Spinal Motion Restriction Feasibility Study
Participant Information Sheet

Project title:	Spinal Motion Restriction Feasibility (SMRF) Study). A prospective randomised two centre comparative study to determine if there is a difference in clinical outcomes and patient experience comparing traditional immobilisation techniques verses Spinal Motion Restriction techniques which include the omission of a rigid cervical spine collar.

Chief Investigator	Lee Thompson
Address:	North East Ambulance Service NHS Foundation Trust. Ambulance HQ, Emergency Operations Centre, Bernicia House, Goldcrest Way, Newburn Riverside, Newcastle Upon Tyne, NE15 8NY
Email:	lee.thompson@neas.nhs.uk
Telephone:	0 (+44) 191 4302399

Principle Investigators:	Gary Shaw. North East Ambulance Service. Gary.Shaw@neas.nhs.uk Charlotte Bates. Northumbria Specialist Emergency Care Hospital. Charlotte.Bates@northumbria-healthcare.nhs.uk Christopher Hawkins. Sunderland Royal Hospital. Christopher.Hawkins@chsft.nhs.uk Lt Col. Paul Hunt. James Cook University Hospital paul.hunt@stees.nhs.uk
Sponsor liaison	**Michelle Jackson,** North East Ambulance Service
IRS Project ID	**253128**
Version:	**V1.1**
Version Date:	**24/01/20**

Name of Researcher:		**Date:**	
Signature:			

Principle investigator:	**Lee Thompson**	**Date:**	**24/01/20**
Signature:			

SPINAL MOTION RESTRICTION FEASIBILITY (SMRF) STUDY PARTICIPANT INFORMATION SHEET

We would like to invite you to take part in the Spinal Motion Restriction Feasibility (SMRF Study. Before you decide whether or not you would like to take part, it is important for you to consider why the research is being done and what it will involve. Please read this information sheet carefully.

What is the SMRF Study?

The Spinal Motion Restriction Feasibility (SMRF) Study is a randomised two centre study comparing patient outcomes between two management options for patients experiencing potential spinal cord injury (SCI).

What is the purpose of the study?

Within the United Kingdom (UK), Cervical Spinal Cord Injury (SCI) is a rare event. Traditional three-point immobilisation (Collar, head blocks and tape) for spinal stabilisation has been the standard clinical practice for trauma patients with suspected cervical SCI for over 50 years. These practices are based on little more than isolated case studies and limited consensus agreement and have become so engrained within trauma management culture that it is difficult to change current practice.

Contemporary literature and consensus reports are now challenging traditional practices in favour of a pragmatic second generation of supportive techniques that follow patient centred Spinal Motion Restriction principles. Spinal Motion Restriction principles include moving away from the routine application of rigid collars and back boards, encouraging self-extrication when appropriate, manual in line stabilisation and alternative approaches to Spinal Motion Restriction while improving patient comfort. These principles empower clinicians to tailor their approach to Spinal Motion Restriction and ensure effective and safe patient centred care.

The benefits of using the traditional ‘three-point immobilisation’ techniques;

• potential prevention of secondary injury to spinal cord from an unstable fracture in a compliant patient,

• provide a visual reminder to all staff and acts as a warning that the patient has a potential spinal injury and has an un-cleared spine.

The risks of using the tradition three-point immobilisation techniques are;

• Airway compromise,

• Impaired ventilation,

• Aspiration risk,

• Patient discomfort,

• Increased agitation,

- Worsening delirium,
- Raised ICP,
- Worsening of injury – spinal deformity,
- Pressure injuries,
- Transport delays.

The aim of this randomised prospective feasibility study is to compare clinical outcomes and patient experience between traditional immobilisation techniques verses Spinal Motion Restriction (SMR) techniques which include the omission of a rigid cervical spine collar.

Why have I been invited to take part?

We are inviting you to participate as a patient who has experienced a traumatic event that was assessed as requiring spinal motion restriction. As a consequence you will have been managed in a way to restrict the movement of your neck either through use of equipment that restricts movement or self-restriction and support by ambulance staff. This may or may not include the use of a neck collar.

What will I be asked to do if I take part?

The study would like to use some of your anonymised data from your patient record (see appendix 1) as well as your personal experiences of your initial management. This would involve completing a brief questionnaire. It is envisaged that this should take approximately 10 minutes.

If you would like to be informed of the results of the study we could inform you via email or post providing you wished to do so. Your address and email would not be used for the study and would and only used to send you the results of the Study.

Who is organizing and funding the research?

This research is sponsored by North East Ambulance Service.

The study will be conducted by Chief Investigator Lee Thompson, a PhD student at Northumbria University and Specialist Paramedic for Trauma with North East Ambulance Service NHS Foundation Trust. Principle Investigators are: Daniel Haworth, Advanced Practice and Pathway Development Manager, North East Ambulance Service, Charlotte Bates, Consultant Emergency Medicine, Northumbria Specialist Emergency Care Hospital and Christopher Hawkins, Consultant Emergency Medicine, Sunderland Royal Hospital and Paul Hunt, Consultant Emergency Medicine, James Cook University Hospital.

Confidentiality

No personal information will be collected and participant experience responses will be collated anonymously using an identifying number known only to the participant, initial research collator undertaking consent and principle investigator. All responses received in the study will be strictly confidential, and your identity will not be divulged. Direct quotes to free-text answers may be used as part of the study report or further study projects/analysis, but these will be not be traceable back to you.

Data protection

Survey responses will be collected via a research co-ordinator at each site and scanned and sent to the principle Investigator to be converted into a spreadsheet on an encrypted network to allow analysis by the research team. Data will be stored for the duration of the research project only and then deleted. You have the right to access submitted information according to UK data protection laws. Any member of the research team will be trained in Good Clinical Practice (GCP) and North East Ambulance Service will take responsibility for the governance of the research.

Research ethics

The proposed study abides by the ethical requirements of the Health Research Authority (HRA) Regional Ethics Committee aiming to assure 'rigour, respect and responsibility' in the conduct of the research project. A copy of the HRA ethics committee application and decision letter is available on request. All participants will be asked to complete a consent form.

General Data Protection Regulation (GDPR):

How patient information may be used for research

When you agree to take part in a research study, the sponsor will collect the minimum personally-identifiable information needed for the purposes of the research project. Information about you will be used in the ways needed to conduct and analyse the research study. NHS organisations may keep a copy of the information collected about you. Depending on the needs of the study, the information that is passed to the research sponsor may include personal data that could identify you. You can find out more about the use of patient information for the study you are taking part in from the research team or the study sponsor. You can find out who the study sponsor is from the information you were given when you agreed to take part in the study.

For some research studies, you may be asked to provide information about your health to the research team, for example in a questionnaire. Sometimes information about you will be collected for research at the same time as for your clinical care, for example when a blood test is taken. In other cases, information may be copied from your health records. Information from your health records may be linked to information from other places such

as central NHS records, or information about you collected by other organisations. You will be told about this when you agree to take part in the study.

Keeping information for future research

Information about you that is collected during a research study may be kept securely to be used in future research in any disease area, including research looking at social and economic factors affecting health. This may include combining it with information about you held by other health or government organisations such as NHS Digital. Usually the information is combined together by matching information that has the same NHS number. Doing this makes maximum use of the information you have provided and allows researchers to discover more.

Researchers may not be able to specify all the possible future uses of the information they keep. It could include providing the information to other researchers from NHS organisations, universities or companies developing new treatments or care. Wherever this happens it will be done under strict legal agreements. The information about you will be depersonalised wherever possible so that you cannot be identified. Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.

On rare occasions NHS organisations may provide researchers with confidential patient information from your health records when we are not able to seek your agreement to take part in the study, for example because the number of patients involved is too large or the NHS organisation no longer has your contact details. Researchers must have special approval before they can do this.

Your choices about health and care research

If you are asked about taking part in research, usually someone in the care team looking after you will contact you. People in your care team may look at your health records to check whether you are suitable to take part in a research study, before asking you whether you are interested or sending you a letter on behalf of the researcher.

In some hospitals and GP practices, you may have the opportunity to sign up to a register to hear about suitable research studies that you could take part in. If you agree to this, then research nurses, researchers or administrative staff authorised by the organisation may look at your health records to see if you are suitable for any research studies.

It's important for you to be aware that if you are taking part in research, or information about you is used for research, your rights to access, change or move information about you are limited. This is because researchers need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from a study, the sponsor will keep the information about you that it has already obtained. They may also keep information from research indefinitely.

If you would like to find out more about why and how patient data is used in research, please visit the Understanding Patient Data website.

https://understandingpatientdata.org.uk/what-you-need-know

Further information is available, depending on where in the UK you live:

England

In England you can register your choice to opt out via the NHS website . If you do choose to opt out you can still agree to take part in any research study you want to, without affecting your ability to opt out of other research. You can also change your choice about opting out at any time.

Northern Ireland

If you would like to find out more about how and why your information is used, including for research purposes, please visit the Department of Health website.

Scotland

Members of the public in Scotland have their rights and responsibilities set out in the Patients Rights (Scotland) Act 2011. For information on confidentiality of data (including in research) please visit the NHS Inform website.

Wales

If you would like to find out more about how and why your information is used, including for research purposes, please visit NHS Direct Wales.

What do I do now?

Thank you for reading this information sheet and for considering taking part in this research. Please let the research co-ordinator who provided you with this information sheet know whether or not you would like to take part. If you wish to participate we would be very grateful if you could also complete the attached consent form.

If you wish to delay participation to allow you to digest the information and you wish to consent to being a participant you may email the chief investigator Lee Thompson:

lee.thompson@neas.nhs.uk

If you have any questions or concerns please do not hesitate to contact me.

Chief Investigator:	**Lee Thompson**	**Date:**	**24/01/20**
Signature:			

Further information: Please do not hesitate to contact the Chief Investigator, Lee Thompson, if you have any concerns or questions.

Contact details:

Address: Trauma Team, Emergency Operations Centre, North East Ambulance Service NHS Foundation Trust, Bernicia House, Goldcrest Way, Newburn Riverside, Newcastle Upon Tyne. NE15 8NY.

Tel: 0 (+44) 191 4302399, email: lee.thompson@neas.nhs.uk