

# FINE-ST: Frailty and inequality in stroke

<b>Submission date</b> 28/06/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 21/03/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 21/03/2022	<b>Condition category</b> 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?  
Dr Tim England, [timothy.england@nottingham.ac.uk](mailto:timothy.england@nottingham.ac.uk)  
Diane Harvard, [diane.havard@nottingham.ac.uk](mailto:diane.havard@nottingham.ac.uk)

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Tim England

**ORCID ID**  
<http://orcid.org/0000-0001-5330-8584>

**Contact details**  
Stroke Trials Unit  
Division of Mental Health and Clinical Neuroscience  
School of Medicine  
Faculty of Medicine & Health Sciences  
University of Nottingham  
Royal Derby Hospital Centre  
Uttoxeter Road  
Derby  
United Kingdom  
DE22 3DT  
+44 (0)1332 724668  
[timothy.england@nottingham.ac.uk](mailto:timothy.england@nottingham.ac.uk)

**Type(s)**  
Public

**Contact name**  
Mrs Diane Havard

**Contact details**  
Stroke Trials Unit  
Queen's Medical Centre  
University of Nottingham  
Nottingham  
United Kingdom  
NG7 2UH  
+44 (0)115 8231775  
[diane.havard@nottingham.ac.uk](mailto:diane.havard@nottingham.ac.uk)

# Additional identifiers

## EudraCT/CTIS number

Nil known

## IRAS number

273619

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

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

## Secondary study design

Cohort study

## Study setting(s)

Hospital

## Study type(s)

Other

## **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet.

## **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 measure**

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.

## **Secondary outcome measures**

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.

## **Overall study start date**

28/11/2019

## **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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

200

**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**

England

United Kingdom

**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

## Sponsor details

Research and Innovation  
University of Nottingham  
East Atrium  
Jubilee Conference Centre  
Triumph Road  
Nottingham  
England  
United Kingdom  
NG7 2RD  
+44 (0)1158467906  
sponsor@nottingham.ac.uk

## Sponsor type

University/education

## Website

<http://www.nottingham.ac.uk/>

## ROR

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

# Funder(s)

## Funder type

Government

## Funder Name

NIHR CRN East Midlands

# Results and Publications

## Publication and dissemination plan

Planned publication in a peer-reviewed journal.

## Intention to publish date

31/12/2022

## 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?
<a href="#">Protocol file</a>	version 1.0	28/11/2019	09/09/2021	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No