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# PARTICIPANT INFORMATION SHEET

## SPaCIS

*Use of the **S**troke **Pa**tient **C**oncerns **I**nventory in **S**troke Outpatient Clinics*

**We would like to invite you to take part in a research study.**
Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please read the following information carefully and feel free to ask questions. Talk to others about the study if you wish. Thank you for reading this information sheet.

**What is the purpose of the study?**
People who have had a stroke are usually offered an appointment at a stroke clinic after they have been discharged from hospital. We want to evaluate the care that people receive at their first outpatient appointment in the stroke clinic. In this study we will test out a prompt list we have developed, called the Stroke Patient Concerns Inventory (sPCI), to see if it has an effect on the care stroke survivors receive. As part of the study, some hospitals will use the sPCI and other hospitals will continue as normal without using the sPCI.

Your hospital has been selected to use the sPCI. All patients attending clinic appointments will be asked to complete the sPCI so that it can be used during the appointment. If you decide to take part in the study, we will collect additional information from you. This information will mean we can compare with hospitals who are not using the sPCI to see if there is any difference.

**Why have I been invited to take part?**
Your hospital is taking part in this study. We are asking all patients invited to their first stroke clinic appointment at this hospital to consider taking part.

**Do I have to take part?**
Taking part is voluntary. If you choose not to take part, your care will not be affected in any way at any time.

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## What will happen to me if I take part?

**Before** your appointment

The researcher will contact you via telephone to check if you are happy to take part in the study and provide **consent**:

- for information about you and your **stroke** to be collected from your medical records
- to have your stroke clinic appointment audio-recorded (**optional**)
- for a researcher to potentially contact you at a later date to see if you would like to take part in an interview about the study (**optional**)

Consent may be taken in writing or verbally and documented. You will then be asked to complete a **questionnaire** about your quality of life.

**During** your appointment

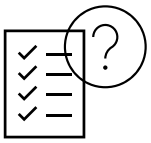
We will collect information about:

- The **prompt list**
- The **length** of the appointment
- What was **discussed**
- Any **referrals** made

If you agree, the appointment will be **audio-recorded.** You may choose for the audio recording to be **deleted** at the end of your appointment. **All audio recordings** will be deleted at the end of the study.

**Soon after** your appointment

You will be asked about **how the prompt list was used** during your appointment, via text message or telephone.



Around **one week after** your appointment

You will receive a **questionnaire** via your preferred method e.g. telephone, post or email, about how your appointment went, and how you are feeling.

Around **three months after** your appointment

You will receive a **questionnaire** asking about your quality of life and use of healthcare services.
Information about your **healthcare use** might also be collected from your medical records.

Towards the **end** of the study

If you agree to be contacted about an **interview** to share your **experience** of taking part in the study, you may be randomly selected for an interview. A researcher will **contact** you to give you more **information** about the interview and **invite** you to take part if you wish. You will not be contacted if you have not been randomly selected for an interview.

**What are the possible advantages and disadvantages of taking part?**
Your feedback will help to improve care in the future for people with stroke. You may find taking part is rewarding on a personal level.

The main disadvantages are that this will take some of your time and you may find thinking or talking about some of the issues is upsetting. If this happens, the research practitioner or university researcher can provide suggestions of who you can talk to, such as helplines or your GP.

**Who will know I am taking part in the study? Will it be kept confidential?**
In addition to the research team at the University of Central Lancashire (UCLan) and Lancashire Clinical Trials Unit, your hospital consultant and GP will also know you are taking part. Once you consent to take part in the study, we send a letter to your GP informing them of your involvement in the study. The GP will be contacted in case we need to check your contact details throughout your participation in the study, or if any concerns arise about your safety.

A copy of the consent form will be sent to you for you to keep. A copy will be kept by the researchers and a copy will also be kept in your medical records.

**What will happen to my data?**
Lancashire Clinical Trials Unit will be the data guardians until the study closes. All data will be managed in line with the University Data Protection Code of Practice and the General Data Protection Regulation and Data Protection Act 2018 for health and social care research. The University privacy notice for research participants can be found on the attached link https://www.uclan.ac.uk/data_protection/privacy-notice-research-participants.php

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| How will we (UCLan) use information about you? | • We will need to use information from you, your medical records and your GP for this research project. This information will include your NHS number, name, date of birth, contact details. This information will be used to do the research or to check your records to make sure that the research is being done properly.<br>• People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.<br>• We will keep all information about you safe and secure.<br>• 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 in the study. |
| What are your choices about how your information is used? | • You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.<br>• We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. |

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| How will my data be stored and anonymised? | • All study data is stored electronically in an anonymous format on the secure UCLan network using a unique numerical code, so any staff who do not need to know your name and contact details will not be able to see them.<br>• We will write our reports in a way that no one can work out that you took part in the study.<br>• Physical copies of information, including paper copies of consent forms, will be stored in locked filing cabinets in locked UCLan rooms only accessible by project and research staff.<br>• National laws may require us to show information to university or government officials (or sponsors), who are responsible for monitoring the safety of this project. In this situation, directly identifying information (e.g. names, addresses) would be safeguarded and maintained under controlled conditions.<br>• Optional audio recordings of the consultations will be recorded using encrypted Dictaphones and transferred to UCLan using a secure method. |
| What measures are in place to protect the security and confidentiality of my data? | • All identifiable information collected from you will be stored separately to your study data.<br>• Only members of the Lancashire Clinical Trials Unit team who need to know your identity, for example, those who process consent and registration forms or post out questionnaires, will have access to your contact details.<br>• Members of the research team will only access data appropriate to their role in the study. We will keep all information safe and secure and follow all privacy rules. |
| If I opt in for my appointment to be recorded, how will the recording be used? | • Optional audio recordings will be analysed to record details about the appointment format, length and concerns discussed. Direct quotes from the recordings will NOT be published. |
| Who will have access to my data? | • Lancashire Clinical Trials Unit, based at the University of Central Lancashire, will be responsible for looking after your information and using it appropriately.<br>• Members of the research team based at the University of Central Lancashire.<br>• Delegated research staff at your hospital. |
| Will my data be archived for use in future research projects? | • The anonymised, aggregated study data set will be kept and added to the UCLan data repository, with open access as appropriate. |
| How long will my data be stored for and then destroyed? | • Identifiable data, including the form which links your contact details and unique numerical code will be permanently deleted will be deleted within 7 years of study closure.<br>• Once the optional audio recordings are analysed, they will be permanently deleted.<br>• De-identified research data generated by the study will be permanently deleted after 20 years from study closure. |

**What will happen if I want to stop taking part?**

You are free to withdraw from the study at any time, with or without giving a reason, but we will keep information about you that we already have. You can withdraw by contacting the local research team, whose details are provided below.

**What will happen if I lose capacity to consent during the study?**
You will be withdrawn from the study. The data already collected with consent will be used in the study, but no further data will be collected.

**What will happen if any safeguarding issues are disclosed during your appointment?**
Your hospital would adhere to their standard procedures for following up any safeguarding issues.

**What will happen to the results of the study?**
Findings will be shared widely using a range of methods including written feedback provided to study participants, presentations at conferences and results published in journals. They will also form part of an application for a larger study.

**Who is organising and funding the research?**
The research is funded by the National Institute for Health and Care Research. The research is being conducted by experienced research staff from the University of Central Lancashire.

**Who has reviewed the study?**
This study has been reviewed and given a favourable opinion by the Research Ethics Committee (Wales REC 3), and Health Research Authority. The study sponsor is the University of Central Lancashire (UCLan).

**Where can you find out more about how your information is used?**
- At www.hra.nhs.uk/information-about-patients/
- Leaflet available from www.hra.nhs.uk/patientdataandresearch or a copy from the research team
- By asking one of the research team
- By sending an email to UCLan's Data Protection Office: DPFOIA@uclan.ac.uk
- By contacting the researcher using email (KPatel@uclan.ac.uk) or telephone (01772 893635).

**What if there is a problem?**
If there is a problem or you wish to complain about any aspect of the study, please do let us know by contacting the Principal Clinical Trial Manager, using email (MRBurns@uclan.ac.uk) or telephone (01772 891781), who will try to help.

If you remain unhappy or would like to speak to someone who is independent from the research team, then please contact the Ethics, Integrity and Governance Unit at OfficerForEthics@uclan.ac.uk. The University strives to maintain the highest

standards of rigour in the processing of your data. However, if you have any concerns about the way in which the University processes your personal data, it is important that you are aware of your right to lodge a complaint with the Information Commissioner's Office by calling 0303 123 1113.

**Further Information**
For further information, or if you have any queries, regarding the SPaCIS study please contact the research team who provided you with this information sheet.

**Local contact details**
Name:
Institution name:
Address:
Telephone:

If you have any concerns about the study before, during or after participating you can contact your local **Patient Advice and Liaison Service**:

Name: [HOSPITAL NAME]
Address: [ADDRESS]
Telephone: [PALS NUMBER]

**Thank you for reading this information sheet and for considering taking part in this research.**