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FRAIL-T: the frailty in major trauma study

Submission date 22/10/2019	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 24/01/2020	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 01/10/2021	**Condition category** Other	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Frailty is a condition that we know can affect people as they get older and means people can be weaker and more vulnerable than they used to be. Things that suggest a person may be frail include: difficulty getting about – slow walking, using a stick or frame, recent or recurrent falls, being confused, and needing help to do everyday tasks. This study aims to determine if it is possible to accurately assess frailty in the emergency department (ED) in patients aged 65 or more admitted with major trauma. The researchers are doing this because it is not currently known how common frailty is in the UK major trauma population or whether it is feasible to carry out early frailty assessment in the ED in this patient group. This early identification could lead to improved pathways of care that positively impact on health and longer term recovery. The researchers also hope to find out if there is a particular measurement tool for frailty in major trauma that more accurately identifies if a patient is frail in the ED. Lastly, they would like to find out about what happens to older patients who are admitted to hospital as a result of trauma, and to see how their recovery is progressing 6 months after discharge.

Who can participate?
Major trauma patients (aged 65 and over) admitted to the Major Trauma Centre requiring activation of a trauma team

What does the study involve?
Participants are assessed for frailty by a nurse in the ED using standardised measurements of frailty. Nurses are 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 carries 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 are 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, are collected on discharge and 6 months.

What are the possible benefits and risks of participating?
Early identification of frailty could lead to improved pathways of care that positively impact on health and longer term recovery. Other research studies have shown that after an accident (which is sometimes referred to as trauma) a frailer person is less likely to recover in the same way as a younger person might. If doctors were able to identify people at risk of being frail early,

for example, as they enter the hospital, they might be able to address their needs more quickly and tailor their care more appropriately. If this is the case then the researchers will go on to make recommendations and write guidelines about to how to best manage a person who has been identified as being frail following trauma. Participation in health-related research aimed at improving care for elderly trauma patients is sincerely valued. 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. 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 major trauma centre 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.

Where is the study run from?
1. Royal London Hospital, Bart's Health NHS Trust (UK)
2. St Mary's Hospital, Imperial College Healthcare NHS Trust (UK)
3. King's College Hospital NHS Foundation Trust (UK)
4. Southampton General Hospital (UK)
5. St George's University Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2019 to October 2020

Who is funding the study?
Burdett Trust for Nursing

Who is the main contact?
1. Mrs Bebhinn Dillane
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Study website
https://www.stgeorges.nhs.uk/frailtystudy/

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2018.0286

Study information

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

Acronym
FRAIL-T

Study objectives
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?

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 22/03/2019, Social Care Research Ethics Committee (Health Research Authority, Ground Floor, Skipton House, 80 London Road, London, SE1 6LH, UK; Tel: +44 (0)20 7972 2545; Email: nrescommittee.social-care@nhs.net), REC ref: 19/IEC08/0006

Study design
Multicenter prospective cohort 3-9 months recruitment with six-month follow-up

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
https://www.stgeorges.nhs.uk/wp-content/uploads/2019/04/2019-03-03-FRAIL-T-Patient-Information-Sheet-v1.2-CLEAN.pdf

Health condition(s) or problem(s) studied
Frailty in elderly major trauma patients

Interventions
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.

Intervention Type
Other

Primary outcome measure
Frailty, initially measured in the emergency department (ED) using three tools; the Clinical Frailty Scale (Rockwood), PRISMA-7 and Trauma Specific Frailty Index (TSFI) and then re-measured and validated using Rockwood within 72 hours of admission

Secondary outcome measures
Measured at point of discharge and at 6 months follow-up:
1. Continuous data: injury severity score, length of stays and EQ-5D-5L scales
2. 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

Overall study start date
23/01/2019

Completion date
02/10/2020

Eligibility

Key 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.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
370

Total final enrolment
372

Key exclusion criteria
1. Patients with no history of traumatic injury
2. Patients under the age of 65 years old
3. Patients discharged from the Emergency Department
4. Patients transferred from another hospital

Date of first enrolment
01/06/2019

Date of final enrolment
02/03/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal London Hospital, Bart's Health NHS Trust
Whitechapel
London
United Kingdom
E1 1BB

Study participating centre
St Mary's Hospital, Imperial College Healthcare NHS Trust
Praed Street
London
United Kingdom
W2 1NY

Study participating centre
King's College Hospital NHS Foundation Trust
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
St George's University Hospitals NHS Foundation Trust
Blackshaw Road
London
United Kingdom
SW17 0QT

Sponsor information

Organisation
St George’s University Hospitals NHS Foundation Trust

Sponsor details
St George's Joint Research Enterprise Service
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St George's, University of London and St George's University Hospitals NHS Foundation Trust
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SW17 ORE
+44 (0)20 8725 3784
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Charity

Funder Name
Burdett Trust for Nursing

Alternative Name(s)
The Burdett Trust for Nursing, Burdett Trust for Nursing | London, burdetttrust

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The study documents are available at: https://www.stgeorges.nhs.uk/frailtystudy/. The researchers hope to publish the protocol in the near future.

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.

Intention to publish date
02/03/2021

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	05/08/2020	06/01/2021	Yes	No
Results article	results	30/03/2021	01/10/2021	Yes	No
HRA research summary			28/06/2023	No	No