ISRCTN70383448 https://doi.org/10.1186/ISRCTN70383448

Patient portal for stroke survivors

Submission date
02/06/2025

Recruitment status
Not yet recruiting

Registration date
03/06/2025

Overall study status
Ongoing

Last Edited
08/07/2025

Condition category
Circulatory System

[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
The South London Stroke Register (SLSR) is a prospective cohort study of stroke survivors which has been running continuously since 1995, and with over 2,000 stroke survivors being currently followed up with interviews at 3 months and then annually for the first 5 years following their stroke. The study collects a wealth of data, including on stroke type and severity, functional recovery, mental health post-stroke, and quality of life, but until now, participants had no easy way to access this data. This feasibility study aims to evaluate a patient portal for SLSR participants, which has the primary objective to allow participants to access their own data (questionnaire/follow-up data) that they have previously provided to the study. We aim to investigate whether diverse stroke survivors can make use of the portal to access their data, and whether it is feasible to use the portal to collect further research data. Finally, we aim to investigate whether it is feasible to use the portal as a platform for conducting efficient randomised trials, using the example of supporting stroke survivors to self-manage their blood pressure (BP).

Who can participate?
All participants of the South London Stroke Register who have the capacity to consent to participation in this feasibility study, have sufficient knowledge of English (as currently only English is provided on the portal), and are not residing in a social care setting.

What does the study involve?
During the 6-month study duration, participants are able to monitor a subset of the data they have previously provided to the SLSR and are encouraged to enter further updates on the EQ-5D-5L into the portal as often as they wish, but at least once following recruitment and after 6 months. A subset of the study participants will be provided with blood pressure monitors and are encouraged to enter their blood pressure readings into the portal twice a day for the first week following recruitment, freely throughout the study duration and again after 6 months twice a day for 1 week. Semi-structured interviews will be undertaken with 40 study participants at 6 months after recruitment to assess intervention acceptability and satisfaction.

What are the possible benefits and risks of participating?
The portal will give SLSR participants information about their recovery since stroke and therefore better insights into their conditions. They can use their recovery curve to discuss their progress with others, e.g. their carers or GP. This will hopefully reduce anxiety, further a sense of

empowerment, and improve health behaviour and engagement with care.
The nested RCT encourages participants to monitor their own blood pressure, and the portal provides a method of systematically recording it. It is hoped that this will lead to more frequent blood pressure monitoring, better medication adherence, and overall improved blood pressure control.
During the semi-structured interview, participants may find personal value in sharing their experiences and feedback on managing personal well-being data and health progress on a patient portal website system. They will also gain a sense of contributing to a meaningful research study that has the potential to improve stroke care.
The potential risks to participants of this study are minimal but could potentially include feelings of distress. Participants will be presented with their own, previously provided data, and asked questions about their health and recovery from stroke. It is possible (though unlikely) that these may cause some degree of anxiety or distress. These questions are identical to those which are part of the regular follow-up as part of the SLSR, and should be of a nature that all participants are used to as part of this study

Where is the study run from?
The study is run by the Stroke Research Group within the Department of Population Health Sciences at King's College London (UK)

When is the study starting and how long is it expected to run for?
December 2023 to December 2026

Who is funding the study?
The study is funded by a National Institute for Health Research (NIHR) Programme Grant for Applied Research (NIHR 202339) (UK)

Who is the main contact?
Eva Emmett, eva.s.emmett@kcl.ac.uk

Study website
https://www.kcl.ac.uk/research/improving-the-lives-of-stroke-survivors-w

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
351030

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 68290

Study information

Scientific Title
Feasibility study of a patient portal for stroke survivors and nested randomised controlled trial

Study objectives
In this feasibility study, we seek to understand the feasibility of using a patient portal for providing participants of a stroke cohort study with access to their own data, collecting questionnaire data electronically from participants, and conducting a nested randomised controlled trial of supported self-management of blood pressure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/05/2025, North West - Greater Manchester West Research Ethics Committee (2 Redman Place, Stratford, London E20 1JQ, UK; +44 (0)207 104 8057, +44 (0)2071048065; gmwest.rec@hra.nhs.uk), ref: 25/NW/0145

Study design
Randomized; Both; Design type: Process of Care, Active Monitoring, Cohort study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
A feasibility study of a patient portal with a nested randomised controlled trial (RCT) within an established cohort of stroke survivors (South London Stroke Register, SLSR). Over a 12-month period, we will invite consecutive, eligible SLSR participants during their routine SLSR follow-up between 3 months and 5 years post-stroke to take part in this feasibility study and use the portal to access their own, previously provided data. This includes information provided during routine SLSR follow-ups, specifically data on activities of daily living (ADL, Barthel Index), fatigue severity score (FSS), and quality of life (EQ5D-5L). Participants will also be able to enter further updates on the EQ5D-5L online at times of their choosing. There will be no control arm to this part of the study. Participation in this feasibility study is for a duration of 6 months from recruitment.

Participants will be offered a tablet device to access the portal if they have no suitable device of their own. They will be given written instructions on how to log into and navigate the portal to view their previously provided research data.

Those instructions contain contact details (telephone number and email) to contact the study office in case participants need further support with the portal. The SLSR fieldworker will offer to show participants how to log into the portal during this initial visit, if they wish.

We will ask all participants to self-report data on quality of life (EQ-5D-5L) at minimum at baseline (independently or with a carer, within 7 days of the recruitment visit) and at 6 months, and freely in between. At 6 months post-recruitment, we will prompt all participants by email or text message (depending on participant preference) to complete a further EQ5D-5L scale on the portal.

There will be no follow-up visit for the majority of participants of the feasibility study, apart from ~40 participants who will take part in semi-structured follow-up interviews at 6 months to collect data on intervention acceptability and satisfaction. These will be assessed quantitatively (through Likert scales) and qualitative interview analysis.

Nested randomised controlled trial:
At the initial recruitment visit, we will additionally invite 50 of the ~190 participants to also participate in a nested RCT to evaluate the feasibility of the portal to support blood pressure (BP) self-management. Participants of this nested RCT will be randomised (via a secure web-based system) to have portal-supported BP management (25 participants) versus usual care (25 participants; portal use without BP self-management module). The portal BP module (visible only to study participants randomised to the intervention arm) supports users to record and monitor their BP according to best practice and NICE guidelines, and provides personalised feedback with regard to BP management.

Participants assigned to the intervention arm will be provided with a validated automated electronic sphygmomanometer and will be trained by the SLSR researcher on how to measure their BP and record the reading in the portal. They will be given written instructions and a link to a training video on how to undertake BP self-measurement.

At recruitment, we will collect additional data from those 50 RCT participants via questionnaire, which will include health and social care service use, and ownership and frequency of prior use of a BP monitor.

Following recruitment, the 25 participants in the intervention arm are encouraged to upload twice-daily records, ideally morning and evening, for a period of 7 days, in line with the British Hypertension Society's guidance on home blood pressure monitoring. Participants are encouraged to enter their systolic and diastolic BP on the portal; the portal will provide feedback as to whether the participant's BP is within the target BP range (following NICE guidelines, and based on the TASMIN II trial). This will be displayed visually as a traffic light system with the following targets/cut-offs:
Green (target BP): <= 135/85 mmHg
Amber: > 135/85 mmHg and <= 170/105 mmHg
Red: >170/105 mmHg

Participants whose BP is higher than the target (>135/85 mmHg) will be advised to repeat the reading at least 5 min apart and seek further advice from their GP if readings are persistently higher than target. In the unlikely event of dangerous BP elevation (>170/105 mmHg), the participant will receive advice to repeat the reading after 5 min and seek emergency assessment at their GP surgery or in A&E, if BP persists in the "red" category. In the event of a "red" BP reading, two designated SLSR fieldworkers and the CI will receive a notification via email (containing study ID), indicating the fact of a dangerously high BP reading. Fieldworkers will contact the participant on the next working day to ensure they have been assessed by a clinician, or advise urgent assessment if this has not yet taken place. We will also send a notification of this dangerously elevated reading to the GP. Participants will be provided with the option to download their readings for their own records and to inform their GP.

Participants will be asked to conduct a minimum of a self-assessment at baseline (twice-daily BP records over a period of 7 days) and at 6 months after recruitment, and will be encouraged to measure and record their BPs on the portal freely throughout the 6-month duration of the study. At 6 months post-recruitment, we will prompt all participants by email or text message (depending on preference) to record a further series of BP measurements (twice-daily BP records over a period of 7 days) on the portal.

All RCT participants will have a face-to-face visit at 6 months to have BP measurements taken by a study researcher and answer a brief questionnaire on health and social care use. At least 15 of the 50 RCT participants will take part in the semi-structured follow-up interviews described above.

At 6 months after recruitment, and after the 6-month follow-up visit/interview for those in the nested RCT, we will end data collection.

SLSR participants who decline to use the portal will be invited to take part in a semi-structured interview to understand the reasons behind their refusal and any barriers to their participation.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Portal utilisation: number of log-ins, time spent on the portal and navigation history per participant over the 6-month follow-up
2. Rates of completion of EQ-5D-5L scale questionnaires online over the 6-month follow-up
3. Quality of life measured using EQ-5D-5L scale over the 6-month follow-up
4. Rates of recording of home BP (for those with BP self-management module) over the 6-month follow-up
5. BP measurements taken by participants and entered on the portal over the 6-month follow-up
6. Proportion of participants and time spent accessing the BP self-measurement training video over the 6-month follow-up
7. Intervention acceptability and satisfaction and decisional conflict, assessed via semi-structured interviews at the 6-month follow-up visit, quantitatively through Likert scales and qualitative interview analysis
8. Chronic disease self-efficacy measured using the Self-Efficacy for Managing Chronic Disease 6-item Scale at the 6-month follow-up visit

Secondary outcome measures
1. The number, duration, and reasons of interactions (email or telephone) between the participant/carer and the study team for support with portal usage over the 6-month follow-up
2. Health and social care service use in the previous 6 months, collected through a 6-month participant follow-up interview
3. Portal maintenance costs measured using the number of researcher hours utilised at the end of study data collection
4. Administrative costs: BP monitors and tablets, delivery and return of devices, postage costs, expenses for field worker travel measured using itemised costs and number of researcher hours utilised at the end of study data collection

Overall study start date
01/12/2023

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Participant has been recruited into the SLSR. Criteria for inclusion into the SLSR are:
1.1. Confirmed stroke (cerebral ischaemic stroke, primary intracerebral haemorrhage, subarachnoid haemorrhage, and stroke not known if ischaemic or haemorrhagic); people with asymptomatic cerebrovascular disease or those with scan-negative TIA are not included in the SLSR.
1.2. Main residence of participants is in the SLSR study area at the time of first stroke (27 electoral wards in the northern part of Lambeth and Southwark; participant's residence within these wards is confirmed by postcode)
1.3. First stroke since 1st January 1995
1.4. Age at first stroke: 18 years or older
2. Participant is due for a routine 3-month to 5-year SLSR follow-up over a 12-month period following the study start date
3. Participant has the capacity to consent to take part in the study
4. Participant has sufficient proficiency in English (currently there is only an English version of the patient portal
5. Participant has given consent to be contacted by the SLSR team for further stroke-related research

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100

Key exclusion criteria
1. SLSR participants who lack the mental capacity to consent will not be included in this study.
2. Non-English speakers will not be included in this feasibility study as there is currently only an English version of this patient portal. Later work might involve offering different language versions. This limitation will need to be considered when interpreting the results of this feasibility study.
3. People residing in a social care setting will be excluded in order to not put a potential additional burden on the care team.

Date of first enrolment
01/09/2025

Date of final enrolment
30/06/2026

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Guy's & St Thomas Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

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Sponsor type
University/education

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http://www.kcl.ac.uk/index.aspx

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https://ror.org/0220mzb33

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Guy's and St Thomas' NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR202339

Results and Publications

Publication and dissemination plan
Results will be communicated to service users through a number of established links, including the KCL Stroke Research Patient and Family Group and “Forward”, our research newsletter distributed biannually to SLSR participants, and to wider patient, public and professional stakeholders via Stakeholder Engagement Group meetings (SEG). These events/communications invite feedback into the interpretation of analysis and decision making on changes needed to improve the intervention. A lay summary of the results will be produced and offered to participants.

We will present findings via the usual academic means, including clinical and social science meetings and through publications in relevant journals.

Intention to publish date

Individual participant data (IPD) sharing plan
Deidentified participant data will be made available through requests to access for academic use. Requests should be made to the SLSR team (https://www.kcl.ac.uk/lsm/research/divisions/hscr/research/groups/stroke/index.aspx). Requests to access the dataset have to be approved by the SLSR Investigators and Data Controllers through a signed data access agreement.

IPD sharing plan summary
Available on request