RE: "Changes in Vertebral Artery and Cerebral Hemodynamics Following Various Head Positions & Cervical Manipulation in Patients with Chronic/Recurrent Neck Pain."

Co-Investigators:
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Pierre Coté, DC PhD
Michael Noseworthy, PhD
Greg Wells, PhD

To whom it may concern,

We thank you for you consideration of this work. Please find below 5 pages consisting of our REB approved consent for participation form.

Sincerely,

Nicholas Moser, BSc, DC

Consent for Participation in a Research Study

Changes in Vertebral Artery and Cerebral Hemodynamics Following Various Head Positions & Cervical Adjustment in Patients with Chronic/Recurrent Neck Pain

Investigators:

Principal Investigator
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Associate Professor, Faculty of Health Sciences, University of Ontario Institute of Technology (UOIT)
Director, UOIT-CMCC Centre for Disability Prevention and Rehabilitation

You are invited to take part in this research study. We are performing a study to determine whether changes in blood flow occur in the neck and back of the brain. We will be looking for changes following different head positions and an adjustment to the neck, in chronic neck pain patients who are already prescribed adjustments to the neck.

Each participant will be asked to undergo a series of magnetic resonance imaging (MRIs) to evaluate whether there are any changes in blood flow in the back of the brain or neck after changes in head position or an adjustment. This study will be conducted over a period of 1 day and each participant can anticipate the testing to take approximately 2 hours. Before agreeing to participate in this study, it is important that you read and understand the following explanation of the procedure, benefits, discomforts, risks, and precautions associated with this study. It also describes your right to refuse to participate or withdraw from the study at any time.

In order to decide whether you wish to participate in this research study, you should understand enough about the risks and benefits to be able to make an informed decision. This is known as the informed consent process. Please ask the study staff member asking you to read this form or the doctor to explain anything that you do not understand before signing this consent form. Make sure all your questions have been answered to your satisfaction before signing this document.

Joint funding for this project has been issued by the NCMIC (National Chiropractic Mutual Insurance Company) and the CCPA (Canadian Chiropractic Protection Association).

Background

Blood flow in the neck has been studied extensively in cadavers, animal models, and in the healthy population using different forms of non-invasive methods. These methods include doppler ultrasound and other imaging modalities, conducted with various head positions and after an adjustment. Of particular interest are the effect extreme head positions, like maximum rotation of the neck, and an adjustment to the neck has on blood flow. There have been inconclusive findings for results of these tasks. Several studies have demonstrated no significant changes in the neck or brain blood flow in healthy volunteers. However, a decrease in blood flow to the brain at the back of the head has been demonstrated in some people, while other research has demonstrated an increase in blood flow.

Investigators have begun to utilize advance imaging to examine the impact of chronic neck pain on blood flow to the brain. There is strong evidence that chronic pain is associated with changes in brain blood flow, but the reason is still uncertain. Advanced imaging using PET scans reflect the metabolism of the brain and is believed to be an indirect indicator of brain blood flow. In the case of patients with chronic neck pain, brain metabolic activity using advanced PET imaging has been shown to be uneven under resting circumstances. In the only study to date, it has been shown that such activity becomes more evenly distributed following an adjustment. Like the work in the neck, there remains too little information, some of it conflicting, to understand whether head positioning and adjustment itself has any effect on brain circulation.

We propose to use 3 non-invasive advanced MRI techniques to measure the blood flow and activity of the neck and brain. These methods detect changes in blood flow and other important activities such as tissue oxygenation. The functional blood level dependent MRI (fBOLD) measures show contrast based on oxygenation, blood volume and proportion of red blood cells. Arterial spin labeling (ASL) perfusion fMRI is a non-invasive measure that utilizes magnetically labeled water in arterial blood flow as a tracer. Signals provide good sensitivity and clear contrast between gray and white matter observed in perfusion intensity. This technique offers reliable measures of blood flow with excellent reproducibility. The General Electric 3T MRI phase contrast method can measure blood flow through the neck and the arteries at the back of the brain.

Purpose of the Study

The purpose of our study is to evaluate the flow of blood in the neck and brain following 3 maneuvers: 1) resting neutral position, 2) maximum rotation of the neck to end-range and 3) spinal adjustment in patients with chronic neck pain who are already prescribed adjustment treatment to the neck. Measures will be made using non-invasive MRI techniques to assess neck and brain blood flow.

Procedures involved in the Research

MRI analysis:

This study will be conducted over a period of approximately 100 minutes. You will be asked to lie on your back in the MRI tunnel, which is narrow. You will be given up to 5 minutes in the MRI before testing begins to ensure that you are comfortable.

Before positioning in the MRI, capsules of vitamin E oil will be taped to the bridge of your nose and one in front of each of your ears. These capsules act as passive markers that are capable of being seen on the MRI images and will only be used to orient the analysis of the MRI. The vitamin E capsules will be removed on completion of the study.

Once preparations are complete, you will undergo 5 minutes of complete rest while you lay on your back. A total of 3 test maneuvers will then be evaluated (rest, maximal voluntary neck rotation, post-adjustment). First, your head position will be verified as being in the neutral position using a simple tool (inclinometer) that will be placed momentarily against your head. Once neutral position is confirmed, you will be placed in the MRI during which time a baseline MRI image will be obtained. Once the images are obtained, this will be followed by a new maneuver, determined on a random basis, into either maximum voluntary rotation of your neck or you will receive an upper neck adjustment. The clinician will determine the site of adjustment by identifying the side of joint restriction and pain with palpation in the upper neck. The adjustment will be performed to your non-dominant hand side if no restriction or pain is identified on either side of the upper neck. For neck rotation, you will be asked to turn your head as far as possible and hold the position for one minute to the same side to which neck adjustment will be performed and then return to the neutral position. The inclinometer will be used as you turn to verify head orientation. After the maneuver you will undergo a second MRI imaging. The remaining maneuver and a third imaging will follow this. The MRI testing is non-invasive, meaning it does not require any injections or blood samples.

You will be asked to refrain from activities that have the potential to change your baseline energy levels for 6-12 hours before the testing. These include staying up later then any typical night, alcohol consumption, and weight training. You must refrain from caffeine for 6 hours before testing and alcohol for 12 hours before testing.

Potential Harms, Risks or Discomforts:

There may be certain risks associated with participation in the study:

1. Some subjects may experience short-term discomfort from minor muscle and ligament stretch as a result of neck adjustment or extremes of posture.

2. There are reported cases of stroke occurring after undergoing many common neck movements including extreme head rotation or from adjustment to the neck. Stroke sometimes causes serious neurological impairment, and may result in paralysis or death. The risk of stroke has been estimated to be anywhere between 1 in 400,000 to 1 in 3,846,153 procedures. The risks for stroke have been found to be essentially equivalent following a visit to a chiropractor as on a visit to a medical physician.

3. There are rare reported cases of disc injuries following cervical spinal manipulation.

A chiropractor with over 30 years experience will perform all of the cervical manipulations and oversee the movements you will be requested to perform. Each participant will be screened with the initial questionnaire and clinically assessed by the chiropractor to help minimize these risks.

4. Claustrophobic subjects should disclose this information to the study supervisor since there is the potential of inducing claustrophobic event while in the MRI machine. If you experience claustrophobia while in the MRI you may withdraw from the study with no repercussions.

Every effort has been attempted to minimize the risk involved in your participation of this study. You will be required to fill out a participation questionnaire, which queries many of the associated risk factors in receiving adjustment of the neck and exposure to MRI. Our clinician, who will perform the manipulation, will also examine you. He will screen your range of motion and will palpate your neck. If he suspects for any reason that you are at an increased risk, the appropriate precautions will be taken and you will not be permitted to continue with the study. In addition, each participant after testing will be observed for 1 hour and contacted 24 hours after release for follow-up on status.

Potential Benefits

The participants will receive typical treatment for their condition and may benefit. Otherwise no specific benefit will accrue from participation in this study.

Payment or Reimbursement

There will be a reimbursement of $75.00 for parking, travel and compensation for your time.

Confidentiality

All information obtained during the study will be held in a password protected server in strict confidence in a locked office at the Office of Research Administration of the Canadian Memorial Chiropractic College for a period of 10 years, and then destroyed. You will be identified with a study number only. No names or identifying information will be used in any publication or presentations of the information obtained. In addition, the REB for audit purposes may review the data.

Participation and Withdrawal

Your participation in this study is voluntary. You may choose not to participate and may withdraw at any time without consequences. Your decision to participate, or to withdraw from the study will have no affect on your rights or privileges to receive care as a patient or, if enrolled as a student, on your academic standing.

Information about the Study Results

The investigators expect to have this study completed by approximately September 2017. If you would like a brief summary of the results, please let us know how you would like them sent to you by indicating in the space provided at the end of this document

Research Related Injury

If you feel that you have suffered any type of injury as a direct result of taking part in this study, necessary medical treatment will be made available to you at no cost. If you suffer any soreness or discomfort that limits your normal activity please report this to Dr. Mior who will arrange a prompt clinical evaluation at no cost. Financial compensation for such things as lost wages, disability or discomfort due to this type of injury are not routinely available. However, if you sign this consent form it does not mean that you waive any legal rights you may have under the law, nor does it mean that you are releasing the investigator(s), institution(s) and/or sponsor(s) from their legal and professional responsibilities.

Questions about the Study

If you are interested in information on the outcome of the study you may request a report from your own data and / or aggregated data either at the time of consent and data capture by signing below or subsequently by written request to the principal investigator.

If you suffer or perceive any other injuries during the study, or if you have any general questions about the study, please call the scientist supervising this study: Dr. Silvano Mior at (416 482 2340 ext. 132). An alternate contact, for your convenience, is Mr. Mark Fillery of the Office of Research Administration who will coordinate with the clinic as necessary. Participants who experience any neurological symptoms within 2 weeks of the procedure should be seen by a neurologist.

This study has been reviewed by the Hamilton Integrated Research Ethics Board (HiREB). The HiREB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call the Office of the Chair, HiREB, at 905.521.2100 x 42013.

CONSENT

I have had the opportunity to discuss this study and my questions have been answered to my satisfaction. I consent to take part in the study with the understanding I may withdraw at any time. I will receive a signed copy of this consent form. I voluntarily consent to participate in this study.

_____	_____	_____
Study Participant's Name (Please Print)	Study Participant's Signature	Date

I confirm that I have explained the nature and purpose of the study to the subject named above. I have answered all questions.

_____	_____	_____
Name of Person Obtaining Consent	Signature	Date

If you would like information on the outcome of the study you may request a report from your own data and / or aggregated data by signing below.

_____	_____	_____
Study Participant's Name (Please Print)	Signature	Date