
Study Protocol

The FRAIL-T study: nurse-led frailty assessment in elderly major trauma
and the impact on outcome



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The FRAIL-T study: nurse-led frailty assessment in elderly major trauma and the impact on outcome

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Information in this protocol is confidential and should not be disclosed, other than to those directly involved in the execution or the ethical review of the study, without written authorisation from St George's Joint Research & Enterprise Services (JRES) or its affiliates.

Statement

The Chief Investigator (CI) and the Sponsor representative have discussed this protocol version. The investigators agree to perform the investigations and to abide by this protocol except where departures from it are mutually agreed in writing.

The Investigator agrees to conduct the study in compliance with the protocol, GCP, the Data Protection Act 2018, the Trust Information Governance Policy (or other local equivalent), the Research Governance Framework 2005 (2nd Edition), the Sponsor's SOPs, and other regulatory requirements as appropriate.

This protocol has been written in accordance to the Sponsor's procedure identified as: JREOSOP0039 "Protocol Design" and is intended for use at UK sites only.

| | | |
|--|---|-----------------------|
| Chief Investigator Professor Heather Jarman St George's University Hospitals NHS Foundation Trust | Signature  | Date 20 March 2019 |
|--|---|-----------------------|

Acknowledgements and protocol contributories

Dr Elaine Cole, London Trauma System conceived the study, and with Prof Heather Jarman, Prof Robert Crouch and Dr Mark Baxter developed the study question, design and methods. All of the study steering committee contributed to refinement of the study protocol and approved the final manuscript.

The following members of the pan-London elderly major trauma group provided advice and consensus opinions on the use of frailty tools and the recruitment processes: Trish Burton, Dr Cara Jennings, Dr George Peck, Dr Dhanupriya Sivapathasuntharam, Dr Rhonda Sturley, Jane Tippett.

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1 List of abbreviations and definitions

| | |
|-------------|---|
| AIS | Abbreviated Injury Score |
| CI | Chief Investigator |
| CRF | Case Report Form |
| CSF | Clinical Frailty Scale |
| ED | Emergency Department |
| ISF | Informed consent form |
| ISS | Injury Severity Score |
| MTC | Major Trauma Centre |
| NHS R&D | National Health Service Research & Development |
| Participant | An individual who takes part in a clinical trial or study |
| PI | Principal Investigator |
| PIS | Participant Information Sheet |
| PROMs | Patient Reported Outcome Measures |
| REC | Research Ethics Committee |
| SMG | Study Management Group |
| SSC | Study Steering Committee |
| TARN | Trauma Audit and Research Network |
| TSFI | Trauma Specific Frailty Index |

2 Study personnel

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3 Study synopsis

| | |
|-------------------------------|---|
| Brief title | FRAIL-T: the frailty in major trauma study |
| Official title | The FRAIL-T study: nurse-led frailty screening in elderly major trauma and the impact on outcome |
| Sponsor reference | 2018.0286 |
| Public database identifier | |
| Research question | Which frailty assessment tool can be used by nurses in the Emergency Department to identify frailty in elderly trauma patients in order to expedite expert care and improve outcome? |
| Study design | Prospective cohort |
| Study population | Major trauma patients aged 65 years and over requiring activation of a trauma team |
| Eligibility criteria | Inclusion criteria: <ul style="list-style-type: none"> Major trauma patients (age 65 years and over) admitted to the MTC who require a trauma team activation |
| | Exclusion criteria: <ul style="list-style-type: none"> Patients with no history of traumatic injury Patients under the age of 65 years old Patients discharged from the Emergency Department Patients transferred from another hospital |
| Target number of participants | 370 |
| Duration | 3-6 months for initial recruitment, with follow-up at 6 months |
| Primary aim | To determine the feasibility of nurse-led assessment of frailty in patients aged 65 or more admitted to Major Trauma Centres in the UK following traumatic injury. |
| Secondary aim(s) | <ul style="list-style-type: none"> To determine the prevalence of frailty in patients aged 65 or more admitted to major trauma centres in the UK To explore the correlation between early nurse-led frailty assessment and geriatrician frailty assessment within 72H of admission To determine the characteristics of patients aged 65 or more admitted to Major Trauma Centres |

| | |
|--------------------|--|
| | <ul style="list-style-type: none"> To examine the relationship between early identification of frailty and outcomes in major trauma patients age 65 and over |
| Sources of funding | Burdett Trust for Nursing |
| Sponsor | St George's University Hospitals NHS Foundation Trust |
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4 Background

There is no universal definition of frailty, but it is regarded as a condition characterised by a cumulative decline of physiological resilience across a number of body systems [1,2,3]. A key principle is that people who are frail are at risk of significant functional, physical and cognitive decline following an episode of illness or injury [4]. The prevalence of frailty is dependent on the definition used and how it is measured. A literature review by Sternberg et al [5] cites rates of 5% - 58%, with prevalence increasing with age. In the UK, Gale et al [6] estimate that in 60-69 year olds the rate is 6.5%, rising to 65% in the over 90s.

4.1 Study rationale

The population is getting older as a result of improvements in healthcare and lifestyle, and in 2016 in the UK, 18% of people was aged 65 and over [7]. As people are living longer and remaining physically fit they follow more active and independent lifestyles resulting in an increased risk of trauma. More elderly people are sustaining major traumatic injury, with the UK incidence in over 75s rising from 8.1% in 1990 to 26.9% in 2013 [8, 9]. Data from Major Trauma Centres (MTCs) in London for the last two years show patients age 65 and over accounted for 31% (1636 of 5348 patients) of major trauma activity in 2016, rising to 33% (1788 of 5486 patients) in 2017. There are similar findings for patients age 65 and over in published data worldwide, with falls being the most common cause of injury. These low energy falls, whilst unremarkable in the younger population, result in disproportionate injuries and mortality rates in the elderly who may have multiple co-morbidities and frailty [4, 11]. International evidence suggests two 'groups' of elderly trauma patients – those functioning well physically prior to the injury, and those who are frail. It is pre-injury frailty status as well as age that appear to influence outcome, with those who are frail suffering worse in-hospital complications and increased mortality. There is some international evidence that frailty leads to an increased incidence of poor health and greater health resource use in major trauma patients compared to the 'non-frail' [12]. Frailty has also been found to be an independent predictor of in-hospital complications and adverse outcome in older trauma patients in the US [13].

Despite the available evidence on the significance of frailty on outcome there is a lack of evidence describing the characteristics and effects of frailty in major trauma in the UK, and we do not know how many severely injured patients are affected by frailty. This could be due to the lack of consensus in defining frailty and lack of standardisation in how it is measured and recorded. Severely injured older people are initially cared for in Major Trauma Centre (MTC) Emergency Departments (ED), yet a recent international scoping review reported only 14% of patients were frailty screened during this phase of care [14]. This may be due to the fact that not all elderly trauma patients 'appear' frail, or that some trauma-specific frailty tools are time and resource intensive to complete [14], or frailty screening is only recommended as part of a comprehensive geriatric assessment at a later stage in the patients' journey [14]. However, a recent study has reported significantly improved outcomes in frail older trauma patients who have early frailty screening and expedited care via a specialist pathway [16]. Frailty screening is predicted to become part of the best practice commissioning tariff within NHS England in 2019-2020, yet there is no evidence or consensus as to who should carry out this assessment or within which timeframe.

There are a plethora of frailty instruments in use making it difficult for clinicians to know which is the most appropriate. Joseph et al [11] estimate that more than 32 frailty indices exist with the

aim of predicting patient outcome and are designed for use in a variety of distinct patient groups. This has led to a lack of consistency in the definitions and measured used to provide outcome data in the various patient groups. The British Geriatric Society [1] makes recommendations for frailty assessment in different clinical groups but do not recommend a specific tool for use in major trauma.

Major trauma is an increasing burden for older people, therefore we wish to focus attention on early identification of frailty in the ED in major trauma patients as a way to underpin frailty specific major trauma pathways, to optimise recovery and improve patient experience. We do not currently know the prevalence of frailty in the UK major trauma population or whether it is feasible to carry out accurate frailty assessment in the ED in this patient group. Nurses are involved in every stage of the major trauma patient pathway and are best placed to provide an early clinical assessment of frailty working with the patient, family and wider multi-professional team to influence ongoing care. Therefore, this study aims to determine the feasibility of nurse-led assessment of frailty in patients aged 65 or more admitted to major

5 Study aims

5.1 Primary aim

The primary aim is to determine the feasibility of nurse-led frailty assessment in the Emergency Department in patients aged 65 or more admitted to major trauma centres in the UK following traumatic injury.

5.2 Secondary aims

- To determine the prevalence of frailty in patients aged 65 or more admitted to major trauma centres in the UK
- To explore the correlation between early nurse-led frailty assessment and geriatrician frailty assessment within 72H of admission
- To determine the characteristics of patients aged 65 or more admitted to Major Trauma Centres
- To examine the relationship between early identification of frailty and outcomes in major trauma patients age 65 and over

6 Study design

The design of this study has been adopted following discussions in the study management committee.

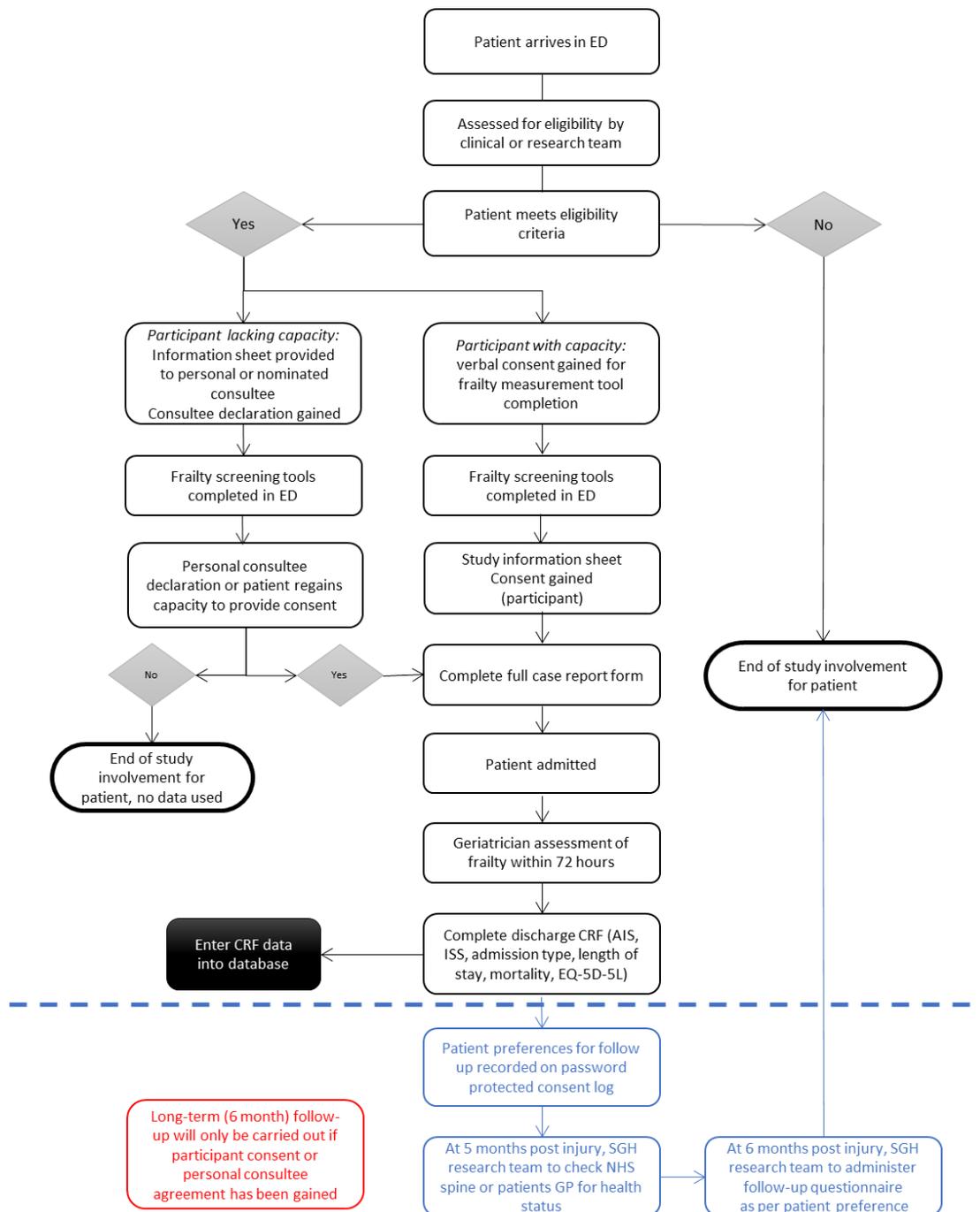
6.1 Overall design

A prospective cohort analysis of consecutive major trauma patients age 65 and over admitted to a Major Trauma Centre (MTC) within the London Trauma System and Southampton will be undertaken. There is no modification to the patient's expected course of treatment as a result of participating in the study.

6.2 Methods

Following a consent process, each participant will be assessed for frailty by a nurse in the ED using standardised measurements of frailty. Nurses will be trained in how to perform a frailty assessment and in the use of the measurement tools (which are brief and take a short time to complete). A geriatrician will carry out a frailty assessment within 72 hours of admission to validate the nurses' measurement and ensure that frailty has not been missed. Demographic, injury and clinical characteristics will be collected on a case report form to provide a greater understanding of the elderly major trauma population. Clinical outcome data, including health status and participant reported outcomes, will be collected on discharge and 6 months.

6.3 Schema of study



7 Participation selection criteria

Participant enrolment will be conducted over a three to six month period across five hospital sites.

Participants will be screened according to the inclusion and exclusion criteria for the study. Participants will be considered eligible for enrolment into this study if they fulfil all of the inclusion criteria and none of the exclusion criteria as defined below. Eligible participants will be entered onto the *screening and enrolment log* and assigned a unique study identifier. Participants who are screened but not eligible will be entered on to the *screening and enrolment log* and their involvement in the study ends.

7.1 Inclusion criteria

Major trauma patients (age 65 years and over) admitted to the MTC requiring activation of a trauma team. The criteria for activation of the trauma team at each site may vary and therefore it is the responsibility of the clinical and / or research nursing staff at each site to identify eligible participants.

7.2 Exclusion criteria

- Patients with no history of traumatic injury
- Patients under the age of 65 years old
- Patients discharged from the Emergency Department
- Patients transferred from another hospital

8 Participant recruitment process

Data collection at a site will only commence once evidence of the following approval / essential documents are in place:

1. REC approval, if applicable
2. Final sponsorship and host site permissions,

All participants will be screened for eligibility and consented by the Principal Investigator, or an appropriate delegate as detailed in the study procedures in section 9.1.

Participants eligible for the study that agree to participate will be assessed and managed clinically in the ED according to standard practice for the site.

9 Consent procedures

9.1 Informed consent

9.1.1 Participants with capacity

Informed consent will be obtained by the local Principal Investigator (PI), or an appropriately trained member of the team, as a two-part process prior to inclusion into the study. As participants presenting to Major Trauma Centres may not be able to read and complete a written consent process within the time frame that they are in the Emergency Department, verbal

consent will be obtained following eligibility assessment in order for the frailty measurement tools to be completed.

If the participant declines to give verbal consent at this stage they may be given further written information and the participant given time to consider their participation.

If verbal consent is used initially then participants will subsequently be given a written participant information sheet and the study team will be available to answer any questions. The participant will be given time to read the information and consider their participation in the study. If they still wish to take part they will then go through the written consent process. This will be deferred written consent for the frailty measurement and written consent for the other aspects of the study. If they choose to end their participation at this point then any data already collected will be destroyed.

The participant will be informed that his/her medical records are subject to review by representatives of the sponsor as necessary and that data will be collected and processed in accordance with the Data Protection Act 2018. The participant will be told that participation in the study is voluntary and that he/she is free to withdraw from the study at any time and without prejudice. If participants are willing to provide a reason for their withdrawal, this information will be recorded. Each participant will be advised that data collected may be published or presented at scientific meetings and may also be subject to audit procedures from Regulatory Authorities. All such personally identifiable data will be anonymised to maintain complete participant confidentiality at all times.

A copy of the signed *Informed Consent Form (ICF)* along with a copy of the most recent approved *Participant Information Sheet (PIS)* will be given to the study participant. An original signed & dated consent form will be retained in the ISF. Copies of both the ICF and PIS will be placed in the medical notes.

If new information results in significant changes to the risk –benefit assessment, the consent form will be reviewed and updated if necessary. All participants, including those already being treated, will be informed of the new information, given a copy of the revised consent form and asked to re-consent if they choose to continue in the study.

Participants will be asked to consent to follow up at six months from injury. There is a risk that participants may have deteriorated or died following discharge from hospital. Therefore the participant's GP will be contacted or the NHS spine will be checked prior to the six month follow up to avoid inadvertently causing distress to the participant's relatives.

9.1.1 Participants who lack capacity

Some participants eligible for the study may have impaired capacity at the time of attendance. This may be due to either the participant's current clinical condition or an existing condition such as dementia. This group is an important cohort in understanding frailty in the major trauma population.

If a *personal consultee* is available then personal consultee advice will be sought. This will be from someone who knows the person who lacks capacity in a personal (non-professional, non-pay) capacity who is able to advise the researcher about the person who lacks capacity's wishes and feelings in relation to the project and whether they should join the research.

In line with DH guidance on nominating a consultee for research involving adults who lack capacity (2008), a *nominated consultee* will only be used if a personal consultee is not available. The role of the nominated consultee in this study is to advise on the patient's participation so that the frailty assessment can be completed in the Emergency Department prior to seeking patient consent or personal consultee advice at a more appropriate time. If the nominated consultee is unable to advise on the patient's participation, the patient will not be enrolled in the study and no information will be collected.

Frailty assessment is an observational, clinically routine intervention which will not cause harm to the patient. This is necessary as frailty screening must take place before the patient leaves the Emergency Department which may occur before it is possible to consult in the usual way. If this is the case then the local research team will ask the patient's consultant to complete the declaration as a nominated consultee. The consultant will take account of any views of the patient if these are known.

Copies of the *personal / nominated declaration form* and *information sheets* will be kept in the medical notes.

As soon as clinically appropriate (determined by the clinical care team in charge of the participant), consent will be sought from the patient (participant) or advice sought from the personal consultee for inclusion of the frailty assessment data in to the study, collection of research specific data (for example, injury characteristics) and long term follow-up. If a participant or declines to give consent for continuation at this stage, his/her wishes will be respected; the same principle will apply if a personal consultee does not advise the inclusion of a participant who lacks the capacity to consent. All data relating to the study will be confidentially deleted.

9.2 Participant transfers out of the MTC

If a participant is transferred to another hospital or moves from the area after discharge from the hospital, every effort will be made to maintain contact to allow the follow-up study procedures to be completed. This will be the responsibility of the participating site. If follow-up study procedures are unable to be completed this should be reported as a protocol breach and the minimum data entered will be the discharge location if known.

9.3 Lost to follow-up

A participant will be considered lost to follow-up for the 6 month data collection if the research team is unable to confirm their status with their GP or NHS spine, and they do not respond to two attempts by the research team to contact them for the 6 month quality of life assessment.

9.4 Definition of the end of study

The end of study is defined as when the last participant recruited has completed the 6 month follow-up (or has been deemed lost to follow-up) and all the data have been cleaned and the database locked.

The REC requires notification of the end of study within 90 days of its planned completion or within 15 days if the study is terminated early. The sponsor will facilitate assistance and compliance with requirements.

10 Study Procedures

Each site will have a nominated study lead and research staff from within the local clinical team. A study website will contain information for participating sites including the protocol, guidance / explanatory notes and frailty screening tool training.

After enrolment, data will be collected prospectively by the study teams for each participant using a paper case record form. All data will be anonymous and participants will be assigned a unique study identifier which will be used throughout the data collection period.

Following a consent or consultee advice process, each participant will have frailty assessment carried out by a nurse in the ED using 3 standardised measures of frailty (a screening tool). Nurses will be trained in how to perform frailty measurement and in the use of the measurement tools. A geriatrician will carry out a frailty assessment within 72 hours of admission to provide validation of the nurse measurements and ensure that frailty has not been missed. Demographic, injury and clinical characteristics will be collected on a case report form to provide a greater understanding of the frail elderly major trauma population. Clinical outcome data, including health status and participant reported outcomes, will be collected on discharge and at 6 months.

10.1 Baseline assessment procedures

All participants will have the following data recorded:

10.1.1 Demographic information

Information on age, gender, race and ethnicity and postcode of the participant's residence and injury location will be collected. To avoid potential identification only the area and district of the postcode will be recorded; for example GU (area) and 15 (district). This data will be used to provide a greater understanding of the older major trauma population. This data is collected as part of routine NHS admission procedures and is not specific to the study.

10.1.2 Injury and clinical characteristics

The following study specific information will be recorded:

- Time and date of traumatic injury
- Time of ED arrival and time of CRF completion
- Type of injury: blunt, penetrating
- Location when injury occurred – type and postcode (i.e. home, street)
- Mechanism of injury
- ED vital signs on presentation: Glasgow Coma Score (GCS), Systolic blood pressure (SBP) and heart rate and temperature
- Physiological characteristics on presentation: lactate measurement in the ED (if taken as part of routine clinical care)
- Past medical history / co-morbidities / number of significant pre-injury medications
- Residential status (i.e. own home, rehabilitation unit, nursing home)

10.1.3 Nurse-led frailty assessment

Designated clinical or research nurses will be trained in how to perform a frailty assessment using the frailty measurement tools to assess their practical application for use in the Emergency Department in major trauma patients. Information pertaining to the participant's pre-trauma frailty status will be collected from the participant or their relatives / friends depending on whichever is most appropriate. Due to the nature of the participants presenting condition there may be times when it is not appropriate or possible for the measurement tools to be completed in the ED. As this is a feasibility study the reasons for non-completion of frailty measurement in the ED is an important component. Nurses completing the assessment will be asked to provide a rating preference and comment on the ease of use of each of the scales, including how they were able to gather the information (i.e patient, relatives, pre-hospital information).

These scales have been chosen by the study steering committee based on consensus. Copies of the tools are shown in

- *The Clinical Frailty Scale (CFS), also known as 'Rockwood'*

This scale has been chosen as it forms part of the routine measurement of frailty by geriatricians in the NHS Best Practice Tariff for Major Trauma from April 2019. It is a validated tool used to assess frailty in the elderly population and is based on clinical judgement [17]. It uses nine pictorial representations alongside a short descriptor to assign a frailty score: 1 (very fit) to 9 (terminally ill). Participants scoring five or more are considered to be frail. The CFS has been validated as a predictor of adverse outcome in the hospitalised elderly population [18, 19].

- *PRISMA-7*

PRISMA-7 is a self-reported questionnaire composed of seven unambiguous questions aimed at identifying frail older adults [20]. It utilises closed questions, 'yes' or 'no' answers, and a score of three or more identifies frailty. The PRISMA-7 has been praised in identifying frailty in older people in the primary care setting [21], however it has been criticised for over-screening frailty [22].

- *The Trauma Specific Frailty Index (TSFI)*

The Trauma Specific Frailty Index (TSFI) is a frailty tool composed of 15 questions designed to assess frailty in the trauma setting. It was validated among 200 geriatric trauma participants and is an independent predictor of unfavourable discharge disposition [23]. It can be completed by participants, or next of kin, if the participant is unresponsive. A TSFI score of >0.27 is found to be an independent predictor of unfavourable outcomes after trauma in this participant cohort. The TSFI is an effective tool that can aid clinicians in planning discharge disposition of geriatric trauma participants.

10.2 Geriatrician assessment procedures

Once the participant is admitted to hospital a further frailty assessment will be performed within 72 hours of admission by a geriatrician at specialist training level of ST3 or above. This will enable the correlation of the ED nursing frailty assessment with that of a specialist clinician, and ensure that frailty has not been missed. Participant's frailty status will be determined by the geriatrician using the Clinical Frailty Score which is the tool used within routine practice during clinical assessment.

10.3 Outcomes follow up

Outcome data will be collected according to the schedule in 10.5.

10.3.1 On discharge from hospital:

- Injury variables: abbreviated injury scores (AIS) and injury severity score (ISS). AIS classifies the severity of injury in each of six defined body regions (head and neck, face, chest, abdomen, pelvis and extremities). ISS is an anatomical scoring system that standardises the severity of traumatic injury [24].
- Critical care admission, critical care length of stay, hospital length of stay, discharge disposition / residential status, date of in-hospital mortality (if appropriate)
- Participant reported outcomes using EQ-5D-5L. Patient reported outcome measures (PROMs) questionnaires including the EQ-5D-5L are routinely collected from eligible patients in participating sites as part of a TARN project. Each site should have a local protocol for completion of PROMs questionnaires on behalf of those participants who do not regain mental capacity during admission.

10.3.2 Procedures in the event of participant death

If a recruited participant dies during admission, the following information will be documented:

- Date of death
- Injury variables: abbreviated injury scores (AIS) and injury severity score (ISS). AIS classifies the severity of injury in each of six defined body regions (head and neck, face, chest, abdomen, pelvis and extremities). ISS is an anatomical scoring system that standardises the severity of traumatic injury [24].
- Critical care admission, critical care length of stay, hospital length of stay, discharge disposition / residential status, date of in-hospital mortality (if appropriate)

10.3.3 At 6 months:

- Residential status compared to pre-injury
- If the participant has been readmitted to hospital, and the reason for the readmission
- Date of death (if relevant)
- Participant reported outcomes using EQ-5D-5L (collected by letter, phone or email as participant prefers)

10.4 Dealing with emotional or psychological distress during follow-up

There is a risk that contact with the participant to complete the 6 month follow-up may induce or exacerbate emotional distress relating to the major trauma event. This risk will be mitigated by telephone follow-up being carried out by senior nurses who are experienced in caring for major trauma patients. If the participant shows or expresses any emotional distress the research team will offer, on their behalf, to contact the participant's keyworker from the Major Trauma Centre (this is a role covered by different staff groups dependent on the MTC and offers a single point of contact for patients post-discharge as part of normal practice). If the patient does not wish the research team to do this they will be advised to contact their GP.

Participants can opt for follow-up to be completed by letter or email. In these cases information signposting the patient to contact their GP or using NHS Choices will be provided in the covering information <https://www.nhs.uk/conditions/post-traumatic-stress-disorder-ptsd/>

10.5 Schedule of study assessments

| | Whilst participant is in ED | Within 72 hours of admission | On discharge / death or transfer from hospital | 5 months post-injury NHS spine / GP check | 6 months post-injury |
|---|-----------------------------|------------------------------|--|---|----------------------|
| Perform routine clinical assessment | X | | | | |
| Check eligibility | X | | | | |
| Obtain verbal consent | X | | | | |
| Complete ED frailty assessment | X | | | | |
| Informed consent or consultee advice (participant / personal / nominated) | X | | | | |
| Complete CRF data not obtained on admission | | X | | | |
| Complete specialist geriatrician frailty assessment | | X | | | |
| Complete discharge CRF | | | X | | |
| Send GP letter For discharged or transferred patients only | | | X | | |
| Outcome follow-up For those with participant consent or personal consultee advice only | | | | X | X |

Table 1: schedule of study assessments

11 Safety events

As this is an observational study there will be no anticipated safety events as a result of participant participation. Notification of death is not recorded as an adverse event, it is reported as an outcome if occurs.

12 Data management and quality assurance

12.1 Confidentiality

All data will be handled in accordance with the Data Protection Act 2018.

Although participant identifiable data will be available to research staff they will not be entering it on to the paper case record form (CRF). Participants will be identified using a participant study identifier (ID) which will be recorded with the participant's name, hospital number and date of birth on the *screening and enrolment log*. This information is required to enable follow-up of participants at 6 months. The *screening and enrolment log* can be used to cross reference participant's identifiable information and will be stored in a locked office at each centre only

accessible to the centre PI and data collectors. Each centre will be identified by a numeric code rather than name.

12.2 Data collection tool

Case Report Forms will be used. The majority of data required to be collected is already recorded as part of routine clinical care. All data will be entered legibly in black ink with a ball-point pen. If the investigator makes an error, it will be crossed through with a single line in such a way to ensure that the original entry can still be read. The correct entry will then be clearly inserted. The amendment will be initialled and dated by the person making the correction immediately. Overwriting or use of correction fluid will not be permitted.

It is the investigator's responsibility to ensure the accuracy of all data entered and recorded in the CRFs. The *Delegation of Responsibilities Log* will identify all study personnel responsible for data collection, entry, handling and managing the database

The source documentation is the CRF.

12.3 Data handling and analysis

Data collected on the paper CRF will be held by each study site and entered as soon as possible in to the password protected study database (REDCap) by the local study team. Hard copies of the questionnaires (CRFs) will be kept securely at each site (they must be kept in a locked cabinet in a locked room).

A password protected coding log will be used which will include identifiable participant data (name, address and date of birth) for participants who have consented to long term outcome follow-up. This will be transferred to the CI at the end of the in-hospital data collection period. At five months after injury the NHS Health and Social Care Information Centre (NHS Spine) or participants General Practitioner (GP) will be contacted to ensure that the participant is still alive at this time point. This will avoid erroneous long term follow up and exposing relatives to undue distress. At 6 months post injury, the EQ5D and questionnaire will be administered to each participant who has provided informed consent.

Paper CRFs will be kept until the end of the study to ensure that the source documentation is available for any query resolution.

13 Archiving arrangements

The study essential documents along with the study database will be archived in accordance with the sponsor requirements. The agreed archiving period for this study will be 5 years.

Each PI at any participating site will archive the study essential documents generated at the site for the agreed archiving period in accordance with the signed Clinical Study Site agreement

14 Statistical design

14.1 Statistical input in study design

Statistical input for this study has been provided by:

Dr Chao Wang

Joint Faculty of Health, Social Care and Education, Kingston University and St. George's, University of London, St. George's Hospital Campus, Cranmer Terrace, London SW17 0RE

E-mail: C.Wang@sgul.kingston.ac.uk

14.2 Endpoints

14.2.1 Primary endpoint

The primary endpoint for this study is frailty, initially measured in the emergency department (ED) and then re-measured and validated within 72 hours of admission.

14.2.2 Secondary endpoints

The secondary end points include:

Continuous data: Injury severity score, length of stays and EQ-5D-5L scales; and

Categorical data: alive/died, critical care admission yes/no, discharge destination - usual place of residence/care home/other, readmission yes/no, reasons for readmission coded e.g. falls, infection etc.

14.3 Sample size and recruitment

14.3.1 Estimated sample size

Data from London-based geriatricians working with trauma participants suggests that frailty affects approximately 37% of those aged 65 or more. Therefore it was determined that we need a sample size of 370 to achieve a 95% CI of (32-42%) at 97% probability of achieving the target population.

14.4 Statistical analysis plan

Data will be analysed using data management software. Comparisons of continuous data will be conducted using unpaired students t-tests or Mann Whitney U tests (for parametric and non-parametric data respectively). Analysis of more than two groups of continuous data will be conducted using ANOVA or Kruskal Wallis tests. Analysis of categorical data such as male/female gender or survival/death will be analysed using Chi square or Fisher's exact tests. A p value of <0.05 is considered statistically significant for univariate analysis.

14.5 Interim analysis

No interim analyses are planned.

15 Committees in involved in the study

Study Management Group (SMG) - responsible for the day-to-day management of the study. The role of the group is to monitor all aspects of the conduct and progress of the study, ensure that the protocol is adhered to and take appropriate action to safeguard participants and the quality of the study itself.

Study Steering Committee (SSC) - provides overall supervision of the study and ensures that it is being conducted in accordance with the relevant regulations. The Study Steering Committee has

agreed the study protocol and any protocol amendments and provides advice to the investigators on all aspects of the study.

16 Direct access to source data

The investigator(s)/institution(s) will permit study-related monitoring, audits, REC review, and regulatory inspection(s), providing direct access to source data/documents. Study participants are informed of this during the informed consent discussion. Participants will consent to provide access to their medical notes.

17 Ethics and research governance requirements

The site will conduct the study in compliance with the protocol as agreed by the Sponsor and which was given favourable opinion by the Social Care Research Ethics Committee (REC reference 19/IEC08/0006).

The Chief Investigator will be provided (via the Sponsor) with file indexes. The CI will be responsible for the maintenance of the TMF and may delegate the responsibility of ISF file maintenance to the PI at each participating site.

It is the responsibility of the Principal Investigator at each site to ensure that all subsequent amendments gain the necessary approval.

Within 90 days after the end of the study, the CI and Sponsor will ensure that the REC is notified that the study has finished by completing the Sponsor's 'End of study declaration'.

The CI will supply an End of Study report of the clinical study to the REC within one year after the end of the study.

17.2 Notification of serious breaches of GCP and/or the protocol

Any protocol deviations or violations will be documented using a protocol deviation form. No serious safety breaches are anticipated as this is a data only study.

A "serious breach" is a breach which is likely to effect to a significant degree:

- (a) The safety or physical or mental integrity of the participants of the study; or
- (b) The scientific value of the study.

The CI will notify the Sponsor immediately of any case where there exists a possible occurrence of a serious breach

18 Finance

This study is fully funded by the Burdett Trust for Nursing. This funding provides a part-time study coordinator; research costs for CRF completion and to perform with long term follow up at each site. The funding also covers statistician input and PPI travel, subsistence and meeting time.

19 Insurance and indemnity

St Georges University Hospitals NHS Foundation Trust is the study sponsor in accordance with the UK Policy Framework for Health and Social Care.

St Georges University Hospitals NHS Foundation Trust is party to NHS Litigation Authority (NHSLA) / NHS Resolution. As an NHS body it is liable for clinical negligence and other negligent harm to individuals covered by their duty of care. NHS Institutions employing researchers are liable for negligent harm caused by the design of studies they initiate.

20 Publication policy

Publication: “Any activity that discloses, outside of the circle of study investigators, any final or interim data or results of the Study, or any details of the Study methodology that have not been made public by the Sponsor including, for example, presentations at symposia, national or regional professional meetings, publications in journals, theses or dissertations.”

All scientific contributors to the Study have a responsibility to ensure that results of scientific interest arising from Study are appropriately published and disseminated. The Sponsor has a firm commitment to publish the results of the Study in a transparent and unbiased manner without consideration for commercial objectives.

To maximise the impact and scientific validity of the Study, data shall be consolidated over the duration of the study, reviewed internally among all investigators and not be submitted for publication prematurely. Lead in any publications arising from the Study shall lie with the Sponsor in the first instance.

20.1 Before the official completion of the study,

All publications during this period are subject to permission by the Sponsor. If an investigator wishes to publish a sub-set of data without permission by the Sponsor during this period, the Study Steering Committee shall have the final say.

Exempt from this requirement are student theses that can be submitted for confidential evaluation but are subject to embargo for a period not shorter than the anticipated remaining duration of the study.

20.2 Up to 180 days after the official completion of the study

During this period the Chief Investigator shall liaise with all investigators and strive to consolidate data and results and submit a manuscript for peer-review with a view to publication in a reputable academic journal or similar outlet as the Main Publication.

- The Chief Investigator shall be senior and corresponding author of the Main Publication.
- Insofar as compatible with the policies of the publication outlet and good academic practice, the other Investigators shall be listed in alphabetic order.
- Providers of analytical or technical services shall be acknowledged, but will only be listed as co-authors if their services were provided in a non-routine manner as part of a scientific collaboration.

- Members of the Steering Group shall only be acknowledged as co-authors if they contributed in other capacities as well.
- If there are disagreements about the substance, content, style, conclusions, or author list of the Main Publication, the Chief Investigator shall ask the Steering Group to arbitrate.

20.3 Beyond 180 days after the official completion of the study

After the Main Publication or after 180 days from Study end date any Investigator or group of investigators may prepare further publications. In order to ensure that the Sponsor will be able to make comments and suggestions where pertinent, material for public dissemination will be submitted to the Sponsor for review at least sixty (60) days prior to submission for publication, public dissemination, or review by a publication committee. Sponsor's reasonable comments shall be reflected. All publications related to the study shall credit the Chief and Co-Investigators as co-authors where this would be in accordance with normal academic practice and shall acknowledge the Sponsor and the Funders.

21 List of protocol appendices

Appendix 1 Summary of Protocol Amendment or Revision History

Appendix 2 Frailty measurement tools

18. Wallis SJ, Wall J, Biram RW, Romero-Ortuno R. Association of the clinical frailty scale with hospital outcomes. *QJM* 2015;108(12):943–9.
19. Basic D, Shanley C. Frailty in an older inpatient population: using the clinical frailty scale to predict patient outcomes. *Journal of Aging Health* 2015;27(4):670–85.
20. Raiche M, Hebert R, Dubois MF. PRISMA-7: a case-finding tool to identify older adults with moderate to severe disabilities. *Arch Gerontol Geriatr* 2008;47(1):9–18.
21. Hoogendijk EO, van der Horst HE, Deeg DJ, Frijters DH, Prins BA, Jansen AP, et al. The identification of frail older adults in primary care: comparing the accuracy of five simple instruments. *Age Ageing* 2013;42(2):262–5.
22. Clegg A, Rogers L, Young J. Diagnostic test accuracy of simple instruments for identifying frailty in community-dwelling older people: a systematic review. *Age Ageing* 2015;44(1):148–52.
23. Joseph B, Pandit V, Zangbar B, Kulvatunyou N, Tang A. et al. Validating trauma-specific frailty index for geriatric trauma patients: A prospective analysis. *Journal of the American College of Surgeons* 2014; 219:
24. Baker S, O'Neill B, Haddon W, Long W. The Injury Severity Score: a method for describing patients with multiple injuries and evaluating emergency care. *Journal of Trauma* 1974;14:187-196.

Appendix 1

Protocol amendment or revision history

| Protocol Version and Date | New text |
|---------------------------|--|
| v1.2 01 03 2019 | Revisions to study schema and section 9.1.1 regarding nominated consultee role and need for personal or participant consent to be gained prior to collection of all data except frailty screening Addition of new section 10.4 providing information on dealing with emotional distress that may arise during the 6-month follow-up |
| v1.3 20 03 2019 | 9.1.1 Revisions to section regarding nominated consultee role in giving advice for patient (participant) to be enrolled into study 10.4 Change of hyperlink on PTSD |
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| | |

Appendix 2

Frailty assessment tools

Clinical Frailty Score [17]

Clinical Frailty Scale

| | |
|--|---|
|  <p>1 Very Fit – People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.</p> |  <p>7 Severely Frail – Completely dependent for personal care, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).</p> |
|  <p>2 Well – People who have no active disease symptoms but are less fit than category 1. Often, they exercise or are very active occasionally, e.g. seasonally.</p> |  <p>8 Very Severely Frail – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.</p> |
|  <p>3 Managing Well – People whose medical problems are well controlled, but are not regularly active beyond routine walking.</p> |  <p>9 Terminally Ill – Approaching the end of life. This category applies to people with a life expectancy <6 months, who are not otherwise evidently frail.</p> |
|  <p>4 Vulnerable – While not dependent on others for daily help, often symptoms limit activities. A common complaint is being “slowed up”, and/or being tired during the day.</p> | |
|  <p>5 Mildly Frail – These people often have more evident slowing, and need help in high order IADLs (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.</p> | <p>Scoring frailty in people with dementia</p> <p>The degree of frailty corresponds to the degree of dementia. Common symptoms in mild dementia include forgetting the details of a recent event, though still remembering the event itself, repeating the same question/story and social withdrawal.</p> <p>In moderate dementia, recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with prompting.</p> <p>In severe dementia, they cannot do personal care without help.</p> |
|  <p>6 Moderately Frail – People need help with all outside activities and with keeping house. Inside, they often have problems with stairs and need help with bathing and might need minimal assistance (cuing, standby) with dressing.</p> | |

| PATIENT QUESTIONS | | |
|---|------------------------------|-----------------------------|
| 1. Are you older than 85 years? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 2. Are you male? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 3. In general, do you have any health problems that require you to limit your activities? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 4. Do you need someone to help you on a regular basis? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 5. In general, do you have any health problems that require you to stay at home? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 6. If you need help, can you count on someone close to you? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 7. Do you regularly use a stick, walker or wheelchair to move about? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| Total checked: | | _____ |

► **Instructions:**

- For questions 3 through 7, do not interpret the answer; simply note the person's answer without considering whether or not it should be "yes" or "no".
- If the respondent hesitates between "yes" and "no", ask him/her to choose one of the two answers.
- If, despite several attempts, he/she persists in answering "a little" or "at times", enter "yes".

SCORING: If the respondent had 3 or more "yes" answers, this indicates an increased risk of frailty and the need for further clinical review.

15-variable Trauma Specific Frailty Index [23]

Appendix. 15-Variable Trauma-Specific Frailty Index

| | |
|------------------------------------|------|
| Comorbidities | |
| Cancer history | |
| Yes | 1 |
| No | 0 |
| Coronary heart disease | |
| Myocardial infarction | 1 |
| Coronary artery bypass grafting | 0.75 |
| Percutaneous coronary intervention | 0.5 |
| Medication | |
| No medication | 0 |
| Dementia | |
| Severe | 1 |
| Moderate | 0.5 |
| Mild | 0.25 |
| None | 0 |
| Daily activities | |
| Help with grooming | |
| Yes | 1 |
| No | 0 |
| Help managing money | |
| Yes | 1 |
| No | 0 |
| Help doing household work | |
| Yes | 1 |
| No | 0 |
| Help toileting | |
| Yes | 1 |
| No | 0 |
| Help walking | |
| Wheelchair | 1 |
| Walker | 0.75 |
| Cane | 0.25 |
| None | 0 |
| Health attitude | |
| Feel less useful | |
| Most time | 1 |
| Sometimes | 0.5 |
| Never | 0 |
| Feel sad | |
| Most time | 1 |
| Sometimes | 0.5 |
| Never | 0 |
| Feel effort to do everything | |
| Most time | 1 |
| Sometimes | 0.5 |
| Never | 0 |
| Falls | |
| Most time | 1 |

(Continued)

Appendix. (Continued)

| | |
|---------------------------|-----|
| Sometimes | 0.5 |
| Never | 0 |
| Feel lonely | |
| Most time | 1 |
| Sometimes | 0.5 |
| Never | 0 |
| Function, sexually active | |
| Yes | 1 |
| No | 0 |
| Nutrition, albumin | |
| <3 | 1 |
| >3 | 0 |