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Falls in stroke survivors

Submission date 29/09/2025	**Recruitment status** Recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 10/10/2025	**Overall study status** Ongoing	
Last Edited 28/05/2026	**Condition category** Circulatory System	

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

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Additional identifiers

Integrated Research Application System (IRAS)
331214

Central Portfolio Management System (CPMS)
57461

National Institute for Health and Care Research (NIHR)
158240

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 stoke 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
Mixed

Lower age limit
18 years

Upper age limit
120 years

Sex
All

Total final enrolment
0

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

Wales

Study participating centre
Lincolnshire Community Health Services NHS Trust
Beech House
Witham Park
Waterside South
Lincoln
England
LN5 7JH

Study participating centre
Norfolk Community Health and Care NHS Trust
Norwich Community Hospital
Bowthorpe Road
Norwich
England
NR2 3TU

Study participating centre
Aneurin Bevan University Health Board
Canolfan Lles, Park Road , Ffordd y Parc
Pont-y-pwl
Wales
NP4 6NZ

Study participating centre
North Tees & Hartlepool NHS Foundation Trust
Hardwick Road
Stockton-on-tees
England
TS19 8PE

Study participating centre
Nottinghamshire Healthcare NHS Foundation Trust
Highbury Hospital, Highbury Road
Nottingham
England
NG6 9DR

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

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?
Participant information sheet	version 1.0	24/07/2025	10/10/2025	No	Yes
Protocol file	version 1.1	23/03/2026	28/05/2026	No	No