

FINE-ST: Frailty and inequality in stroke

Submission date 28/06/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 21/03/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 21/03/2022	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Stroke is the commonest cause of neurological disability and death in the UK (>100,000 per year). The majority of strokes occur in the older generation (58% aged >70 years), whilst over one third (38%) occur in middle-aged adults.

Risk of TIA and stroke are increased in the older population, both age and frailty negatively impacting on outcomes. However, the influence of frailty on stroke outcomes (including physical function and cognition) is not well understood. Second, the association between death from cardiovascular disease (including stroke) and health inequality is also stark with greater inequality associated with worse outcomes from heart attacks and strokes. It is therefore important to understand how diversity and inequality across the region relate specifically to mini-strokes (transient ischaemic attack, TIA) and strokes.

We therefore plan to identify patients assessed through the rapid access TIA clinics and stroke units in the East Midlands with the aim to explore the relationships between frailty, co-morbidity, health inequality and clinical outcomes. This information will help inform future trial design in the frail elderly population with stroke, and enable us to tailor more appropriate, potentially cost saving approaches to treatment.

Who can participate?

Patients aged over 40 years, who have had a stroke in the past 3 years

What does the study involve?

The study simply collects information through administration of a questionnaire at two time points (baseline and 90 days later) in two groups (within 6 weeks of the TIA/stroke; and >6 weeks of the TIA/stroke). The questionnaire at baseline is administered either face-to-face whilst in hospital, or sent via the post if the participant is at home. The questions asked 90 days later will be performed over the telephone.

What are the possible benefits and risks of participating?

None

Where is the study run from?

University of Nottingham (UK)

When is the study starting and how long is it expected to run for?
November 2019 to December 2021

Who is funding the study?
National Institute for Health Research CRN East Midlands (UK)

Who is the main contact?
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Contact information

Type(s)

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

273619

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 273619, CPMS 44689

Study information

Scientific Title

Frailty, Inequality and Co-morbidity: a cohort study in TIA and Stroke

Acronym

FINE-ST

Study objectives

Frailty, co-morbidity and health inequality negatively impact stroke outcomes. Understanding the relationship between frailty, multi-morbidity, inequality and outcome will inform the design of trials for current and future health care interventions in an ageing stroke population.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 18/03/2020, HRA and Health and Care Research Wales (HCRW) (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)2920 785738; Wales.REC1@wales.nhs.uk), ref: 20/WA/0039

Study design

Multi-centre pilot prospective population based longitudinal cohort study

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

To initiate a stroke cohort to inform the relationship between frailty, multi-morbidity, socioeconomic status and clinical outcome in TIA and stroke.

Interventions

The study simply collects information through administration of a questionnaire at two time points (baseline and 90 days later) in two groups (within 6 weeks of the TIA/stroke; and >6 weeks of the TIA/stroke). The questionnaire at baseline is administered either face-to-face whilst in hospital, or sent via the post if the participant is at home. The questions asked 90 days later will be performed over the telephone.

Intervention Type

Other

Primary outcome(s)

1. Frailty will be measured using the CFS, PRISMA 7 and FI-GCA at baseline and day 90.
2. Functional outcome will be measured using the MRS at baseline and day 90.

Key secondary outcome(s)

1. Frailty will be measured using the CFS, PRISMA 7 and FI-GCA at baseline and day 90.
2. Disability will be measured using the Barthel Index (BI) at baseline and day 90.
3. Dysphagia will be measured using the Dysphagia Severity Rating Scale (DSRS) at baseline and day 90
4. Cognition will be measured using the Montreal Cognitive Assessment (MoCA) and Telephone Mini Mental State Examination (t-MMSE) at baseline and day 90
5. Mood will be measured using the Geriatric Depression Scale (GDS) and Zung Depression Scale (ZDS) at baseline and day 90.
6. Inequality will be measured using the English Indices of Deprivation scale at baseline and day 90.
7. Fatigue will be measured using the Fatigue Assessment Scale (FAS) at baseline and day 90.
8. Co-morbidity will be measured using the Charleston Co-morbidity Index (CCI) at baseline.

Completion date

31/12/2021

Eligibility

Key inclusion criteria

1. TIA, ischaemic or haemorrhagic stroke in the last: 6 weeks (subacute group), or 6 weeks to 3 years (chronic group)
2. Age >40 years
3. Written consent from participant or proxy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Probable stroke mimic (e.g. migraine, functional neurology, brain tumour)
2. Life expectancy <3 months
3. Not expected to complete follow up at day 90 (e.g. homeless, out-of-area)
4. Level of consciousness prohibits engagement in baseline measures

Date of first enrolment

17/09/2020

Date of final enrolment

31/12/2021

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Royal Derby Hospital

University Hospitals of Derby and Burton NHS Foundation Trust
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre

Nottingham City Hospital

Nottingham University Hospitals NHS Trust Stroke Services
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Sponsor information

Organisation

University of Nottingham

ROR

<https://ror.org/01ee9ar58>

Funder(s)

Funder type

Government

Funder Name

NIHR CRN East Midlands

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version 1.0	28/11/2019	09/09/2021	No	No