

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.

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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.

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

Why me?



You have **had a stroke**

Your stroke **may** cause you to **fall**

Who is doing the research?



The research is run by the **Nottingham Clinical Trials Unit**



It is sponsored by the **University of Nottingham**



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**

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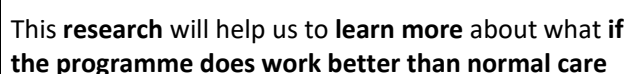
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There will be an extra visit if the patient falls or moves home.

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

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



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**

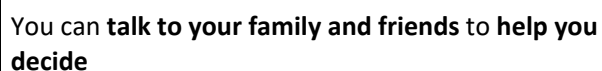


	If you say yes , the team may contact you
How long will the research last?	
	The whole research will last for 4 years Your part will last for 12 months once you have left hospital
Will I get paid?	
	You will not get paid for taking part in the research
Do I have to take part?	
	Taking part is your choice 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?

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We will keep your study data for a maximum of **7 years**.

 	<p>The study data will then be fully anonymised and securely archived or destroyed.</p> <p>We will tell your doctor that you are part of this research</p> <p>Your name and number will be shared with Esendex, our text messaging provider</p> <p>This will be used to send you text message reminders about the study and study questionnaires</p>
Where can I find out more about how my information is used?	
 	<p>See how your information is used by reading our privacy statement:</p> <p>https://www.nottingham.ac.uk/utilities/privacy/privacy-information-for-research-participants.aspx</p> <p>To find out more about what will happen to your information</p> <p>Use the websites below:</p> <ul style="list-style-type: none"> • www.hra.nhs.uk/patientdataandresearch • www.nottingham.ac.uk/utilities/privacy/privacy-information-for-research-participants.aspx • www.nctu.ac.uk/data-protection/data-



	<p>protection.aspx</p> <p>And you can email our Data protection officer at: dpo@nottingham.ac.uk</p>
Will my data go outside the UK?	
	<p>Yes – your data may be shared outside of the UK for further research. This will be anonymous.</p> <p>We may share data with other researchers, for example stroke and falls researchers.</p> <p>There is a similar study taking place at the same time called FISS Australia. We are working closely with this team.</p>
	<p>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.</p>
	<p>We will keep your data protected and safe. Researchers must follow strict rules to protect your data – just like in the UK.</p>
What might be good about taking part?	
	<ul style="list-style-type: none"> 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?	
	<ul style="list-style-type: none"> 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?	
	<p>A committee decides if the research can happen</p> <p>This is the ethics committee</p> <p>They say that this research can happen</p> <p>They say that it is safe</p> <p>They say that it has been planned properly</p>
What if something goes wrong?	



on the website www.nottingham.ac.uk/FISS/



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