FISS (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.

Final Version 1.0
24-Jul-2025

Short title:	Falls In Stroke Survivors
Acronym:	FISS
ISRCTN:	33761832
IRAS Project ID:	331214
Study Sponsor:	University of Nottingham
Sponsor reference:	25035
Funding Source:	National Institute for Health Research HTA Programme (NIHR HTA Project NIHR158240) is providing funding for research costs for the project duration to cover study set up, study conduct, analysis and report writing.

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CI and Sponsor Approval Page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), amended regulations (SI 2006/1928) and any subsequent amendments of the clinical trial regulations, GCP guidelines, the Sponsor's (and any other relevant) SOPs, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies and serious breaches of GCP from the study as planned in this protocol will be explained.

This protocol has been approved by:	
Study Name:	FISS
CI Name:	Pip Logan
Study Role:	Chief Investigator
Signature and date:	
Date:	__ __ - __ __ __-20 __ __ (dd-mmm-yyyy)

Statistical approval	
Statistician name:	Trish Hepburn
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Protocol Development

Amendment number	Protocol version number	Type of amendment	Summary of amendment

SYNOPSIS

Title	A randomised controlled trial to evaluate the clinical and cost effectiveness of the Stroke Action Falls (SAF) rehabilitation programme compared to usual care alone to reduce falls in stroke survivors (FISS)
Acronym	FISS
Short title	Falls In Stroke Survivors
Chief Investigator Deputy Chief Investigator	Professor Pip Logan Dr Vicky Booth
Objectives	Primary objective: To determine the effect of SAF and usual care on the rate of falls in stroke survivors in the 12 months after discharge from hospital, compared to usual care alone. Secondary objectives: • To determine the effect of SAF and usual care on the number of falls reported by stroke survivors in the 12 months after discharge from hospital and each 3-month period compared to usual care alone. To determine the effect of SAF and usual care on the participant reported severity of falls in stroke survivors in the 12 months after discharge from hospital and each 3-month period compared to usual care alone. • To determine the effect of SAF and usual care on stroke survivors' fear of falling compared to usual care alone. • To determine the effect of SAF and usual care on stroke survivors' ability to perform instrumental activities of daily living compared to usual care alone. • To determine the effect of SAF and usual care on stroke survivors' and non-professional carers' psychological stress compared to usual care alone. • To determine the effect of SAF and usual care on stroke survivors' quality of life compared to usual care alone. • Establish the health economic implications of SAF • Explore whether SAF may influence fall outcomes, for which stroke survivors, in what circumstances, and why, using a process evaluation with a realist approach.
Study Configuration	Pragmatic, parallel group multicentre randomised controlled trial (RCT)
Setting	10 UK NHS stroke services; intervention at home provided by a 'Falls Lead' from the hospital or appropriate community service.
Sample size estimate	464 participants (232 per arm) will allow detection of a 33% reduction from 2.5 to 1.675 falls/year with 90% power at the 5% significance level (2-sided) assuming 10% loss of evaluable primary outcome data. This sample size also provides 90% power to detect a relative difference of 34% and 36% if the falls rate was lower than expected at 2 and 1.5 falls/year.

Number of participants	464 participants (232 per arm) from 10 UK stroke services Participants will be randomised on a one-to-one basis. For the Process Evaluation we will purposively sample up to 30 individuals who have been randomised to receive SAF. In this we will select individuals from different recruiting services (i.e., those with a greater or less rate of strokes); those with different clinical circumstances (i.e., stroke severity, clinical/discharge journey); and those with different demographic characteristics (i.e., age, gender, ethnicity, socio-economic status). For each participant we will collect data at multiple timepoints. Each participant will represent a case study. They will be interviewed up to three times (interviews may include a family member). Their Falls Lead will also be invited to be interviewed.
Eligibility criteria	**Inclusion Criteria:** Aged 18 or over; confirmed stroke diagnosis in hospital; planned to be discharged to home, (including sheltered accommodation, somebody else's home), able to report number of falls and complete questionnaires either individually or via a carer/family member/personal consultee; provided consent* or assent from consultee.** **Exclusion Criteria:** Resident of, or being discharged to, a care home***; and/or on end-of-life pathway. *Consent will be accepted by any mechanism suitable to the participants' abilities. ** Stroke survivors who are lacking capacity to give consent will be eligible to take part as they are as likely to fall as other patients and may benefit from the intervention. We will endeavour to make the falls recording as accessible as possible to include people with aphasia, writing, reading and communication limitations (please see the data collection section). ***Care home residents are excluded as the AF programme is being rolled out by NHSE through their Enhancing Health in Care Homes programme (Personal Communication: Emma Self. Service, Policy, Delivery and Implementation Lead for Enhanced Health in Care Homes NHSE) and implementation is being studied by a team led by Professor Logan with the Wessex ARC (10).
Description of interventions	Usual care plus SAF program. The SAF program will be delivered a maximum of five times. Session 1: Within 2 weeks of randomisation Session 2: Within 4 weeks of randomisation Session 3: 6 months post-randomisation Triggered visit: following first fall or change of residence The comparator to the intervention will be usual care, where usual care is defined as the absence of staff trained in any version of AF (including SAF) and AF documents and processes embedded in record systems.
Duration of study	Study duration: 48 months (start date September 2024). Recruitment will begin once all relevant approvals are in place. Participant duration is for 12 months.
Randomisation and blinding	Participants will be randomised (1:1) to one of the two groups using a minimisation algorithm with a random element using stroke service (including hospital and community care), residence (living alone or living

	with others), age (>65 or ≤ 65 years), and baseline Modified Barthel Index (MBI) score (>14 or ≤14) as factors. Participants and the health care professionals providing the SAF intervention cannot be blinded to treatment allocation. The NCTU team analysing the data and the Chief Investigator will remain blinded throughout. One or more designated members of the trial management team may interact with participants to obtain outcome data and therefore may become unblinded to treatment allocation.
Outcome measures	**Primary outcome:** Annual fall rate: The rate of falls over the year from randomisation **Secondary outcomes:** • Number of falls in each 3-month period (months 1-3, 4-6, 7-9, 10-12) and over all 12 months • Number and severity of falls • Fear of falling • Activities of daily living • Psychological stress (Participants and carers(optional)) • Quality of life • Resource use Falls data will be collected monthly. The number of falls will be recorded, and the severity of each fall categorised using the National Database of Nursing Quality Indicators (NDNQI) scale. The following measures will be collected at baseline, 3, 6, 9 and 12 months: • Nottingham extended activities of daily living (NEADL) • Short Falls Efficacy Scale-International (Short FES-I) • Patient Health Questionnaire (PHQ) • Patient Health Questionnaire (PHQ) to assess psychological distress of non-professional carers • Quality of life (EQ-5D-5L) • Resource usage **Safety outcomes:** Adverse events (serious and non-serious) will not be collected in this study. Falls and falls severity will be specifically collected as primary and secondary outcomes monthly. **Process evaluation outcome measures:** Contextual and individual factors and processes which impact upon the delivery and success of SAF in stroke rehabilitation.
Statistical methods	The primary outcome is the rate of falls over the year from randomisation. The number and severity of falls will be collected monthly via short forms (paper, electronic or telephone). Evaluation of the primary outcome will be performed on an intention to treat basis without imputation of missing data and using a negative binomial model including minimisation factors. Secondary outcomes will be analysed using appropriate regression models which include the

	minimisation factors and the baseline value of that variable where available.
Health Economics	**Economic Outcomes:** The primary economic outcome will be quality-adjusted life years using the EQ-5D-5L self-reported at baseline,3, 6, 9 and 12 months along with survival. Falls averted will be considered as a secondary outcome if appropriate. **Resource Use:** Data collection will include the resource use and cost implications for the delivery of the SAF programme. This will be alongside patient self-reported resource use for health service and broader societal costs related to falls and their prevention in the usual care and the intervention groups. It will include utilisation of secondary care, primary care, medications, equipment and aids, social care, indirect costs (employment), informal care and out of pocket expenses at 3,6,9 and 12 months. **Analysis:** The economic analysis will report the incremental cost effectiveness ratio (ICER) for SAF compared with usual care where appropriate. The costs and benefits will be analysed using the incremental Net Monetary Benefit (iNMB) approach. Cost Effectiveness planes and cost effectiveness acceptability curves (CEACs) will be plotted between SAF and usual care.

ABBREVIATIONS

AE	Adverse Event
AF	Action Falls
AUC	Area Under the Curve
BNF	British National Formulary
CEACs	Cost Effectiveness Acceptability Curves
CI	Chief Investigator
CRF	Case Report Form
DMC	Data Monitoring Committee
EOI	Expression of interest
FES-I	Falls Efficacy Scale-International
FinCH	Falls in Care Home (study)
GCP	Good Clinical Practice
GP	General Practitioner
HEAP	Health Economic Analysis Plan
ICER	Incremental Cost Effectiveness Ratio
ICF	Informed Consent Form
iNMB	Incremental Net Monetary Benefit
JLA	James Lind Alliance
NDNQI	National Database of Nursing Quality Indicators
NEADL	Nottingham Extended Activities of Daily Living
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NCTU	Nottingham Clinical Trials Unit
PHQ	Patient Health Questionnaire
PI	Principal Investigator (at a local centre)
PIS	Participant Information Sheet
QALY	Quality Adjusted Life Year
QA	Quality Assurance
QC	Quality Control
QoL	Quality of Life
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
R&D	Research and Development department
SAE	Serious Adverse Event
SAF	Stroke Action Falls
SAP	Statistical Analysis Plan
TMF	Trial Masterfile
TMG	Trial Management Group
ToR	Terms of Reference
TSC	Trial Steering Committee

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1. STUDY BACKGROUND INFORMATION AND RATIONALE

In the UK NHS and social care, falls prevention is part of every stroke rehabilitation programme as falls can lead to fractures, immobility, psychological distress, and fear of falling ([1, 2]). 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[3]. While 88% of stroke survivors are discharged to community settings[4] and a third are of working age[5], there is a notable gap in effective, evidence-based multifactorial falls prevention interventions.

Current UK National Clinical Stroke Guidelines (2023) recommend assessment but only minimal intervention[6], but with no published evidence-based multifactorial falls prevention interventions for stroke survivors, there is a clear need for further research into multifactorial strategies that encompass education, environmental adaptations, strength and balance training, and approaches targeting stroke-specific factors. Previous research evidence is limited but suggests exercise might reduce fall rates but highlight a lack of high-quality evidence.

A 2019 Cochrane review of falls prevention intervention for stroke survivors[7] included 1,358 participants from 14 studies, but only one was focused on a multifactorial intervention. Ten studies evaluated exercise, three an environmental adaptation (glasses, pre-discharge home visits, servo-assistive rollator), and one transcranial stimulation. Results showed that exercise may reduce the rate of falls but there was uncertainty about this result (rate ratio 0.72, 95% CI 0.54 to 0.94, 765 participants).

Despite growing interest in stroke-specific falls prevention, study are limited, with the ongoing Australian Falls in Stroke Trial (FAST)[8] representing the most advanced effort. Within FAST the intervention group receive a home-based, tailored intervention consisting of habit-forming exercise (LiFE), community mobility and home safety training depending on their level of disability.

Action Falls (AF) (formally known as the Guide to Action to Prevent Falls) is an expert-led, individualised, self-management intervention where patients are empowered to reduce avoidable falls. It is a multifactorial falls prevention action plan, comprising a review of 30 evidence-based items that are known to increase risk of falls.

AF has been found to be effective in both clinical service and care home settings[4]. It has been used since 2012 by Nottingham City Stroke Rehabilitation Service (System1) and NHS England recommended its implementation in care homes across England (Personal Communication: Emma Self. Service, Policy, Delivery and Implementation Lead for Enhanced Health in Care Homes NHSE) and an implementation study in care homes is underway[9].

However, the positive result cannot be generalised to the acute stroke population as a) the care home environment is different from the home environment, and b) only 16% of the care home study participants were stroke survivors. That said, there are similarities in the populations in physical, cognitive and psychological characteristics, to suggest that AF could be beneficial to stroke survivors. The stroke-adapted AF intervention aims to reduce falls rates in newly discharged stroke patients thereby decreasing fractures, fear of falling and increasing independence in activities of daily living.

The NHS England's Demand Signalling asks for research into the management of common stroke complications and into the optimal ways to manage and treat the non-apparent (hidden) effects of stroke. Falls are a truly 'hidden' effect of stroke. They are rarely mentioned or explicitly focused on within research and patients shy away from reporting them. This is evidenced by the 2019 Cochrane review of falls prevention interventions for stroke only being

able to include 14 studies[7] and Age UK published “Don’t mention the ‘F’ word”[10], a report that evidenced how people are hesitant to mention a fall in case it triggers care home placement.

Our research fits with three James Lind Alliance (JLA) Priorities. Firstly, falling causes severe emotional (psychological) distress though the ongoing fear of falling[11]. Our PPI group stated this can lead to isolation and poorer mobility if carers are afraid when the stroke survivor moves and then only encourage seated activity. SAF is aimed at all stroke survivors including people with severe stroke (people can fall from a wheelchair or hoist), it is applied over 6 months (continuing after usual rehabilitation has ceased) and is embedded in people’s lives (families, friends, neighbours, visitors) meaning it addresses the long-term needs of people with stroke. Thirdly, as the intervention, which can be provided in-person and, potentially, via telehealth includes information provision and shared decision-making, it enables people with stroke to take control of their own lives.

FISS UK and Australia Collaboration

This study is one of two parallel international RCTs using the Stroke AF intervention, with a second study conducted in an Australian stroke population. The Australian study (FISS-Australia) will replicate the key elements of the UK study, allowing for pooled individual participant meta-analysis to enhance statistical power for secondary and exploratory outcomes.

Given the key differences between UK and Australian healthcare systems, running two independent studies is essential to evaluate intervention delivery, acceptability, and implementation feasibility across settings. While the UK NIHR-funded study will provide definitive evidence on the effectiveness and cost-effectiveness of SAF in the UK, insights from both studies will inform global policy and practice.

Key benefits of this collaboration include:

- Cross-country comparisons of outcomes in distinct healthcare systems.
- Shared protocols, data collection methods, and analysis plans to enhance study efficiency.
- Separate primary publications with future pooled data analysis to explore treatment moderators (e.g., age, stroke severity).
- Strengthened research capacity through mentoring and training initiatives, including the NIHR Associate Principal Investigator scheme in the UK.

Together, these studies hope to provide world-leading evidence to optimise fall prevention interventions for stroke survivors internationally.

2. STUDY OBJECTIVES AND PURPOSE

2.1 PURPOSE

The purpose of the study is to investigate whether the addition of the Stroke Action Falls (SAF) rehabilitation programme alongside usual care reduces falls in stroke survivors who are discharged home (in the community) in comparison to usual care alone.

The study will evaluate the clinical and cost-effectiveness of the SAF rehabilitation programme from the perspective of patients and their carers (both medical professionals and significant others) via participant reported questionnaires as well as interview data for a sample of participants who have received the SAF intervention.

2.2 PRIMARY OBJECTIVE

To determine the effect of SAF and usual care on the rate of falls in stroke survivors in the 12 months after discharge from hospital, compared to usual care alone.

2.3 SECONDARY OBJECTIVES

The secondary objectives are

- To determine the effect of SAF and usual care on the number of falls reported by stroke survivors in the 12 months after discharge from hospital and each 3-month period compared to usual care alone. To determine the effect of SAF and usual care on the participant reported severity of falls in stroke survivors in the 12 months after discharge from hospital and each 3-month period compared to usual care alone.
- To determine the effect of SAF and usual care on stroke survivors' fear of falling compared to usual care alone.
- To determine the effect of SAF and usual care on stroke survivors' ability to perform instrumental activities of daily living compared to usual care alone.
- To determine the effect of SAF and usual care on stroke survivors' and non-professional carers' psychological stress compared to usual care alone.
- To determine the effect of SAF and usual care on stroke survivors' quality of life compared to usual care alone.
- To establish the cost-effectiveness of introducing SAF into post-stroke care from an NHS and personal social services perspective and from a broader societal perspective.
- To explore whether SAF may influence fall outcomes, for which stroke survivors, in what circumstances, and why, using a process evaluation with a realist approach.

3. INTERNAL PILOT

An internal pilot review will take place after ten months, to assess the ongoing feasibility of the study. This will assess recruitment, adherence and primary outcome collection.

Table 1: Stop-go criteria for internal pilot phase

Parameter for feasibility assessment	**Progression criteria at 10 months into recruitment**		
Recruitment	**GREEN**	**AMBER**	**RED**
Number of participants randomised of the 176 anticipated over 10 months	≥100%	50[4]% to 99%	<50%
Number of services open of the 10anticipated[1]	≥100%	50% to 99%	<50%
Adherence			
Number of SAF interventions started within 2 weeks of randomisation[2]	≥100%	75% to 99%	<75%
Primary outcome collection			
% of participants returning at least 50% of their monthly falls data[3]	>90%	50% to 90%	<50%

Progression to main study	Proceed to main study if all criteria are met	Discuss with TSC: Action needed adapt and resolve issues	Discuss with TSC and funder: Consider stopping

[1]Number of services will be assessed, but this is not an independent assessment criterion. This will only be considered significant if recruitment is considered unacceptable overall.

[2]Calculation made based on number randomised by Month 9.

[3]A one month time window for the return of data will be allowed for this calculation

[4]50% of planned recruitment would mean that the study would be 4 months behind in its recruitment projections

The Trial Management Group (TMG), Trial Steering Committee (TSC) and Data Monitoring Committee (DMC) will meet to assess study progress against these criteria as soon as possible after the timepoint of 10 months after randomisation of the first participant. The TSC will make a recommendation to the funder about study progression.

4. DETAILS OF INTERVENTION

4.1 DESCRIPTION

The SAF Intervention is an expert-led, manualised self-management approach to reduce falls, using a training package, education booklet and a checklist and action plan that is individualised for each stroke patient (participants). The healthcare professional training will include all the information a healthcare professional requires to deliver the SAF intervention to stroke patients, with associated communication support documentation. The SAF checklist includes a definition of a fall along with a list of risk factors and suggested actions on several key themes including falls history, medical history and environment. The action plan is where the stroke patient's individual risks and actions are recorded to be used as a reminder of the actions they need to take and provide a place for them to track their own progress of complete and outstanding actions.

4.2 HEALTH CARE PROFESSIONAL TRAINING

At least one registered stroke trained health care professional within each stroke service (e.g. hospital or associated rehabilitation unit or community service) will be trained by the research team at University of Nottingham to deliver the SAF intervention to randomised participants. Following training, all SAF trained staff will be referred to as a Falls Lead.

Training will include guidance on how to deliver SAF to participants and their families (completing the action plan and checklist) and use case studies to practice delivering and completing the action plan. Following the training, Falls Leads will be given a manual to support the implementation of SAF within the participant's home. The manual will include the training session slides, falls information (including definitions of falls and causes of falls) and guidance on how to complete the SAF checklist. University of Nottingham research team will provide Falls Leads with ongoing support with intervention training and delivery throughout the study.

4.3 STROKE ACTION FALLS (SAF) SESSIONS

The SAF program will be delivered a maximum of five times.

<u>Session 1 (up to 2 weeks post-randomisation)</u>
The Falls Lead will make an appointment to see the participant at home and begin the SAF programme. They will provide all intervention participants with the education booklet, checklist and action plan and work with participants and family/carer (if appropriate), to review the SAF

checklist and identify the appropriate actions for the participant to work through. This may be started during the initial visit.

Participants will be advised to contact their Falls Lead if they fall or move residence during the first 6 months of their study participation. This participant-initiated contact will trigger a review of the checklist and action plan to ensure it remains suitable.

Session 2 (4 weeks post-randomisation – approx. 2 weeks after session 1)
Within the first two weeks after the initial session the Falls Lead will phone the participant to check on their progress and provide guidance as necessary on unresolved actions identified during the initial visit.

For participants unable to communicate by phone, an alternative method of follow-up will be agreed during session 1 in line with local NHS policy.

Session 3 (6 months post-randomisation)
Six months after randomisation 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 (Following first fall **or** first residence change)
Following the first reported fall
After receiving notification from the participant of their first fall, the Falls Lead should contact the participant to review their action plan and ensure its ongoing suitability. If the participant has not moved residence since their first intervention visit, this follow-up assessment can be made in person or by phone.

Following a residence change
After receiving notification from the participant that they have changed residence, the Falls Lead will make an appointment to see the participant in their new home and provide them with a new checklist and action plan.

Any participant who falls or moves residence will have a triggered SAF visit to review their action plan and ensure it remains appropriate. Visits will only occur on the first fall or first residence change and must be within the first 6 months post-randomisation. If a participant has multiple falls or house moves or has both a fall and a house move they will only have a maximum of 1 triggered session in total.

Session format
Where possible, Session 1, Session 3 and a Residence change session should all be conducted as an in-person home visit. Session 2 and the First reported fall session can be conducted by remotely (telephone or video call), where appropriate.

Relocation during the study
Participants must live within the agreed geographical area to be eligible to participate in FISS UK (see section 5.6). If a participant relocates outside the area during the study, they can continue providing monthly falls data and responding to follow-up questionnaires but their continued participation in the SAF intervention will be subject to stroke service discretion. Decisions will be made on a case-by-case basis, depending on service-specific resources and logistics. Participants who do not receive the intervention due to relocation can continue in the study.

Data collection
Falls Leads will be required to record the details of each SAF visit including (but not limited to) visit date, duration (including travel), and type (in-person, video call, or phone call) and whether

the visit was completed. In instances where a visit is not completed, the reasons for the missed visit must be reported.

4.4 FISS FALLS DIARY

All study participants will be given a Falls Diary, for their personal use, which will be posted to them by the central research team following randomisation. The Falls Diary will contain a definition of a fall. Participants will be asked to record the number of falls they have over each month and record the severity of the fall based on fall outcome in line with the NDNQI definitions (e.g. fall resulted in injury that required surgery would be classed as 'major' or for FISS participant documentation, category D). Participants will be encouraged to use the Falls Diary, but use of the diary is not a requirement of the study. Falls Diaries will not be collected or used as source data.

Reminders (electronic or telephone) to participants to report monthly falls data will be coordinated by the central research team. Participants will have the option to provide falls data by post, online form or telephone. Reminders and follow-up calls may be made for non-responders. Participants will be followed up a maximum of twice each month to ask for falls data.

To ensure accurate data collection, the database will be restricted to allow falls data entry only within a one-year period from the randomisation date. Any falls occurring before or after this period will be prevented from being recorded in the system.

5. STUDY DESIGN

5.1 STUDY CONFIGURATION

FISS is a pragmatic, parallel group, multicentre, randomised controlled trial (RCT) comparing the SAF intervention and usual care to usual care for people discharged home after a stroke, confirmed using either a CT or an MRI scan.

Embedded within the study is a theoretically informed mixed-methods process evaluation study. Qualitative data will be collected during interviews with participants (and dyad interviews with some family members) and their Falls Lead. See section 9 for further details.

A health economic evaluation will be conducted to establish the cost-effectiveness of the SAF intervention in addition to usual care compared to usual care alone. See section 8 for more details.

A study within a trial (SWAT) will be included to determine whether access to an animated video translated into four commonly spoken languages, in addition to the participant information sheet, improves recruitment and retention into the FISS study compared to the participant information sheet alone. See section10.

5.1.1 Primary Endpoint

The primary outcome is the rate of reported participant falls in the 12 months following randomisation.

Table 2: Primary Endpoint

Objective	Endpoint Measure	Time Point	Method of Collection

To determine the effect of SAF and usual care on the rate of falls in stroke survivors in the 12 months after discharge from hospital, compared to usual care alone.	Number of falls reported by a participant expressed as a rate.	Randomisation to month 12.	Participant reported by short forms online, by phone or by post each month.

5.1.2 Secondary Endpoint

Table 3: Secondary Endpoints

Objective	Endpoint Measure	Time Point	Method of Collection
To determine the effect of SAF and usual care on the number of falls reported by stroke survivors in the 12 months after discharge from hospital and each 3-month period compared to usual care alone.	Number of falls reported by a participant.	Monthly for 12 months Every 3 month period for 12 months (month 1-3, 4-6, 7-9, 10-12)	Participant reported on-line, by phone or by post each month.
To determine the effect of SAF and usual care on the participant reported severity of falls in stroke survivors in the 12 months after discharge from hospital and each 3-month period compared to usual care alone.	Participant reported severity of falls.	Randomisation to month 12 as well as each 3-month period (month 1-3, 4-6, 7-9, 10-12)	Participant reported by short forms online, by phone or by post each month. Number and type of fall severity (using NDNQI[12] scale).
To determine the effect of SAF and usual care on stroke survivors' fear of falling compared to usual care alone.	Participant reported fear of falling.	6 and 12 months	Participant Questionnaire – Short Falls Efficacy Scale-International (Short FES-I)[13] (7 questions, resulting in score between 7 and 28).
To determine the effect of SAF and usual care on stroke survivors' ability to perform instrumental	Participant reported independence.	6 and 12 months	Participant Questionnaire – Extended activities of daily living

Objective	Endpoint Measure	Time Point	Method of Collection
activities of daily living compared to usual care alone.			(NEADL)[14] (22 questions, resulting in score between 0 and 22).
To determine the effect of SAF and usual care on stroke survivors' and non-professional carers' psychological stress compared to usual care alone.	Participant reported psychological stress.	6 and 12 months	Participant Questionnaire – Patient Health Questionnaire (PHQ).[15]
	Non-professional carer reported psychological stress.	6 and 12 months	Carer Questionnaire- Patient Health Questionnaire Carer (PHQ) to assess psychological distress of non-professional carers.
To determine the effect of SAF and usual care on stroke survivors' quality of life compared to usual care alone.	Participant reported quality of life.	3, 6, 9 and 12 months	Participant Questionnaire – EQ-5D-5L[16] Index/preference scores (minimum value -0.285 and maximum value 1) will be generated from participant responses to the 5 domains.
			Participant Questionnaire – EQ-5D-5L[16] EQ-VAS (score between 0 and 100).
To determine the cost of implementing SAF and usual care in stroke survivors compared to usual care alone.	Additional treatment and healthcare usage	3, 6, 9 and 12 months	Participant Questionnaire – Health Economics
Process evaluation. To determine whether the SAF	Final interview	< 12 months	Qualitative interviews Number of adaptations made

Objective	Endpoint Measure	Time Point	Method of Collection
programme may influence fall outcomes for who and in what circumstances			Number of falls

5.1.3 Safety Endpoints

The intervention being evaluated is a falls reduction action plan with no expected adverse reactions. The number and severity of falls are collected throughout the study and will be reported as study outcomes. No additional endpoints will be collected for safety.

The severity of each fall will be recorded according to the NDNQI[12] fall severity scale which categorises injurious falls into five levels of severity: None, Minor, Moderate, Major and Death. As this will be collected directly from the participants, "Death" will be removed from the self-report severity scale and where applicable captured separately. For the participant documentation the severity levels will be relabelled as A, B, C, and D, with accompanying descriptions provided to participants instead of the original severity terms.

5.1.4 Stopping rules and discontinuation

There are no planned formal interim analyses. The Sponsor and funder reserve the right to discontinue this study at any time for failure to meet expected recruitment goals, for safety or any other administrative reason. The Sponsor and funder will seek advice from the TSC and DMC before making this decision.

5.2 RANDOMISATION AND BLINDING

5.2.1 Randomisation

Eligible participants will be randomised (1:1) to receive either SAF and usual care or usual care alone. In line with the pragmatic nature of the study, usual care will be determined by local policy and practices.

Treatment allocation will be via a secure, concealed, web-based randomisation service maintained by the Nottingham Clinical Trials Unit (NCTU) hosted on a secure server and accessed via a secure website. Allocation will use a minimisation algorithm including a random component and will minimise on the criteria listed in Table 4 which are all deemed to have potential association with the primary outcome.

Table 4: Minimisation criteria

Stroke service	Minimise imbalances with local factors such as ethnicity and deprivation.
Residence	Minimise imbalances related to discharge residence: living alone or living with others.
Age	Age of participant is associated with the chance of falling and severity of falls. The following two categories will be used: • Aged > 65 years at randomisation • Aged ≤ 65 years at randomisation
Baseline MBI score	MBI score is associated with the chance of falling and severity of falls. The following two categories will be used:

	• Baseline MBI score > 14 • Baseline MBI score ≤ 14

5.2.2 Blinding

Participants and the health care professionals providing the SAF intervention cannot be blinded to intervention allocation. This may introduce unconscious bias that has the potential to either inflate or deflate the number of reported falls. However, there is no reason to assume that there would be systematic inflation or deflation of falls in either of the two groups. At a minimum, the NCTU team analysing the data and the Chief Investigator (CI) and Deputy Chief Investigator (DCI) will be blinded to the participant randomised intervention.

Study role	Blinding status	Comments
Participant	Not blinded	The participant will know whether they receive the additional SAF intervention as well as their usual care.
Principal Investigator and other stroke service staff (research staff or stroke healthcare professionals)	Not blinded	The stroke service staff will be unblinded to the treatment allocation either as part of the study team randomising and delivering the intervention or as part of the usual care team who could become aware following documentation in patient medical notes or usual care home visits.
Chief Investigator and Deputy Chief Investigator	Blinded	The CI and deputy CI will remain blinded to treatment allocation overall.
Database Programmer	Not blinded	The database programmer will be responsible for the management of the randomisation system and will have access to unblinded datasets within the study database.
Study Management staff within NCTU	Blinded as far as practically possible	The study management team will remain blinded where possible and not have access to information such as SAF visit data that could unblind them. One or more members of the study management team may take up the role of follow-up coordinator and therefore may be unblinded.

Follow-up Coordinator	Not blinded	The study follow-up coordinator will not be blinded to study intervention to allow full access to study data to support follow-up telephone calls with participants.
Data Management	Not blinded	Data management staff will have access to the unblinded datasets within the study database to ensure data quality and undertake central monitoring activities. They will have access to all data fields across the SAF intervention participants and usual care.
Study Statistician and Senior Study Statistician	Blinded	The study and senior study statistician will not have access to intervention allocations or data which has the potential to unblind until after the first database lock for the analysis.
Independent Statistician	Not blinded	A statistician, independent to the study team, will be responsible for the generation of closed reports for the Data Monitoring Committee (DMC) and other reports with potentially unblinding data and will therefore be unblinded to study treatment allocations.

Maintenance of randomisation codes and procedures for breaking code
The stroke service staff, Falls Leads and participants (and carers and/or friends/relatives as applicable) will be aware of which arm the participant is randomised to. Therefore, there is no process required for code breaking. NCTU will retain the randomisation codes for participants for the duration of the study.

At their request, the DMC may review unblinded data. This will be prepared by a statistician from NCTU not involved in the study (i.e., an independent statistician), who will store all unblinded output in a secure and access-controlled area.

The study statistician will receive the treatment allocation only after the SAP has been finalised and approved, and the database has been locked.

5.3 STUDY MANAGEMENT

The study is funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) Programme. The Sponsor is the University of Nottingham.
The study will be managed from a central coordinating centre at University of Nottingham supported by Nottingham Clinical Trials Unit.

The Chief Investigator (CI) has overall responsibility for the study and shall oversee all study management. The data custodian will be the CI.

5.3.1 Study Committees

Trial Management Group (TMG)
The TMG will meet on a regular basis (approximately monthly) and will be responsible for the day-to-day management of the study. The CI, deputy CI, co-applicants (where required) and representatives from FISS Australia, qualitative and NCTU teams (study management, data management, statistical and health economic representatives) are responsible for the day-to-day management of the study and will form the TMG.

The TMG will ensure high quality study conduct, to time and within budget, monitor all aspects of the conduct and progress of the study, ensure that the protocol is adhered to and take appropriate action to safeguard participants and the integrity of study itself. The TMG will also be responsible for ensuring project milestones are achieved.

Trial Steering Committee (TSC)
The role of the TSC is to maintain oversight of the study, monitor progress and provide advice to the TMG and funder. The TSC will consist of an independent chair, and other independent members with clinical and research expertise including parent representatives. The CI and Study Manager will be non-independent (non-voting) members of the TSC. Other members of the TMG may join TSC meetings (in a non-independent, non-voting capacity) as deemed necessary. Representatives from the funder and Sponsor may be invited to attend as observers.

The TSC will operate in accordance with a study-specific charter (outlining the committee's terms of reference), the funder's guidelines and the relevant NCTU Standard Operating Procedures (SOPs).

The TSC will meet at least once a year during the study, including following completion of a 10-month internal pilot period to review the results of the internal pilot and decide on recommendations regarding study progression. Additional meetings may be called and the TSC may, at their discretion, request to meet more frequently.
The TSC will consider and act, as appropriate, upon the recommendations of the Data Monitoring Committee.

The Data Monitoring Committee (DMC)
The role of the DMC is to give advice on whether the accumulated data from the study, together with the results from other emerging research, justifies the continuing recruitment of participants.

Members of the DMC will be independent of the study and have relevant clinical, statistical and other methodological experience of clinical studies.

The DMC will operate in accordance with a study-specific charter (outlining the committee's terms of reference), the funder's guidelines and the relevant NCTU SOPs.

The DMC will meet at least once a year during the study, including following completion of the 10-month internal pilot phase to review the results of the internal pilot and make recommendations to the TSC on study progression. They will also be responsible for monitoring the data for consistency with the sample size assumptions and recommending, if necessary, a requirement for changes to assumptions which could lead to changes in the planned sample size. Additional meetings may be called, and the DMC may, at their discretion, request to meet more frequently or continue to meet following completion of recruitment. An emergency meeting may also be convened if a safety issue is identified.

The DMC will report directly to the Chair of the TSC who will convey the findings of the DMC to the TSC, TMG and Sponsor as applicable.

5.4 DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT

Study Duration: Study funding is for 48 months (from the start of contract delivery to final report).

Participant Duration: The participation period for FISS is 12 months following randomisation.

End of the study
The end of study will be the final database lock. The end of participant involvement in the study will be the last data collection (at 12 months post-randomisation) of the last participant. NCTU will notify the Research Ethics Committee (REC) that the study has ended within 90 days of the end of study. Should the study be terminated early, NCTU will inform REC within 15 days of the end of study. NCTU will provide them with a summary of the clinical study report within 12 months of the end of study.

Selection of participants
Identification
Participants will be identified from 10 hospital stroke services across the UK which should ensure a diverse mix of participants. Patients who are aged 18 or over who have a confirmed stroke diagnosis (CT or MRI scan) and are potentially eligible will be approached about the FISS study.

Please see section 5.7 for more information on identification of participants and section 5.8 for information on withdrawal/discontinuation/change in participant status.

5.5 SCREENING

The participating stroke services will maintain a list of potentially eligible patients who were identified and approached about the study. Stroke services will enter anonymised data (totals) from the logs monthly into the study database.

The NCTU may request copies of the full screening logs from recruiting stroke services for the purpose of monitoring.

Please see section 6.1 for more information on screening of participants.

5.6 ELIGIBILITY CRITERIA

The target population are patients who have had a confirmed stroke (MRI or CT scan) with planned discharge to their/a home. Eligibility criteria are assessed as part of routine

assessments, no additional study-specific assessments are required to ascertain eligibility for FISS.

5.6.1 Inclusion Criteria

- Aged 18 or over
- Confirmed stroke diagnosis in hospital
- Planned to be discharged to home, (including sheltered accommodation, somebody else's home)*
- Able to report number of falls and study questionnaires either individually or via a carer/family member/personal consultee
- Ability to provide informed consent from participant or personal consultee.

5.6.2 Exclusion Criteria

- Resident of, or being discharged to, a care home
- On end-of-life pathway

*Geographical Eligibility for Participation

Participants must live within the geographical area covered by the participating stroke service delivering the intervention, as determined by postcode. However, the specific postcodes included will vary by stroke service. Each stroke service will decide its eligible geographic criteria based on its standard care approach, some will use the participant's home address, while others will align care with Primary Care Networks (PCNs) and GP practices. This ensures consistency with existing healthcare structures. Individuals residing outside the designated area will not be eligible to take part in the study. Postcode information and any associated restrictions will be included in the localised study information.

If a participant relocates outside the area during the study, they can continue providing monthly falls data and responding to follow-up questionnaires but their continued participation in the SAF intervention will be subject to stroke service discretion. Decisions will be made on a case-by-case basis, depending on service-specific resources and logistics.

Carers eligibility (for completion of the carer questionnaire):

Inclusion Criteria

- Individuals who provide unpaid care and support to a stroke survivor.
- This includes:
    - Partners or spouses
    - Family members (e.g., parents, children, siblings)
    - Friends or neighbours
- Carers who assist with daily living tasks, emotional support, coordination of care, or other forms of assistance related to the stroke survivor's recovery.

Exclusion Criteria

- Individuals who are paid professionals providing care (e.g., nurses, support workers, personal care assistants).

5.7 INFORMED CONSENT

All participants must provide informed consent prior to participation (or personal consultee advice for those who lack capacity). Informed consent or advice can be taken in person or remotely. The informed consent form (ICF)/electronic ICF (eICF) will be signed and dated by either the participant, witness (in the case of people who have capacity to consent for

themselves but are physically unable to sign a consent form) or personal consultee, prior to any research activity starting. The PI or delegate will explain the details of the study, provide the PIS and ensure that sufficient time is given to consider participation. The PI or delegate will answer any questions that the patient or their carer/family has concerning participation in the study.

In some cases, patients may be discharged from the hospital relatively soon after their stroke, requiring consent to be obtained remotely. These patients should be provided with a FISS discharge pack (including a discharge letter, and the PIS) either at the point of hospital discharge or sent (post or email) to them soon after discharge. This discharge pack can be provided by any member of research staff or FISS trained stroke healthcare professionals. The discharge pack will include contact details of the local research team, allowing potential participants to easily contact them if they wish to express their interest in taking part or ask any questions.

Stroke services will be asked to contact all potential participants (previously provided with a discharge pack) to provide further information and ask if they would be interested in participating. For individuals who are interested in joining the study but are unable to use their phone or experience difficulties in doing so, an appropriately delegated member of the stroke service is able (where possible) to visit them at home to facilitate the consent process.

Consent (in person or remote) should be completed as soon as possible, but no later than 28 days post-discharge. To ensure patient eligibility, the individual obtaining consent will ask the patient to provide their discharge date (patient-reported).

For participants who provided consent in a hospital or inpatient rehabilitation unit, if the time from consent date exceeds 28 days at the time of randomisation, they must confirm that they are still happy to take part in the study. This confirmation will be obtained at the point of baseline/randomisation and documented in the Research Electronic Data Capture system (REDCap).

Participants will have the option to provide consent to receive a summary of the study results when available and to be contacted about participation in the process evaluation interviews (information on these interviews and who will be contacted to participate will be provided in the PIS).

5.7.1 Written Informed Consent

Paper ICFs will be completed by the patient and the PI or delegate.Patients must tick each consent point and sign and date the consent form. Optional consent points will require a tick in a ‘Yes’ or ‘No’ box. The researcher who is taking consent must verify and countersign the form at the point the patient signs the consent form. The patient must be given a copy of the paper consent form, a copy must be filed as part of their medical records and a copy scanned and uploaded to the REDCap database for NCTU review. In person consent can be completed electronically (e-consent) where appropriate.

For individuals unable to complete remote consent electronically (see section below), written informed consent must be obtained in person at the participant’s home address. During the same visit, the baseline questionnaire and randomisation process can also be completed. However, e-consent will be prioritised unless the participant encounters difficulties preventing its use.

5.7.2 Electronic Consent (e-Consent)

E-consent can be used to consent patients to the study remotely. If e-consent is being used remotely then the PIS and eICF will be sent electronically (by SMS or email) via a hyperlink. After the patient has had the opportunity to read and consider the study, they must then tick a box against each statement to indicate they are giving fully informed consent for each element of the eICF. They must then complete their name and electronically sign the form. Returned electronic consent forms are then verified and countersigned by the investigator or delegate. A copy of the fully signed eICF is then sent to the participant and the participating stroke service by email. A copy will be filed in the participant's medical notes.

5.7.3 Additional consent options

Witnessed Consent
Patients who are eligible and are deemed to have the capacity to consent, but who cannot sign a consent form (e.g. due to significant sight loss or dexterity issues) may give verbal consent to the study to the PI or delegate. This will be recorded on the 'witness consent' section of the participant consent form by a member of the research team. This consent will be witnessed by an independent witness who will countersign the consent form. Witnessed consent must be completed in person and cannot be completed via remote e-consent.

Consent for participants without capacity If a patient is deemed not to have capacity to consent, then a personal consultee will be approached to provide advice to the researcher on the patient's wishes and feelings regarding participation in the study. The personal consultee will be a person that the patient has a close personal relationship with (e.g., a family member or friend) or person with lasting power of attorney. The personal consultee will be provided with a consultee declaration form and the PI or delegate will explain the details of the study. The personal consultee will have time to consider participation on the patient's behalf and have the opportunity to ask questions. A signed consultee declaration form (paper or by e-consent) will then be collected from the personal consultee before the participant can undergo any interventions related to the study.

Continued participation is voluntary, and the participant is free to withdraw from the study should they wish. Withdrawal will be clearly documented in the participant's medical records and the study database.

Documenting consent
Once the participant is entered into the study, the participant's unique study identification number will be entered on the ICF that is kept in the Investigator Site File (ISF). One copy of the ICF will be provided to the participant (or personal consultee), one copy will be filed in the medical notes, one copy will be uploaded electronically in the study database for central monitoring by NCTU, and where paper consent is recorded, the original will be placed in the ISF.

Details of the informed consent discussions will be recorded in the participant's medical notes. This will include date of discussion, the name of the study, version number of ICF signed and the date consent received. Where consent is obtained on the same day that the study related assessments are due to start, a note will be made in the medical notes as to what time the consent was obtained and what time the procedures started.

Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the study, continuing consent will be obtained using an amended Consent form which will be signed by the participant.

5.8 RECRUITMENT

5.8.1 Expected duration of participant participation

Participants will be involved in the study for 12 months once randomised. Active participation ends once the participant completes the final set of questionnaires and falls reporting at 12 months, or as soon as possible thereafter.

5.8.2 Co-enrolment

There is a chance that patients may be approached for participation who are already enrolled in another clinical trial or study. Co-enrolment alongside FISS may be acceptable. Decisions on co-enrolment will be approved on a case-by-case basis following discussions with the participating stroke service staff responsible for assessing eligibility and the FISS CI or deputy CI.

5.8.3 Removal of participants from therapy or assessments /participant withdrawal

Participants (and personal consulteess where appropriate) are free to withdraw consent at any time during the study, without giving a reason and without impacting their usual NHS care. Participants will be encouraged to discuss reasons for withdrawal with staff to determine whether discontinuation from a specific study activity may be more appropriate.

Participants will be made aware (via the information sheet and consent form) that should they withdraw, the data collected to date cannot be erased and may still be used in the final analysis. In accordance with the guidance for researchers, we will attempt to minimise the number of participants withdrawing consent (PeRSEVERE project[17]).

Participants are able to withdraw from the study at any time. Withdrawal from the study means discontinuation of all trial activities and communications (including results). If a participant wants to continue in the study but discontinue a specific activity (e.g. no longer receive text messages) their participation status could be amended. Activities that could change a participant's status are outlined in Table 5.

Table 5: Change in participant status

Activity type	**Discontinuation procedure**	**Use of data that is already collected**
Discontinue from receiving study intervention.	Participants who discontinue from the study intervention will remain in the study and their data will be collected as per protocol, unless they explicitly state otherwise. Post-request no further intervention visits or phone calls will take place.	Data collected will be retained and used.
Discontinue from completing follow-up questionnaires (3, 6, 9 or 12 months) but willing to continue with monthly falls reporting.	Participants who discontinue from completing questionnaires at any of the 3, 6, 9 and 12 month timepoints will remain in the study. These questionnaires will not be sent to the participant. Monthly falls	Any data collected prior to request (i.e. data obtained at baseline or previous questionnaires) will be retained and used.

	data will continue to be collected as per protocol.	
Discontinue from other study communications.	Any patient who requests to be withdrawn from other study communications will be removed from all mailing lists for ongoing study contact (e.g. newsletters and reminders) but will still receive study questionnaires. Study data will continue to be collected as per protocol.	Data collected will be retained and used.
Discontinue from reporting monthly falls data or full study withdrawal.	Any participant that requests to stop completing primary outcome data or requests have no further involvement in the study will be marked as withdrawn on the study database. No further questionnaires will be sent to the participant, and no further data (including monthly falls data) will be collected.	Any data collected prior to participant withdrawal will be retained and used. No further data will be collected.

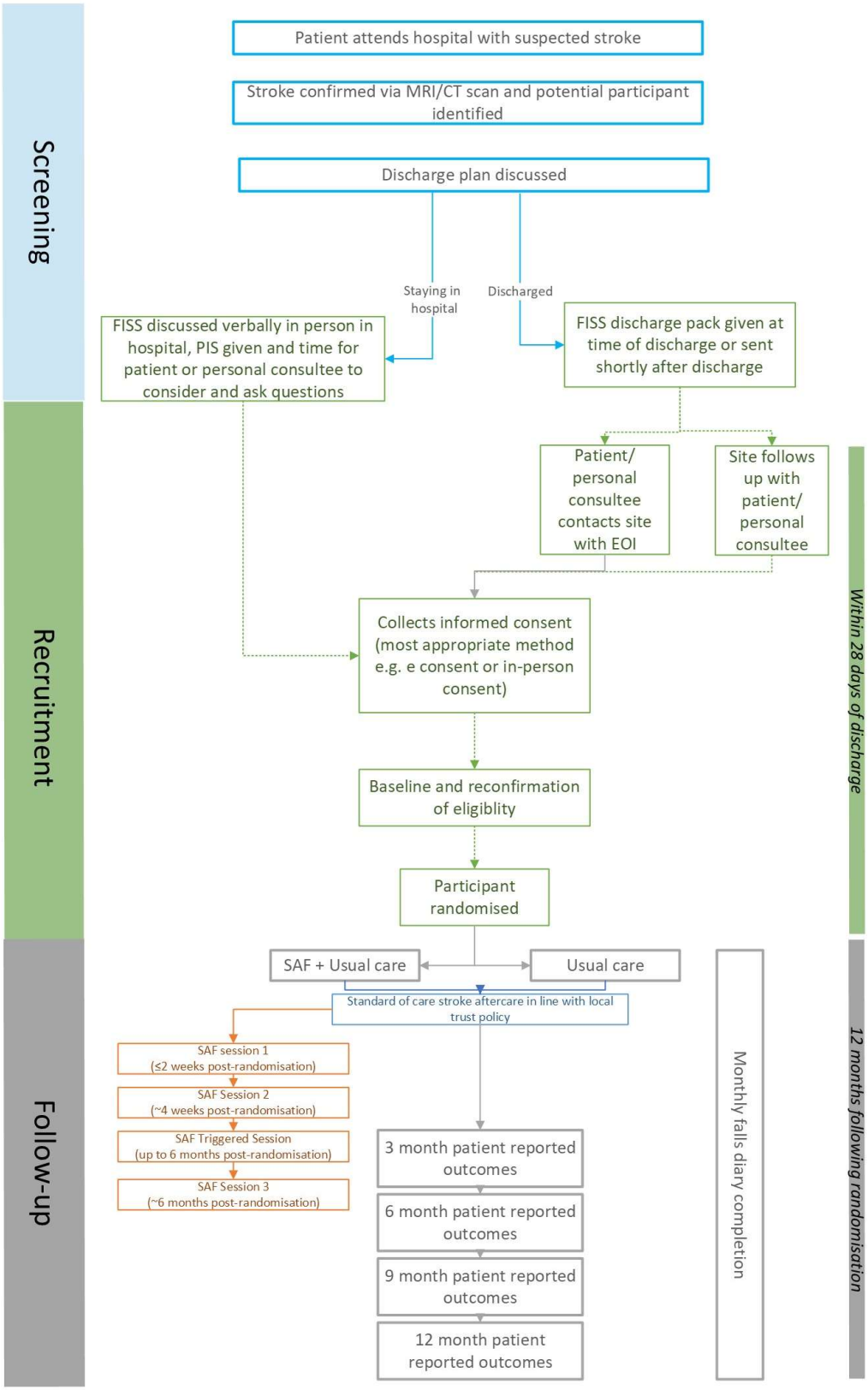
Participating stroke services may withdraw participants from the study at their own request, request of a personal consultee or at the discretion of a stroke healthcare professional.

Any change in participant status must be completed within REDCap. Additional support can be provided by the NCTU research team as required.

Withdrawn participants will not be replaced. The sample size has allowed for up to 10% non-collection of primary outcome data.

6. STUDY TREATMENT AND REGIMEN

Flow Diagram 1: Patient pathway



6.1 IDENTIFICATION AND SCREENING

Participants will be identified from 10 stroke services across the UK. Patients who are aged 18 or over who have a confirmed stroke diagnosis (CT or MRI scan) and are deemed as potentially eligible will be approached about the FISS study.

The initial approach will be from a member of staff from the participating stroke service (which may include the PI, research team, hospital or community service). Flexible study recruitment will reflect local clinical practice and will allow participants to be approached by a member of the recruiting service as an in-patient (e.g. the stroke unit or other department within the recruiting trust such as A&E or a rehabilitation unit), an out-patient at a follow-up appointment or once they have been discharged home. The initial approach could be done in person, by letter/email (discharge pack) or by phone. Information about the study may also be on display in the relevant clinical areas (at each individual stroke service's discretion).

The PI (or delegate) will inform the participant or their personal consultee, of all aspects involved in the participation in the study. Sufficient time will be given for the patient to consider participation, and the patient will be given the opportunity to ask questions throughout the process. Consent will be taken from patients directly in hospital or remotely via electronic consent, or where patients lack capacity to complete consent, advice may be given by a personal consultee. No study specific assessments will be undertaken prior to informed consent provided.

It will be explained to the potential participant that entry into the study is entirely voluntary and that their treatment and care will not be affected by their decision to participate. It will also be explained to patients prior to joining the study, that they can withdraw at any time but that attempts may be made to avoid this occurrence. In the event of their withdrawal of consent from all study activities, it will be explained that their data collected so far cannot be erased and we will use the data in the final analyses where appropriate. This information will be reiterated at the point of receiving the withdrawal request.

If needed, the usual local NHS interpreter and translator services will be available to assist with discussion of the study, the PIS, and consent forms.

6.1.1 Baseline

Following consent but prior to randomisation, baseline data will be collected, this will include (but not limited to) demographic and contact details and the following baseline questionnaires:

- Nottingham Extended Activities of Daily Living (NEADL) [14]
- Short Falls Efficacy Scale-International (Short FES-I) [13]
- Patient Health Questionnaire 8 (Participant PHQ-8) [15]
- Modified Barthel Index (MBI)
- Quality of Life (EQ-5D-5L) [16]
- Health Resource Questionnaire
- Patient Health Questionnaire 8 (Carer PHQ-8)*

Baseline data will be collected by research staff or FISS trained stroke healthcare professionals once they are discharged, either in person at the participant's home or over the phone, where possible. Data will be captured directly into REDCap, or where an electronic device is not available, into a paper workbook transcribed into REDCap.

Participants will be randomised using a web-based, concealed randomisation system to receive either the SAF intervention in addition to usual care or usual care alone. The participant

will be told by a member of stroke service which arm of the study they have been randomised to at the time of randomisation (where possible) or as soon after randomisation is completed.

Baseline data collection and randomisation is likely to take place on the same day and will need to be collected within 28 days of discharge as per remote consent. Where this is not possible, randomisation can take place remotely and the participant contacted to inform them of their treatment allocation. This will need to be within 1 or 2 days of collecting the baseline data.

*The Carer PHQ will be posted to the participant's contact address once the participant is randomised. The baseline carer PHQ will be completed by the carer (electronic or post) and returned to the NCTU. Where randomisation is done in person and the carer is available, this can be done at the point of randomisation.

6.1.2 Usual care

Participants randomised to usual care alone will receive stroke aftercare in line with their local standard of care.

6.1.3 Stroke Action Falls in addition to usual care

Participants randomised to SAF and usual care will receive stroke aftercare in line with their local standard of care as well as the SAF intervention in line with section 4.3 Stroke Action Falls (SAF) visits.

6.2 FOLLOW-UP

Table 6: Data collection schedule

Timepoint (month)	**0 (baseline)**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Assessment													
Fall Diary		x	x	x	x	x	x	x	x	x	x	x	x
Short FES-I	x						x						x
PHQ - patient	x						x						x
PHQ - carer	x						x						x
NEADL	X						x						x
Modified Barthel Index	x												
EQ-5D-5L	x			x			x			x			x
Health Resource use				x			x			x			x
SAF sessions	X (≤2 weeks)	x			(x)*		x						

*Triggered SAF sessions, can take place any time up to 6 month visit.

All participants and their carers will be asked to complete study questionnaires up to 12 months post-randomisation in line with Table 6: Data collection schedule.

6.2.1 Monthly Falls Reporting

Follow-up of participants will start one month after randomisation and continue for the duration of their 12-month participation. Participants will be asked to keep a record of any fall they have during their 12-month participation. Participants will be provided with Falls Diary to support recollection of the falls they have had each month. The use of the Falls Diary will be encouraged but not mandated and Falls Diaries will not be considered source data.

Each month, participants will be contacted about any falls they may have had in the previous 30 days. They will be asked up to three questions about their falls; if they have fallen; how many falls they have had and the severity of each of the falls. Monthly falls reporting will be collected electronically, via telephone or via post using paper forms (if required). If a participant has not fallen in the previous 30 days, they will need to complete the monthly falls report as no falls for that reporting period.

Falls severity will be assessed using the National Database of Nursing Quality Indicators (NDNQI) [12] scale. The scale categorises falls into five levels, however for the purpose of the study, only four will be used: none, minor, moderate and major. The fifth level, death, won't be self-reported via questionnaires.

6.2.2 3-and 9-month follow-up questionnaires

Participants will complete a questionnaire pack (online, postal or telephone) 3- and 9-months after randomisation which will include the following:

- Quality of Life (EQ-5D-5L) [16]
- Health Resource Questionnaire

6.2.3 6-and 12-month follow-up questionnaires*

Participants and their carers will complete a questionnaire pack (online, postal or telephone) 6- and 12-months after randomisation which will include the following:

- Nottingham Extended Activities of Daily Living (NEADL) [14]
- Short Falls Efficacy Scale-International (Short FES-I) [13]
- Patient Health Questionnaire (Participant PHQ) [15]
- Quality of Life (EQ-5D-5L) [16]
- Health Resource Questionnaire
- Patient Health Questionnaire (Carer PHQ)

* Where participants are not able to complete to questionnaires themselves or have a family or friend to support questionnaire completion, additional support may be available from their local stroke service. Availability of this will depend on local service resource and may vary from service to service.

There will be the option to complete questionnaires at all timepoints online, by post or telephone (where possible). Outstanding questionnaires not received back from participants will be followed up by a member of the central research team (e.g. email, SMS, post or telephone reminders). Questionnaire data may be completed over the telephone where necessary to increase data completeness.

Participants will be asked to complete the questionnaires themselves, but where this is not possible, participants can be supported by another person (e.g., a family member or friend) to complete as appropriate.

Participants and carers will be advised that questionnaires should be completed within approximately 4 weeks of being sent (e.g. scheduled completed date +4 weeks). Questionnaires completed and returned after this time will be analysed according to the SAP.

6.2.4 Use of prompts and reminders

Participant and personal consultee (where relevant) contact details will be collected as part of the informed consent process. Strategies to minimise loss to follow-up will include online

(website) newsletters communicating study progress, and e-mails, text messages and phone calls will be sent/made to prompt completion of follow-up questionnaires. Participants may also be contacted by a member of the study team by telephone to collect primary outcome falls data.

Participants and personal consultees (where relevant) name and telephone number will be shared with Esendex, our text messaging provider and their subprocessors, and will be used to send text message reminders about the study and study questionnaires.

6.3 ADHERENCE

6.3.1 Adherence to SAF intervention delivery

Fall Leads' adherence to delivering the intervention to protocol will be monitored via the electronic Case Report Form (eCRF) where each intervention session will be recorded with information of the format and length of the session. Any reasons for non-compliance, such as a session not taking place, will be documented in the eCRF.

Adherence to SAF intervention delivery will be monitored and reported regularly to the TMG according to the current version of the monitoring plan.

6.3.2 Patient adherence to SAF action plan

SAF is a self-directed intervention to be actioned by the participant (with support from family etc. as required). A participant's ongoing adherence to the SAF intervention cannot be observed outside of SAF intervention sessions therefore adherence to the intervention will not be captured in the eCRF. A subset of participants randomised to the intervention will be interviewed to better understand their views on the action plan as part of the study process evaluation, see section 9 for more details.

6.4 PROTOCOL DEVIATIONS AND NON-COMPLIANCES

Protocol non-compliance will be monitored via central monitoring of eCRF data. Where non-compliances are detected, they will be reviewed by the TMG and recorded and escalated to the Sponsor and other committees as required.

Where the outcome of the initial assessment is a serious breach or other serious protocol violation, it will be reported immediately to the CI and further investigated following the relevant NCTU SOPs.

The CI will notify the Sponsor if a deviation or violation has an impact on participant safety or integrity of the study data. The Sponsor will advise on appropriate measures to address the occurrence which may include reporting of a serious Good Clinical Practice (GCP) breach, conduct of an internal audit of the study, and seeking counsel of the study committees and the REC.

6.5 CRITERIA FOR TERMINATING STUDY

On the recommendation of the TSC, the Sponsor (in collaboration with the TMG) may stop the study if emerging evidence of efficacy or major safety concerns arise, or if there are significant concerns regarding study conduct. There should be proof beyond reasonable doubt for overall efficacy or major safety concerns (internal or external evidence) for the TSC, DMC and TMG to recommend the study is stopped.

Stroke services may be closed to recruitment prior to the end of the study if the TMG identifies unacceptable performance related to monitoring triggers (outlined in the current version of the FISS Monitoring Plan). In the case where a participating service closure has been decided, the TMG may make this decision without consultation with the TSC. Where screening and recruitment activity has taken place, research data should not be destroyed (it should be archived according to the archiving section below).

If following the pilot phase the study is not deemed feasible to continue (using the agreed criteria) and the funding is discontinued, the study will be terminated.

7. STATISTICS AND DATA MANAGEMENT PLAN

7.1 DATA MANAGEMENT PLAN

The Data Management Plan (DMP) for this study is a standalone document and is stored/maintained centrally within NCTU systems. The current version of the DMP contains detailed information regarding data capture, queries, validation, cleaning and database lock and will be finalised prior to commencement of recruitment.

7.1.1 General

The DMP will include the agreed roles and responsibilities for the study data and user access. Additional manual and electronic reviews may also be conducted, and data queries / clarifications may arise from such reviews. Data validation is covered by the data validation document (DVD).

The study database to be used is REDCap. It is a validated secure web-based platform which allows for data tracking via date stamped audit logs. FISS participants will be identified on REDCap only by a unique participant identifier (their study/participant ID) and initials to protect from bias and ensure confidentiality.

Data will be held on secure servers. These servers are located within The University of Nottingham data centres, which are managed and monitored regularly. Security is both physical (secure limited role-based access) and electronic (behind firewalls, access via user accounts (username and password) on encrypted connections, restricted access for some users (e.g. stroke service staff) who only have access to their patient data, and by user type/role). All access and data transactions will be logged in a full audit trail.

7.1.2 Data Capture and Data Queries

All study data will be entered onto the study specific database through the secure eCRF.

Data will be collected and entered by the local research team and directly from participants who receive a secure link via a text message or email for online questionnaires. Participants who are unable or unwilling to complete online questionnaires will be offered alternatives to complete data (e.g. by post, telephone or in-person). Questionnaire data returned to the NCTU will be entered into the database by the NCTU research team. More information on who captures the data is listed in the current version of the FISS DMP.

Only staff listed on the delegation log and training log will be given access to the relevant sections of the study database e.g., stroke service 1 staff will only have access to stroke service 1 study participants while the study team including the research teams will have access to the wider database. Individual study and research team member access will vary depending on role and associated blinding status.

Data reported on each eCRF will be checked for missing data or discrepancies and will be queried. Staff delegated to complete eCRFs will be trained to adhere to relevant aspects of GCP associated with data entry.

Data queries will not be raised on participant or carer completed questionnaires.

7.1.3 Description of Data Entry Validation

Programmed validation and manual checks will be used to identify data anomalies. All programmed validation checks are documented in the data dictionary and data quality rules on the REDCap database.

Programmed validation checks will automatically flag discrepancies at the point of data entry or will be executed by data management at the point of data cleaning. Data identified as missing or having discrepancies, may require a manual data query to be raised within REDCap by the Data Management team at NCTU.

7.1.4 Data Cleaning and Database Lock

Once all data has been collected, is cleaned and signed off by the local PIs, the study database will be locked.

The database will be hard locked as per the relevant NCTU SOP using the associated checklist. All user rights will be removed, and it will be read only. Further details will be included in the current version of the study DMP.

7.1.5 Monitoring

Onsite and central monitoring will be carried out as required, following a risk assessment and as documented in the current version of the study Monitoring Plan.

7.2 STATISTICS

7.2.1 Methods

The study will be analysed and reported in accordance with CONSORT guidelines for RCTs[18] and in line with the guidance for evaluation of complex interventions[19]. A detailed Statistical Analysis Plan (SAP) will be finalised prior to database lock and treatment allocation release. The study and senior study statisticians will be blinded to treatment allocation throughout the study.

Primary analyses: The primary analyses, after 12 months follow-up of all participants, will be as randomised (intention to treat) without imputation of missing data and will use a negative binomial model including minimisation factors and incorporating exposure time to estimate the between group difference and placing due emphasis on the 95% confidence intervals. Sensitivity analyses will be performed to determine the impact of missing data and may also include further co-variates if visual inspection of baseline variables show marked imbalanced between groups.

Baseline and secondary outcomes: Baseline variables will be summarised using descriptive statistics only and presented by treatment group. Secondary outcomes will be analysed using appropriate regression models which include the minimisation factors and the baseline value of that variable where available. Associated measures of the between treatment difference such as the difference in means, will be presented alongside 95% confidence intervals. The

secondary analyses will be considered supportive to the primary and interpreted in that light, and no multiplicity adjustments will be made.

No interim analyses are planned in this study.

7.2.2 Sample size and justification

We assume that stroke survivors will have an annual falls rate somewhere between that in community dwelling stroke survivors up to 5 years post stroke in the FAST study (1.8 falls per year) and that of participants in care homes observed in the FinCH study (3.2 falls per year). Using the upper limit of the 95% confidence interval for the overdispersion parameter (FinCH study; 1.1) and assuming an annual falls rate of 2.5 falls per year per participant, 416 evaluable participants would be required to detect a relative difference of 33% in falls rates (i.e. to 1.675 falls per year) using a negative binomial model, with 90% power at the 5% significance level (2-sided) – or 208 per arm. Sample size calculations were performed using PASS 2022 (NCSS).

This difference was deemed a clinically important difference by our FISS PPI group and in the FinCH study. A survey of occupational health professionals showed that 15/27 (58%) would consider adoption of the SAF program if the falls rate was reduced from 3 to 2 falls per year (a 33% reduction), with 3/27 (11.5%) saying they would not consider adoption.

The negative binomial model takes into account exposure, but there is a risk that no robust primary outcome data are collected from some individuals. Therefore, we will inflate the sample size by 10% and aim to randomise 464 participants, or 232 per arm. This sample size also provides 90% power to detect a relative difference of 34% and 36% if the falls rate was lower than expected at 2 and 1.5 falls/year.

The primary outcome event rate is based on the best evidence currently available. However, we recognise that it is an estimate, and our assumptions will be monitored by the DMC throughout the study. They will advise whether a sample size adjustment is necessary.

7.2.3 Assessment of efficacy

Primary outcome: The evaluation of the primary outcome will be performed using a negative binomial model that includes the minimisation factors (stroke service, living alone or with others, aged >65 years or <=65 years and baseline modified Barthel Index (MBI) score of >14 or <=14). The model will incorporate exposure time to estimate the between group difference which will be summarised using the incident rate ratio (IRR) and its associated 95% confidence interval.

The primary analysis will be ‘as randomised’ with no imputation of missing data.

Sensitivity analyses: Sensitivity analyses will be conducted to investigate the impact of missing data using techniques such as multiple imputation and may also include alternative models where visual inspection of the baseline variables show marked imbalances in potentially prognostic variables, between groups. Further sensitivity analyses may be performed if participants show major non-compliances (e.g., who do not receive the intervention when randomised to do so or receive the intervention when randomised to standard care alone).

Sub-group analyses: Exploratory subgroup analyses for the primary outcome will be performed according to the minimisation variables by including appropriate interaction terms

in the primary model. The interpretation of any subgroup effect will be based on the interaction tests (i.e., evidence of differential treatment effects in different subgroups). It is acknowledged that these investigations will not be adequately powered.

Secondary outcomes: Secondary outcomes will be analysed using appropriate regression models which include the minimisation factors and the baseline value of that variable where available. Continuous outcomes will be analysed using linear mixed models and count/rate outcomes will be analysed using negative binomial models. Associated measures of the between treatment difference, such as the difference in means or incidence rate ratio, will be presented alongside 95% confidence intervals. The secondary analyses will be considered supportive to the primary and interpreted in that light, and no multiplicity adjustments will be made.

7.2.4 Assessment of safety

Safety outcomes: Adverse events (serious and non-serious) will not be collected in this study. Falls and fall severities will be specifically collected as primary and secondary outcomes monthly. The assessment will therefore be as specified in Section 7.2.3.

7.2.5 Procedures for missing, unused and spurious data

Spurious data will be queried using processes documented in the data management plan. Where appropriate, self-evident corrections may be made. All attempts will be made to collect missing data. Where data remains missing, investigations will be made to assess whether these data are likely to be missing completely at random.

The primary analysis will use only data collected, and the negative binomial model will take into account exposure (i.e., the number of months over which data was collected). No imputation techniques will be used in the primary analysis. The SAP will document where methods to address missing data (for example multiple imputation in a sensitivity analysis) will be used.

7.2.6 Definition of populations analysed

Intention to treat dataset: All randomised participants are summarised/analysed according to their randomised treatment irrespective of the treatment(s) they actually received. This is the primary dataset to be used in all analyses unless stated otherwise in the SAP.

8. HEALTH ECONOMICS

8.1 AIM

A within-study economic evaluation will be conducted at 12 months post-randomisation to determine whether the addition of the SAF program to usual care is more cost effective in the ongoing care and prevention of falls for stroke patients than usual care alone.

8.2 METHODS

The economic assessment of SAF will be conducted in accordance with the National Institute for Health and Care Excellence (NICE) guidelines for health technology evaluations (2022) and performed primarily from an NHS and Personal Social Services perspective[20]. Secondary analyses will establish broader effects on participants, families/friends, and society such as private care costs, informal care requirements and time lost from work because of falls and related care. This will enable a broader societal perspective to be reported alongside a

health & PSS perspective in evaluating the cost effectiveness of SAF plus usual care versus usual care alone for stroke patients.

8.3 OUTCOME MEASUREMENT

Participants' health-related quality of life will be measured using the EQ-5D-5L, [16] a validated questionnaire designed to generically describe and value health[21]. HRQoL data (EQ-5D-5L) [16] will be collected at baseline and at 3,6,9 and 12 months. The HRQoL of trial participants will be calculated using the methodology and relevant value sets outlined within NICE guidelines at the time of the analysis. In line with current NICE guidelines, the HRQoL of study participants will be calculated using a published mapping of EQ-5D-5L[16] responses onto EQ-5D-3L preference scores: the crosswalk index[22]. QALYs accrued in each arm during the study will be calculated using Area Under the Curve analysis (AUC). Incremental differences will be compared between the groups.

Differences in the observed and estimated rate of falls between arms will also be considered to calculate the cost per fall averted from SAF.

8.4 RESOURCE USE MEASUREMENT

Resource use data will be collected directly from participants using a purposely designed health resource use questionnaire. This will be designed in conjunction with the PPI group to help identify relevant and important costs. Data collection will occur at 3,6,9 and 12 months and consider primary, secondary and community care utilisation, patient and carer private expenditures (e.g., equipment and aids), and broader informal care and employment consequences between follow-ups. Health service and societal costs will be calculated using relevant unit costs from National sources (e.g. NHS reference costs, Personal Social Services Unit (PSSRU), Drugs and pharmaceutical electronic market information tool eMIT, British National Formulary BNF, etc.).

To calculate intervention-related resource use and costs, we will record the costs of intervention materials, the personnel, grade, time and travel taken to conduct SAF visits and consultations for each patient. We will work with SAF leads to assess any relevant staff training costs. The intention is to measure this for every patient, site and team.

As SAF will be provided as an adjunct to usual care, the economic analysis will assume commonality in usual care costs between the arms. Although the work will not undertake a micro- costing, the health economics and trial teams will liaise with sites and site selection to ensure that usual care is broadly similar in delivery.

All data will be analysed on an intention-to-treat basis. Within-study findings will not be discounted as the analysis will be completed within a 12-month time horizon. Missing cost and outcome data will be multiply imputed and analysed using Rubin's rules[23].

8.5 ANALYSIS

An incremental approach will be used to analyse the data between the two groups of usual care and SAF. Measures of cost effectiveness may include the incremental cost effectiveness ratio (ICER). This provides a measure of the additional cost per additional unit of health gain (i.e. cost per QALY) generated by SAF compared with usual care, and an incremental net monetary benefit (iNMB) representing the monetary value from the health gains SAF provides less the additional costs it incurs relative to usual care. Interventions with a positive iNMB, and ICERs below threshold values, are deemed cost effective. The health economic analysis will consider the range of thresholds adopted by NICE (£20,000–30,000 per QALY). Deterministic

analyses will assess the impact of specific uncertainties in the design and delivery of SAF on cost effectiveness; probabilistic sensitivity analysis will explore the underlying uncertainty surrounding base case costs and effects. Cost Effectiveness Acceptability Curves (CEACs) will plot the probability of SAF being cost effectiveness versus usual care across a broad range of threshold values.

Exploratory economic analyses may consider the relationship between falls, their severity, and consequent impacts on stroke survivors' HRQoL and resource utilisation. Such estimates may facilitate the extrapolation of downstream benefits from differences in fall rates that may persist beyond final study follow-up (12-months). Any modelled costs and QALYs beyond the study horizon will be discounted at 3.5% per annum (1).

A detailed plan for the design and analysis of the economic evaluation will be contained within the Health Economic Analysis Plan (HEAP).

9. PROCESS EVALUATION

9.1 PROCESS EVALUATION

We will use a realist approach, as previously used in the Falls in Care Home (FinCH) study, to inform the Process Evaluation. A programme theory will be generated to describe how the SAF programme should work in ideal circumstances, based on its prior use in care homes and discussion with key stakeholders. These stakeholders are adapting the intervention for stroke survivors. They are therapists (physiotherapists and occupational therapists) from the UK and Australia with experience of the Action Falls intervention in care homes and/or experience working with stroke survivors. An online focus group will identify their views and opinion on how the programme should work with stroke survivors. The programme theory generated will be fed back to this group before being finalised. To test the programme theory, we will purposively sample approximately 30 individuals who (in different circumstances) have been randomised to receive SAF. In this we will select individuals from different recruiting stroke services (i.e., those with a greater or less rate of strokes); those with different clinical circumstances (i.e., stroke severity, clinical/discharge journey); and those with different demographic characteristics (i.e., age, gender, ethnicity, socio-economic status). These will be our case studies.

Inclusion criteria (stroke survivor):

- Stroke survivor in the FISS study who is receiving the SAF Programme
- Ability to provide informed consent for the Process Evaluation

Exclusion criteria (stroke survivor):
Unable (with support of family member) to recall receiving the SAF Programme or unable to communicate their views of the programme.

Inclusion criteria (family member):

- Family member/friend of stroke survivor on the FISS study who can provide support in the interviews.

Exclusion criteria (family member):
None, provided inclusion criteria (above) met.

For each participant we will collect data at multiple timepoints and will collect both quantitative and qualitative data. We will complete up to 30 case studies. Quantitative data will include the number of actions completed as well as the number of falls reported in interviews. Qualitative data will include up to three interviews with the stroke survivor (and in some cases dyad

interviews with a family member) (up to 90 interviews in total) and an interview with their Falls Lead (up to 30 interviews in total). Stroke survivors and Carers/ Family members taking part in the Process Evaluation will be given a £30 thank you voucher for each interview completed.

Inclusion criteria for Falls Lead:

- Trained in delivery of the SAF programme
- Delivered the SAF programme to the named stroke survivor

Exclusion criteria for Falls Lead:

- None, provided inclusion criteria (above) met

9.2 INTEGRATED PROCESS EVALUATION

This Process Evaluation will run concurrently (and independently from the FISS study) during the implementation of the intervention. Interviews with selected participants will be conducted by qualitative researchers trained in Process Evaluation. Interview guides for stroke survivors and Falls Leads, for each stage of the intervention process, will be used. These are iterative and will be developed as data is collected. Both consent to contact participants about the Process Evaluation as well as consent to participate in the Process Evaluation will be obtained prior to interviews.

Participating in the process evaluation

Participants, or participant/consultee dyads, may be invited to participate in stakeholder interviews conducted by qualitative researchers trained in Process Evaluation. Interview topics will reflect upon stakeholder experience of being exposed to the modified SAF.

Process Evaluation consent

Stroke survivors: Participants will be contacted by phone or email (according to participant preference (as indicated on the FISS consent form) about the Process Evaluation. Interested participants will be provided with the Process Evaluation Participant Information Sheet. Consent will be obtained in one of two ways dependent upon the format of the interview. If interviewed face to face, the participant will complete the paper version of the consent form. If interviewed by phone or via a Voice Over Internet Protocol (VOIP) platform such as Microsoft Teams, they will verbally complete the consent form. The researcher will go through each of the consent statements and ask the participant to confirm their consent to each statement. There will be a separate audio file of consent.

Falls Leads: The Falls Lead for each stroke survivor participating in the Process Evaluation will be contacted by email/phone and sent a Participant Information Sheet and consent form. The researcher will answer any questions the participant has concerning the interview.
Interviews will be conducted either face to face, over the telephone or on a VOIP platform such as Microsoft Teams.

9.3 PROCESS EVALUATION ANALYSIS

All interviews will be audio recorded, transcribed verbatim, and anonymised. Data will be analysed in two stages: 1) inductive thematic analysis to identify underlying themes and 2) synthesis of data into Context-Mechanism-outcome (C-M-O) configurations to reflect variations of the utility of the programme theory. Stage one will involve the PPIs in analysing the data. The Process Evaluation team has experience of working with PPIs in thematic inductive analysis. The team will train the PPIs in Thematic Analysis before commencing the analysis. Data will be handled using the NVivo Software package.

10. STUDY WITHIN A TRIAL (SWAT)

10.1 BACKGROUND

Participant information sheets are often only provided in written English, which may limit study participation for people who have difficulty understanding written English. It is important to make participation in clinical studies as inclusive as possible and researchers are exploring the best ways to do this. Media tools are increasingly used to engage potential participants, but there is limited data on what is most effective.

Our 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 study compared to written information alone.

10.2 INTERVENTION

Group 1: Written participant information plus translated animation.
Group 2: Written participant information only

10.3 METHOD OF ALLOCATION

Randomisation for the SWAT will occur at service level (cluster) to prevent contamination with the intervention. Stroke services will be randomised in 1:1 ratio to either access to the translated animation or not. An independent study statistician will generate the randomisation schedule. For stroke services randomised to use of the animation, a link and/or QR code will be provided as part of the study PIS for participants to access the animation on their personal device. Participants will be provided with the relevant PIS before being randomised in the main study.

10.4 OUTCOME MEASURES

The primary outcome is the proportion of eligible patients who consent to take part in the study.

The secondary outcomes are the proportion of:

- randomised participants who provide primary outcome follow up for the whole study
- people from ethnic minority groups who randomise into the study
- people from ethnic minority groups who provide primary outcome.

10.5 SAMPLE SIZE

The sample size for the SWAT will be predicated by that of the FISS study. We anticipate including 10 stroke services in the SWAT.

10.6 ANALYSIS

Detailed analysis methods for this SWAT will be documented in the study SWAT statistical analysis plan. Between group differences will be presented alongside the associated 95% confidence intervals.

10.7 DISSEMINATION

The SWAT will be registered on the Northern Ireland MRC Trials Hub for Methodology Research SWAT registry. The SWAT will be aligned with SWAT no.156.[24]. The findings will

be made publicly available as soon as possible after the end of the SWAT and will be made available to researchers conducting meta-analysis in this field.

11. ADVERSE EVENTS

Adverse events (serious and non-serious) will not be collected in this study. Falls and falls severity will be specifically collected as primary and secondary outcomes monthly.

This is a low-risk intervention. No specific risks, untoward incidents or adverse events were reported during feasibility work. If participants become distressed during the SAF assessment or when completing the checklist and suggested actions, the process will be halted until the participant assessed as to whether they can continue with the intervention. The participant has the right to decline any intervention at any time.

Fall rates will be monitored for harm and reported to the DMC and TSC. The DMC and TSC have the ability to recommend changes to the study protocol if fall rates are substantially higher than expected. The DMC will review unblinded safety data including reported frequencies of primary and secondary outcomes by treatment arm annually. This will be provided by the NCTU via a secure email.

SAF assessments and or/actions may be stopped in the event that the participant shows evidence of distress. This will be documented. However, the participant will not be withdrawn from the study.

As the SAF intervention is copyrighted by the University of Nottingham, it is responsible for any issues which arise due to the design of the intervention, training given to SAF leads or any issues with the tool itself.

12. ETHICAL AND REGULATORY ASPECTS

12.1 ETHICS COMMITTEE AND REGULATORY APPROVALS

The study will not be initiated before the protocol, informed consent forms and participant information sheets have received favourable opinion from the Research Ethics Committee (REC), the respective National Health Service (NHS) or other healthcare provider's Research & Development (R&D) department, and the Health Research Authority (HRA) if required. Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant and GP information sheets (if appropriate) have been reviewed and received favourable opinion from the REC and R&D departments. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately providing that the REC are notified as soon as possible, and an approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice, and the UK Department of Health Policy Framework for Health and Social Care, 2017.

12.2 INFORMED CONSENT AND PARTICIPANT INFORMATION

The process for obtaining participant informed consent and personal consultee advice will be in accordance with the REC guidance, Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced. The investigator or delegate and the participant or other

legally authorised representative shall both sign and date the electronic or paper Informed Consent Form (ICF) before the person can participate in the study.

The participant or personal consultee will receive a copy of the signed and dated forms and the original will be retained in the REDCap. A second copy will be filed in the participant's medical notes and a signed and dated note made in the notes that informed consent was obtained for the study.

The decision regarding participation in the study is entirely voluntary. The investigator or delegate shall emphasize to them that consent regarding study participation may be withdrawn at any time without penalty or affecting the quality or quantity of their future medical care, or loss of benefits to which the participant is otherwise entitled. No study-specific interventions will be done before informed consent has been obtained.

The PI (or delegate) will inform the participant of any relevant information that becomes available during the course of the study, and will discuss with them, whether they wish to continue with the study. If applicable they will be asked to sign revised consent forms.

If the ICF is amended during the study, the PI (or delegate) shall follow all applicable regulatory requirements pertaining to approval of the amended ICF by the REC and use of the amended form (including for ongoing participants).

12.3 RECORDS

Electronic Case Report Forms (eCRFs)
Each participant will be assigned a study identity code number, allocated at enrolment for use on eCRFs, other study documents and the electronic database. The documents and database will also use their initials (of first and last names separated by a hyphen or a middle name initial when available) and date of birth (dd/mm/yyyy).

Each eCRF will be filled in by qualified and trained personnel who are familiar with the specific study protocol and data collection procedures. This includes PIs and other delegated staff at each stroke service. Each entry will be dated and signed by the responsible individual to maintain transparency and accountability. These individuals will be responsible for data entry in a timely manner and ensuring that all necessary fields are completed. The identifiers used in eCRFs will adhere to regulatory guidelines and will only include de-identified information such as study ID numbers rather than personal data.

The REDCap database will be used to securely store eCRFs. Only authorised personnel involved in the clinical study will have access and confidentiality protocols will be in place to ensure that the data remains protected. REDCap is encrypted and password protected to maintain confidentiality.

Quality control checks will be in place to review the completeness and accuracy of the data entered into eCRFs. This will include double data entry in the form of PI sign-off on complete subject records at the end of study participation, quality control checks of questionnaire discrepancies on data entered at NCTU, and regular data cleaning of the eCRFs to raise and resolve any data queries. eCRFs will be treated as confidential documents and held securely in accordance with regulations. eCRFs shall be restricted to those personnel approved by the CI or local PI and recorded on the 'Trial Delegation Log.' The CI or local PI shall sign a declaration ensuring accuracy of data recorded in the eCRF.

Participant contact details will be logged separately to the clinical eCRF data, to ensure participant identifiable data are separate to data used for analysis. The study team may also

use participant contact details to send out study related questionnaires, correspondence and follow-ups, limited to the duration of the participant's participation in the study. Participants may also consent to their contact details being retained beyond the duration of their participation in the study, in order to be updated about the outcomes of the research.

12.4 SOURCE DOCUMENTS

Source documents shall be filed at the PI's stroke service and may include but are not limited to, consent forms, current medical records, and paper questionnaires completed at baseline (where relevant). A eCRF/CRF may also completely serve as its own source data. Only service staff as listed on the Delegation Log shall have access to study documentation other than the regulatory requirements listed below. Where postal questionnaires (for those who opt to complete it on paper) are returned to NCTU they will be filed as source data as part of the TMF.

12.5 DIRECT ACCESS TO SOURCE DATA / DOCUMENTS

The eCRF/CRF and all source documents shall made be available at all times for review by the CI, Sponsor's designee and inspection by relevant regulatory authorities.

12.6 DATA PROTECTION

All study staff and investigators will endeavour to protect the rights of the study's participants to privacy and informed consent, and will adhere to the Data Protection Act, 2018. The CRF will only collect the minimum required information for the purposes of the study. CRFs will be held securely, in a locked room, or locked cupboard or cabinet. Access to the information will be limited to the study staff and investigators and relevant regulatory authorities (see above). Computer held data including the study database will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one-way encryption method).

Information about the study in the participant's medical records / hospital notes will be treated confidentially in the same way as all other confidential medical information.

Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

13. QUALITY ASSURANCE & AUDIT

Insurance and Indemnity
Insurance and indemnity for study participants and study staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but study participants may have recourse through the NHS complaints procedures.

The University of Nottingham as research Sponsor indemnifies its staff with both public liability insurance and clinical studies insurance in of claims made by research participants.

13.1 STUDY CONDUCT

Study conduct may be subject to systems audit of the TMF for inclusion of essential documents; permissions to conduct the study; Trial Delegation Log; CVs of study staff and training received; local document control procedures; consent procedures and recruitment logs and adherence to procedures defined in the protocol (e.g. inclusion / exclusion criteria, correct randomisation, timeliness of visits).

The NCTU QA team shall carry out systems and study audits as part of the NCTU risk adapted annual audit programme. Should this study be selected for audit, an audit report shall be issued to the Study Manager and can be disseminated to the appropriate committees should this be appropriate. Where monitoring has identified the need for an audit, or this is requested of the TMG/TSC, this shall be carried out by a trained member of NCTU staff.

13.2 STUDY DATA

Monitoring will be carried out as required following a risk assessment and as documented in the current version of the study monitoring plan. The NCTU research team will be in regular contact with local research teams to review progress and address any queries. The NCTU research team will review incoming eCRF data for compliance with the protocol, data consistency and missing data. Stroke services will be asked for clarifications on missing data and discrepancies, participant completed data (study questionnaires) will not be queried.

Onsite monitoring visits may be triggered, for example by poor data quality/completion, excessive number of participant withdrawals or deviations. If a monitoring visit is required, NCTU will contact the site to arrange a date for the proposed visit and will provide the service with written confirmation. Investigators will allow NCTU study staff access to source documents as requested.

Study data and evidence of monitoring and systems audits will be made available for inspection as required.

13.3 RECORD RETENTION AND ARCHIVING

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Research Code of Conduct and Research Ethics, the CI or local PI will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

The Trial Master File (TMF) and study documents held by the CI on behalf of the Sponsor shall be finally archived securely in the Microsoft cloud which has multiple redundant systems and backup services. This archive shall include all study databases and associated meta-data encryption codes. Access to files once archived (e.g. for inspection purposes), will be managed by the NCTU archivist and will only be accepted on approval of the University of Nottingham sponsor.

13.4 DISCONTINUATION OF THE STUDY BY THE SPONSOR

The Sponsor reserves the right to discontinue this study at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice from the TSC and DMC as appropriate in making this decision.

13.5 STATEMENT OF CONFIDENTIALITY

Individual participant medical information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above. Participant confidentiality will be further ensured by utilising identification code numbers to correspond to treatment data in the computer files.

Such medical information may be given to the participant's medical team and all appropriate medical personnel responsible for the participant's welfare.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

Data generated as a result of this study will be available for inspection on request by the participating physicians, the University of Nottingham representatives, the REC, local R&D Departments and the regulatory authorities.

14. PUBLICATION AND DISSEMINATION POLICY

Results (main clinical results, health economic results and results of the process evaluation) of this study will be submitted for publication in a peer reviewed journal. The manuscript will be prepared by the TMG, led by the Chief Investigator who will be the corresponding author. All co-authors will meet the relevant authorship criteria. The authorship will be determined by mutual agreement. Results may also be published on relevant websites and presented at conferences.

Participant newsletters will be created to update on study news and progress. Participants who provide consent will be notified of the results in an end of study newsletter and will be able to view the results on the website. An infographic and/or video/animation will be created to share the results across multiple digital platforms (e.g. website, social media etc).

Any publications and presentations prepared by Investigators must be reviewed by the TMG. Draft manuscripts must be submitted to the TMG in a timely fashion and in advance of being submitted for publication, to allow time for review and resolution of any outstanding issues. Participants will not be identified in any publications or presentations. Publications and presentations (other than the protocol) will typically happen after the end of the study.

De-identified individual participant data may be shared with researchers external to the study research team in accordance with the NCTU's data sharing Standard Operating Procedure (SOP 33) wherein the request is considered by a data sharing committee which includes the CI and the Sponsor and where a data sharing and use agreement would be required prior to the release of any data.

15. USER AND PUBLIC INVOLVEMENT

The perspectives of stroke patients and their carers/family/friends are key to this research. PPI will be embedded throughout the project to ensure maximum impact and value to the research.

Two PPI co-applicants, who are stroke survivors, are co-applicants and have been involved in the development of the study since inception. They are members of the TMG and will contribute to writing documents, study management, recruitment, interpretations of findings and dissemination of outcomes. Funding has been included as part of the HTA award for all PPI involvement.

A PPI group consisting of stroke patients and carers (including family members and/or friends) will be involved in the development of study documents and the development of the study. The group will be asked to meet at key points throughout the study to continue to be involved in the research at each stage. We will also have at least one independent PPI member will join the TSC.

16. STUDY FINANCES

16.1 FUNDING SOURCE

This study is funded by NIHR (HTA Reference Number: *NIHR158240*). The funder is not involved in the conduct, analyses, interpretation or reporting of the study.

16.2 PARTICIPANT STIPENDS AND PAYMENTS

Participants will not be paid to participate in the main study. Participants and carers who take part in the Process Evaluation interview will be given a £30 thank you voucher. This payment will be for the stroke survivors only.

17. SIGNATURE PAGES

Signatories to Protocol:

Chief Investigator: (name)_____

Signature: _____

Date: _____

Co- investigator: (name) _____

Signature: _____

Date: _____

Study Statistician: (name)_____

Signature: _____

Date: _____

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