Spinal Motion Restriction Feasibility Study

SMRF Study

Protocol

Version 1.1

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There are no conflicts of interest.

Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, HRA, host organisation, and members of the Research Ethics Committee, unless authorised to do so.

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1. SYNOPSIS

Study 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 Spinal Motion Restriction techniques which include the traditional use of a rigid cervical spine collar versus the omission of a rigid collar.	
Internal ref. no. / short title	Spinal Motion Restriction Feasibility (SMRF) Study.	
Protocol Version	V1.1	
Protocol Date	24/01/2020	
Study Design	A prospective randomised two centre comparative intervention study.	
Study Participants	Patients who have experienced a mechanism of injury that would suggest a potential SCI.	
Planned Sample Size	50 intervention participants, 50 control participants and 100 clinicians	
Planned Study Period	16 months in total (6 months intervention/control followed by 6 months control/intervention at each of two sites. 1 month training for clinicians and research assistants with 3 months data collation, analysis and writing up of conclusions/discussion).	
Number of Study Sites	Three. North East Ambulance service, James Cook University Hospital, Northumbria Specialist Emergency Care Hospital.	
	Objectives	**Outcome Measures**
Participant Clinical Outcomes	To compare the clinical outcomes of Spinal Motion Restriction principles where intervention group omit the use of rigid collar on potential SCI versus current standard immobilisation practices which includes the use of rigid collar.	• Time: on scene, to scan, in ED. • Neurology (Gross) • Fractures/Injury • Tissue Viability/Pressure sores • Compliance
Participant Experience	To compare the patient experience outcomes of Spinal Motion Restriction principles where intervention group omit the use of rigid collar on potential SCI versus current standard immobilisation practices which	• Comfort • Pain • Understanding • Complications (anxiety, breathing)

	includes the use of rigid collar.	
Clinician Experience	To compare the clinicians experience of Spinal Motion Restriction principles where intervention group omit the use of rigid collar on potential SCI versus current standard immobilisation practices which includes the use of rigid collar.	• Clinician experience (Qualitative)

2. ABBREVIATIONS

CI	Chief Investigator
CRF	Case Report Form
ED	Emergency Department
GCP	Good Clinical Practice
GP	General Practitioner
HRA	Health Research Authority
ICF	Informed Consent Form
NEAS	North East Ambulance Service
NHS	National Health Service
NRES	National Research Ethics Service
NICE	National Institute for Health and Care Excellence
PI	Principal Investigator
PIL	Participant/ Patient Information Leaflet
R&D	Research and Development
REC	Research Ethics Committee
RTC	Road Traffic Collision
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SCI	Spinal Cord Injury

3. BACKGROUND AND RATIONALE

Within the United Kingdom (UK), Cervical Spinal Cord Injury (SCI) is a rare event. Traditional three-point immobilisation for spinal stabilisation has been the standard clinical practice for trauma patients with suspected cervical SCI for over 50 years.

The literature highlights a variable global incidence of traumatic SCI of between 9.2 and 246 per million persons per year with a prevalence of 236 to 1,298 per million population (Furlan et al., 2013). In their pre-hospital study Oteir et al. (2016) estimated that of the 106,059 patients who were identified as having potential traumatic SCI, less than 0.5% had confirmed SCI.

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.

Initial recognition of the need for immobilisation was documented by Rogers (1957) who analysed a case series involving 77 patients who all had significant spinal injuries. Of these 77 cases it was noted that 8 patients developed new or worsening symptoms after arrival at the hospital. Upon reflection, it was hypothesised that if these patients had an adjustable neck brace fitted for the purposes of extrication and transfer then some of these deteriorations may have been avoided.

A further study by Geisler et al. (1966) retrospectively analysed 958 patient charts where 29 patients had worsened neurology after initial injury. In 2 cases they concluded that paralysis occurred as a consequence of failing to recognise the initial injury and therefor protect an unstable spine. This suggested that the initial management of SCI can exacerbate the initial insult. An earlier paper by Kossuth (1965) hints at the need for early recognition and management of potential SCI. A significant comment stated that emergency room staff simply accept trauma patients without questioning if the injury was a result of the initial insult or compounded by the extrication and transport by pre-hospital care providers. Kossuth's paper implies it was necessary to introduce measures that would prevent worsening the initial injury.

Clear guidance on extrication and immobilisation was published by Farrington (1967) who recommended that a *"physician must act.....preventing the sloppy and inefficient removal of a victim from a smashed vehicle".* Farrington's paper illustrated pioneering techniques to extricate patients from vehicles using ropes and long/short boards as well as neck immobilisation. Although some techniques are questionable, the basics of immobilisation have remained the standard practice of pre-hospital care providers to date.

In 1976 the principles of Advanced Trauma Life Support (ATLS) were conceived by Dr James Styner who, along with his family, was involved in a devastating plane crash. His poor experiences of care at local hospitals with lack of basic trauma skills and equipment to stabilise potential SCI, prompted his desire to promote good trauma care to all areas. The first ATLS course was held in 1978 and was adopted by the American College of Surgeons in 1980. ATLS has been taught to over a million people in 63 countries and remains part of the syllabus of most emergency departments and pre-hospital care providers (American College of Surgeons, 2012). Although the equipment may have evolved with the introduction of new materials and technologies, ATLS immobilisation techniques remain almost unchanged from those first

principles described by Farrington and incorporate three point immobilisation of rigid collar, head blocks and tape, with the addition of long board/scoop in the pre-hospital phase.

The widely accepted methods of cervical spine immobilisation described above have been adopted worldwide and have been relatively unchallenged until the publication of the controversial paper by Hauswald et al. (1998). The Hauswald paper compared two separate emergency departments with similar resources and skill levels that received patients with similar mechanisms of injury. The first department in Malaysia received blunt force trauma patients who had no pre-hospital immobilisation prior to hospital arrival. The second department in New Mexico received blunt force trauma patients who were all immobilised in the traditional manner in the pre-hospital phase of care. Reviewing the remarkable similarities in injury patterns and in hospital management the paper concluded that those patients who received full 'traditional' pre-hospital immobilisation were at higher risk of disability compared to those who did not receive any immobilisation at all. These findings were in stark contrast to the assumptions we have come to accept that traditional immobilisation reduces the risks of disability.

The 2001 Cochrane review into pre-hospital spinal immobilisation identified that, although the judicious and routine use of immobilisation techniques continues, no prospective, randomised control trial (RCT) related to patient outcomes has ever been undertaken (Kwan et al., 2001).

Abram and Bulstrode (2010) critically reviewed the evidence of routinely immobilising trauma patients and its advantages and disadvantages. They concluded that routine immobilisation could be contributing to mortality and morbidity in some patients.

The 2014 guidelines from the National Association of EMS Physicians (NAEMSP) and the American College of Surgeons Committee on Trauma (ACS-COT) highlight that unstable spinal injuries are extremely rare and, as a consequence, a high volume of patients are unnecessarily immobilised with no potential benefit (White et al., 2014).

As the literature has provided little empirical evidence into the benefits of traditional and the potential negative consequences, Myer and Perina (2016) suggest we have created a 50 year culture of immobilising patients for the sake of routine. This culture has perpetuated a fear of the consequences of not routinely immobilising for secondary spinal injury prevention with no real evidence to support this fear.

Spinal motion studies using healthy volunteers or cadavers have provided conflicting evidence when studying the movement of the spine under various conditions. Perry et al. (1999) identified that various techniques and equipment that are routinely used in the traditional method of immobilisation do not eliminate neck motion during extrication or transport. Other studies have identified that using conventional techniques and equipment may actually increase neck motion (Engsberg et al., 2013, Dixon et al., 2014).

Aside from the range of motion studies, healthy volunteers have also reported increased pain to many body regions while being immobilised on a long board compared to being immobilised in a vacuum mattress (Chan et al., 1996).

Oto et al. (2015) reviewed a significant volume of literature from 1979 to 2013 to identify those patients with early secondary neurologic deterioration after blunt spinal injury. 41 cases of neurological deterioration were identified post injury in 12 papers. 12 of these cases had documented triggers which

included 1 collar removal, 2 due to the fitting of a halo device, 1 agitated patient, 1 while a patient was having flexion/extension views, 2 after having 2 further falls, 2 due to collar placement in patients with ankylosing spondylosis, 1 on extrication from a vehicle and 2 as a result of manipulation. Only 13 cases were identified in the review as occurring in the pre-hospital setting and none were associated with sudden or provoked movement. The review did identify that those at risk were patients who have an altered mental status and those patients with ankylosing spondylitis who have collars forced upon them.

Davies et al. (1996) identified the association of increased intra-cranial pressure (ICP) when using a hard cervical collar which was also identified by Mobbs et al. (2002) and Dunham et al. (2008). The 2001 Cochrane review highlighted that the use of cervical collars can contribute to airway compromise and may also contribute to the increased risk of mortality and morbidity (Kwan et al., 2001).

A literature review by Oteir et al. (2014) stated that the most important variables in determining improved outcomes for spinal injured patients were effective resuscitation and the early transfer of patients to specialist spinal care units.

Most of the guidance on who to immobilise/image have been based on models similar to, or a combination of, the Canadian C-Spine Rules (Stiell et al., 2001) or NEXUS criteria (Michaleff et al., 2012). These models, however, are not designed to identify who to immobilise but rather to identify which patients are at risk of SCI and require imaging for diagnostic purposes.

The consensus statement from the Faculty of Pre-Hospital Care (Connor et al., 2013) highlight the growing concerns of traditional immobilisation and take the pragmatic view of applying a clinical assessment to ensure a bespoke patient centred care plan for blunt force trauma patients. Essentially the consensus statement recommends:

- The long board is for extrication only and Manual In-Line Stabilisation (MILS) is an acceptable alternative to the rigid cervical collar,
- An immobilisation algorithm needs to be adopted and that various options may be required based on conscious level (although no clear guideline has been submitted),
- Penetrating trauma with no neurology does not require immobilisation,
- Standing take downs should be avoided,
- In the absence of intoxication or major distracting injuries or physical entrapment, the patient should be encouraged to self-extricate. They may then be laid supine and assessed.

The National Institute for Health and Care Excellence (NICE) (2016) trauma guidelines recommend the use of collar, scoop, stretcher, blocks and tape for patients who meet the criteria for immobilisation. However, there is a caveat that anatomy, deformity, confusion or agitation requires a pragmatic approach to spinal support. Their advice in these circumstances is to aim for a position that is comfortable for the patient which may require manual immobilisation. They also recommend that children are immobilised manually with assistance from the family and may require utilising car seats and blankets if available.

Connor et al. (2013) conclude that this patient centred approach is not only beneficial for the patient but also protects and empowers clinicians to tailor their approach to ensure effective and safe care. It was

also recommended that non-professional pre-hospital care providers should be made aware of MILS and minimal handling techniques.

Unfortunately the consensus statement from the Faculty of Pre-Hospital Care and the NICE guidelines are in direct conflict with one another and this leads to both confusion and uncertainty for pre-hospital and Emergency Department (ED) clinicians.

An exhaustive spinal immobilisation literature review by the Queensland Ambulance Service provided the evidence to change their approach to immobilisation and remove the use of hard cervical collars from their day to day practice (Quinn and Enraght-Moony, 2015). Due to adverse events associated with the use of hard cervical collars Princess Alexandra Hospital moved to a soft collar approach with the Queensland Department of Health highlighting that no adverse events had been reported since their introduction (Queensland Ambulance Service, 2014). The Quinn and Enraght-Moony (2015) review added credibility to their new approach to Spinal Motion Restriction practices which not only removed the use of hard collars but adopted a more selective approach to those requiring Spinal Motion Restriction and futility of immobilising isolated penetrating trauma.

Queensland Ambulance Service adopted the soft collar, which provides minimal support. However, one of the crucial advantages for using the soft collar is that it also acts as a visual marker to identify to all staff in the ongoing patient care that there is a suspected cervical spine injury that has not been cleared. Also, those patients who are unconscious or lack neck control will still require clinicians to provide pragmatic neck support.

Kornhall et al. (2017) highlight the systematic review commissioned by the Norwegian National Competence Service for Traumatology with regards to pre-hospital management of potential spinal injuries. Based on this robust review several recommendations were made to support pre-hospital care providers in their spinal motion restriction decision making.

It was recommended that, while SCI is a rare event, potential spinal injuries should still continue to have spinal stabilisation. The consensus from the literature was not to abandon a strategy of immobilisation but to adopt a selective approach with minimal handling which may reduce spinal movement, reduce pain and potentially promote haemostasis. However, spinal stabilisation should "*never delay or preclude lifesaving interventions"* (Kornhall et al., 2017). The Norwegian team also highlighted that there is no evidence to support immobilising isolated penetrating injuries and that triaging tools should be based on clinical findings.

A key recommendation was that cervical stabilisation does not always require the traditional approach and should be a goal achieved using various means due to the complications that may arise from using hard cervical collars (which have already been identified in this paper). They recognised that three-point immobilisation is not a one size fits all panacea for cervical spine management and that they needed to support staff to use alternative means to achieve their goals in providing patient centred care.

They recommend that transfer from the ground or between stretchers should be facilitated by using a scoop stretcher and where possible patients transported supine. Vacuum mattresses and ambulance stretchers were recommended for patient transport and that hard-surfaced systems should be minimised and only used for the shortest of journeys. The left lateral trauma position was also highlighted and, although not common practice, it may be beneficial for airway drainage and maintenance and minimises patient handling.

Under the right conditions, it is recommended that patients should be encouraged to self-extricate, thus expediting extrication, providing safe extrication under the patients control and reducing on-scene times. Those able to self-extricate will protect their own spine through their own muscle tone and are highly unlikely to exacerbate an injury. This method of extrication was also highlighted by Dixon et al. (2015) who, in their proof of concept study, concluded that haemodynamically stable patients who had controlled self-extrication had less movement of the cervical movement when compared to extrication using 'traditional' methods.

In August 2016 the NTN formed the Older Person Trauma Working Group in response to the growing concern over the proportion of major trauma being sustained by older people and the differences in response to this. This group has been looking at a wide range of issues faced by older patients sustaining major trauma and trying to improve the pathway at every point. One area the group has reviewed has been the problems encountered when transferring older patients with suspected cervical spine injury. These patients are arguably at most risk of the potential problems associated with the use of the hard collars mentioned above. This work culminated in the proposal of a flow chart for use to provide support for patients with suspected cervical spine injury to provide spinal motion restriction while abandoning the routine application of the hard collars. While this sort of approach is being used pragmatically across the country to our knowledge no other ambulance services in the UK have formally adopted this attitude.

Queensland Australia did formally abandon the use of hard collars in April 2016 and to our knowledge they have not encountered any problems as a result however they have also not published any results of their change in practice.

As the potential problems associated with hard collar use mentioned above are anecdotal only and there is a real paucity of evidence around the use of hard collars to date. We suggest this feasibility study should enable us to obtain prospective information on both the tradition method of immobilisation and transfer, employing the hard collars as routine, and compare this with prospective data using the flow chart (see Appendix A) and abandoning the use of the hard collars while still encouraging spinal motion restriction with a much more pragmatic approach. The routine use of hard collars has already been abandoned for paediatric patients for similar reasons to those discussed above. It was thought that it might be very confusing for ambulance crews to have inclusion criteria for this study being complicated by age and frailty etc and therefore it was decided to roll out the proposed changes for all patients with suspected SCI with the anticipation that the older frail patients will perhaps benefit most. The exception being that paediatric patients are currently not managed using rigid collars (NICE, 2016) and therefore excluded from the study.

Based upon the limited literature the aim of this study is to determine if there is a difference in clinical outcomes and patient experience, as well as the experiences of the clinicians taking part in the study, comparing traditional immobilisation techniques, which include a rigid collar versus Spinal Motion Restriction (SMR) techniques which include the omission of a rigid cervical spine collar.

Brief description of the intervention:

Patients experiencing a mechanism of injury that would suggest a potential spinal injury will have the JRCALC immobilisation guidelines (Canadian C spine rules) applied on assessment. If, after assessment, the patient is positive for spinal stabilisation then the intervention group will apply Spinal Motion

Restriction (SMR) principles which omit the use of a rigid collar. The patient will be manged as standard with the only change being the omission of the rigid collar. To assist is providing a visual marker for the patients ongoing management an additional sticker will be placed upon the head blocks/tape/blanket rolls which states 'C-Spine NOT Cleared'. Participants from both the control and intervention groups as well as the clinicians themselves will be asked to complete an experience questionnaire after the event.

Risks and benefits: There is little evidence for or against rigid collar use. There is a potential that if patients are managed poorly (rough handling) then neurology may be compromised. The benefits are that on scene times may be reduced (patient comfort through environmental factors) and overall patient comfort will be improved and reducing the risk of pressure sores and associated risk of infection.

The study is applicable to any patient experiencing a significant mechanism of injury that would suggest a spinal cord injury such as (but exclusive to) fall from height, Road Traffic Collision, assaults etc. It is believed the results of the study will be generalised and applicable to the wider trauma population with potential spinal cord injury. It in no way underplays the seriousness or risks associated with a spinal cord injury.

4. OBJECTIVES AND OUTCOME MEASURES

The wording of the objectives should be clear, unambiguous and as specific as possible – the study will be judged on how, and how well, the objectives were satisfied. Complete table below with all relevant information.

Please ensure these match with those stated in the synopsis and on the IRAS form.

Objectives	**Outcome Measures**	**Timepoint(s) of evaluation of this outcome measure (if applicable)**
Participant clinical outcomes (50 x JCUH, 50 x NSECH)	To compare the clinical outcomes of Spinal Motion Restriction principles where the intervention group omit the use of rigid collar on potential SCI versus current standard immobilisation practices which includes the use of rigid collar. • Time on scene, to scan, in ED • Neurology (Gross), • Fractures/injury, • Tissue viability/Pressure sores, • Compliance.	Within 5 days of transport to ED
Participant Experience (50 x JCUH, 50 x NSECH)	To compare the patient experience outcomes of Spinal Motion Restriction principles where the intervention group omit the use of a rigid collar on potential SCI versus current standard immobilisation	Within 72 hours of transport to ED

	practices which include the use of rigid collar. • Comfort • Pain • Understanding • Complications (anxiety, breathing).	
Clinician Experience (100 x NEAS)	To compare the clinicians experience outcomes of Spinal Motion Restriction principles where the intervention group omit the use of a rigid collar on potential SCI versus current standard immobilisation practices which include the use of rigid collar.	Earliest opportunity

5. STUDY DESIGN

Participants will be pre-randomised based on the hospital sites they are attending. Northumbria Specialist Emergency Care Hospital (NSECH) and James Cook University Hospital (JCUH) are the two nominated research sites. Initially the two participating sites will be randomised to either intervention or control site. After six months duration the sites will reverse and whichever site was originally randomised as intervention site will become the control site for the remaining six months and the control site will become the intervention site.

The participants will be selected by the attending trained North East Ambulance Service (NEAS) personnel and enrolled into the study if they are positive for a mechanism of injury and clinical assessment that would suggest a Spinal Cord Injury. NEAS are acting as the Participant Identification Centre (PIC) for patient participants and research site for clinical experience.

Control group: Over a six-month period this group will be managed in the traditional manner. This will involve patients being advised of the need for a hard collar, blocks and tape. For a variety of reasons this may not be tolerated by some patients and this non-compliance will be recorded for the purposes of the study outcome results, although these patients will be included in the 'traditional' method of motion restriction numbers.

Intervention group: Over a six-month period intervention group patients transported by NEAS crews with a suspected cervical spine injury being taken to the randomised intervention site with their cervical spine motion restriction managed in accordance with the proposed flow chart (appendix B). For these patients unless the exclusion criteria apply, no hard collars will be employed.

After the initial six-month intervention/control phase the receiving sites will reverse the process and undertake another six month phase as the control/intervention phase.

Each participant enrolled will be followed up on site by a research clinician and clinical outcomes measured as stated on the Computerised Tomography (CT) report and/or patient notes. Patient experience outcomes will be collected by a research clinician using a dementia friendly adapted Likert scale type survey prior to discharge or at 72 hours whichever is earliest. Participants will also be

consented at this point. It is expected that only one visit will be required unless participants wish to delay consent to consider the information.

Participant outcome measures will include:

- Time: on scene, to scan, in Emergency Department.
- Neurology (Gross)
- Fractures/Injury
- Tissue Viability/Pressure sores
- Compliance

Participant experience outcome measures will include:

- Comfort
- Pain
- Understanding
- Complications (anxiety, breathing)

Additional data will be obtained from a clinicians experience of managing SCI patients within the SMRF Study. A simple clinician experience questionnaire will be completed after each participant has been managed by a SMRF Study clinician.

Data will be collected in a Microsoft excel spread sheet and analysis will be undertaken using Statistical Package for the Social Sciences (SPSS) version 22.0.

Free text from the patient and clinician experience questionnaire will be coded and analysed using NVivo qualitative data analysis Software; QSR International Pty Ltd. Version 11, 2015.

6. PARTICIPANT IDENTIFICATION

6.1. Study Participants

NEAS will act as the Participant Identification Centre (PIC). Participants will include those patients who have experienced a mechanism of injury that would suggest a potential SCI. No upper age exclusions or pregnancy restrictions will apply. Those aged less than 18 will be excluded.

6.2. Inclusion Criteria

Inclusion Criteria

Any participant aged 18 years and older may enter the study if ANY of the following apply:

- Participant has had a mechanism of injury suggestive of SCI. Example mechanisms include (but not exclusive too) RTC's, falls from height, serious assaults AND transported by NEAS crew to either NSECH or JCUH. In the elderly or frail patient this may include a fall from standing height and should be based on a thorough clinical exam (see appendix A),
- Symptoms consistent with cervical spine injury (note for older patients any neck pain including muscular should be considered as suspicious for cervical spine injury),
- Those with dementia/delirium who are unable to communicate reliably regarding potential injury consider those with significant head injury as at risk of potential cervical spine injury and include them in study.

6.3. Exclusion Criteria

Exclusion Criteria

The participant may **NOT** enter the study if ANY of the following apply:

- Children aged <18 years,
- Those patients NOT transported to NSECH or JCUH,
- Participant requires airway support for whatever reason,
- The participant has a GCS ≤13,
- The participant is displaying **obvious** signs of new neurology such as paralysis,
- The participant has significant facial injuries that may benefit from the support a rigid collar may provide.
- The participant has already been immobilised with a rigid collar by a non-study clinician or third party provider prior to **intervention group** clinician assessment.

7. STUDY PROCEDURES

7.1. Recruitment

Potential participants will be identified by the trained recruiting ambulance personnel based upon the mechanism of injury and a clinical examination suggestive of a SCI as per the Spinal Motion Restriction Screening Tool in appendix A. Clinicians will be NEAS employees and NEAS are acting as the Participant Identification Centre (PIC) throughout the study. Clinicians who volunteer for the study will have also consented to undertake a Clinician Experience Questionnaire after each participant interaction.

7.2. Screening and Eligibility Assessment

The participants will be screened for eligibility by the attending crew based on the Spinal Motion Restriction Screening Tool in appendix A and inclusion/exclusion criteria applied. These clinicians are employed by North East Ambulance Service who are acting as the Participant Identification Centre (PIC)

for patient participants and will also act as a research site for the clinician experience element of the study.

If the patient is positive for immobilisation using the screening tool (appendix A) and in the catchment area of the nominated receiving research sites which will be Northumbria Specialist Emergency Care Hospital (NSECH) at Cramlington, Northumberland or James Cook University Hospital (JCUH) at Middlesbrough then they will be identified as a potential participant in the SMRFS intervention or control group.

Age (unless aged less than 18 years), sex, previous medical history or pregnancy status will not be used to exclude participants.

7.3. Informed Consent

There will be information communicated to the public prior to the initial roll out asking patients to opt out if they wish in advance. Following this initial inclusion in the study will be assumed. A website has been made available to the public during this study:

https://www.neas.nhs.uk/our-services/research-and-development/smrf.aspx

The study relates directly to patients who have experienced an acute traumatic event which is unpredictable and delaying management may be detrimental and, therefore, consent to access patient records will be delayed until the sub-acute phase of care in the Emergency Department. Consulting a carer or registered medical practitioner without placing the participant at risk of harm from delaying emergency treatment is not appropriate.

Eligible participants (see section 7.2) will be given the 'Participant Information Sheet' (see appendix C) by the trained transporting crew on arrival at either study receiving site (NSECH/JCUH).

As participants will be enrolled into the study during a traumatic event, they will be in a compromised, pained state and need immediate care. To ask for consent at that juncture would delay care and surmount to no more than a signature with little comprehension by the participant. If minimal risk is presented to the participant (substituting one form of spinal motion restriction for another), then respecting patient' rights and dignity accompanies being able to understand what they are being asked.

Participants' care will proceed almost exactly as it would have with or without the study, the patients are not uniquely imposed with non-clinical risks or burdens, and will be given the best quality care available to them based on current evidence. It is unknown (before the study) whether traditional immobilisation or new spinal motion restriction (no hard collar) presents a better treatment, and therefore participants would have been treated with one through an arbitrary decision.

Consequently, this study is not looking to consent the participant into undertaking an intervention but will retrospectively consent the patient after the event to allow the research team to use their information within the study.

The participant or parent/guardian or legally authorised representative must personally sign and date the latest approved version of the Informed Consent form before any information will be included in the study.

Written and verbal versions of the Participant Information Sheet and Informed Consent will be presented to the participants or participants carers detailing no less than: the exact nature of the study; what it will involve for the participant; the implications and constraints of the study; the known side effects and any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, without affecting their legal rights, and with no obligation to give the reason for withdrawal.

Capacity shall be assessed on the basis of the patient being able to understand the nature and purpose of the project, the risks and benefits of taking part and can demonstrate that they have retained and weighed up the information before making an informed choice.

Those with dementia and/or delirium will be included in this part of the study and if they are unable to consent themselves consent will be sort from the next of kin or person with power of attorney.

The participant/carer will be allowed as much time as wished to consider the information, and the opportunity to question the Investigator, their GP or other independent parties to decide whether they will participate in the study. Written Informed Consent will then be obtained by means of participant dated signature and dated signature of the person who presented and obtained the Informed Consent. The person who obtains the consent will be suitably qualified, experienced and have been authorised to do so by the Chief/Principal Investigators. A copy of the signed Informed Consent will be given to the participant. The original signed form will be retained at the study site and scanned to a secure folder held on the North East Ambulance Service network.

Clinicians who are involved within the study and completing a clinician experience questionnaire will also be consented using the above principles after undertaking training.

7.4. Randomisation, blinding and code-breaking

Within the context of this study it is almost impossible to blind the intervention/control to either the participants or clinicians carrying out the intervention/control because of the type of equipment used.

There are two receiving sites within the study. One will be randomised to being either the intervention site for the first six months followed by six months as the control site. The other receiving site will therefore be randomised as the opposing site acting as the control site for the first six months followed by the intervention site for six months.

The two sites will be randomised as either:

(1) Intervention (6 months) followed by control (6 months) or
(2) Control (6 months) followed by Intervention (6 months).

To assist in this randomisation the online tool “Research Randomizer” will be used.

https://www.randomizer.org/

7.5. Protection against bias

7.5.1. Study design

One of the major potential sources of bias in randomised trials is inclusion of different patients in the arms of the trial. This can arise where a large proportion of potentially eligible patients are not included in the trial, and the probability of inclusion is related to the intervention. In this study we aim to identify and include close to 100% of the eligible patients, using a combination of methods for identifying eligible patients, including direct notifications by ambulance clinicians and review of routine ambulance service data.

7.5.2. Threshold for intervention

As ambulance clinicians delivering the interventions will not be blinded, there is a possibility that bias could be introduced by different thresholds between the intervention group (no rigid collar) and control group (standard care including rigid collar). If they believe strongly that non-collar use is effective, some of them may attempt spinal motion restriction without using the collar for patients who are not appropriate, excluded from the study or in the control group of the study and therefore inappropriate. This would result in a group of patients being inappropriately recruited or excluded from the trial potentially masking any beneficial or negative effect of non-collar use. We will use several strategies to prevent this bias from occurring, to detect it if it happens, and to correct it if necessary.

First, the criteria that are used to determine whether spinal motion restriction is appropriate, and hence whether the patient is eligible, are as objective as possible. The guidance in appendix A used by all participating ambulance clinicians in the study to determine when spinal motion restriction is appropriate/not appropriate will continue in the trial. Ambulance clinicians will already be familiar with the application of these criteria, and no change of practice will be needed during the trial with the exception of including those participants over the age of 65 years who have had a mechanism of injury potentially causing injury and complaining of any pain or discomfort in the neck area.

Second, all ambulance clinicians in the study will be trained in the study procedures, to ensure that they understand the rationale for the study and the importance of following the study procedures correctly. The training will include a review of existing evidence so that participating ambulance clinicians understand the current position of equipoise regarding the effectiveness of rigid collars, and discussion of potential sources of bias in the study and the importance of applying the inclusion/exclusion criteria rigorously to both arms. Training will continue throughout the recruitment period, to ensure that any new staff are trained before recruiting, and that important messages are continually reinforced.

Third, we will institute a programme of regular monitoring by analysing the characteristics of patients recruited to the intervention group (non-collar) and control group (standard care including rigid collar) and the proportion of potential spinal cord injured patients recruited, to detect any imbalances that may be caused by different thresholds for spinal motion restriction. If a lower threshold for attempting spinal motion restriction in the intervention group (non-collar use) exists we will find a greater number of recruits and a greater proportion of incidents with spinal motion restriction attempts. The frequency and mechanism of monitoring will be discussed with the Data Monitoring Committee.

If we suspect that a different threshold for spinal motion restriction is being applied by any personnel recruiting to the study, the first step will be to identify the personnel involved and ensure that their training in the trial procedures is up to date, and reinforce the essential messages about the rationale for the trial. The investigators will develop close working relationships with the ambulance clinicians recruiting patients, and will be ideally placed to undertake this role.

Finally, we can, if necessary, correct for any inclusion bias in the statistical analysis of the study, by adjustment of the analysis to take account of imbalance in factors such as mechanism of injury and time since 999 call. We expect any potential inclusion bias to affect only the group of patients least likely to have any detrimental outcomes, and it would not affect patients for whom spinal motion restriction would always be undertaken and therefore a comparison between intervention group (non-collar) and control group (standard care including rigid collar) in the subgroups of patients in whom spinal motion restriction is known to be appropriate would be unaffected.

7.5.3. Crew Preferences

A potential source of bias is that ambulance clinicians who are motivated to not use the rigid collar may avoid using it during the control phase of their participation in the study. In order to check for this possibility, we will monitor crews attending incidents that are potentially managed with spinal motion restriction and investigate any suspicious patterns such as non-compliance with the allocated treatment. If found, the staff involved will be given extra training in the study procedures.

7.5.4. Blinding

Due to the nature of the interventions, ambulance clinicians cannot be blinded, and will be aware of treatment allocations. Ambulance emergency operation centre dispatch personnel will be blinded to the allocation of the ambulance service vehicles, to ensure that there is no bias in whether a vehicle with a study trained clinician (intervention or control) or non-study vehicle is sent to an incident that is likely to involve spinal motion restriction. Patients themselves will be aware of their treatment allocation at the time of the intervention. Research clinicians assessing outcomes at the receiving hospitals not be blinded to treatment group due to the contents of the patient notes and liaising with the patients during their in-hospital phase who were not blinded.

7.6. Study Visit

There are two elements to the study. In the first element there will be two research sites located at Northumbria Specialist Emergency Care Hospital (NSECH) and James Cook University Hospital (JCUH) to follow up Patients who are participants. The second element will involve NEAS as a research site to follow up clinicians as participants to understand their experience of the study.

Patient participants will be approached while in the Emergency Department (ED) after the CT report has been received or up to 72 hours if admitted. Those who are discharged without CT or prior to the research clinician visit will be followed up via telephone interview. The study visit will be a single visit and will not be repeated unless the participant wishes to have time to reflect upon the information and make a delayed consent at a time and date suitable for them.

Participants may opt to be informed of the results of the study via the consent form if they wish to do so.

Base line variables will not be possible to collect prior to entry into the study and can only be completed from a patient perspective.

The study visit will include the following questions during the Participant Experience questionnaire and will be collected in person by the research co-ordinator at NSECH or JCUH unless participant wishes to delay this and complete during a home visit or via email:

1.				?
How did you feel when the ambulance crew assessed and prepared you for transport?				
Free Text:				

2.	YES	NO	?
Did you feel you received sufficient explanation as to why your neck movements were being controlled?			
Free text:			

3.				?
How did you feel about the way your neck movements were controlled during your transfer / transport?				
Free Text:				

4a.	YES	NO	?
Did you have any concerns about how your neck was controlled while you were transferred to hospital?			

Free text:	

4b.	YES	NO	?
Were your concerns about how your neck was controlled taken into account by the ambulance crew?			
Free text:			

5.	YES	NO	?
Did you experience any breathing problems during your management and/or transport to hospital?			
Free text:			

6.	YES	NO	?
Did you experience any pain or discomfort as a result of the control of your neck movements during transfer?			
Free text:			

7.	YES	NO	?
Did you experience any other complications as a result of the control of your neck movements			

during transfer?			
Free text:			

Thank you for completing this participant experience questionnaire.

Once informed consent is obtained the patient's notes will be reviewed, including ambulance and nursing documentation to obtain the following data:

Participant Information	
Age:	
Frailty Score (prior to injury):	
Mechanism of Injury:	
Symptoms causing suspicion of Cervical Spine Injury:	
How was patient transported with regards to spinal motion restriction:	
Problems with non-compliance:	
Injury sustained:	
Stability of injury:	
Any neurology associated with injury and at what time post injury:	

Any evidence of pressure damage due to application of collar:	
Any evidence of delirium during / after transfer:	

7.7. Discontinuation/Withdrawal of Participants from Study

Each participant has the right to withdraw from the study at any time. In addition, the Investigator may discontinue a participant from the study at any time if the Investigator considers it necessary for any reason including:

- Pregnancy
- Ineligibility (either arising during the study or retrospectively having been overlooked at screening)
- Significant protocol deviation
- Significant non-compliance with treatment regimen or study requirements
- Withdrawal of Consent
- Loss to follow up

After the initial participant visit for the participant experience questionnaire and collection of data from participant notes no further observations will be required.

Withdrawal of consent from a participant will exclude the data for that participant from analysis.

Withdrawn participants will NOT be replaced.

The reason for withdrawal will be recorded in the CRF.

7.8. Definition of End of Study

The end of study is the date of the last visit / telephone follow up / home visit of the last participant which is expected to be on or around 30th November 2019.

8. INTERVENTIONS

The flow chart for all participants in the Spinal Motion Restriction Feasibility Study is shown in appendix D.

Intervention group: Over a six-month period intervention group patients (suspected cervical spine injury – see appendix A for guidelines) will be transported by NEAS crews to the randomised intervention site. See appendix B for SMRF Study Intervention Group Guideline.

Participants will have their cervical spine motion restriction managed in accordance with the proposed flow chart (see appendix B). For these patients unless the exclusion criteria apply, NO rigid collars will be used. The control group will follow existing clinical guidelines and use a rigid collar (appendix E).

9. SAFETY REPORTING (Adverse Event Management)

Use of hard collars in association with blocks and tapes in the manner described above has been accepted practice to reduce the risk of further damage due to movement of potentially unstable injuries for many years. Although there appears to be mounting expert opinion that the application of hard collars may cause more harm than good we must be vigilant against the potential of causing more harm in these patients. If there should be a case of new neurology developing post transfer during the study period the trial would need to be halted while a full and thorough investigation was undergone into whether the use of or lack of a hard collar caused or contributed to deterioration in neurological function. This study is not aimed at underplaying the risk of SCI or the need for appropriate management.

9.1. Definition of Serious Adverse Events

An adverse event is 'Any untoward medical occurrence in a patient or clinical investigation participant taking part in health care research, which does not necessarily have a causal relationship with the research.

A serious adverse event is any untoward medical occurrence that:

- results in death
- is life-threatening
- requires inpatient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- consists of a congenital anomaly or birth defect.

Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences.

NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

9.2. Reporting Procedures for Serious Adverse Events

A serious adverse event (SAE) occurring to a participant should be reported to the REC that gave a favourable opinion of the study where in the opinion of the Chief Investigator the event was 'related' (resulted from administration of any of the research procedures) and 'unexpected' in relation to those procedures. Reports of related and unexpected SAEs should be submitted within 15 working days of the Chief Investigator becoming aware of the event, using the HRA report of serious adverse event form (see HRA website).

All of the patients in this study will have experienced an acute injury requiring an emergency ambulance for transportation to either a trauma unit or major trauma centre and as such will be expected to have

injuries from the initial insult of the trauma. Through monitoring of the receiving sites, it is believed that if there is an obvious deterioration/change between pre and post management of the intervention group compared to the control group then the incident must be reported and study halted.

All serious adverse events should be reported to the site primary investigator and chief investigator using the appropriate form at the earliest opportunity. (See appendix F)

9.3. End of the Study

The study will end when the final patient has been recruited and their outcomes extrapolated from the patient notes or classified as lost to follow up. This is believed to be approximately 7 months from the start of participant recruitment.

The study will be stopped prematurely if:

- Mandated by the ethics committee,
- There is an obvious differentiation between the outcomes of control and intervention groups,
- There is a serious adverse event which prevents the ongoing study to be viable.

10. STATISTICS AND ANALYSIS

The sub-headings given below are suggestions. Add/delete as appropriate.

10.1. Description of Statistical Methods

Describe the statistical methods to be employed, including timing of any planned interim analysis(es).

The primary analysis will be by intention to treat, comparing the outcomes between all participants randomised to Intervention (non-collar) and all those randomised to Control (normal practice). The focus of the analysis will be on estimation of treatment effects and the uncertainty around them. A detailed statistical analysis plan will be developed by the trial statistician.

Results will be presented as estimates of the treatment effect with 95% confidence intervals. Dichotomous outcomes will be analysed using logistic regression models, both unadjusted and adjusted for appropriate covariates. Time to event outcomes such as time on-scene or time to CT will be analysed using time to event techniques. Continuous outcomes will be analysed by regression methods and the results presented as the difference in means between the groups and 95% confidence intervals. Reporting of analyses will follow CONSORT guidelines.

The following exploratory analyses will be used to investigate potential modifiers of the treatment effect of non-collar use:

- Age
- Mechanism
- Compliance

The free text from participant and clinician experience questionnaires will be managed and explored with NVivo qualitative data analysis Software; QSR International Pty Ltd. Version 11, 2015. Coding will be undertaken and reviewed to identify emerging themes (Saldaña, 2013) (including theoretical and conceptual). As data will be collected concurrently, constant comparison will undertaken throughout and new codes identified for qualitative thematic analysis. The data analysis framework approach recommended by Pope et al. (2000) will be used throughout the study.

10.2. Interim analysis

The Data Monitoring Committee will monitor the accumulating outcome data, and one of their roles is to recommend cessation of recruitment if a clear result has been reached (i.e. if either intervention or control is clearly superior). We suggest that different thresholds of evidence for early termination are adopted if non-collar or collar being more effective, as it is likely that stronger evidence would be needed to change current practice (collar use) if non-collar use is found to be superior. We therefore propose that interim analyses are conducted frequently in the early stages of the trial, so that, if collar use is superior, this can be detected early. Thus we will minimise any risks to patients while producing robust evidence that will change practice.

10.3. The Number of Participants

This will be a feasibility study and as such an underpowered study with no power calculations. It is expected that if the results are favourable then a full multi-centred clinical trial will follow.

As such, a sample size of 50 participants per site (JCUH and NSECH) as well as 100 (NEAS) clinicians will be expected over the 6 month study period (N=200). It is unknown how many participants will drop out of the study, however, due to a single study visit it is believed that there will be a very low drop/withdraw rate.

10.4. Analysis of Outcome Measures

The primary analysis will be by intention to treat, comparing the outcomes between all participants randomised to Intervention (non-collar) and all those randomised to Control (normal practice). The focus of the analysis will be on estimation of treatment effects and the uncertainty around them. A detailed statistical analysis plan will be developed by the trial statistician.

Results will be presented as estimates of the treatment effect with 95% confidence intervals. Dichotomous outcomes will be analysed using logistic regression models, both unadjusted and adjusted for appropriate covariates. Time to event outcomes such as time on-scene or time to CT will be analysed using time to event techniques. Continuous outcomes will be analysed by regression methods and the results presented as the difference in means between the groups and 95% confidence intervals. Reporting of analyses will follow CONSORT guidelines.

The following exploratory analyses will be used to investigate potential modifiers of the treatment effect of non-collar use:

- Age

- Mechanism
- Compliance

The free text from participant and clinician experience questionnaires will be managed and explored with NVivo qualitative data analysis Software; QSR International Pty Ltd. Version 11, 2015. Coding will be undertaken and reviewed to identify emerging themes (Saldaña, 2013) (including theoretical and conceptual). As data will be collected concurrently, constant comparison will undertaken throughout and new codes identified for qualitative thematic analysis. The data analysis framework approach recommended by Pope et al. (2000) will be used throughout the study.

11. DATA MANAGEMENT

11.1. Access to Data

Direct access will be granted to authorised representatives from the Sponsor and host institutions for monitoring and/or audit of the study to ensure compliance with regulations.

11.2. Data Recording and Record Keeping

The data will be stored on an encrypted North East Ambulance Service network to allow analysis by the research team. To comply with the research data management policy, data for research projects must be retained in an appropriate format for at least ten years from the end of the project. This is in accordance with the Research Records Retention Schedule.

https://www.northumbria.ac.uk/static/5007/respdf/data-prot_secure_storage.pdf

https://www.northumbria.ac.uk/research/research-data-management/-/media/corporate-website/documents/pdfs/research/research-data-management-policy-version-7.ashx

Participants have the right to access submitted information in accordance with UK data protection laws.

12. QUALITY ASSURANCE PROCEDURES

12.1. Sponsor

The North East Ambulance Service NHS Foundation Trust will act as sponsor of the study.

Contact details:

Michelle Jackson. Research and Development Manager. North East Ambulance Service NHS Foundation Trust. Ambulance HQ. Bernicia House, Goldcrest Way, Newburn Riverside, Newcastle. NE15 8NY.

Michelle.Jackson@neas.nhs.uk

12.2. Indemnity

Staff employed by the NHS will be covered by the Clinical Negligence Scheme for NHS Trusts. Negligent harm cover will be provided by the standard NHS arrangements (HSGG(96)48). NHS Indemnity does not give indemnity for compensation in the event of non-negligent harm, so no specific arrangements exist for non-negligent harm for this study.

12.3. Administration

The study co-ordination will be based at North East Ambulance Service NHS Foundation Trust, Research and Development Department.

12.4. Study Management Group

The Study Management Group, consisting of the project investigators involved with the day to day running of the study, will meet regularly throughout the project. Significant issues arising from management meetings will be referred to the Study Steering Committee.

Michelle Jackson. North East Ambulance Service Research and Development.

Lee Thompson. North East Ambulance Service.

Dr. Charlotte Bates. Northumbria Specialist Emergency Care Hospital.

12.5. Investigators Group

The study Investigators Group will meet regularly throughout the trial, either face to face, teleconference or other means of communication.

Lee Thompson, North East Ambulance Service,

Dr. Charlotte Bates, Northumbria Specialist Emergency Care Hospital,

Dr. Christopher Hawkins. Sunderland Royal Hospital.

Lt Col. Paul Hunt, James Cook University Hospital

12.6. Study Steering Committee

A Study Steering Committee, consisting of several independent clinicians and trialists lay representation, investigators and an independent Chair, will oversee the trial. Face to face meetings, teleconference or other means of communication will be held at regular intervals determined by need but not less than once a month.

The SSC will take responsibility for:

- Approving the final study protocol
- Major decisions such as a need to change the protocol for any reason
- Monitoring and supervising the progress of the trial
- Reviewing relevant information from other sources

- Considering recommendations from the Data Monitoring Committee
- Informing and advising on all aspects of the trial The membership of the SSC is:

Dr Alasdair Corfield. NHS Greater Glasgow and Clyde.

Dr Peter McMeekin. Northumbria University.

Michelle Jackson. North East Ambulance Service Research and Development.

Lee Thompson. North East Ambulance Service.

Dr Charlotte Bates. Northumbria Specialist Emergency Care Hospital.

12.7. Data Monitoring Committee

The Data Monitoring Committee will consist of independent experts with relevant clinical research, and statistical experience. During the period of recruitment into the study, interim analyses of the accumulating data will be supplied, in strict confidence, to the Data Monitoring Committee, along with any other analyses that the committee may request. The frequency of these analyses will be determined by the committee.

The Data Monitoring Committee will advise the Chair of the Study Steering Committee if, in their view, the randomised comparisons have provided both (i) 'proof beyond reasonable doubt' that for all, or some, the treatment is clearly indicated or clearly contra-indicated and (ii) evidence that might reasonably be expected to materially influence future patient management. Following a report from the Data Monitoring Committee, the Steering Committee will decide what actions, if any, are required. Unless the Data Monitoring Committee request cessation of the trial the Steering Committee and the collaborators will remain ignorant of the interim results.

The membership of the DMC is:

Dr Peter McMeekin. Northumbria University.

Dawn Evison. North East Ambulance Service Clinical Audit.

Gary Shaw. North East Ambulance Service.

Lee Thompson. North East Ambulance Service.

12.8. Essential Documentation

A study master file will be set up and held securely at North East Ambulance Service NHS Foundation Trust.

13. MONITORING OF STUDY PROCEDURES

13.1. Compliance

Participants recruited into the study will have their clinical records audited to ensure clinicians adhered to the study protocol by the local investigator and verified by an independent research clinician.

13.2. Completeness of Data

Audits of routine ambulance service data will be performed at regular intervals to identify patients who were potentially eligible participants who were not reported to the study.

13.3. Differential recruitment

Characteristics of participants recruited into the two trial arms will be monitored (as well as those patients attended to by non-trial vehicles) on a regular basis to detect any imbalances that maybe caused by thresholds to perform interventions. Analyses will be performed by the study statistician on a regular basis.

13.4. Training

All ambulance clinicians participating in the study will be trained in spinal motion restriction principles for both the intervention and control phases of the study. Research staff will be given training in Good Clinical Practice and obtaining consent.

14. ETHICAL AND REGULATORY CONSIDERATIONS

14.1. Declaration of Helsinki

The study will be conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki and are consistent with MRC Good Clinical Practice and applicable regulatory requirements.

14.2. Guidelines for Good Clinical Practice

The Investigators will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice.

14.3. Approvals

The protocol, informed consent form, participant information sheet and any proposed advertising material will be submitted to an appropriate Research Ethics Committee (REC), and HRA for written approval.

The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

14.4. Reporting

The CI shall submit after the first phase of the study, or on request, a progress report to the REC Committee, HRA, host organisations and Sponsor. In addition, an End of Study notification and final report will be submitted to the same parties.

14.5. Participant Confidentiality

The study staff will ensure that the participants' anonymity is maintained. The participants will be identified only by a participant ID number on all study documents and any electronic database, with the exception of the participants consent form. All documents will be stored securely and only accessible by study staff and authorised personnel. The study will comply with the Data Protection Act, which requires data to be anonymised as soon as it is practical to do so.

Data management will comply with the North East Ambulance Service data management policy. Data for research projects must be retained in an appropriate format for at least ten years from the end of the project.

Participants have the right to access submitted information in accordance with UK data protection laws.

14.6. Expenses and Benefits

No expenses will be provided for the participants or paramedic research staff. Full training will be given and refreshments provided.

14.7. Other Ethical Considerations

Include any other general and study-specific ethical considerations, e.g. involvement of vulnerable participants, or participants who are unable to consent for themselves.

Questionnaires were designed in conjunction with dementia friendly groups to ensure content was easy to read, understand and answer. Font, layout and design was considered as well as actual research content.

Focus groups were undertaken at three locations to obtain a clinicians perspective of the study. There were a total of 45 participants within all the focus groups.

15. FINANCE AND INSURANCE

15.1. Funding

The NEAS small research grant for this project was won through competitive application in March 2019 for the sum of £1000. There is another £200 from industry funding (Prometheus Medical) for additional administration costs. Apart from NEAS, no research site will receive any funding throughout this study.

Stationary/printing/posters	£200
Training venues and refreshments	£300
Tablets/software	£300
Clinician packs	£200
Transcription costs (Focus groups)	£200
Total	**£1,200**

15.2. Insurance

NHS bodies are legally liable for the negligent acts and omissions of their employees. If participants are harmed whilst taking part in a clinical research study as a result of negligence on the part of a member of the study team this liability cover would apply.

Non-negligent harm is not covered by the NHS indemnity scheme. The Oxford University Hospitals NHS Foundation Trust, therefore, cannot agree in advance to pay compensation in these circumstances.

NHS indemnity operates in respect of the clinical treatment that is provided.

16. DISSEMINATION AND PUBLICATION

The results of the study will be reported first to study collaborators. The main report will be drafted by the study co-ordinating team, and the final version will be agreed by the Study Steering Committee before submission for publication, on behalf of the collaboration. The study will be reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines. The main publications will be the report to the sponsor and hosting organisations and a journal publication. In addition, the results will be presented at international conferences.

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge any study was funding if applicable. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

17. REFERENCES

ABRAM, S. & BULSTRODE, C. 2010. Routine spinal immobilization in trauma patients: what are the advantages and disadvantages? *Surgeon,* 8**,** 218-22.

AMERICAN COLLEGE OF SURGEONS 2012. *Advanced Trauma Life Support Program for Doctors: 9th ed,* Chicago, American College of Surgeons.

CHAN, D., GOLDBERG, R. M., MASON, J. & CHAN, L. 1996. Backboard versus mattress splint immobilization: A comparison of symptoms generated. *Journal of Emergency Medicine,* 14**,** 293-298.

CONNOR, D., GREAVES, I., PORTER, K. & BLOCH, M. 2013. Pre-hospital spinal immobilisation: an initial consensus statement. *Emergency Medicine Journal,* 30**,** 1067.

DAVIES, G., DEAKIN, C. & WILSON, A. 1996. The effect of a rigid collar on intracranial pressure. *Injury,* 27**,** 647-649.

DIXON, M., O'HALLORAN, J. & CUMMINS, N. M. 2014. Biomechanical analysis of spinal immobilisation during prehospital extrication: A proof of concept study. *Emergency Medicine Journal,* 31**,** 745-749.

DIXON, M., O'HALLORAN, J., HANNIGAN, A., KEENAN, S. & CUMMINS, N. M. 2015. Confirmation of suboptimal protocols in spinal immobilisation? *Emerg Med J,* 32.

DUNHAM, C. M., BROCKER, B. P., COLLIER, B. D. & GEMMEL, D. J. 2008. Risks associated with magnetic resonance imaging and cervical collar in comatose, blunt trauma patients with negative comprehensive cervical spine computed tomography and no apparent spinal deficit. *Critical Care,* 12.

ENGSBERG, J. R., STANDEVEN, J. W., SHURTLEFF, T. L., EGGARS, J. L., SHAFER, J. S. & NAUNHEIM, R. S. 2013. Cervical spine motion during extrication. *J Emerg Med,* 44**,** 122-7.

FARRINGTON, J. D. 1967. Death in a ditch. *Bulletin of the American College of Surgeons,* 52**,** 121-130.

FURLAN, J. C., SAKAKIBARA, B. M., MILLER, W. C. & KRASSIOUKOV, A. V. 2013. Global incidence and prevalence of traumatic spinal cord injury. *Can J Neurol Sci,* 40**,** 456-64.

GEISLER, W. O., WYNNE-JONES, M. & JOUSSE, A. T. 1966. Early management of the patient with trauma to the spinal cord. *Medical services journal, Canada,* 22**,** 512-523.

HAUSWALD, M., ONG, G., TANDBERG, D. & OMAR, Z. 1998. Out-of-hospital spinal immobilization: its effect on neurologic injury. *Acad Emerg Med,* 5**,** 214-9.

KORNHALL, D. K., JØRGENSEN, J. J., BROMMELAND, T., HYLDMO, P. K., ASBJØRNSEN, H., DOLVEN, T., HANSEN, T. & JEPPESEN, E. 2017. The Norwegian guidelines for the prehospital management of adult trauma patients with potential spinal injury. *Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine,* 25**,** 2.

KOSSUTH, L. C. 1965. THE REMOVAL OF INJURED PERSONNEL FROM WRECKED VEHICLES. *Journal of Trauma and Acute Care Surgery,* 5**,** 703-708.

KWAN, I., BUNN, F. & ROBERTS, I. 2001. Spinal immobilisation for trauma patients. *Cochrane database of systematic reviews (Online)*.

MICHALEFF, Z. A., MAHER, C. G., VERHAGEN, A. P., REBBECK, T. & LIN, C. W. 2012. Accuracy of the Canadian C-spine rule and NEXUS to screen for clinically important cervical spine injury in patients following blunt trauma: a systematic review. *CMAJ,* 184.

MOBBS, R. J., STOODLEY, M. A. & FULLER, J. 2002. Effect of cervical hard collar on intracranial pressure after head injury. *ANZ Journal of Surgery,* 72**,** 389-391.

MYER, J. R. & PERINA, D. G. 2016. The changing standard of care for spinal immobilization. *Emergency Medicine,* 48**,** 153-157.

OTEIR, A. A. O., SMITH, K., STOELWINDER, J. U., COX, S., MIDDLETON, J. W. & JENNINGS, P. A. 2016. The epidemiology of pre-hospital potential spinal cord injuries in Victoria, Australia: a six year retrospective cohort study. *Injury Epidemiology,* 3**,** 25.

OTEIR, A. O., SMITH, K., JENNINGS, P. A. & STOELWINDER, J. U. 2014. The prehospital management of suspected spinal cord injury: An update. *Prehospital and Disaster Medicine,* 29**,** 399-402.

OTO, B., COREY, D. J., II, OSWALD, J., SIFFORD, D. & WALSH, B. 2015. Early secondary neurologic deterioration after blunt spinal trauma: A review of the literature. *Academic Emergency Medicine,* 22**,** 1200-1212.

PERRY, S. D., MCLELLAN, B., MCILROY, W. E., MAKI, B. E., SCHWARTZ, M. & FERNIE, G. R. 1999. The efficacy of head immobilization techniques during simulated vehicle motion. *Spine,* 24**,** 1839-1844.

QUEENSLAND AMBULANCE SERVICE 2014. Introduction to cervical soft collars. *In:* QUEENSLAND AMBULANCE SERVICE (ed.).

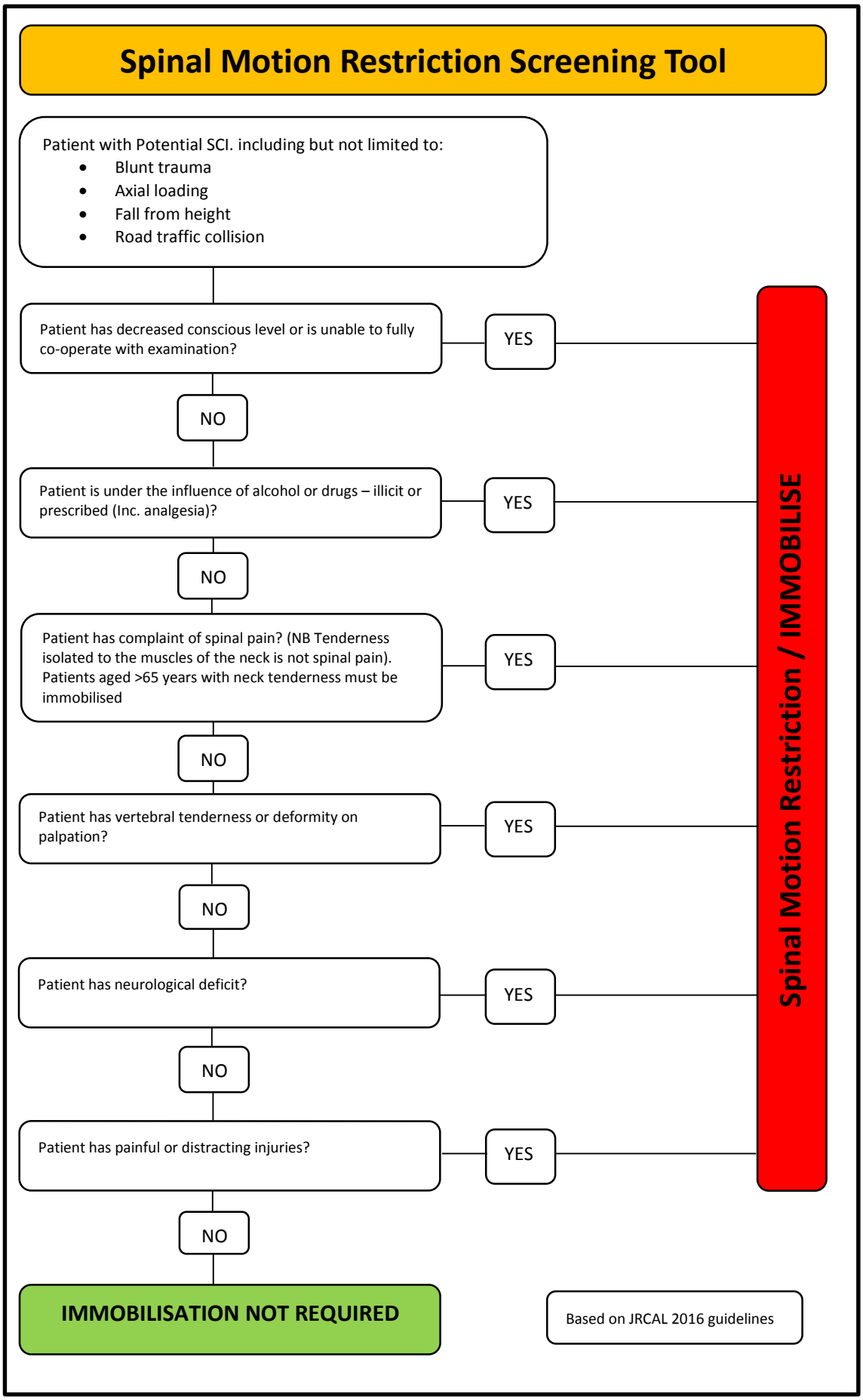
QUINN, J. & ENRAGHT-MOONY, E. 2015. Spinal Immobilisation: Evidence Review. ueensland Ambulance Service.

ROGERS, W. A. 1957. Fractures and Dislocations of the Cervical Spine: An End-Result Study. *JBJS,* 39**,** 341-376.

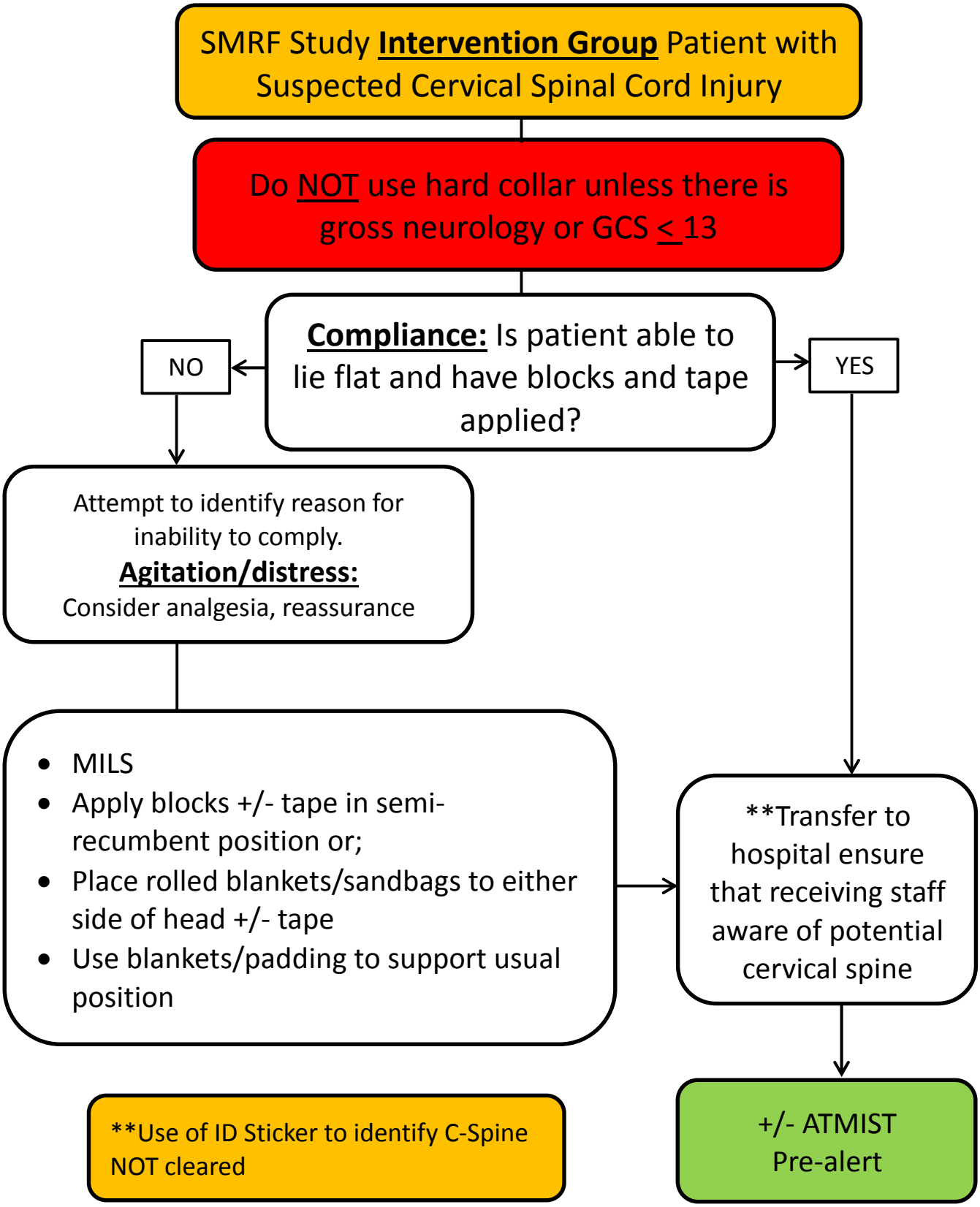
STIELL, I. G., WELLS, G. A., VANDEMHEEN, K. L., CLEMENT, C. M., LESIUK, H., DE MAIO, V. J., LAUPACIS, A., SCHULL, M., MCKNIGHT, R. D., VERBEEK, R., BRISON, R., CASS, D., DREYER, J., EISENHAUER, M. A., GREENBERG, G. H., MACPHAIL, I., MORRISON, L., REARDON, M. & WORTHINGTON, J. 2001. The Canadian C-spine rule for radiography in alert and stable trauma patients. *Journal of the American Medical Association,* 286**,** 1841-1848.

WHITE, C. C. T., DOMEIER, R. M. & MILLIN, M. G. 2014. EMS spinal precautions and the use of the long backboard - resource document to the position statement of the National Association of EMS Physicians and the American College of Surgeons Committee on Trauma. *Prehosp Emerg Care,* 18**,** 306-14.

18. APPENDIX A: Spinal Motion Restriction Screening Tool



19. APPENDIX B: SMRF Study Participant Intervention Group Guideline



20. APPENDIX C: 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 versus 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:	Daniel Haworth. North East Ambulance Service. **Daniel.haworth@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:	**v**
Version Date:	

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

Principle investigator:	**Lee Thompson**	**Date:**	
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 versus 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, 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:**	
Signature:			

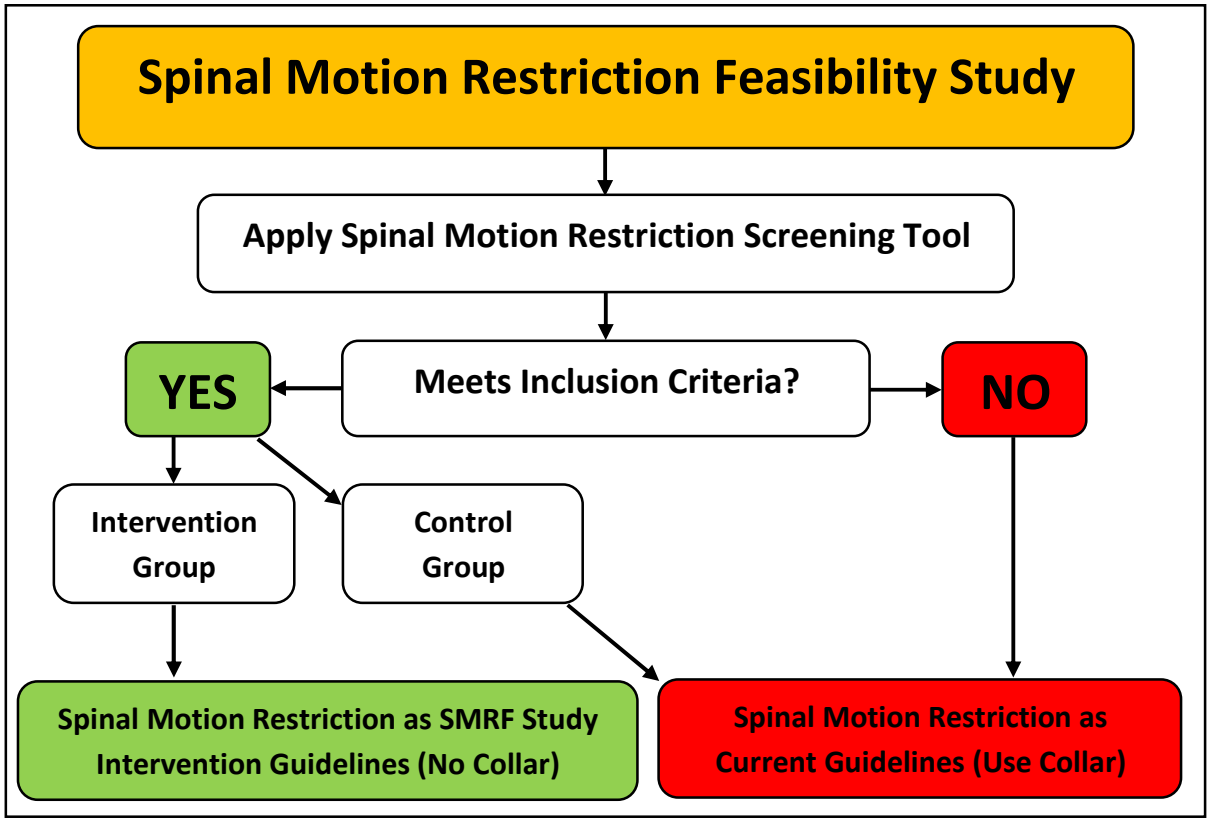
Further information: Please do not hesitate to contact the Chief Investigator, Lee Thompson, if you have any concerns or questions.

Contact details:

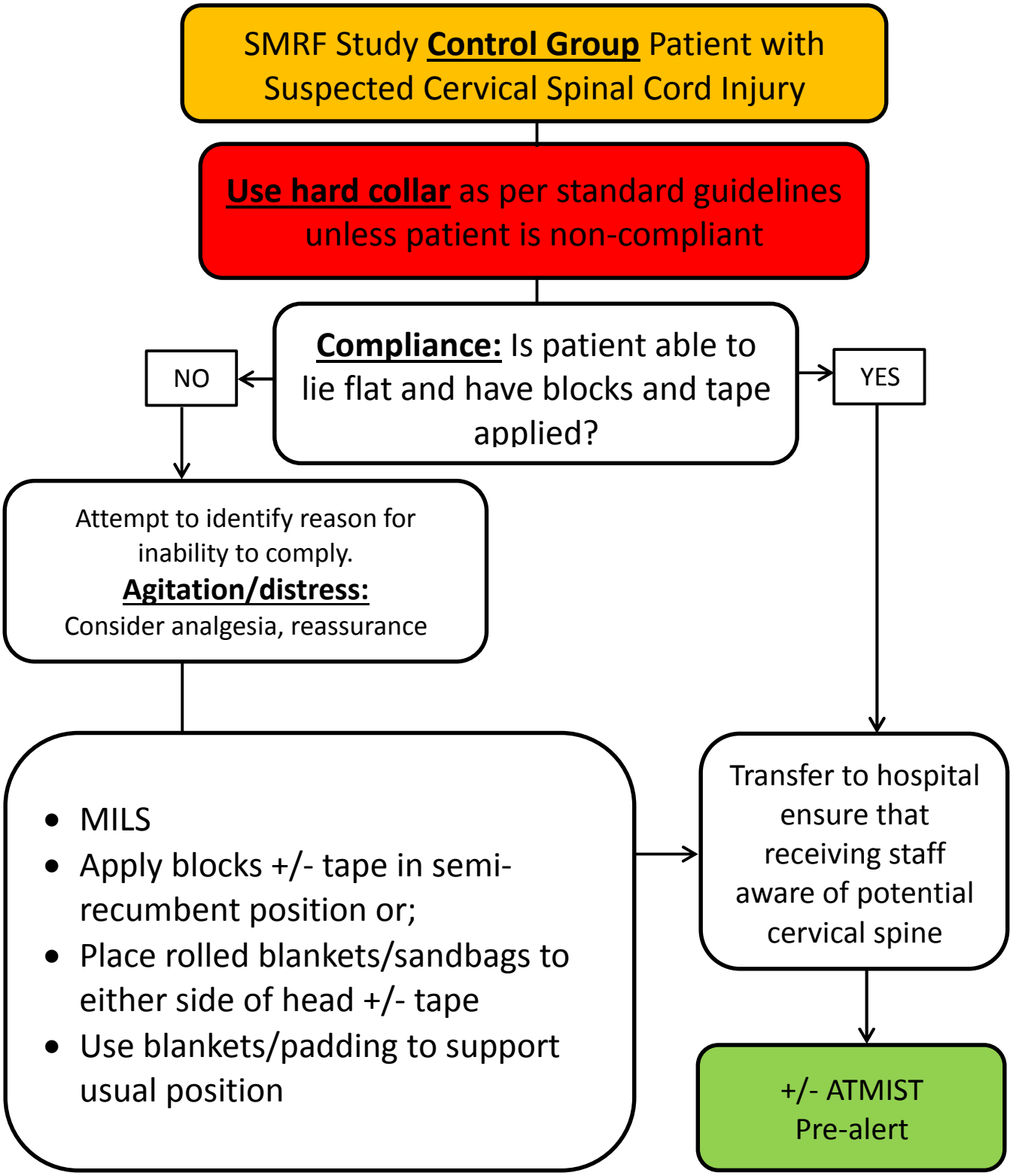
Address: Trauma Team, Emergency Operations Centre, North East Ambulance Service NHS Foundation Trust, Bernicia House, Goldcrest Way, Newburn Riverside, Newcastle Upon Tyne. NE15 8NY.

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

21. APPENDIX D: Spinal Motion Restriction Feasibility Study Participant Flow Chart



22. APPENDIX E: SMRF Study Participant Control Group Guideline



23. APPENDIX F: Serious Adverse Event Reporting Form

REPORT OF SERIOUS ADVERSE EVENT (SAE)
(For all studies except clinical trials of investigational medicinal products)

The Chief Investigator should report any SAE that is both related to the research procedures and is unexpected. Send the report to the Research Ethics Committee that gave a favourable opinion of the research within 15 days of the CI becoming aware of the event.

1. Details of Chief Investigator

Name:	
Address:	
Telephone:	
Email:	
Fax:	

2. Details of study

Full title of study:	
Name of main REC:	
Main REC reference number:	
Research sponsor:	
Sponsor's reference for this report: (if applicable)	

3. Type of event

Please categorise this event, ticking all appropriate options:

Death ☐	Life threatening ☐	Hospitalisation or prolongation of existing hospitalization ☐
Persistent or significant disability or incapacity ☐	Congenital anomaly or birth defect ☐	Other ☐

4. Circumstances of event

Date of SAE:	
Location:	
Describe the circumstances of the event: *(Attach copy of detailed report if necessary)*	
What is your assessment of the implications, if any, for the safety of study participants and how will these be addressed?	

5. Declaration

Signature of Chief Investigator:	
Print name:	
Date of submission:	

6. Acknowledgement of receipt by main REC (please insert name):

The [ ] Research Ethics Committee acknowledges receipt of the above.

Signed:	
Name:	
Position on REC:	
Date:	

Signed original to be sent back to Chief Investigator (or other person submitting report)
Copy to be kept for information by main REC.

24. APPENDIX G: Participant experience Questionnaire

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 versus Spinal Motion Restriction (SMR) techniques which include the omission of a rigid cervical spine collar.

Chief Investigator	Lee Thompson Specialist Paramedic (Trauma). Post Grad. Research Northumbria University.
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

Primary Investigators:	**Daniel Haworth.** Advanced Practice and Pathway Development Manager. North East Ambulance Service NHS Foundation Trust. Daniel.haworth@neas.nhs.uk **Charlotte Bates**. Consultant Emergency Medicine. Northumbria Specialist Emergency Care Hospital. Charlotte.bates@northumbria-healthcare.nhs.uk **Christopher Hawkins**. Consultant Emergency Medicine. Sunderland Royal Hospital. Christopher.hawkins@chsft.nhs.uk **Gary Shaw**. Specialist Paramedic, North East Ambulance Service NHS Foundation Trust. Gary.shaw@neas.nhs.uk **Lt Col. Paul Hunt**, Consultant Emergency Medicine, James Cook University Hospital. paul.hunt@stees.nhs.uk
IRS Project ID	**253128**
Version:	**v**
Version Date:	

Participant Identification Number for this project

Number:	

Research Co-ordinator completing the form

Name:		
Site (circle):	**NSECH**	**JCUH**
Group (circle):	**Intervention**	**Control**

Please ensure participants are eligible to participate:

Inclusion Criteria

Any participant aged 18 years and older may enter the study if ANY of the following apply:

- Participant has had a mechanism of injury suggestive of SCI. Example mechanisms include (but not exclusive too) RTC's, falls from height, serious assaults AND transported by NEAS crew to either NSECH or JCUH. In the elderly or frail patient this may include a fall from standing height and should be based on a thorough clinical exam (see appendix 1),
- Symptoms consistent with cervical spine injury (note for older patients any neck pain including muscular should be considered as suspicious for cervical spine injury),
- Those with dementia/delirium who are unable to communicate reliably regarding potential injury consider those with significant head injury as at risk of potential cervical spine injury and include them in study.

Exclusion Criteria

The participant may **NOT** enter the study if ANY of the following apply:

- Children aged <18 years,
- Those patients NOT transported to NSECH or JCUH,
- Participant requires airway support for whatever reason,
- The participant has a GCS ≤13,
- The participant is displaying obvious signs of new gross neurology such as paralysis,
- The participant has significant facial injuries that may benefit from the support a rigid collar may provide.

(Circle)	**Included**	**Excluded**
Reason for exclusion:		

1.				?
How did you feel when the ambulance crew assessed and prepared you for transport?				
Free Text:				

2.	YES	NO	?
Did you feel you received sufficient explanation as to why your neck movements were being controlled?			
Free text:			

3.				?
How did you feel about the way your neck movements were controlled during your transfer / transport?				
Free Text:				

4a.	YES	NO	?
Did you have any concerns about how your neck was controlled while you were transferred to hospital?			
Free text:			

4b.	YES	NO	?
Were your concerns about how your neck was controlled acknowledged by the ambulance crew?			
Free text:			

5.	YES	NO	?
Did you experience any breathing problems directly related to having your neck movements controlled during your management and/or transport to hospital?			
Free text:			

6.	YES	NO	?
Did you experience any pain or discomfort as a result of the control of your neck movements during transfer?			
Free text:			

7.	YES	NO	?
Did you experience any other complications as a result of the control of your neck movements during transfer?			
Free text:			

Demographics:

Age	18-24	
	25-34	
	35-44	
	45-54	
	55-64	
	65-74	
	75-84	
	85+	
	Prefer not to say	

Gender **How would you describe your gender?**	Male	
	Female	
	In another way: ……	
	Prefer not to say	

Disability (1) **Are your day to day activities limited because of a health problem or disability which has lasted or is expected to last over 12 months? (include any issues or problems relating to old age)**	Yes, a lot	
	Yes, a little	
	No	
	Prefer not to say	

Disability (2) **If yes, What category would you consider best describes your disability/condition? (read through the options)**	Hearing - due to Deafness or partial hearing	
	Learning –- affects how a person learns concentrates or remembers	
	Mental Health	
	Mobility – difficulty walking short distance, climbing or lifting	
	Stamina or breathing difficulties	
	Social or behavioural issues - neuro diverse conditions such as Autism, Asperger's' syndrome or Attention deficit	
	Vision – blindness or partial sight	
	Other impairment – anything not covered above	
	Prefer not to say	

Ethnicity	White	
	English/Welsh/Scottish/Northern Irish/British	
	Irish	
	Gypsy or Irish Traveller	
	Any other White background	
	Asian/Asian British	
	India	
	Pakistani	
	Bangladeshi	
	Chinese	
	Other Asian ethnic background	
	Black/African/Caribbean/Black British	
	Caribbean	
	African	
	Any other Black / African / Caribbean background	
	Mixed/Multiple ethnic groups	
	White and Asian	
	White and Black African	
	White and Black Caribbean	
	Any other Mixed/Multiple ethnic background	
	Other ethnic group	
	Arab	
	Any other ethnic group	
	Prefer not to say	

Thank you for completing this participant experience questionnaire.

Completion:

Please return scanned or electronically completed forms via email to:

lee.thompson@neas.nhs.uk

Or return hard copies to:

Lee Thompson, North East Ambulance Service NHS Foundation Trust, Ambulance HQ, Trauma Team, Emergency Operations Centre, 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: 0 (+44) 191 430 2399

email: lee.thompson@neas.nhs.uk

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

25. APPENDIX G: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made

List details of all protocol amendments here whenever a new version of the protocol is produced. This is not necessary prior to initial REC submission.