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Exploring the use of a stroke patient concerns inventory during stroke follow-up appointments

Submission date
07/11/2024

Recruitment status
No longer recruiting

Registration date
22/11/2024

Overall study status
Completed

Last Edited
04/03/2026

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Stroke survivors experience ongoing physical, psychological and social concerns affecting quality-of-life. There is a lack of systems and tools that allow healthcare staff to identify stroke survivors' concerns and so they are often not adequately addressed. Stroke outpatient follow-up appointments are time-limited, reducing opportunity for patients to discuss, and staff to identify, concerns.

The Patient Concerns Inventory (PCI), is used in cancer-care appointments. The PCI lists potential concerns for patients to select from before their appointment which they would like to discuss. Research shows that using the PCI increased satisfaction with appointments and improved patient quality-of-life, without lengthening appointment time. The PCI has been adapted for stroke (Stroke Patient Concerns Inventory (sPCI)) and a large study is needed to see if it is also effective. Firstly, the study design and the sPCI need to be tested in a smaller study. This study, funded by the NIHR, aims to determine if the sPCI can be used in stroke outpatient services by both staff and patients.

Who can participate?
Four stroke services performing follow-up appointments will recruit a total of 96 participants, who are: stroke survivors within 7-months of stroke, aged 18 years and over, and attending their first follow-up appointment.

What does the study involve?
Two sites will receive training in the sPCI (using it during appointments to discuss concerns and manage them appropriately), and provide their participants the sPCI to complete before their appointment (in addition to their usual practice). The remaining two sites will continue their usual practice. Data collection will include: participants' demographic and stroke information, and quality-of-life at baseline; completed sPCI and participants' feedback on its use immediately after the appointment; participants' satisfaction and empowerment within one-week of the appointment; and participants' quality-of-life and use of health services three-months later. A selection of participants and staff will be interviewed about their experiences of the study.

What are the possible benefits and risks of participating?
Benefits: Not provided at time of registration
Risks: 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.

Where is the study run from?
University of Central Lancashire (UK)

When is the study starting and how long is it expected to run for?
May 2024 to April 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
esaviciute@uclan.ac.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
344756

Central Portfolio Management System (CPMS)
64325

National Institute for Health and Care Research (NIHR)
206217

Study information

Scientific Title
Use of the Stroke Patient Concerns Inventory in Stroke Outpatients Clinics: a feasibility cluster randomised controlled trial

Acronym
SPaCIS

Study objectives
To determine whether a future, larger study can be conducted to explore how effective the Stroke Patient Concerns Inventory (sPCI) is when used in stroke outpatient clinics.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 04/10/2024, Wales REC 3 (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 2922 940963; Wales.REC3@wales.nhs.uk), ref: 24/WA/0259

Study design
Interventional non-randomized

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Stroke

Interventions
Four stroke services performing follow-up appointments will recruit a total of 96 participants, who are: stroke survivors within 7-months of stroke, aged 18 years and over, and attending their first follow-up appointment. Two sites will receive training in the sPCI (using it during appointments to discuss concerns and manage them appropriately), and provide their participants the sPCI to complete before their appointment (in addition to their usual practice). The remaining two sites will continue their usual practice.

Data collection will include: participants' demographic and stroke information, and quality-of-life at baseline; completed sPCI and participants' feedback on its use immediately after the appointment; participants' satisfaction and empowerment within one-week of the appointment; and participants' quality-of-life and use of health services three-months later. A selection of participants and staff will be interviewed about their experiences of the study.

Intervention Type
Behavioural

Primary outcome(s)

1. The rate of completed sPCIs is measured using the number of sPCIs completed at the clinical follow-up appointment
2. sPCI use in consultation is measured using a participant's immediate feedback question on whether they recall the use of the sPCI in their consultation and audio recordings of consultations at clinical follow-up appointments and immediate feedback
3. Participant feedback on the use of sPCI is measured using an immediate feedback question on whether they recall the use of the sPCI in their consultation at immediate feedback
4. Patients completing sPCI is measured using the number of sPCIs completed at clinical follow-up appointments and process evaluation interviews
5. sPCI use during the consultation is measured using a participant's immediate feedback question on whether they recall the use of the sPCI in their consultation and audio recordings of consultations at clinical follow-up appointments and process evaluation interviews
6. Staff trained in sPCI use is measured using the number of staff trained during the training period and process evaluation interviews
7. sPCIs provided before the appointment are measured using the number of sPCIs sent to patients at the clinical follow-up appointment
8. Completed sPCIs available to staff conducting consultations are measured using data on consultation CRF about whether sPCI was available at the clinical follow-up appointment
9. Sites recruited are measured using the number of sites in the study at the end of the recruitment period
10. Participants recruited are measured using the number of participants recruited to the study at the end of the recruitment period
11. Eligibility rate is measured using screening logs at the end of the recruitment period
12. The recruitment rate is measured using screening logs and the number of participants recruited to the study at the end of the recruitment period
13. Retention/completion rates are measured using the number of completed 3-month questionnaires at the end of the data collection period
14. Questionnaire completion rates are measured using the number of completed 1-week and 3-month questionnaires at the end of the data collection period and process evaluation interviews
15. Patient satisfaction, empowerment, and quality of life are measured using the Patient Satisfaction Survey and Southampton Stroke Self-Management Scale at 1-week, and EQ-5D-5L at 3-months of data collection and process evaluation interviews
16. Case report form completion rates are measured using the number of completed 1-week and 3-month questionnaires at the end of the data collection period and process evaluation interviews
17. Stop/Go criteria is measured using pre-defined criteria and process evaluation at the end of the study

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
30/04/2026

Eligibility

Key inclusion criteria
1. >= 18 years.
2. Experienced acute stroke within previous 7 months.
3. Attending first routine post-discharge stroke clinic appointment.

4. Able to complete sPCI, either themselves, with assistance for those physically unable to complete for themselves (e.g. have visual or motor problems), or by proxy for those without capacity to consent (i.e. relative/carer completes with their opinion of what the participant's concerns are).
5. Able to communicate in English, or have a relative/carer willing to translate trial communications and materials for the participant, or able to use site-specific translation services, if available.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
120 years

Sex
All

Total final enrolment
85

Key exclusion criteria
1. Lack of capacity to consent themselves and no consultee assent available.

Date of first enrolment
25/11/2024

Date of final enrolment
01/03/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Lancashire Teaching Hospitals NHS Foundation Trust
Royal Preston Hospital
Sharoe Green Lane

Fulwood
Preston
England
PR2 9HT

Study participating centre
Royal Cornwall Hospitals NHS Trust
Royal Cornwall Hospital
Treliske
Truro
England
TR1 3LJ

Study participating centre
The Royal Wolverhampton NHS Trust
New Cross Hospital
Wolverhampton Road
Heath Town
Wolverhampton
England
WV10 0QP

Study participating centre
East Lancashire Hospitals NHS Trust
Royal Blackburn Hospital
Haslingden Road
Blackburn
England
BB2 3HH

Sponsor information

Organisation
University of Central Lancashire

ROR
https://ror.org/010jbqd54

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Control group version 1.1	27/09/2024	18/11/2024	No	Yes
Participant information sheet	Intervention group version 1.1	27/09/2024	18/11/2024	No	Yes