Spinal Motion Restriction Feasibility Study
Clinician Recruiter Information and Consent Form

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 (SMR) techniques which include the omission of a rigid cervical spine collar.

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Email:	lee.thompson@neas.nhs.uk
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Principle Investigators:	**Gary Shaw.** North East Ambulance Service NHS Foundation Trust. Gary.shaw@neas.nhs.uk **Charlotte Bates**. Northumbria Specialist Emergency Care Hospital. Charlotte.bates@northumbria.nhs.uk **Christopher Hawkins**. Sunderland Royal Hospital. Christopher.Hawkins@chsft.nhs.uk **Paul Hunt**. James Cook University Hospital. paul.hunt@stees.nhs.uk
Sponsor liaison	**Michelle Jackson.** North East Ambulance Service
IRAS Project ID	**253128**
Version:	**V1.1**
Version Date:	**24/01/20**

Name of Clinician:		**Date:**	

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SPINAL MOTION RESTRICTION FEASIBILITY (SMRF) STUDY CLINICIAN RECRUITER INFORMATION SHEET

We would like to invite you to take part in the Spinal Motion Restriction Feasibility (SMRF) Study as a recruiting clinician. 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 SMRFS?

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.

Traditional Three Point Immobilisation		
Assumptions	Benefits (Potential)	Risks
• There is always a potential unstable spinal injury when blunt force trauma is applied to the spine or head; • Movement may make the injury worse; • Immobilisation will prevent movement; and • Benefits of intervention outweigh the risks.	• Potential prevention of secondary injury to spinal cord from an unstable fracture in a compliant patient; and • 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.	• Airway compromise • Impaired ventilation • Aspiration risk • Patient discomfort • Increased agitation • Worsening delirium • Raised ICP • Worsening of injury – spinal deformity • Pressure injuries • Transport delays

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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 clinician who works in the pre-hospital environment who manages patients who have experienced trauma causing potential spinal injury who may attend either Northumbria Specialist Emergency Care Hospital (NSECH) or James Cook University Hospital (JCUH).

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

The study aims to recruit participants who have experienced potential traumatic spinal injuries who would traditionally be managed with spinal motion restriction (immobilised) using rigid collar, scoop, blocks and tape. The control group will manage these patients following existing guidelines and the intervention group will omit the use of rigid collar.

As the recruiting clinician you will manage the participant as part of the control or intervention group and inform the research staff you have recruited a SMRF Study patient via the dedicated telephone number (07904145178) indicating:

- destination,
- patient name,
- case number
- control or intervention group
- estimated time of arrival
- compliance
- record details within the ePCR highlighting patient is potential SMRF Study patient.

You will also be asked to complete a simple questionnaire about your experiences while managing a SMRS Study participant.

Who is organizing and funding the research?

This research is sponsored by North East Ambulance Service with financial support from NEAS research and development small research grant as well as industry funding for administration costs from Prometheus Medical.

Further information can be accessed via the study website: https://www.neas.nhs.uk/our-services/research-and-development/smrf.aspx

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The study will be conducted by Lee Thompson, a PhD student at Northumbria University and Specialist Paramedic for Trauma with North East Ambulance Service NHS Foundation Trust as chief investigator (CI). Principle Investigators (PI's) are: Daniel Haworth, Consultant Paramedic, NEAS; Gary Shaw, NEAS; Charlotte Bates, Consultant Emergency Medicine, Northumbria Specialist Emergency Care Hospital; 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.

Data protection

Responses to patient experience will be collected via a research co-ordinator at each site and scanned and sent to the chief Investigator to be converted into a spreadsheet on a password protected folder at North East Ambulance Service and only accessed by the research team for analysis. Data will be stored for the duration of the research project only and then deleted after minimum time required for data management. You have the right to access submitted information according to UK data protection laws. All members 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), 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. (IRAS project ID 253128.)

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 clinician recruiter you may email the principle investigator Lee Thompson:

lee.thompson@neas.nhs.uk

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

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

Further information: Please do not hesitate to contact the Principle 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

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Study sponsor liaison	**Michelle Jackson**, R&D Manager, NEAS
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1. **I confirm that I have read and understand the information sheet explaining the above research project and I have had the opportunity to ask questions about the project.** ☐

2. **I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without there being any negative consequences.** ☐

3. **I have been given the appropriate training and materials to carry out my role within the study.** ☐

4. **I agree to take part in the above research project which includes completing a questionnaire after managing participants.** ☐

Name of Clinician:		**Date:**	
Signature:			

Name of Researcher gaining consent:		**Date:**	
Signature:			

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

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Consent to be informed of the results of the study:

I confirm that I wish to be sent the results of the study.

☐

Name of Participant:		**Date:**	
Signature:			

Please provide email or address you wish the results of the study to be sent to:

Email:	
And/or Address:	

Completion:

Please return scanned or electronically completed forms via email to:

lee.thompson@neas.nhs.uk

Or return hard copies to:

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

Further information: Please do not hesitate to contact the lead researcher if you have any concerns or questions. Contact details: Tel: 07962057041. email: lee.thompson@neas.nhs.uk

Copies: Please retain a copy of the completed consent from for your personal records. An additional copy will be held in a University secure location for the duration of the research study.