Falls In Stroke Survivors (FISS)

Participant Information Sheet

You are **invited to take part** in our research study called FISS (Falls In Stroke Survivors).

This information is to explain the study and what happens if you take part.

Please **read it carefully**. **Ask questions** if anything is unclear.

Please visit our website www.nottingham.ac.uk/FISS/ for more information.

Contents

What is the research?	
	We (the sponsor, University of Nottingham) are doing some **research** It is about **falls after a stroke**
	We need to **know** if a special programme called Stroke Action Falls with normal care is better at **reducing falls** than normal care on its own.
Why me?	
	You have **had a stroke** Your stroke **may** cause you to **fall**
Who is doing the research?	
NOTTINGHAM CLINICAL TRIALS UNIT at the University of Nottingham	The research is run by the **Nottingham Clinical Trials Unit**
University of Nottingham UK | CHINA | MALAYSIA	It is sponsored by the **University of Nottingham**
FUNDED BY NIHR | National Institute for Health and Care Research	The **National Institute for Health Research** is **paying** for this research
Why are we doing the research?	
	Research can **test new** ways to **help patients**

Commented [RH1]: This might be a bit too much info here

There is a **programme** that may help **reduce falls** after a stroke called **Stroke Action Falls**.

This **research** will help us to **learn more** about what **if the programme does work better than normal care**

What happens in the research?

We are **comparing** two different ways of reducing falls in people who have had a stroke

We want to know **which is best**

Treatment plan A is the **Stroke Action Falls programme and normal care.**

Stroke Action Falls is a **personal care plan** created for **each patient** to help them **manage falls and falls risks themselves.**

Stroke Action Falls is made up of **a checklist and action plan.** A researcher **will help the patient develop their action plan.**

The Stroke Action Falls programme has **3 sessions** that take place **within 6 months after hospital discharge.**

Some sessions will be in person, in the patient's own home and some will be a telephone call.

There will be **an extra visit** if the **patient falls or moves home.**

Commented [RH2]: @Aisha Shafayat (staff) can you go through the text that I have added to make sure that only the key worlds are made bold please?

	Treatment plan B is **normal care only.** **Normal care** in **treatment plan A** and **treatment plan B** will be your **local NHS care**. We want **464 people** to take part **Half the people** will have treatment plan A **Half the people** will have treatment plan B You will have an **equal chance** of **receiving treatment plan A or treatment plan B** Your treatment will **not start** until you have **left the hospital** **Both patients in treatment plan A** and **treatment plan B** will be asked to **report their falls to the research team every month for 12 months.** **Patients** will be asked to **complete** a **longer questionnaire at 3, 6, 9 and 12 months** after they **join the research.** The **questionnaires** will ask them about the **impact of any falls** they have had and **their general wellbeing.**
What will I have to do?	
	In the research you will **answer** some **questions**

You will be asked to **write** down any **falls you have** in a **diary**

We will ask you about them each **month for 12 months**

We will send you **questionnaires**

You can do these **at home**

They can be sent to you **online** or by **post**

It is **your choice**

This information will be kept **safe**

Tell us if you need help

We will **help you**

If you join the **falls programme** you may be asked to **talk about your experience**

This will be a **friendly chat**

It is your **choice**

	If you say **yes**, the team **may contact you**
How long will the research last?	
	The **whole research** will last for **4 years** **Your part** will last for **12 months** once you have **left hospital**
Will I get paid?	
	You will **not get paid** for taking part in the research
Do I have to take part?	
	Taking part is **your choice** If you change your mind you can **stop at any time** You **don't** have to **give a reason** **If you stop** you will still get **normal treatment** If you don't take part you will **still get normal treatment**
When do I need to decide?	
	You don't need to decide now, you can **think about it**

Commented [RH3]: @Aisha Shafayat (staff) I thin this section within this PIS can stay the same, I think they might be referring to the withdrawal in the other non aphasia PIS' because our standard text refers to not having to completely withdraw. Could you revert this section back and check the other carer and PE PIS docs please?

	You can **read** the information **again** You can **talk to your family and friends** to **help you decide**
Who will see the information about me?	
	We will need to **use information from you** for this research project This information will include your **name**, **contact details** and **answers** to our questionnaires People will **use this information** to do the **research** or to **check your records** to make sure that the research is being done **properly**
	People who do not need to know who you are **will not see your name or contact details** Your data will have a **code number** instead
	The University of Nottingham is **responsible** for **looking after your information** We will keep your study data for a maximum of **7 years.**

	The study data will then be **fully anonymised** and **securely archived or destroyed.**
	We will **tell your doctor** that you are part of this research
	Your **name and number** will be shared with **Esendex**, our **text messaging provider**
	This will be used to send you **text message reminders** about the study and study **questionnaires**
Where can I find out more about how my information is used?	
	See how your **information is used** by reading our privacy statement: https://www.nottingham.ac.uk/utilities/privacy/privacy-information-for-research-participants.aspx
	To find out **more** about **what will happen to your information**
	Use the **websites** below: • www.hra.nhs.uk/patientdataandresearch • www.nottingham.ac.uk/utilities/privacy/privacy-information-for-research-participants.aspx • www.nctu.ac.uk/data-protection/data-

	protection.aspx And you can email our **Data protection officer** at: dpo@nottingham.ac.uk
Will my data go outside the UK?	
	Yes – your data may be shared outside of the UK for further research. This will be **anonymous**. We may share data with **other researchers**, for example stroke and falls researchers. There is a **similar study** taking place at the same time called **FISS Australia**. We are working closely with this team.
	We will share your **anonymous** data with this team at the end of the study to **combine the results** to see if SAF works in both countries.
	We will keep your data **protected** and **safe**. Researchers must follow **strict rules** to protect your data – just like in the UK.
What might be good about taking part?	
	• You **may be helped** by the treatment plan • You will **help us to learn**

	This may **prevent falls** in stroke survivors in the **future**
What might be difficult about taking part?	
 	• We **don't think** it is **dangerous** however the **treatment plan may not help** you • You may find some questions **distressing** You do not have to answer these questions • It may take up **your time**
Is the research safe?	
 	A committee **decides if the research can happen** This is the **ethics committee** They say that **this research can happen** They say that it is **safe** They say that it has been **planned properly**
What if something goes wrong?	

	This is very **unlikely** The committee will **monitor the research** If you **take part** and think you were **harmed** there are **people to talk to** **Contact [add details of PALS]**
What will happen to the results?	
	Once we have **finished** the study, we **will keep some of the data** so we can **check** the results We will write our reports in a way that **no-one can work out that you took part** We will share the **results**
	with **other researchers** at **conferences** and **meetings,**
	in **academic journals,** on the **website** www.nottingham.ac.uk/FISS/

	We will also make a **short film** of the results
What next?	
	If you decide to take part you will need to **sign a consent form** This says **you understand** the research and **you agree** to take part
	If you want **more information** **Contact us** as **[insert appropriate contact details]**