

# Falls in stroke survivors

<b>Submission date</b> 29/09/2025	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/10/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 10/10/2025	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

After a stroke, some people may have balance problems leaving them unsteady on their feet and increasing their risk of falling when moving around. Falls are a prevalent and costly concern for stroke survivors discharged from the hospital, with 73% experiencing at least one fall within their first-year post-stroke.

Currently stroke services provide some information about preventing falls after a stroke as part of standard care, but the information and support provided depends on the patient's regional service.

The research aims to find out whether the addition of the Stroke Action Falls (SAF) programme to usual care is better than usual care alone in reducing the number of falls in stroke survivors 12 months after discharge from hospital.

### Who can participate?

Stroke patients aged 18 years and over who were discharged home (their home, a friend /relative's home etc)

### What does the study involve?

Participants are randomly allocated into two groups. Participants allocated to the usual care group will receive the same post-stroke care they would receive if they hadn't joined the trial, and this will be in line with local NHS stroke service practice. Participants who are randomly allocated to SAF plus usual care will receive the NHS service post-stroke care plus will be contacted by their local Falls Lead to complete the SAF programme.

The SAF programme comprises of a checklist and action plan which each stroke patient completes with the support of a Falls Lead, to identify their falls risks and suitable actions to minimise these. The checklist and action plan will be completed at an in-person home visit (where possible), with scheduled follow-ups to ensure that each participant's action plan remains suitable in the 6 months after their discharge from hospital.

Participants record their falls monthly (or have a patient legal representative, friend, relative or carer willing to complete on their behalf) for 12 months after they join the trial. Participants will also be sent questionnaires 3, 6, 9 and 12 months after they join the trial.

### What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?  
University of Nottingham (UK)

When is the study starting and how long is it expected to run for?  
October 2025 to October 2028

Who is funding the study?  
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?  
Aisha Shafayat, aisha.shafayat@nottingham.ac.uk

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Mrs Aisha Shafayat

### Contact details

Nottingham Clinical Trials Unit  
Applied Health Research Building  
University Park  
The University of Nottingham  
Nottingham  
United Kingdom  
NG7 2RD

-  
aisha.shafayat@nottingham.ac.uk

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

331214

### Protocol serial number

CPMS 57461, NIHR158240

## Study information

### Scientific Title

Falls In Stroke Survivors: A randomised controlled trial to evaluate the clinical and cost effectiveness of the Stroke Action Falls rehabilitation programme compared to usual care alone to reduce falls in stroke survivors

### Acronym

FISS

### **Study objectives**

The primary purpose of the trial is to investigate whether the addition of the Stroke Action Falls (SAF) rehabilitation programme alongside usual care reduces the rate of falls in stroke survivors who are discharged home in comparison to usual care alone in the 12 months following hospital discharge.

The secondary objectives are:

1. To find out whether the number of falls reported by participants is less in the SAF intervention arm compared to usual care
2. To determine the effect of SAF on the participant reported severity of falls compared to usual care
3. To find out the effect of SAF on the participant's fear of falling compared to usual care
4. To find out the effect of SAF compared to usual care on participant ability to perform daily living activities
5. To find out the impact of SAF compared to usual care on the psychological stress of patients and carers
6. To find out the effect of SAF compared to usual care on participant quality of life
7. To find out the cost of implementing SAF plus usual care in stroke survivors compared to usual care alone
8. To find out, through interviews, who and in what circumstances, the SAF programme works

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 18/08/2025, North East - Newcastle & North Tyneside 2 Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)207 104 8086, +44 (0)207 104 8140, +44 (0)207 104 8055; newcastlenorthtyneside2.rec@hra.nhs.uk), ref: 25/NE/0135

### **Study design**

Interventional randomized controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Stroke

### **Interventions**

The study is investigating whether the SAF programme compiling of a checklist, action plan and supporting materials (such as training) can reduce falling in patients who are discharged to their home after a stroke. The SAF programme is being tested as part of the FISS trial which is taking place in stroke services across the UK.

Patients will be introduced to the study either in hospital or shortly after discharge, and those who are interested in taking part will be asked to provide consent. Due to the patient population and the challenges some patients face after stroke, consent can be provided written /electronically by the patient, verbally by the patient (witnessed by friend, healthcare professional etc) or provided by a personal consultee. Following consent, but before randomisation, information about the participant will be collected such as their demographic details, information on their stroke and any previous falls and they will be asked to complete questionnaires (these will be asked by a healthcare professional in person or over the phone). Participants will be randomised into one of two groups: SAF plus usual care or usual care alone. Neither the participant, or any other stroke service staff can choose which group each participant is allocated to, this is decided randomly.

Participants randomised to the usual care group will receive the same post-stroke care they would receive if they hadn't joined the trial, and this will be in line with local NHS stroke service practice. Participants who are randomised to SAF plus usual care, will receive the NHS service post-stroke care plus will be contacted by their local Falls Lead to complete the SAF programme.

The SAF programme comprises of a minimum of three sessions with the potential for a fourth triggered session should a participant fall or move home. The sessions take place as follows: Session 1 (2 weeks after randomisation)- in person at participants home (where possible) – the Falls Lead and participant will work through the checklist to identify the appropriate risks and associated actions and the Falls Lead records this on their action plan.

Session 2 (4 weeks after randomisation) - telephone call - Falls Lead calls participant to check on action progress.

Session 3 (6 months after randomisation) - in person at the participant home, the Falls Lead will make another appointment to see the participant at home to review the participants action plan and progress to date.

Triggered session - Falls Lead will contact participant to review the checklist, and actions should they fall or move home.

All participants will be followed up as part of the trial for 12 months and will be asked to complete a monthly falls diary, where they record the number and severity of falls in the previous 30 days. Additionally, they will be sent a questionnaire pack to complete at 3, 6, 9 and 12 months.

A subset of 30 participants in the SAF programme group will be invited to take part in interviews to discuss their experience of SAF. Healthcare professionals delivering the SAF programme will also be invited to share their thoughts. Participant carers will be approached to complete a questionnaire at 6 and 12 months, separate consent will be obtained from the carers to collect this information.

A study within a trial (SWAT) is included in the trial design; the SWAT will investigate whether access to an animated video translated into 4 commonly spoken languages in addition to English in addition to reading the written participant information sheet improves recruitment and retention, in general and specifically of ethnic minority populations, into the FISS trial compared to written information alone. This will be randomised at a stroke service level with half the sites using the animated video and half using written information alone.

The trial aims to recruit 464 participants from stroke services across the UK. Participants may be approached in hospital by the hospital stroke or research teams, or by a member of the

community stroke team once they have been discharged. Stroke patients, carers and/or friends relatives of stroke patients as well as stroke healthcare professionals have all contributed to the design of the FISS trial as well as the patient facing documentation.

### **Intervention Type**

Behavioural

### **Primary outcome(s)**

Annual fall rate: The rate of reported participant falls in the 12 months following randomisation

### **Key secondary outcome(s)**

1. Number of falls reported in each 3-month period (months 1-3, 4-6, 7-9, 10-12) and over all 12 months
2. Number and severity of falls categorised using the National Database of Nursing Quality Indicators (NDNQI) scale monthly for 12 months
3. Fear of falling measured using Short Falls Efficacy Scale-International (Short FES-I) at baseline, 3, 6, 9 and 12 months
4. Activities of daily living measured using Nottingham Extended Activities of Daily Living (NEADL) at baseline, 3, 6, 9 and 12 months
5. Psychological stress (participants and carers (optional)) measured using Patient Health Questionnaire (PHQ-8) at baseline, 3, 6, 9 and 12 months
6. Quality of life measured using EQ-5D-5L at baseline, 3, 6, 9 and 12 months
7. Resource use measured using questionnaire at baseline, 3, 6, 9 and 12 months

### **Completion date**

01/10/2028

## **Eligibility**

### **Key inclusion criteria**

1. Aged 18 years or over
2. Confirmed stroke diagnosis in hospital
3. Planned to be discharged to home, (including sheltered accommodation, somebody else's home)
4. Able to report number of falls and complete questionnaires either individually or via a carer /family member/personal consultee
5. Ability to provide informed consent from participant or an advice form from Personal consultee

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Resident of, or being discharged to a care home
2. And/or on end-of-life pathway

**Date of first enrolment**

01/06/2025

**Date of final enrolment**

01/10/2028

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre****Lincolnshire Community Health Services NHS Trust**

Beech House  
Witham Park  
Waterside South  
Lincoln  
United Kingdom  
LN5 7JH

**Study participating centre****Royal Devon University Healthcare NHS Foundation Trust**

Royal Devon University NHS Ft  
Barrack Road  
Exeter  
United Kingdom  
EX2 5DW

**Study participating centre****Norfolk Community Health and Care NHS Trust**

Norwich Community Hospital  
Bowthorpe Road  
Norwich  
United Kingdom  
NR2 3TU

# Sponsor information

## Organisation

University of Nottingham

## ROR

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

# Funder(s)

## Funder type

Government

## Funder Name

National Institute for Health and Care Research

## Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## 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?
<a href="#">Participant information sheet</a>	version 1.0	24/07/2025	10/10/2025	No	Yes

