



Information for volunteers:

Low back inter-vertebral motion patterns in healthy adults: (MRI sub study).

I would like to invite you take part in this research study. Before you decide it is important for you to understand why the research is being done and what it would involve for you. **My contact details are at the end of this information and I would be happy to answer any questions you may have.**

This information leaflet will:

1. Outline the purpose of the research.
2. Explain why you have received this leaflet.
3. Describe what happens next.
4. Describe what will happen if you decide to participate.
5. Clarify the risks and benefits to you of taking part.
6. Inform you about confidentiality and data protection.
7. Describe what to do if you have a problem
8. Explain what will happen to the results of this research
9. Tell you who is funding the research
10. State who has reviewed the study
11. Give contact details for the clinical investigator so you can ask any further questions.



1. Purpose.

This study is being conducted to establish a database of the normal mechanics of the low back in people without back pain. This is so there will be a reference for patients being investigated for mechanical pain to help with treatment. A lot of treatment for back pain is based on improving the mechanics of the spine, however, until now it has been impossible to measure these in living people. Quantitative Fluoroscopy is an X-ray video method of doing this which was invented and developed at the Anglo-European College of Chiropractic (AECC) and is called 'OSMIA' (Objective Spinal Motion Imaging Assessment). This research is to determine the limits of normal inter-vertebral motion so that clinicians who use it in the future will be able to interpret its results and researchers will be able to test the ability of treatments to improve spinal mechanics in living people.

A small number of volunteers will also be asked if they would like to participate in the 'MRI sub-study' which will investigate the structure of the discs using MRI and relate this to the movement patterns between the vertebrae. If you are invited to take part in this sub study it will be a separate 45 minute appointment to attend our open upright MRI scanner for an MRI scan of your lower back.

2. Why Have I Received this Leaflet?

You have received this leaflet because you are aged between 21 and 70 years and you replied to an email or advertisement asking for volunteers who fit the inclusion criteria and who would like to take part in this research study. This leaflet will explain the research in further detail.

3. What Happens Next?

After you have read this leaflet I will contact you to ask if you are still interested in taking part. **I am happy to answer any questions you may have but it is entirely your decision whether or not you decide to join the study. You are free to refuse to participate or withdraw at any time prior to the taking of the x-ray video without giving a reason (see Confidentiality and Data Protection).**

4. What Will Happen if I Decide to Participate?

If you take part in this research your name, gender, age, height and weight, address and telephone number and email will be stored on a password protected database. You will be invited to attend the x-ray department at a time convenient to you. I will meet and go through



this Information Leaflet with you and explain the examination. If you are happy to proceed you will be asked to sign two consent forms, one of which will be for you to keep.

You will then be allocated to have either a forward-backward bending examination or a side-bending one. You may also be asked if you are also willing to participate in the MRI sub-study. You will be shown to a changing room and asked to change into a gown and we will show you how the equipment works. OSMIA uses specially designed motion tables and low dose video x-rays. You can view this in advance on the College website if you wish.

(<http://www.aecc.ac.uk/imrci/osmia.aspx>). The tables rotate so that the upper half of the body moves slowly from side to side.

One table is for lying examinations and the other is for weight-bearing.

First you will be asked to lie on the motion table. The upper half of the table will swing slowly from side to side and video x-rays will be taken showing the movement of your vertebrae as you bend. Then you will be asked to move to an upright motion apparatus. This will guide you while you bend, following a moving arm rest, while the x-rays are taken simultaneously. Before we take the x-rays we will find the range of bending that you are comfortable with.

MRI sub-study only: If you have agreed to participate in this study you will be invited back within a week for an MRI scan of your lower back. An MR radiographer will show you the equipment and ask you some screening questions. Then you will be asked to lie still in the scanner for approximately 20 minutes. (This is an open scanner so you will not feel claustrophobic.) Then you will be asked to stand still in the scanner for 20 minutes, after which you will be free to go.

During the OSMIA examinations, your lower abdomen will be covered with a lead apron to protect the reproductive organs. You will also be provided with a button that will stop the table should you begin to feel pain or discomfort. The whole OSMIA procedure will take no more than 30 minutes.

If you are also taking part in the MRI sub-study then before undertaking it we will check to make sure you have had no disabling back pain since the OSMIA. If you have, we will not proceed with the examination.



5. Risks and Benefits of Participating.

OSMIA uses x-rays. Therefore it is important you understand the risks and benefits of taking part. **Females please note, x-rays may harm an unborn child. It is therefore vital that you inform us beforehand if you are pregnant or suspect you might be.**

The radiation dose from the examination is roughly the same amount of naturally occurring background radiation you would receive in the UK over a 17 month period. Experts agree that it is very difficult to determine the risk of inducing cancer from such low doses, however it is estimated that there is a **1 in 8,000 – 1 in 13,000 extra chance of getting cancer from this examination. (This is in addition to the quoted 1 in 3 natural lifetime risk of you contracting cancer throughout your lifespan.)** You may wish to consider this risk in relation to some more familiar events in the table below. There is no direct benefit to you from the radiation dose; however, the risk is seen as minimal.

<u>Some familiar risks (Sedgwick and Hall 2003)</u>	<u>Chance they will happen</u>
Getting three balls in the UK national lottery	1 in 11
Needing emergency treatment in the next year after being injured by a can, bottle, or jar	1 in 100
Death by an accident at home	1 in 7100
Getting five balls in the UK national lottery	1 in 11 098
Death by an accident at work	1 in 40 000
Death playing soccer	1 in 50 000
Death by murder	1 in 100 000
Being hit in your home by a crashing aeroplane	1 in 250 000

“Teaching medical students and doctors how to communicate risk.” [BMJ 327\(7417\): 694-695.](#)

There is also a chance that an ‘incidental’ finding will be seen on your video x-ray. An incidental finding is one that is discovered unintentionally. To date more than 100 participants have undergone this examination and there have been no significant incidental findings. I will be reviewing all video x-rays and in the event of an incidental finding you will be referred to your



GP if that is what you would like. Such detection has the benefit of starting treatment early but in a small number of cases may have implications for future employment and insurance. There may be no overall benefit to you from this study but the information I receive might help improve the diagnosis of patients with low back pain. You may find the experience educational and you will be able to watch the movement of your lumbar vertebrae and see a report on it.

If you also participate in the MRI sub-study there are also no significant additional risks but you will be checked for the presence of metal objects by the MRI radiographer.

6. Confidentiality and Data Protection

Ethical and legal practice will be followed with respect to any information obtained from you in this study. Your details will be kept on a password protected database until all the volunteers have been recruited. After this, all identifying details will be destroyed. If you enter the study your GP will be informed if there is an incidental finding (if that is your wish) and you will be asked to provide your GP's details (name and address) on the consent form. Following review of your video x-rays (and MRI scans if applicable) all of your data will be anonymised so you cannot be identified. Consequently, you will not be able to withdraw from the study once your data have been collected. This does not affect your right to withdraw from the study prior to, or during data collection. Your anonymised data will also be retained indefinitely for use in further studies.

7. What if there is a problem?

If you have a concern about any aspect of the study you should speak to me in the first instance and I will do my best to answer your questions. If you remain unhappy and wish to complain formally you can do this by contacting Professor Thiel, the Chief Executive of the AECC.

In the event that something does go wrong and you are harmed during the research due to someone's negligence, you may have grounds for legal action for compensation against the AECC but you may have to pay your own legal costs.

8. What will happen to the results of this study?

The results from this study will be anonymised, collated and analysed and published in scientific journals as a reference database. It will also be presented at international conferences such as



the Society for Back Pain Research. Some data will be referred to on the AECC website (www.aecc.ac.uk). You are welcome to keep up to date with the study's progress by periodically checking the website, or by contacting me at any time; my details are at the end of this leaflet.

9. Who is funding the research?

This research is being funded by the Anglo-European College of Chiropractic. The MRI sub study is funded by the Radiological Research Trust.

10. Who has reviewed the study?

This research has been extensively reviewed by a spinal surgeon, a radiologist, a statistician a medical physics expert, a bioengineer an ergonomist, a chief superintendent radiographer and the South West 3 Research Ethics Committee (REC Reference 10/H0106/65). The MRI sub-studies has also been reviewed by the AECC Patient and Public Involvement group.

11. Further information and contact details

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