UNIVERSITY OF CAMBRIDGE
Department of Public Health and Primary Care

University Hospitals of Leicester NHS
NHS Trust

Participant Information Sheet

Improving Primary Care After Stroke: Testing a new stroke service in your General Practice

IRAS Reference: 233891

Version 2.0

19th December 2017

NHS
National Institute for Health Research

This study is funded by the National Institute for Health Programme Grant for Applied Research.

We would like to invite you to take part in a study to test a new service for people who have had a stroke.

Before you decide to take part it is **important** for you **to understand why** this study is being done and **what** it will involve.

Pages **2** and **3** of this booklet give a **summary** of what the study involves. Pages **4** to **12** provide more **detailed information** about the study.

Please read the following information carefully. Feel free to talk to others about the study if you wish. Please **take time to decide** whether or not you wish to take part.

Please **ask us** if anything **is not clear** or if **you would like more information**. We can talk to you **over the telephone.** Or we can **arrange a visit** to you from one of the research team. Contact us on **01223 748696**	

Why are we conducting the study?

Many long-term needs of stroke survivors are not being met. We have developed a new General Practice service for people who have had a **stroke**. We are conducting this study **to test this new service.** This study is called "**I**mproving **P**rimary **C**are **A**fter **S**troke" **(IPCAS).**

What would I have to do?

- Complete the **Consent Form** and **Questionnaire** included with this letter.
- Complete a Questionnaire in a few weeks' time. This will be sent to you by post.
- Complete a Questionnaire in **6 months'** time.
- Complete a Questionnaire in **12 months'** time.

We hope that your family or friends can help you fill in the information if necessary. If your family or friends are **unable to help** and you would like help, **please let us know**.

You may also be invited to attend a **stroke review** at your **GP Surgery**. Not all participants will be invited to attend a stroke review.

What are the possible benefits?

- Your participation will help us to evaluate the new service for people who have had a stroke.
- This will inform future long-term care for stroke survivors.

What else should I know?

- You **do not have to** take part in this study.
- The **risks** to you in taking part in the study are **very low**.
- However, some people may find thinking about their care **upsetting.**
- The research team will contact you to follow-up about the study. You can indicate on the questionnaire your preferred method of contact.
- The researchers would also like to **review your medical records**. This is to learn how your care needs were met during the study.
- Your study data will be stored **securely** and kept **confidential**.

If you are interested in taking part please continue to read the rest of this information sheet.

If you want to take part please complete the enclosed **Consent Form** and **Questionnaire.** Please return these to the research team.

Full Participant Information Sheet

Who are we?

We are a team of **researchers** from the Primary Care Unit at the **University of Cambridge** and **University Hospitals of Leicester NHS Trust.**

The **manager** of this research is **Jonathan Mant**	

What is the study about?

People who have had a **stroke** get help after they come back home from the hospital. We are interested in **how GP Surgeries could better support people** who have had a stroke.

We have developed a new General Practice service for people who have had a stroke. To develop this new service, we talked to stroke survivors, their carers, and health care professionals.

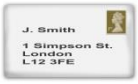
We are conducting this study to **test this new service.** We will launch the new service in a number of GP surgeries. We will test how well these do compared to current care for stroke survivors.

Why have I been invited to participate?

You have been invited to take part because: ▪ Your **surgery** is taking part in **testing this new service**. ▪ You are **registered** with the GP surgery. ▪ **Your records** indicate that **you have had a stroke**.	

What will happen to me if I take part in the study?

1.Consent Form (included)

You will be asked to complete a consent form. You can find it enclosed with this letter. Please read each statement carefully. If you agree **initial** each box. Please **print your name** under the last statement along with the date. Please write your **signature**. Please send it back to the research team in the FREEPOST envelope provided. If you sign the consent form, we will **tell your doctor** that you are taking part in this research.	 

2. Questionnaires

You will be asked to complete a series of questionnaires. The first one is enclosed with this letter. A second one will be sent to you in a few weeks' time. The questionnaires ask about **common difficulties** after stroke. These may take **10-20 minutes** to complete. **Take your time.** You can **take breaks** or complete them over a couple of days. Please send them back in the FREEPOST envelope provided.	 

3. Stroke Care Review

If you have decided to **give your consent** to take part in the study and **completed the questionnaires** you may be invited to a **stroke care review** at your **GP surgery**. It will last approximately **20 - 30 minutes**.	 

Not all participants will be invited to attend a stroke review.

If you are invited to a stroke review it will be with a member of the GP Practice team (probably the Practice Nurse). They will review your care and may do some health checks.

A **family member** or a **friend** who helps you with stroke is also **welcome to attend**.

4. Follow-up questionnaires – 6 months

In six months' time, we will send you another set of questionnaires by post.

These questionnaires will be similar to the ones at the start of the study. This questionnaire could also take about **30 minutes** to complete.

5. Follow-up questionnaires – 12 months

In 12 months, we will send you another set of questionnaires by post. These questionnaires will be similar to the ones at the start of the study.

We will also ask you questions about your experience of care as a whole. This will help us understand how useful the new service was.

This questionnaire could take about **45 minutes** to complete.

6. Interview (optional)

The research team would like to **interview** some stroke survivors. This is to ask about their experiences during the study.

The interview will last around **30 minutes.** The interview will be **audio-recorded** and typed out word for word. Anything you tell us in the interview will be **confidential**. This interview is **optional.** If we ask to interview you, we will ask you to complete an additional **consent form**. You can participate in the study and not agree to this interview. **Not all participants will be interviewed**.	

7. Review of medical records

The research team would like to **learn how your care needs were met**. To do this, they will **review your medical records** from your GP surgery. These data will **only be accessed by authorised members** of the research team. The team **will not have access** to your medical records **after the study has ended**. Your medical data will be **stored securely**.	 

8. Contact by the research team

The research team may contact you by telephone to help you to complete your questionnaires.

9. Audio tape of your stroke review

The researchers may also want to **audio record** some of the appointments you attend as part of this study. This is **optional.** You can indicate on the **consent form** (section 8) if you agree to it. You can take part in the study and not agree to be recorded.

How will my data be stored?

All the information that we collect for this study will be kept **strictly confidential**. This information includes questionnaires, audio recordings and information from your medical records. All data will be stored securely by the **University of Cambridge**.

We will remove your **name** and **address** from the information about you so that you cannot be recognised from it. To protect your privacy we will use a **coded link to anonymise** your data. This means that a **code number** will be assigned to you. Only this code number will appear on your information from the study. No one will be able to identify you from this alone. The file linking your code number and identifying information will only be stored securely within the University of Cambridge. This file will only be accessed by relevant, authorised individuals from the research team	 **XS0101** 

If you have given your consent to be audio recorded, all recordings will be stored securely within the University of Cambridge. These recordings will only be accessed by relevant, authorised individuals from the research team.

We will be writing about the results of our study for publications. No information will be attributed to specific individuals.

At the end of the study, **confidential data** will be stored securely for **3 years** and then destroyed. Confidential data is for example your name and address and audio recordings.

Your **anonymised research data** (for example, your answers to the questionnaires) will be **completely separated** from your personal details. Your research data will be stored **permanently** on a secure server within the University of Cambridge.

Who will have access to my information?

1. Members of the research team

The research team at the University of Cambridge will collect and analyse the information about you. Your information will not be used or made available for any purpose other than for research.

However, if you told us information that led us to believe that **you or others could be at risk of harm**, we have a duty of care to **inform the relevant people about this**. We would always **try to do this with your permission**, but under certain circumstances this may not be possible.

2. Other researchers upon ethical approval

Your research data may be shared with other researchers in **this country** and in **other countries**. This will help with other research about stroke. This will not include your personal details. The use of data in future research will require prior approval by an appropriate Research Ethics Committee. The data will remain strictly confidential.

3. Quality monitoring agencies

To ensure our research is conducted soundly, our studies may occasionally be monitored, for example by the University of Cambridge or the National Institute for Health Research. This procedure is routine and carried out by fully qualified officials. Data confidentiality is preserved at all times.

What are the possible benefits of taking part?

The direct benefit of the new service has not yet been evaluated. Therefore, there are **no proven** benefits of taking part.

However, your participation will help us to evaluate the new service for people who have had a stroke. This will inform future long-term care for stroke survivors.

What are the possible disadvantages of taking part?

The **risks** to you in taking part in the study are **very low**. Some people may find it **difficult to think** about their care needs and experiences. If you are invited to attend a stroke review the nurse conducting the review will be experienced in dealing with sensitive issues.

If you have any concerns at all about your stroke before, during or after the study, we advise you to contact your GP or Practice Nurse.

Do I have to take part?

It is **entirely up to you** to decide whether or not to take part in this study. If you decide not to take part you **do not have to give a reason**. It will not affect the health care that you receive in any way.	

What if I want to change my mind?

If you decide to take part but change your mind later **that is not a problem**. Please let the research team know. You are free to withdraw **at any time**. You **do not have to give a reason**. It will not affect the care you receive.

What will happen to the study results?

The study results will be **presented for publication** in appropriate health journals. We may use some of what you say in the questionnaires when writing about the study. **All information that could identify you would be removed**. The results will be used to **help us evaluate** our new model of General Practice services for people who have had a stroke. We will use this information to make recommendations for future stroke care.

Who has reviewed the study?

All clinical research is looked at by **an independent group of people**, called a **Research Ethics Committee**. This is to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the **Bradford Leeds NHS Research Ethics Committee.** The study was also reviewed by several independent scientists as part of the funding process.

Who is organising and funding the study?

The study is organised by the University of Cambridge, with colleagues at University Hospitals of Leicester. The study is funded by the National Institute for Health Research.

What if there is a problem?

If you have any reason to complain about any aspect of the way you have been approached or treated during the course of this study, you should ask to **speak to the research team.** They will do their best to answer your questions (details are on the back page).

If you remain unhappy and wish to complain formally, please first contact Cambridgeshire and Peterborough Clinical Commissioning Group **patient experience team.**

FREEPHONE: **0800 279 2535** or **01223 725 588**
Email: CAPCCG.pet@nhs.net.

Post: Patient Experience Team | Lockton House | Clarendon Road | Cambridge | CB2 8FH

In the event that something does go wrong and you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation against the University of Cambridge. However, you may have to pay your legal costs.

What should I do next?

If you decide to take part you will need to complete and sign the enclosed **consent form** and **questionnaire**. Please send these to us via post using enclosed a FREEPOST envelope.

If you agree to take part you will be asked to complete another set of questionnaires. These will be sent to you by post. Your **GP surgery** may also invite you to attend a **stroke review**.

Further information

It is important that you have **read this information carefully** and that you **understand what is involved** before you consent to take part in the study. If you have any **questions** please feel free to contact us:

Lizzie Kreit (Study Co-ordinator)

Dr Ricky Mullis (Senior Research Associate)

Victoria Theobald (Research Administrator)

Telephone: 01223 748696

Monday to Friday 9am – 5pm. If you receive no answer please leave your name and number and we will return your call as soon as we can.

Email: ipcas@medschl.cam.ac.uk

Address: IPCAS | Primary Care Unit | Strangeways Research Laboratory | Worts' Causeway | Cambridge | CB1 8RN