

Information Letter

The effect of instrument assisted spinal manipulation on mechanical pain sensitivity in a healthy population compared to control: A feasibility randomised trial.

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You are invited to participate in this study.

Background

Instrument Assisted Spinal Manipulation, otherwise known as Activator Technique, is commonly used by chiropractors for the treatment of musculoskeletal complaints. However, there is limited evidence to support the use of Instrument Assisted Spinal Manipulation in the treatment of spinal pain, and there is a lack of understanding of how Instrument Assisted Spinal Manipulation causes pain relief.

Improving our understanding of the neurological and physiological effects of Instrument Assisted Spinal Manipulation will enhance the use of this technique in the management of individuals with painful conditions.

Aim of the Study

This study aims to investigate the effects of Instrument Assisted Spinal Manipulation upon pain sensitivity at locations close to and remote to the lumbar spine. We are also investigating whether any changes in pain sensitivity are maintained for a period of up to 30 minutes. In addition, we will be examining whether changes to pain sensitivity occur on both sides of the body or not, when the technique is applied to only one side.

What Does Your Participation Involve?

In order to participate in the study you must be between 18-65 years of age. You must also have no current lower back pain or chronic pain anywhere in your body (pain that has lasted for more than 3 months). This includes frequent (daily) headaches or other pain that recurs regularly.

As a participant in this study you will be asked to attend the Murdoch University Chiropractic Research Facility, located opposite the Chiropractic Clinic on the South Street campus. A brief questionnaire will be given to you in order to rule out any factors which may prevent you from being a participant in this study.

Once it is determined that you are eligible to participate, a researcher will need to mark eight locations on your body (four on each side); on the lower back, shoulder blade, the front of your lower leg and calf. A marker will be used which is safe for your skin and can easily be wiped off following the measurements. We ask that you please wear loose fitting clothing that will enable us to access these areas. Jewellery and make-up will not affect the measurements. A device called an algometer will then be used to measure your sensitivity to pressure three times at each of these locations. The algometer will be pressed into your skin until the feeling of pressure first becomes painful, after which the pressure will be released.



Once these measurements have been taken initially, an Instrument Assisted Spinal Manipulation procedure will be performed on your lower back, which involves laying on your stomach and having an experienced researcher apply a rapid thrust to your lower back using a hand held instrument commonly referred to as the Activator. During the performance of the manipulation you should not experience any pain. If at any time during the procedure you feel pain or are uncomfortable please notify the researcher immediately.

Immediately following the manipulation, the pressure measurements will be repeated, and again 10, 20 and 30 minutes after the manipulation. While measurements are not being taken you will be asked to wait quietly in the room. Following the final set of measurements at 30 minutes, you will be able to leave. The total amount of time for which you will be required is estimated to be 60 minutes.

Voluntary Participation and Withdrawal from the Study

It is important that you understand that your involvement in this study is voluntary. While we would be pleased to have you participate, we respect your right to decline. There will be no consequences to you if you decide not to participate or choose to withdraw from the study. If you decide to discontinue participation at any time, you may do so without providing an explanation. If you withdraw, all information you have provided will be destroyed.

Your Privacy

Your privacy is very important to us. Your participation in this study and any information will be treated in a confidential manner. Your name and identifying details will not be used in any publication arising out of the research. Following the study the data will be kept in a de-identified format, in a locked cabinet in the office of the co-investigator Dr. Barrett Losco.

Possible Benefits

Aside from a sense of satisfaction that may result from helping to improve our knowledge in this area, there will be no benefit to the participant.

Possible Risks

There are some risks associated with the procedures involved in this study. You may feel mild soreness or stiffness in the low back for a short period of time (up to 24 hours) which should resolve on its own. There is a small risk that you may experience tenderness or bruising at a location where pressure sensitivity was measured, which should be mild and resolve over one to seven days. Other more concerning risks are rare to very rare, and all precautions are taken to ensure you are at the lowest risk possible of experiencing these. The more serious risks include lumbar disc herniation, worsening of neurological symptoms, cauda equina syndrome, and rupture of an abdominal aortic aneurysm. If you experience any concerning symptoms following participation in this study, you are encouraged to contact one of the researchers to discuss this.

Reimbursement

Participants who meet the criteria and are eligible for the study will be offered a \$20 Coles-Myer gift card as reimbursement for participation in the study.

Questions

If you would like to discuss any aspect of this study please feel free to contact Dr Jean Theroux at j.theroux@murdoch.edu.au or by telephone on (08) 9360 7567 Alternatively, you may contact Dr. Barrett Losco at b.losco@murdoch.edu.au or by telephone on (08) 9360 6913. The researchers would be happy to discuss any aspect of the research with you.

Once we have analysed the information we will place a summary of our findings on the School of Health Professions website, which can be accessed by following the link provided <http://www.murdoch.edu.au/School-of-Health-Professions/Research/Chiropractic-Research/>.



This study has been approved by the Murdoch University Human Research Ethics Committee (Approval xxxx/xxx). If you have any reservation or complaint about the ethical conduct of this research, and wish to talk with an independent person, you may contact Murdoch University's Research Ethics Office (Tel. 08 9360 6677 (for overseas studies, +61 8 9360 6677) or e-mail ethics@murdoch.edu.au). Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.