releasing, or relaxing of the tissue.</p> <p>Other Names:</p> <ul style="list-style-type: none">• Cranial osteopathic manipulations, cranial osteopathic techniques, cranial OMT procedure
<p>Sham Comparator: Sham manipulation The osteopathic physician placed his hands on the skull of the subject but did not influence cranial motion.</p>	<p>Procedure/Surgery: Sham manipulation The osteopathic physician placed his hands on the skull of the subject but did not influence cranial motion.</p> <p>Other Names:</p> <ul style="list-style-type: none">• Sham
<p>No Intervention: Non touch group The control group whose members did not receive any manipulations.</p>	

Outcome Measures

Primary Outcome Measure:

1. Heart rate variability

The heart rate variability test was used to study the effect of OMT on heart rate and, by inference, on autonomic nervous system activity. A decrease in heart rate accompanied by an increase in vagal and decrease in sympathetic activity would indicate parasympathetic activation by OMT.

[Time Frame: The responses were measured immediately after the physician finished OMT/Sham (after Manipulations phase) and 10 minutes after post-OMT/Sham recovery phase (“Recovery”, “after rest”).]

2. Myocardial contractility

Changes in impedance cardiography parameters, such as stroke volume (SV) and cardiac output (CO), were used to evaluate the effect of OMT on myocardial contractility. An increase in cardiac output (CO) and stroke volume (SV) would indicate the stimulatory effect of selected OMT on myocardial contractility.

[Time Frame: The responses were measured immediately after the physician finished OMT/Sham (after Manipulations phase) and 10 minutes after post-OMT/Sham recovery phase (“Recovery”, “after rest”).]

3. Blood pressures

Systolic and diastolic blood pressure were measured by sphygmomanometer. A decrease in systolic blood pressure in response to OMT would indicate a decrease in vascular sympathetic tone.

[Time Frame: The blood pressure was measured manually before (before pre-OMT rest) and after the experimental procedure (after "Recovery" phase).]

Eligibility

Minimum Age: 21 Years

Maximum Age: 35 Years

Sex: All

Gender Based: No

Accepts Healthy Volunteers: Yes

Criteria: Inclusion Criteria:

Young adults

- Exclusion Criteria: Any pre-existing chronic cardiovascular diseases,
- Any pre-existing pulmonary diseases,
- Any pre-existing renal diseases,
- diabetes mellitus,
- endocrine disorders affecting the cardiovascular system,
- pregnancy,
- musculoskeletal conditions that can affect the use of the cranial OMTs, or
- acute illness that necessitates consulting a healthcare provider.

Contacts/Locations

Central Contact Person: Marina loudina, MD, PhD, MS
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Study Officials: Marina loudina, MD, PhD, MS
Study Principal Investigator
Touro University Nevada

Locations:

IPDSharing

Plan to Share IPD: Yes
All IPD that underlie results in a publication

Supporting Information:
Study Protocol
Informed Consent Form (ICF)

Time Frame:
Starting 6 months after publication

Access Criteria:
By direct contact with study authors

URL:

References

Citations: Żurowska A, Malak R, Kołcz-Trzęsicka A, Samborski W, Paprocka-Borowicz M. Compression of the Fourth Ventricle Using a Craniosacral Osteopathic Technique: A Systematic Review of the Clinical Evidence. *Evid Based Complement Alternat Med*. 2017;2017:2974962. doi: 10.1155/2017/2974962. Epub 2017 Oct 18. Review. PubMed 29234380

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Links:

Available IPD/Information:

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services