FULL PROTOCOL TITLE OF THE STUDY

Feasibility Study of a Patient Portal for Stroke survivors and nested randomised controlled trial

SHORT STUDY TITLE

Patient portal for stroke survivors

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PROTOCOL VERSION NUMBER AND DATE

Version Stage	Versions No	Version Date	Protocol updated & finalised by;	Detail the key protocol update
Current	1.1	10.07.2025	Dr Iain Marshall, Dr Eva Emmett, Dr Matthew O'Connell	inclusion of verbal telephone consent
Previous	1.0	02.04.2025	Dr Iain Marshall, Dr Eva Emmett, Dr Matthew O'Connell, Professor Julia Fox-Rushby, Professor Yanzhong Wang	Initial version

SIGNATURE PAGE

The Chief Investigator and the R&D (sponsor office) have reviewed this protocol. The investigators agree to perform the investigations and to abide by this protocol

The investigator agrees to conduct the trial in compliance with the approved protocol, EU GCP, the UK Data Protection Act (2018), the Trust Information Governance Policy (or other local equivalent), the UK policy Framework for Health and Social Care research, the Sponsor's SOPs, and other regulatory requirements as amended.

Chief investigator

Signature Date

This Protocol template is intended for use with UK sites only.

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1 LIST OF ABBREVIATIONS AND DEFINITIONS

AE	Adverse Event
CI	Chief Investigator - The overall lead researcher for a research project (Outside the UK the term Coordinating Investigator or Investigator may be used). Chief investigators are responsible for the overall conduct of a research project.
CRF	Case Report Form
EQ-5D-5L	EuroQol 5-dimension 5-level (health-related quality of life questionnaire)
FSS	Fatigue Severity Scale
GAfREC	Governance Arrangements for NHS Research Ethics Committees
HRA	Health Research Authority
ICF	Informed Consent Form
Main REC	Main Research Ethics Committee
NHS R&D	National Health Service Research & Development
PI	Principal Investigator- An individual responsible for the conduct of the research at a research site. There should be one PI for each research site. In the case of a single-site study, the chief investigator and the PI will normally be the same person.
PPI	Patient and Public Involvement
PSC	Programme Steering Committee
Participant	An individual who takes part in a clinical trial
RCT	Randomized Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SEG	Stakeholder Engagement Group
SLSR	South London Stroke Register
SOP	Standard Operating Procedure
Sponsor	The organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project.

2 SUMMARY/SYNOPSIS

Title	Feasibility Study of a Patient Portal for Stroke Survivors and nested randomised controlled trial
Protocol Short Title	Patient Portal for Stroke Survivors
Study Phase if not mentioned in title	Feasibility study
Is the study a Pilot?	No
IRAS Number	351030
REC Reference	25/NW/0145
EDGE reference	176771
Study Duration	July 2025 to July2026
Methodology	Feasibility study with nested randomised controlled trial
Health condition(s) or problem(s) studied	Stroke
Purpose of clinical trial	In this non-commercial, NIHR-funded study, we seek to understand the feasibility of using a patient portal in stroke for: 1. Providing participants of a stroke cohort study (South London Stroke Register) with access to their own data 2. Collecting questionnaire data electronically from participants 3. Conducting a nested randomised controlled trial, with embedded economic evaluation, of supported self-management of blood pressure
Primary objectives	● Objective 1: To assess the rates of use and acceptability of using a portal to share data with diverse groups of stroke survivors ● Objective 2: To assess the quality of questionnaire data collected via the portal ● Objective 3: To assess the feasibility of using the portal to support and evaluate the effectiveness and efficiency of blood pressure self-management among stroke survivors (nested randomised controlled trial)
Secondary objectives	N/A
End of study definition	End of data collection and database lock, after 6-month follow-up of last recruited participant
Number of Participants	estimated 100 participants
Study Type	Observational study with nested randomised controlled trial
Human Tissue Samples (if applicable)	N/A
Data collected/storage (if applicable)	Data collected and stored at King's College London

3 INTRODUCTION

The South London Stroke Register (SLSR) is a prospective cohort study of stroke survivors, which has been running continuously since 1995; and with >2,000 stroke survivors being currently followed up with interviews at 3 months and then annually for the first five years following the stroke.(1) The study collects a wealth of data, including on stroke severity, functional recovery, mental health post-stroke, and quality of life; but until now, participants had no easy way to access this data. This protocol describes the evaluation of a patient portal for SLSR participants which has the primary aim of allowing participants to access their own data (questionnaire/follow-up data) which 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. This will allow participants to track their stroke recovery over time, giving them a better understanding of their health condition, and possibly identifying any patterns that might occur and why. Finally, we aim to investigate whether it is feasible to use the portal as a platform for conducting efficient randomised trials (based on the Trials Within Cohorts [TwiCs] approach)(2), using the example of support stroke survivors to self-manage their blood pressure (BP).

A patient portal is defined as a patient-facing, web-based technology offered by healthcare organisations to provide patients with access to their electronic health record (EHR) data and also often provide additional features to engage patients in their healthcare. Providing stroke survivors and carers with access to such portals remains controversial.(3) Such access has been found to improve medication adherence, blood pressure and glycaemic control,(4) improve health ownership, reduce high-cost healthcare utilisation in patients with long-term conditions, and decrease primary care and speciality care visits.(5) Patients have reported improved access to information, better insight into their conditions, reduced anxiety, improvements in health behaviours and better engagement with care.(6, 7)

Portals are a promising intervention, but key uncertainties remain. Low adoption has been noted among older adults and those with lower educational attainment, though most older adults are interested in access to their EHRs.(8) As one third of stroke survivors have some degree of communication difficulty (including speaking, listening, reading and writing), there are also accessibility implications when engaging with technology.

Patient portals have received widespread support from policymakers and healthcare organisations as part of the shift towards personalised and digitised healthcare delivery, but significant challenges to implementation, as well as evaluation have been identified. There is uncertainty about which data are most useful, and what role portals will play in the existing doctor-patient relationship.(8) Patients have expressed concerns about data security and confidentiality;(6, 9) a preference for face-to-face communication and care;(10) as well as a need for portals which are easy to use.(11) Portals combined with tailored messaging services have been found to facilitate the use of evidence in health policy.(12) Further challenges

include difficulties integrating portals into clinical workflow, the costs to the healthcare organisation/provider, and concerns about data security.(7)
Most studies have been conducted in the United States (with differing data recording practices) and evaluated portals for patients with long-term conditions such as diabetes or hypertension, and which aimed to facilitate specific tasks such as medication management.(8) Finally, design has been shown to be a crucial factor in adoption and use of patient portals.(13) The potential to use research data in portals to engage with patients, and potentially improve longer-term stroke care, has not been fully realised and evaluated.
When implemented, portal access and use vary. While the evidence is limited, it suggests some ethnic groups, older adults, and those with lower levels of education or literacy are less likely to use patient portals.(14-16) For these groups, understanding patient attitudes and perceptions towards portals have been identified as a way to increase engagement.(17) With the often older age of stroke patients, embedding their perspectives and involvement in the design, development and implementation of new portals is crucial if we are to maximise their engagement and use.

Main outcome measures of this feasibility study will include:

For all participants:

- frequency & duration of portal use over the 6-month follow-up period (objective 1)
- participant perspectives on the acceptability and satisfaction of the portal (qualitative, objective 1)
- rates of completion of EQ-5D-5L online (objective 2)
- quality of portal collected EQ-5D-5L in comparison to data collected at face-to-face interview (objective 2)

For participants of the nested RCT:

- rates of successful recording of BP home measurement (objective 3)
- proportion of participants meeting national target of 135/85mmHg (objective 3)

4 PATIENT AND PUBLIC INVOLVEMENT

This study has been designed and will be managed with strong involvement of patients and the public. In the design of the portal and this study, we used a participatory design method, aiming to ensure that the technology addresses the needs of diverse stroke survivors. We collaborated between researchers, stroke survivors, and other stakeholders at each stage. We held meetings with stroke survivors, their carers, and family members, health professionals (stroke physicians/neurologists and therapists), commissioners, policy makers, and stakeholders from the charitable sector. Informed by these results, we created

prototypes – initially building ideas into several high-fidelity 'mock-ups' using a rapid prototyping tool, before coding a functional version.
We have held 7 meetings and 30 interviews with patients and other stakeholders where we presented them with an early rapid prototype of the portal and then sought feedback on design ideas and functionality. These meetings comprised 1 Policy Lab, 3 Stakeholder group meetings, 2 patient group meetings, and 1 meeting with the steering group (including a patient member). Our co-design work with stroke survivors received the Best Paper Award by the International Conference on Healthcare Informatics 2024, the leading global conference on user-centred technology in health and was Highly Commended by the European Life after Stroke Forum 2024. Further usability testing will be undertaken (IRAS 341961), involving 30 SLSR participants accessing and feeding back on all current functions of the portal.

As part of our wider stroke research programme, this feasibility study is supported by our programme's Patient and Public Involvement Group (16 members), the South London Stroke Research Patient and Family Group (~35 stroke survivors and carers, meeting every ~2 months), and our Stakeholder Engagement Group (SEG, 20 members; including stroke survivors and carers, national stroke opinion leaders and researchers, allied health professionals, and healthcare managers and commissioners; meeting at least twice a year). Involved in all aspects of our work, the PPI group and SEG will be particularly important in our feasibility work. In addition to their input in designing this study, meetings will be held with both groups at key points in the feasibility study to:

- Discuss progress and solutions to any problems encountered
- Complete initial findings
- Supporting the analysis of the evaluation work and their implications
- Findings and identify refinements for future trial

In addition to publications in academic journals and conference presentations, findings will be disseminated through presentations to our PPI groups and the SLSR Newsletter.

5 TRIAL OBJECTIVES AND PURPOSE

Purpose
In this non-commercial feasibility study, developed as part of a NIHR Programme, we seek to understand the feasibility of using a patient portal in stroke, for:

- Providing participants of a stroke cohort study with access to their own data
- Collecting research data electronically from participants

- Conducting a nested randomised controlled trial, with embedded economic evaluation, of supported self-management of blood pressure

Objectives

Our objectives are:

- Objective 1: to estimate the rates of use and acceptability of using a portal to share data with diverse groups of stroke survivors (including a range of ages, education level, IT literacy, stroke severity/impairments, ethnic group, country of birth; and stroke survivors with carers).
- Objective 2: to investigate the feasibility of data collection and quality of questionnaire data collected via the portal (completeness and comparability to data collected in fieldworker follow-up)
- Objective 3: to investigate the feasibility of using the portal to support and evaluate the effectiveness and efficiency of BP self-management among stroke survivors

6 STUDY DESIGN & FLOWCHART

6.1 Study Design

We propose a feasibility study of a patient portal, with nested RCT, within an established cohort of stroke survivors (SLSR).

- Feasibility study: Over a 12-month period, we will invite consecutive, eligible participants due for routine SLSR follow-up at 3-months and up to 5-years post-stroke to use the portal to access their own data and complete a validated outcome scale online at times of their choosing (estimated ~100 participants). There will be no control group to this part of the study. After six months of participation, we will assess acceptability of and satisfaction with using the portal through semi-structured interviews of a sample of study participants. (Objective 1 & 2)
- Nested RCT: We will also invite 50 of these ~100 participants to participate in a nested RCT to evaluate the feasibility of the portal to support BP self-management, and embedded economic evaluation. (Objective 3)

Summary of intervention - a co-designed patient portal for South London Stroke Register participants

Background — design of the portalWe have developed a patient portal using participatory design approach, aiming to ensure that the technology addresses the needs of diverse stroke survivors.(17, 18) This approach involved a collaboration between researchers, stroke survivors, and other stakeholders at various stages, seeking feedback on design ideas and functionality. To facilitate this collaboration, we have so far undertaken 30 qualitative interviews with stroke survivors, 2 patient participation group meetings, 3 stakeholder group meetings, a steering group meeting and a policy lab. Our qualitative interviews confirmed that stroke survivors and carers informally collect substantial data about their stroke and health post-stroke. Tracking BP to prevent stroke recurrence was particularly common in these accounts but often completed haphazardly with no systematic way of recording and acting upon this data.

Informed by the results of this work, we created prototypes – initially building ideas into several high-fidelity 'mock-ups' using a rapid prototyping tool (Axure), before coding a functional version. This approach, based on Wilson et al's. notion of '*Tangible Design Languages*",(19) was chosen as it afforded us tangible prototypes to critique, meaning reduced language and cognitive demands for stroke survivors, whilst still allowing for meaningful discussion of design choices and ideas.

From the final designs, we have created a working prototype, addressing the key needs identified: accessing participants' own stroke data, tracking recovery, and recording BP reading in a systematic way. Screenshots of the prototype are provided in Figures 1 and 2. We have gathered initial user feedback on the portal developed so far through moderated usability testing with stroke survivors from the SLSR PPI group, targeting diversity in age, ethnicity, stroke severity/disability, and with carers for those who have them. We used example patient data to simulate real-world interactions with the interface.

During testing, users first provided their general impressions of the interface (e.g. as someone who has never seen the portal before) to assess the overall design. This was followed by task-based usability testing with nine tasks using the example patient data, where users tried to understand key information such as biographical details (e.g., 'type of stroke'), medical data (e.g., 'blood pressure'), and predictive capabilities (e.g., 'chance of stroke recurrence'). We measured task performance, such as task success rates, and gathered quantitative data through accessible Likert rating scales and qualitative data through interviews. Overall, we observed positive results - users successfully completed the vast majority of tasks, with shortcomings highlighting potential design improvements which will be integrated into future versions of the portal. Participants found outcome-related metrics (e.g., stroke risk) to be particularly valuable.

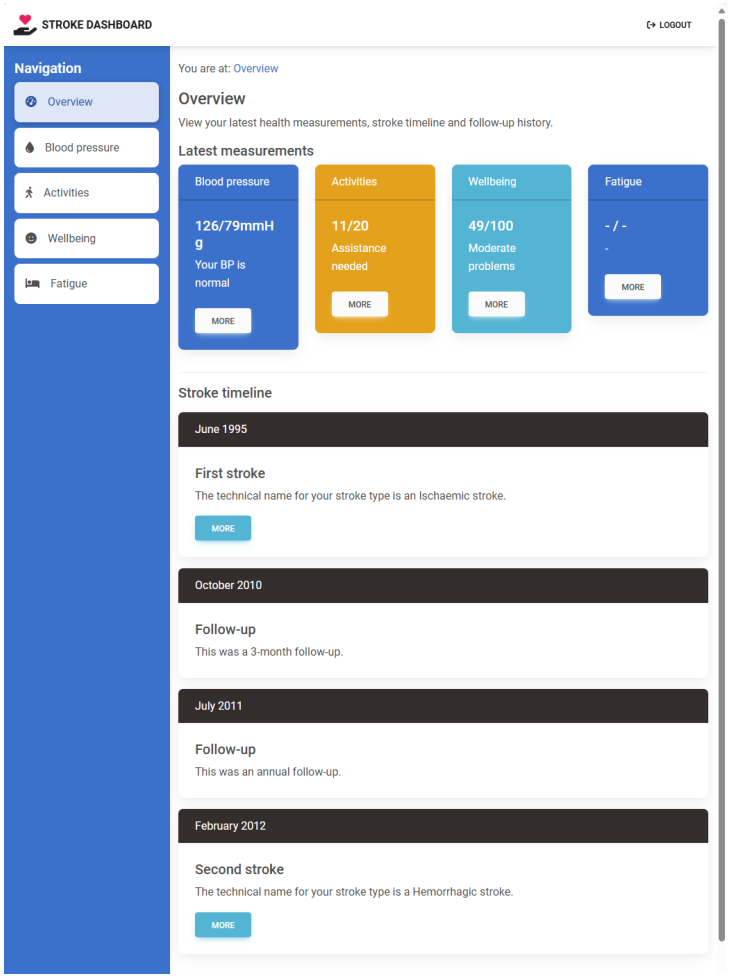


Figure 1. Example of overview page showing an example participant's data.

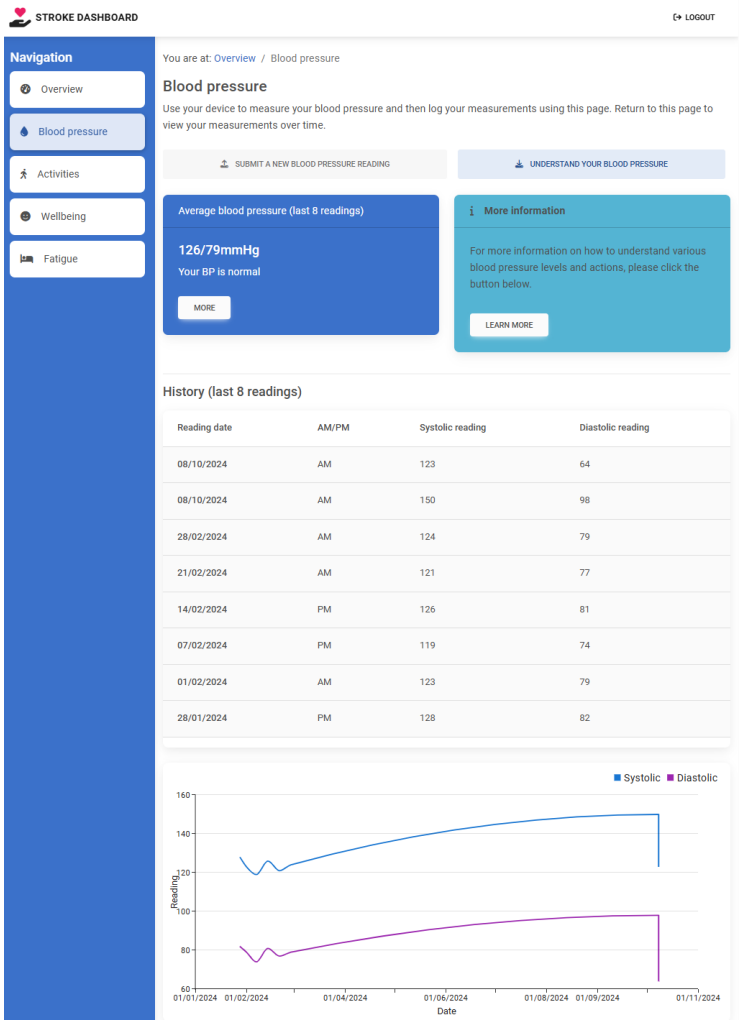


Figure 2: example of page showing a participant's data

Study intervention - Usage of the patient portal

The portal is an application that uses the same technologies that underpin online banking to allow SLSR participants to safely and securely log on and view health-related data they have previously contributed to the SLSR. This includes stroke-related data recorded at the time of recruitment into the SLSR, as well as 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 (EQ-5D-5L). The portal currently also provides the facility for participants to enter further updates on the EQ-5D-5L scale online and, for a subgroup of participants, to record home BP measurements.

Objective 1 & 2:

Over a 12-month period, we will invite consecutive, eligible SLSR participants at their routine follow-up to use the portal to view their own data and enter further data on the EQ-5D-5L scale online. We estimate to recruit up to 100 participants into the feasibility study (further details under 6.2. Participant Selection). Participants will be offered the option of providing portal access to a nominated carer or family member. There will be no control group to this part of the study.

In the future, we might aim to extend the range of stroke outcome measures participants can record online and to provide personalised health information (for example, estimates of the risk of future stroke). This would form part of a future trial.

Semi-structured interviews

Aiming for data saturation and maximum variation in terms of age, gender, stroke severity, living situation and socio-economic status, semi-structured interviews will be completed at 6 months with at least 40 participants, to additionally collect data on intervention acceptability and satisfaction. These 40 interviewees will include at least 15 of the 50 RCT participants and at least 25 across two groups: (1) those who are using the portal but are not taking part in the trial to understand their experiences of using the portal and how we might improve its usability and utility, and (2) those who declined to use the portal but agreed to the interview, to understand the reasons behind their refusal and any barriers to their participation.

These interviews will collect both quantitative and qualitative data. Acceptability and satisfaction will be assessed quantitatively (through Likert scales) and qualitative interview analysis. Incorporating qualitative methods in the interviews, allow us to discuss and understand participants' experiences. As part of the evaluation of the portal, these semi-structured interviews will enable us to explore how participants used the portal over the 6-

month period; understand what worked well; identify where improvements can be made; and document any unintended consequences of portal use.

Objective 3: Feasibility of a nested RCT with embedded economic evaluation

During the routine SLSR follow-up visit, we will additionally invite 50 of the ~100 participants who have agreed to portal use to also join a RCT examining blood pressure (BP) self-management. Participants of this nested RCT will be randomised 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(20), by providing personalised feedback with regards to BP management (see details under 6.10 Schedule of assessments for each visit).

All RCT participants will be asked to answer a brief questionnaire on health and care service use at recruitment. They will also have a face-to-face visit at 6-months to have BP measurements taken by a study researcher and answer another health and care service use questionnaire (objective 3).

Outcome measures

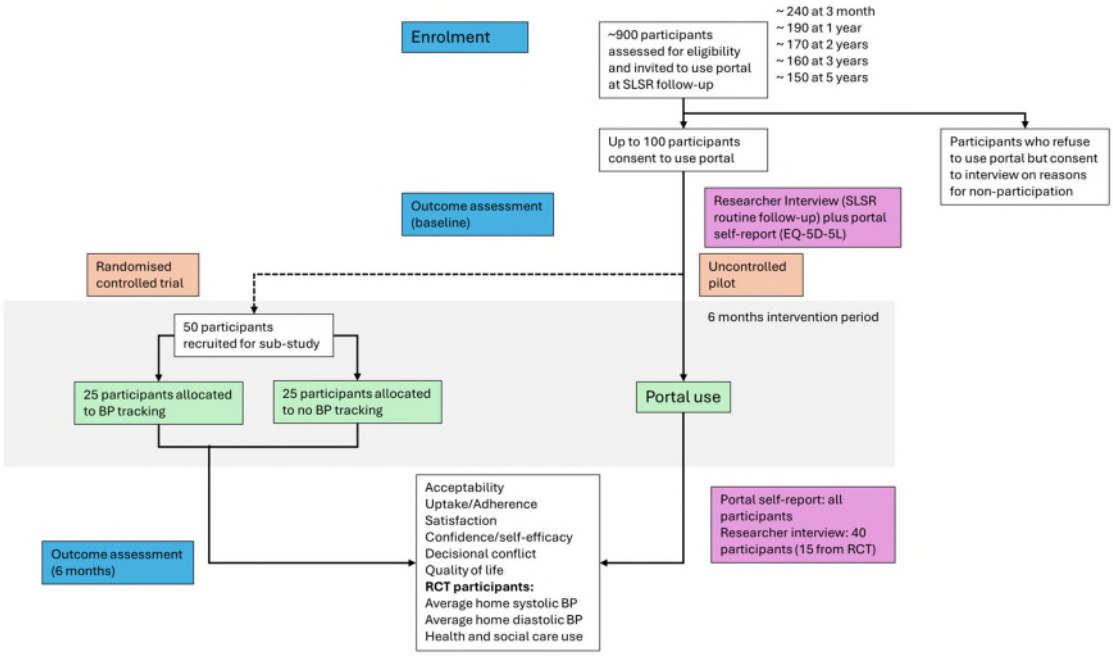
For all participants (n~100):

- portal utilisation - number of logins, time spent on the portal, and portal navigation history over the 6-month study duration per participant and disparities in usage depending on age, gender, ethnicity, and stroke severity (Objective 1)
- participant perspectives on the acceptability of the portal and participant satisfaction (qualitative; Objective 1)
- chronic disease self-efficacy (6-month follow-up; Objective 1)
- A 5-Likert scale questionnaire that collects participants' opinions, attitudes, motivations and more (6-month follow-up; Objective 1)
- rates of whole- and part-completion of outcome measures (EQ-5D-5L) online over the 6-month study duration and disparities in completion depending on age, gender, ethnicity, living status and stroke severity; disparities between fieldworker versus online-collected outcome measures (Objective 2)

For participants of the RCT (n=50):

- rates of successful completion of BP home monitoring (Objective 3)
- proportion of participants meeting national target of 135/85mmHg, comparing those having access to the portal BP module to those not having access to the BP module, and assessed via BP measurements collected by study researcher at 6-month follow-up (Objective 3)
- extent and quality of health and care service use, comparing data collected at recruitment and follow-up and accessed through linkage with LDN and SSNAP datasets (Objective 3)

Study flow diagram:



6.2 Participant Selection

Participants will be recruited solely from participants of the South London Stroke Register, a study co-sponsored by King's College London and Guy's and St Thomas' NHS Foundation trust. This is an observational, population-based registry of adults with first-ever stroke while resident in a certain geographical area of London (defined by electoral wards within the northern half of Lambeth and Southwark). SLSR participants have regular contacts with the study team for follow-ups scheduled at 3 months, and then annually up to 5 years post-stroke.

SLSR participants who have consented (or consultee advice was taken) to be contacted by the study team for further stroke-related research will be invited by a member of the SLSR study team to take part in this patient portal feasibility study during routine SLSR follow-up. No further participating sites will be involved in the study.

~900 SLSR participants are due for routine follow-up over a 12-month period, of whom ~30% are, based on previous fieldwork experience, expected to be lost-to-follow-up or lack mental capacity to consent. All others (~630 SLSR participants) will consecutively be invited to use the portal. Of those, we estimate that around 30% or 190 participants would consent to take part in this feasibility study of 6-month duration. However, we will stop recruiting into the study, if and when we have reached 100 participants overall and 50 participants for the embedded RCT, with numbers based on recommendations for feasibility studies. There will be no stratified sampling for this nested trial, but consecutive, consented portal users will be invited to the trial until the sample target of 50 has been reached.

Only adults with mental capacity to consent are eligible for this study. Consent in emergency situations will not be required, but consent will occur at routine SLSR follow-ups during which participants can take as long to consider participation as they choose. For this purpose, we will offer the option of a follow-up visit by the fieldworker if they so wish.

6.3 Participant inclusion criteria

1. Participant has been recruited into the SLSR. Criteria for inclusion into the SLSR are:
    a. 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.
    b. living 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)
    c. first stroke since 1st January 1995
    d. 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 study start date
3. Participant has given consent to be contacted by SLSR team for further stroke-related research
4. Participant has capacity to consent to take part in the study

5. Participant has sufficient proficiency in English

6.4 Participant exclusion criteria

- SLSR participants who lack mental capacity to consent will not be included in this study. Participants with mental capacity to consent but comprehension or cognition difficulties, or other difficulties using the patient portal can nominate a next-of-kin or carer to use the portal on their behalf.
- 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 results of this feasibility study.
- People residing in a social care setting will be excluded in order to not put a potential additional burden on the care team.

6.5 Study Procedures:

6.5.1 Screening Procedures

Participants will be identified by SLSR fieldworkers, who are not members of the direct care team. However, a dedicated section on the SLSR consent form specifies consenting to being contacted for further stroke-related research. Only SLSR participants who have consented (or consultee advice was given) to be approached for further stroke-related research by the SLSR study team may be eligible to take part in this study.

The study is compliant with the NHS national data opt-out as all SLSR participants have consented (or consultee advice was given) to being approached for further research and will subsequently be consented to take part in this study.

SLSR participants take part in regular follow-ups post-stroke. Up to 20% of SLSR participants cannot be contacted despite repeated attempts and are lost-to-follow-up at each time point. For those who can be reached, a home visit by a SLSR fieldworker for a face-to-face interview is arranged or, depending on participant preference and suitability, the follow-up is carried out over the telephone.

During this face-to-face or telephone interview the SLSR fieldworker will assess capacity to consent. The research team is a multi-disciplinary team with clinical and research experience working with people who have problems making and/or communicating decisions. Study researchers will have completed appropriate training in following the provisions of the Mental Capacity Act 2005. As during the SLSR recruitment process, we will informally use the 4-stage test of capacity: 1) can people understand the information we are giving them about the research? 2) can they weigh the information? 3) can they make a decision? 4) can they communicate the decision?. Only those with capacity to consent will be invited to take part. Additionally, non-English speakers will not be included in this feasibility study as there is currently only an English version of the portal. There will be no further screening procedures.

During the same initial visit, those who have agreed to portal usage will also be invited to take part in the nested RCT. There are no additional inclusion or exclusion criteria for the RCT beyond those for the main feasibility study. We aim to recruit 50 consecutive participants who agree to take part in the RCT.

A screening log will be maintained at King's College London.

6.6 Randomisation Procedures

Participants of the nested RCT will be randomised to have supported BP management via the portal (25 participants), versus usual care (portal use without BP management, 25 participants) at 1:1 ratio using block randomisation with varying block sizes of 4 and 6. Randomization will occur during the recruitment visit via a secure web-based system.

6.7 Masking & other measures taken to avoid bias

6.7.1 Masking

Masking will not be applied in this study. The intervention consists of certain activities undertaken by participants, i.e. usage of the portal and blood pressure measurement and recording and therefore not amenable to masking.

6.7.2 Other measures taken to minimise / avoid bias

All SLSR participants who are contacted for their regular SLSR follow-up (3-month to 5-year follow-up) over a 12-month period following the start of the study will be invited to take part in this portal feasibility study. In 2023, 733 SLSR follow-ups were successfully completed, a number large enough to ensure a wide spread of participant characteristics with regards to socio-demographic and health-related background.
We will exclude those unable to consent, non-English speakers, and those residing in social care settings from the study which is likely to affect certain socio-demographic groups disproportionately. This will have to be considered when drawing conclusions from the study's results.
We will not be undertaking any further measures to minimise bias, as the rate of consent and consequent usage of the portal is an important study outcome, together with an investigation of disparities in those rates between groups differing by socio-demographic or health-related variables.

6.8 Participant recruitment

Eligible participants will be identified by SLSR fieldworkers at a routine SLSR face-to-face or telephone follow-up by assessing their capacity to consent and ability to understand English (see details under 6.5.1. Screening procedures).
We will **not** recruit any further participants outside the SLSR cohort, such as through Participant Identification Centres or publicity (posters, leaflets, adverts, or websites). The study does not involve any travel or other expenses for those taking part and they will not receive any payment for taking part in the study.

A SLSR fieldworker will approach the potential participant during a routine SLSR face-to-face or telephone follow up to introduce and discuss the study.

If the first contact occurs during a face-to-face follow-up, a participant information sheet (PIS) will be provided, that contains information on both the main portal feasibility study and the nested RCT. An aphasia-friendly PIS will be provided as appropriate. The potential participant will have the opportunity to read it, ask questions, and discuss with others should they wish.

In theory, we will allow participants as long as they wish to consider participation. In practice, we will agree with the participant a time to re-contact them, ideally within 2 weeks of first contact. We will set no minimum length of time needed before agreeing to participate. As the intervention of this study (portal usage and BP pressure monitoring and recording) is entirely led by the participant, they can withdraw from undertaking the intervention at any time.

The consent form provides the options to only consent to the main feasibility study, and to additionally consent to the semi-structured interviews at the end of the 6-month study duration and the RCT. Participants who decline to use the portal will still be eligible to participate in short interviews to understand any barriers to their participation if they wish. Consent to those interviews only will be recorded on the main consent form.

We will record consent by asking the participant to sign a consent form. Some participants may have capacity to consent verbally but might be unable to read or sign a form (for example due to stroke-related impairments). Verbal consent can be taken by the fieldworker in the presence of a witness, typically a next-of-kin or carer. Verbal consent will be documented by the study fieldworker and witness on the consent form.

If the routine SLSR follow-up takes place by telephone, we will invite the potential participant by telephone to take part in the study. The study will be explained in detail by running through all points listed in the participant information sheet. As for face-to-face consent, the potential participant can take as long as they wish to consider participation, including arranging a second phone call at a later timepoint. Verbal consent can be obtained over the telephone by the participant verbally agreeing to all consent clauses on the consent form. Verbal consent will be documented by the researcher on the consent form. In case of telephone consent, the participant information sheet and a copy of the completed consent form will be sent out by mail or email depending on participant preferences.

Participants who lack capacity to consent, non-English speakers, or children will not be able to take part in the study. We will not take consent in emergency situations.

Participants who have consented to take part in the patient portal feasibility study will then have the option to also take part in the nested RCT of BP self-management. The same consent procedures as for the main study will be applied to this nested trial. The same consent form as above will cover both the main feasibility study and the nested RCT, and a specific paragraph on the RCT will allow the participant to opt into or out of the nested RCT.

6.9 National Data opt-out

The study is compliant with the NHS national data opt out as only SLSR participants who have consented (or consultee advice was given) to be approached for further research will be invited and are then subsequently consented to take part in this study.

6.10 Schedule of assessments for each visit

Schedule of assessment table

Time point	Procedure	Participants	Comment
Screening visit	Potential participants given PIS	All potential participants	
Recruitment visit	Informed consent	All participants	Anticipated to be in most cases at the same time as the screening visit.
	Introduction to portal without BP module	All participants undertaking portal use	Undertaken by study researcher
	Questionnaire on health and social care service use	50 participants of nested RCT	Questionnaire embedded on portal
	Introduction to portal with BP module	25 participants of nested RCT randomised to BP tracking	Undertaken by study researcher
Semi-structured interview for refusals	reasons for non-participation in portal use	eligible participants who declined to take part in the portal use but agreed to interview	At a time/location convenient to non-participant
During 6-month duration of study	Participants enter EQ-5D-5L on portal	All participants undertaking portal use	Data entry as often as they which but at least once following recruitment and after 6 months (prompt provided)
	Participants enter blood pressure readings on portal	25 participants of nested RCT randomised to BP tracking	Data entry as often as they wish but at least twice per day during week following recruitment and after 6 months (prompt provided)
6-month follow-up visit	Questionnaire on health and social care service use; BP measurement by study researcher	50 participants of nested RCT	Questionnaire and researcher BP entry embedded on portal

6-month semi-structured interviews	Intervention acceptability and satisfaction	40 interviews will be undertaken; this will include at least 15 participants of the nested RCT	Can coincide with 6-month follow-up visit or depending on participant preference

Recruitment visit

All participants

Recruitment will occur during a routine SLSR face-to-face follow-up, unless a potential participant requires further time to consider participation.

At the recruitment visit, participants will be invited to use the portal on their own device. They will be offered the option of providing portal access to a nominated carer or family member who will be given their own login details. This will be logged on the participant database. They 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 log into the portal with the participant 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 to complete a further EQ-5D-5L scale on the portal.

Nested RCT

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.

. Participants assigned to the intervention arm (BP self-management) will be provided with a validated automated electronic sphygmomanometer for the 6 months of the study and will be trained how to measure their BP and record the reading in the portal by the SLSR fieldworker. They will be given written instructions and a link to a training video on how to undertake BP self-measurement for reference.

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 (Appendix 2). The portal will record participants' systolic and diastolic BP; together with feedback as to whether the participant's BP is within the target BP range (following NICE guidelines and based on the TASMIN II trial).(21) 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
- red: >170 / 105.

Participants whose BP is higher than target (>135/85) 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 (amber on traffic light system). In the unlikely event of dangerous BP elevation (red on traffic light system) 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 to be 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 record 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.

Follow-up Procedures

There will be no follow-up visit for participants of the main portal feasibility study, apart from those taking part in the **semi-structured interviews** at 6 months to collect data on intervention acceptability and satisfaction. These will be assessed quantitatively (through

Likert scales) and qualitative interview analysis. An indicative interview guide is provided as Appendix 1.

For the 50 participants of the nested RCT, we will conduct an in-person follow up visit. During this visit, we will collect:

- 2 BP measurements, at least 5 minutes apart, taken by the study researcher
- additional data on health and social care service use during the previous 6 months
- Semi-structured interviews with at least 15 of the 50 participants, to collect data on intervention acceptability and satisfaction

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

6.11 Radiology Assessments

There will be no radiology assessments conducted as part of this study. Data on radiological assessments if done as part of regular care are collected in the SLSR and will be utilised as appropriate in this study to characterise participants' health status.

7 END OF STUDY DEFINITION

Data collection will end and database lock will occur after the 6-month follow-up of last recruited participant.

8 ASSESSMENT OF SAFETY

The intervention of this study consists of the use of a patient portal through which participants can track their own health data on a small number of validated outcome scales (Barthel Index/ADL, Quality of life/EQ-5D-5L, Fatigue severity score) and enter their data regarding quality of life (EQ-5D-5L). No SAEs are anticipated to occur as a result of portal use within this design and any potential distress or intrusion due to the study, e.g. due to the recruitment and follow-up visit or the semi-structured interview will be minimal.

Possible adverse events which may occur include:

Anxiety or distress

Participants will be presented data and asked questions around their health and recovery from stroke. It is possible, (though unlikely) that these may cause 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. Participants have the right to stop or interrupt visits or interviews and stop using the portal at any time and withdraw from the study without any need for justification if they so wish. We will analyse and evaluate any distress arising from portal use or BP monitoring through information collected at the 6-month follow-up visit and semi-structured follow-up interview.

Detection of elevated blood pressure

Although not caused by the study; it is possible that we will detect elevated blood pressure levels in participants (by encouraging self-monitoring), which they would not have otherwise known about. The portal will evaluate blood pressure levels using the 'traffic light' risk system, as used previously in TASMIN II and following NICE guidelines. Participants will be provided with appropriate advice on the portal depending on the blood pressure level. Where blood pressure is severely elevated, and urgent action is required; participants will be advised via the portal on seeking further urgent assessment. As a backup, the study team will contact them by telephone on the next working day to reiterate that advice; and a notification will be sent to the participant's GP.

Recurrent stroke, or other cardiovascular events

Our target participants have all experienced a prior stroke and therefore have an increased risk of further stroke compared with the general population. It is therefore possible that participants may experience a further stroke or related event during the course of the study. As this study does not involve any change to treatment, any such event would not be caused by participation. For blood pressure monitoring, the portal provides appropriate advice to seek medical assessment (with the urgency determined by the level of blood pressure) to follow up; but does not make any treatment recommendations or suggestions to modify ongoing therapies otherwise.

Breach of data privacy

8.1 Although every possible social and technical step has been taken to secure patients' data, it is possible (although extremely unlikely) that a new vulnerability may emerge that threatens both the portal and similar infrastructure (e.g. banking, NHS platforms, etc). In the event of a wide data breach that includes the stroke portal, impact will be significantly limited by there being no personally identifiable data stored in the portal.Ethics Safety Reporting

In the unlikely event of related and unexpected SAEs, these will be reported to R&D immediately upon knowledge of the event and always within 24 hours. Reports should be submitted to the Main REC within 15 days of the chief investigator becoming aware of the event, using the NRES template.

The form should be completed in typescript and signed by the chief investigator. The main REC will acknowledge receipt of safety reports within 30 days. A copy of the SAE notification and acknowledgement receipt should be sent to the gstt.RandD@nhs.net and stored in the TMF/Site file.

8.2 SAEs, particularly further strokes and cardiovascular events would be expected to occur in a proportion of stroke patients. As the study involves no variations in participants' usual treatment, frequency of these would not be linked to study participation or procedures and in this case would not require notification. These would be recorded as detailed in Appendix 3.Trial Steering Committee

The overall stroke research programme, of which this study is a part, is managed by a Programme Executive Group (PEG), chaired jointly by the Chief Investigator and SLSR lead. The PEG meets bi-weekly to review study progress, discuss outputs, necessary research staff training, etc. The PEG is overseen by an independent NIHR Programme Steering Committee (PSC), which includes a patient representative. The PEG and PSC together form the Programme Board (PB), who discuss Programme governance. The PB meets bi-annually with the Stakeholder Engagement Group (SEG) to report its governance decisions. The SEG as well as our Stroke Research Patients and Family Group will be asked for peer review and feedback regarding the study progress and interim findings. These arrangements are in accordance with the Funder's monitoring and audit procedures.

8.3 Ethics & Regulatory Approvals

This study has received regulatory approval from the NHS REC [North West – Greater Manchester West Research Ethics Committee, 2 Redman Place, Stratford, London E20 1JQ] and HRA Approval.
This study will be registered with ISRCTN and reported in accordance with the CONSORT extension for pilot and feasibility studies [21] and the TiDier checklist for complex interventions [22].

Before any patients are enrolled into the study, the Chief Investigator/Principal Investigator or designee will ensure that the appropriate regulatory approvals have been issued, and NHS Confirmations of Capacity and Capability and Sponsor green lights are in place.

For any amendments to the study, the Chief Investigator or designee, in agreement with the Sponsor, will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with the relevant R&D department as well as the study delivery team to confirm ongoing Capacity and Capability for the study.
All correspondence with the Sponsor, REC and HRA will be retained. The Chief Investigator will notify the Sponsor and REC of the end of the study.

9 COMPLIANCE AND WITHDRAWAL

9.1 Participant compliance

Participants are invited to use the portal freely during the 6-month duration of the study. A main outcome measure of the study is to investigate rates of use and factors associated with use/non-use of the portal, which will be evaluated by recording the number of log-ins, time spent on the portal, and navigation history. Participant compliance is therefore one of the outcome measures.

At 6 months post-recruitment, participants will be prompted by email or text to record an updated EQ-5D-5L on the portal, and further BP measurements for those in the intervention arm of the RCT. As above, compliance with this prompt will be one of the outcome measures.

We are seeking to undertake a 6-month follow-up for the 50 participants of the nested RCT, regardless of their prior use/non-use of the portal. We anticipate the number of participants lost-to-follow-up to be low in this feasibility study as they have shown interest in this type of research by consenting. As with SLSR follow-up visits, to arrange follow-ups we will try to contact participants by telephone. If we initially cannot get through to participants, we will try to contact them on different days of the week/ time of day and also via NOKs. No further procedure is in place in case of loss-to-follow-up.

9.2 Withdrawal / dropout of participants

Participants may withdraw from the study at any time without the need for any justification and through any means of contact. Information on how to withdraw is provided in the Participant Information Sheet.

There is no specific documentation to be completed on withdrawal; we will record the participant's decision and will not contact them again for subsequent interviews. Data up to the date of the withdrawal will be retained, but no further data will be collected on these participants.

In case of participants who have initially agreed to the 6-month interviews being no longer available, we will aim to back-fill for those participants.

9.3 Protocol Compliance

Any protocol deviations will be monitored through the CI and recorded in the site file. Any significant protocol deviations or deviations which are found to frequently recur will be reported to the study sponsor and action taken through Corrective and Preventative Actions (CAPA). The CI will also assess to see if an amendment to the protocol is required.

The CI and sponsor must be notified immediately of a serious breach. Serious breaches will be reported to the REC with the sponsor in copy within 7 days from the breach being confirmed as serious.

10 DATA

10.1 Data to be collected

- **At recruitment** we will collect data on health and social care service use (only collected from participants of the nested RCT)
    - type, dose, and frequency of anti-hypertensive medications and time spent taking blood pressure at home in previous week
    - primary health care use in previous 4 weeks
    - use of hospital services and overnight care outside the home in previous 6 months
- ownership and frequency of prior use of BP monitoring device (only collected from participants of the nested RCT)
- length of time spent by fieldworker showing participant how to a) access personal data on the portal, b) record health outcomes, c) record BP measurements

This data will be complemented with routine SLSR data for the intended analyses.

During the 6 months following recruitment, we will record:

- portal utilisation - number of log-ins, time spent on the portal and navigation history per participant
- rates of completion of EQ-5D-5L scale questionnaires online over the 6 months follow-up
- EQ-5D-5L scale data
- rates of recording of home BP (for those with BP self-management module)
- BP measurements taken by participants and entered on portal
- proportion of participants and time spent accessing BP self-measurement training video
- number, duration, and reasons of interactions (email or telephone) between participant/carer and the study team for support with portal usage

6 months after recruitment, we will prompt all participants via email or text to enter an updated EQ-5D-5L on the portal, and we will prompt all participants of the intervention arm of the nested RCT to enter a further 7-day series of BP measurements. We will undertake a follow-up face-to-face visit for participants of the RCT (n=50), during which we will additionally record:

- BP measurements (2 measurements taken 5 min apart) taken by the researcher
- data relating to health and social care service use in previous 6 months

With ~40 of the study participants (at least 15 RCT participants) we will conduct semi-structured interviews to collect data on:

- data on intervention acceptability and satisfaction, and decisional conflict, collected via semi-structured interviews. These will be assessed quantitatively (through Likert scales) and qualitative interview analysis.
- chronic disease self-efficacy (Appendix 1)

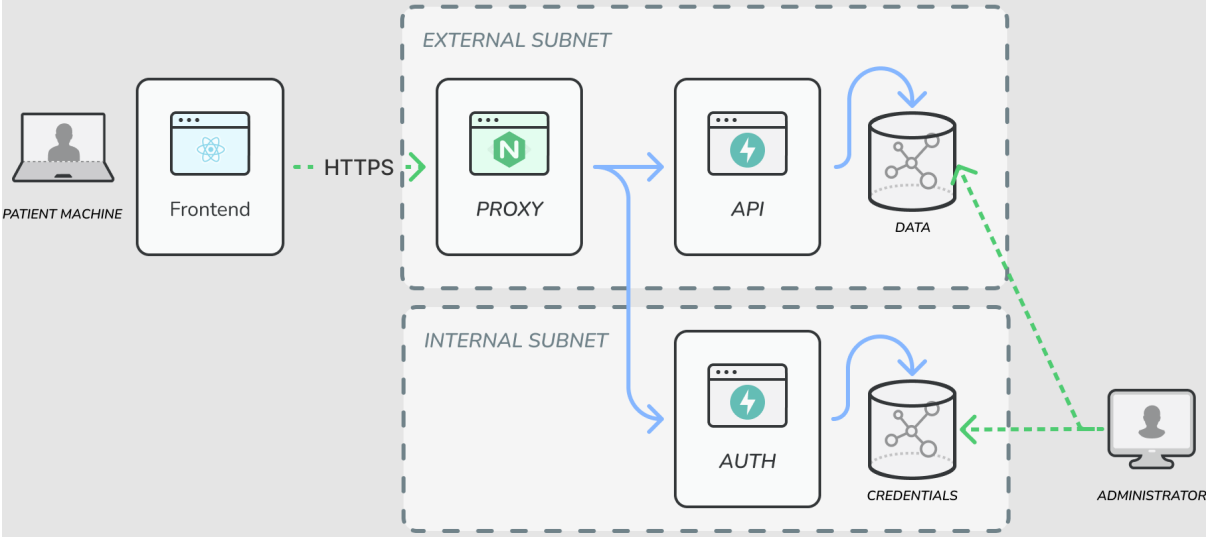
In addition, we will record:

- portal maintenance costs
- administrative costs: BP monitors and tablets, delivery and return of devices, postage costs, expenses for field worker travel
- health and care service use data from LDN and SSNAP

10.2 Data handling and record keeping

All data will be collected and stored at King's College London using the university's e-Research platform 'CREATE'. 'CREATE's data centre is located in London, and thus this is where all data will physically reside.

The deployment architecture of the portal is as follows:



Under this architecture, which is deployed to 'CREATE Cloud' - CREATE's internal cloud service - we achieve data security in the following ways:

1. Data at rest

- Authentication data is stored on an internal subnet (not WWW facing) to reduce potential attack surfaces. Access to the authentication service attached to this data (e.g. to login) will be mediated by a reverse proxy on a WWW-facing network.
- We employ modern database software (Mariadb) that is kept up to date and is auditable. This software also provides table-level encryption. Backups are taken regularly and encrypted on disc.
- Passwords are hashed.
- The volumes attached to the cloud instances on which our services and databases reside are encrypted at rest.

2. Data in transit

- All point-to-point communication – including between the frontend and the server, between the individual services, and between the services and databases – uses SSL (https) and is thus encrypted.
- The use of a reverse proxy adds additional security to SSL connections (e.g. DH Parameters).

3. Data in use

- User credentials and existing health data will be manually added to the databases in the backend to reduce the vulnerabilities potentially introduced by WWW-facing admin dashboards.
- User credentials will consist of randomly generated user IDs (no PID) and strong passwords, which are provided to users. User IDs cannot be changed and passwords can only be updated by an administrator.
- Health data will be pseudonymised at source before it is uploaded, and any new data to be collected is not personally identifiable.
- A single administrator from a dedicated machine will have access to the remote databases. Should access need to be granted to any additional users, the extent of this access will be carefully determined by Role-based Access Control (RBAC).
- In addition to the above, the separation of admin and patient data inherently enforces data access permissions.

10.3 Data sharing

As with all research projects involving personal data undertaken by KCL, this project is registered on the King's Data Protection Register (KDPR) to confirm compliance with the GDPR for local Research Governance purposes.

No patient data will be leaving GSTFT in connection with this feasibility study. All data displayed on the portal or used in statistical analyses for this trial, are data previously collected by SLSR field workers from SLSR participants and currently stored at King's College London or collected directly from the participant as part of this trial.

Data previously and currently collected for the SLSR and already stored at KCL will be used to complement statistical analyses of this study. Both studies are part of the research programme "Improving the lives of stroke survivors with data" and funded through the same NIHR Programme Grant NIHR202339.

A transcription service, which has previously signed a confidentiality agreement, will be used to transcribe the audio of interviews. Audio files will be transferred to the transcription service via the supplier's secure file transfer service, the transcription service will remove personal data (names, locations), and the transcription file will be returned via password-protected email attachments.

There is currently no intention of onward sharing the data of this study.

10.4 Personal Data Breaches

Personal data breaches will be immediately reported to the sponsor and data controller, and to the data protection officer at KCL. This report will include full details of the nature of the breach, an indication of the volume of material involved, the sensitivity of the breach (and any time frames that apply), and steps that have been taken to mitigate the risk, such as trying to retrieve the data by asking third parties to delete information that was sent to them in error.

The sponsor/data controller will determine whether the breach meets the definition of a serious breach and warrants reporting to the regulators including the ICO.

11 MONITORING AND AUDITING

The CI will be responsible for the ongoing management of the study. The Sponsor will monitor and conduct audits on a selection of studies in its clinical research portfolio. Monitoring and auditing will be conducted in accordance with the UK Policy Framework for Health and Social Care and in accordance with the Sponsor's monitoring and audit procedures.
This feasibility study will follow Good Clinical Practice requirements and adhere to research governance guidelines.

12 STATISTICAL CONSIDERATIONS

Recruitment and sample size

Recruitment for the study is planned to take place over a 1-year period. Approximately 900 SLSR participants are due for routine follow-up during a 12-month period. Of those 900 potential participants, a proportion will be lost-to-follow-up in this year or lack mental capacity to participate and therefore be ineligible. Based on our historic follow up rates, we assume either of those conditions could affect up to 30% of the follow-up cohort, leaving 630 participants.

We estimate to recruit up to 100 participants into this feasibility study, which will provide reasonably precise estimates for outcome variables with a margin of error of 7% at 95% confidence level. This is based on binary outcomes. As this is a feasibility study and most analyses will be descriptive, the conventional and precise sample size calculation is not applicable. We only use the above sample size calculation as an indication of the approximate power in the context of this feasibility study.

Estimated recruitment rates are based on fieldworker experience and recruitment rates of another recent study of a patient portal in stroke,(22) where approximately 25% of those eligible were randomised. Given that our potential participants have already consented to take part in the SLSR, and that we have an existing relationship with them; we envisage that our consent rate could be higher. One objective of this study is to investigate which groups are likely to use a patient portal of this kind (e.g. differences in age, education, ethnicity, stroke severity).
50 of the portal study participants will be enrolled in the nested RCT. Numbers are based on recommendations for feasibility studies.(23) This would require a ~8% consent rate of those

eligible. While the actual rate of consent is uncertain and a key outcome measure of this study, we anticipate consent rates to be significantly higher than 8% and therefore should be achievable.

Statistical analysis

Analyses will be conducted by the study investigators and the broader team of stroke researchers and PhD students. Researchers and PhD students will only have access to a pseudonymised dataset that will be available to them via the KCL Trusted Research Environment TRE. Work will be completed using Stata and R software packages, and NVivo for the qualitative analyses.

Objective 1: The rates of use and acceptability of using a portal to share data with diverse groups of stroke survivors

Descriptive analysis of users

The numbers of participants from different age, sex, ethnicity groups and socioeconomic groups (indexed by education, occupation, and Index of Multiple Deprivation (IMD)) will be reported as percentages of the recruited sample based on data from the core SLSR data collection. The percentage of accesses by the participants themselves or from a family member or carer will also be reported.

Associations between demographics and use

Number of logins (counts) and time spent on the portal (minutes) will be treated as continuous variables and summarised as mean (SD) or median (IQR) depending on distribution. Navigation history will be summarised as the number of times different resources are accessed by participants. These indices of usage will be summarised for the different demographic groups of participants.

Multivariable models will be used to estimate associations between demographic groups (age, sex, ethnicity) and socioeconomic groups (education, occupation, and IMD). The number of logins will be modelled as a count using negative binomial regression and time on portal in minutes will be modelled as a continuous outcome using linear regression.

Semi-structured interviews / qualitative analysis

Semi-structured interviews will be completed at 6 months with at least 25 of the 50 randomised participants, to additionally collect data on intervention acceptability and satisfaction. These will be assessed quantitatively (through Likert scales) and qualitative interview analysis.

Qualitative data will be analysed using thematic analysis for both a descriptive and analytic account of the acceptability, patient experience and any unintended consequences of this intervention. (24, 25)Data analysis will incorporate quantitative responses to Likert scales. using qualitative data to add texture to our understanding of each patient's responses. In addition to this patient level analysis, the qualitative interview data will be analysed for all intervention participants together to enable a detailed understanding of how the intervention works, how it is experienced and where changes are needed to make it more effective.

Objective 2: The reliability of collecting questionnaire data via the portal

The numbers of times the EQ-5D-5L scales are completed by participants will be summarised across all participants and stratified by demographic and socio-economic groups.

The serial collections of EQ-5D-5L data will be plotted against time to summarise any potential trend in repeated measurement. The stability of the measures collected by the portal will be assessed using the correlations between measurements and the within person standard deviation.

To investigate the utility of portal data collection compared to traditional fieldwork, we will assess the agreement between the 2 methods of collecting EQ-5D-5L using Bland-Altman plots, estimate test-retest reliability using the intra-class correlation coefficient, and model the impact of measurement bias on portal data collection via multivariable, multilevel logistic regression.

The quantity and quality of the collected outcome scale EQ-5D-5L, for each questionnaire collected, in the portal will be assessed through:

- Quantity of data provided
    - Numbers of questionnaires completed per patient (and carer) and distribution of questionnaires submitted over time from baseline
    - Number of new readings submitted within 1-6 hours after completing a questionnaire, with information on last completed questionnaire within portal

- Analysis of speed of completion
- Number of downloads of outcome data by arm and time period from baselines
- Data completeness
    - Descriptive analysis to assess distribution and proportion of missing value and completion rates for whole questionnaire and at item-level
    - Logistic regression to quantify impact of age, gender, ethnicity, living status, stroke severity, time since stroke of completion of EQ-5D-5L and EQ-VAS
- Responsiveness:
    - 'ceiling' and 'floor' effects at baseline and 6 months,
    - response distribution by time point, % of responses only increasing, only falling and not changing from baseline to 6 months
    - responsiveness of changes in EQ5D-5L to other changes measured at the same time
- Test-retest reliability
    - The sample will consist of all questionnaires submitted by the same person within a 2-week period using a) the same data collection mode (ie portal) or
    - different data collection modes (ie portal and F2F). Continuous variables will be tested using intra-class correlation coefficient (ICC), and categorical variables using Cohen Kappa. An ICC of <0.5, 0.5-0.75 and >0.75 will be interpreted as having poor, moderate and good agreement
- Inter-rater reliability: this opportunistic sample will compare questionnaires where a patient and carer have each submitted an assessment of the same patient within a 2-week period using a) the same data collection mode (ie portal) or b) different data collection modes (ie portal and F2F). Continuous variables will be tested using the ICC, and categorical variables using Cohen Kappa.
- Known group validity: data from each questionnaire will be pooled. Mean values (95% CI) for EQ-5D-5L index (from the cross-walk method) and EQ VAS will be compared across the following 'known groups' to assess their ability to detect differences in: a) original stroke severity and b) Activities of daily living (Barthel score) at study enrolment c) level of education d) age groups e) gender f) overnight stay in hospital or care home in last 6 months. Appropriate tests of statistical significance will be used, depending on sample size and skewness and whether 2 or more samples are tested.

Continuous data will be presented as mean, SD and median and categorical variables are frequency and percentage. Agreement of continuous measures will use the ICC and Cohen Kappa (k) for categorical measures. An ICC of <0.5, 0.5-0.75 and >0.75 will be interpreted as

having poor, moderate and good agreement. A k >0.68, 0.36-0.67 and <0.36 will be interpreted as having good, moderate and poor agreement.

Objective 3: The feasibility of using the portal to support blood pressure self-management

Descriptive characteristics of the two arms of the nested RCT will be summarised as mean (SD) or median (IQR) for continuous variables and count (%) for categorical variables. The number of times entering BP data in the intervention group will be summarised as a count and minutes spent accessing support materials will be summarised as mean (SD).

Description of outcome data collected

BP recorded by researchers and the chronic disease self-efficacy scale at baseline and the 6 month follow up will be summarised as mean (SD). Linear regression will be used to estimate indicative between group effect sizes to use in designing a definitive trial.

Data will be analysed according to Intention To Treat analysis.

Progression criteria

For the nested randomised trial, we are using the following progression criteria to decide on the feasibility of a future full trial:

- Recruitment: achieving 80% of the target sample size within the recruitment period.

- Retention: retaining at least 70% of participants at the final follow-up.

- Adherence: at least 70% of participants adhering to the intervention protocol.

- Data completeness: obtaining complete primary outcome data for at least 70% of participants.

Health economics

The embedded, within-trial, economic evaluation will take an NHS and personal social services perspective. Research and portal development costs will be excluded. Resource use and costs measured will include set up (e.g. training fieldworkers and patients to measure blood pressure, provision of BP monitors and tablets) and monitoring (e.g. phone and letter contacts to patients and GPs following orange or red BP ratings, time spent servicing patient phone calls) and consequences for use of hospital, primary and community

health and social care services. This part of the study will focus on completion rates and quality of data capture for resource use for intervention delivery, health and care service use as well as the EQ-5D-5L; costs per patient by arm and main contributors to cost, with a view to informing design of a full trial.

Analyses for the embedded economic evaluation

Missing data will be presented as frequency (%) by trial arm and data input variable. Continuous and count data for resource and health/care service use, costs and EQ-5D-5L utility scores will be summarised as mean (SD) and frequency (%) by trial arm. Costs will additionally be categorised by set up and monitoring activities, and any key cost drivers will be identified.

All statistical analyses will be conducted by King's College London statisticians under the supervision of co-investigators Professor Yanzhong Wang and Professor Abdel Douiri, joint Heads of Medical Statistics, Department of Population Health Sciences, KCL. Analysis of economic data will be conducted under the supervision of Professor Julia Fox-Rushby, Head of Health Economics. Semi-structured interviews and qualitative analyses will be conducted under the supervision of Dr David Wyatt. All analyses will be carried out at the end of data collection.

13 PEER REVIEW

This study is part of an NIHR Programme Grant for Applied Research, which as a whole underwent external peer review, and statistical review as part of the application. This study specifically was outlined in the Checkpoint Report v2 June 2024 and has been peer-reviewed by the NIHR Programme Grants committee, who have provided several rounds of feedback and approved the final plans. This protocol has been peer-reviewed and approved by the independent Programme Steering Committee: Professor Anne Forster [Professor of Ageing and Stroke Research, University of Leeds; committee chair], Professor Kate Tilling [Professor of medical statistics, University of Bristol], Professor Matt Sutton [Chair in Health Economics, University of Manchester], Ms Marney Williams [Lay representative for the Intercollegiate Stroke Working Party].

14 FINANCING

This non-commercial study is funded by the NIHR Programme Grants for Applied Research scheme (NIHR 202339). This Programme Grant runs until 31 December 2026.

The CI has no financial interests in the intervention of this non-commercial feasibility study.

15 INSURANCE AND INDEMNITY

This study is co-sponsored by King's College London (KCL) and Guys and St Thomas' NHS Foundation Trust (GSTFT). The co-sponsors will, at all times, maintain adequate insurance for the design, management and conduct of the study: (a) KCL through its' own professional indemnity (Clinical Trials) & no-fault compensation policy; and (b) GSTFT through NHS Resolution cover, in respect of any claims arising as a result of negligence by its employees, brought by or on behalf of a study participant.

No further sites will be involved in this study.

16 DATA CONTROLLER

Guy's and St Thomas' NHS Foundation Trust (GSTFT) and King's College London (KCL) are co-sponsors of this research project and have shared Data Controller responsibilities. Where Personal Data is disclosed by GSTFT to KCL or vice versa, directly or indirectly to satisfy the requirements of the Protocol, or for the purpose of monitoring or reporting adverse events, or in relation to a claim or proceeding brought by a Participant in connection with the Trial, KCL and GSTFT agree to comply with the obligations placed on a Controller by the Data Protection Legislation. This is not limited to, but includes, being responsible for and able to demonstrate compliance with the principles relating to Processing of Personal Data (Article 5 UK GDPR).

GSTFT and KCL have outlined their Data Controller to Controller arrangements in an overarching Master Data Sharing Agreement which sets out the principles of data sharing in accordance with UK GDPR, regulatory and statutory laws. GSTFT and KCL have agreed to the mutual study specific Joint Controller data sharing template which details their individual roles and responsibilities at a study level

17 INTELLECTUAL PROPERTY (IP)

The study is not expected to generate any IP; but will make use of the SLSR portal, which is open-source software. This forms part of the IP plan for the wider NIHR Programme, agreed between GSTFT and King's College London.

18 REPORTING AND DISSEMINATION

We will communicate the results of the present study to Stroke care practitioners via established links including the South London Stroke Research Group, local primary care networks and the Stroke Forum (the annual national stroke research meeting sponsored by the Royal College of physicians, therapy professional bodies, the Stroke Association and others).

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 bi-annually 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.

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20 APPENDICES

Appendix 1: Indicative interview guide for semi-structured interviews

Questions for Group who are only using the Portal

1. **How acceptable are patient portals to you in managing your data/[name of stroke survivor]'s data?**
    - How does your/their stroke affect your use of the portal?
    - What alternative methods might we use to manage data relating to stroke survivors?
2. **How might we as researchers, ensure that the portal is used by a diverse range of individuals?**
    - Design?
    - Demographic factors? ((including a range of ages, education level, IT literacy, stroke severity/impairments, ethnic group, country of birth; and stroke survivors with carers)
3. **To what extent do you feel the portal reflects your current health status?**
    - What does the portal tell us about your health? Does this enable better management of your condition?
    - What data is missing? How might the portal be improved?
4. **To what extent do you feel the portal is efficient in enabling you to manage your health?**
    - How? Why?
    - How might the portal be adapted/improved?
5. **What factors made you want to engage with the portal?**
    - **How often did you log into the portal?**
    - **What made you want to keep coming back to the portal?**
6. **To what extent will the portal benefit you as an individual?**
    - What features do you find appealing? Why?
    - To what extent will it help you manage your health on a daily/monthly basis?
    - If not, why?
    - What portal features might make you want to engage in the future?
7. **Is there anything else you think we as a research team need to consider?**

Additional Questions for those undertaking BP Monitoring

1. **To What extent has the portal enabled you to effectively and efficiently manage your BP?**
    - Why?
    - How?
    - How did the process make you feel?
2. **How did you ensure that you provided blood pressure when you needed to?**
3. **How did you find the process of supplying blood pressure reading?**
    - Did the monitoring raise any concerns which meant you need to seek further medical advice?
    - How did the process make you feel?

4. **Is there anything else which we have not discussed which you feel is important for the research team to consider when it comes to BP monitoring?**

Questions for those who refused to use the portal

1. **what was it about our patient portal that made you not wish to use it?**
    - What concerns did you have? Why?
2. **To what extent do you feel your social circumstances stopped you from wanting to use the portal?**
    - To what extent was this impact by effects of stroke/time/financial/social support?
3. **How might we better engage you in future research?**
    - How was your participation in the project enabled?
    - What barriers did you face to participating in the project?

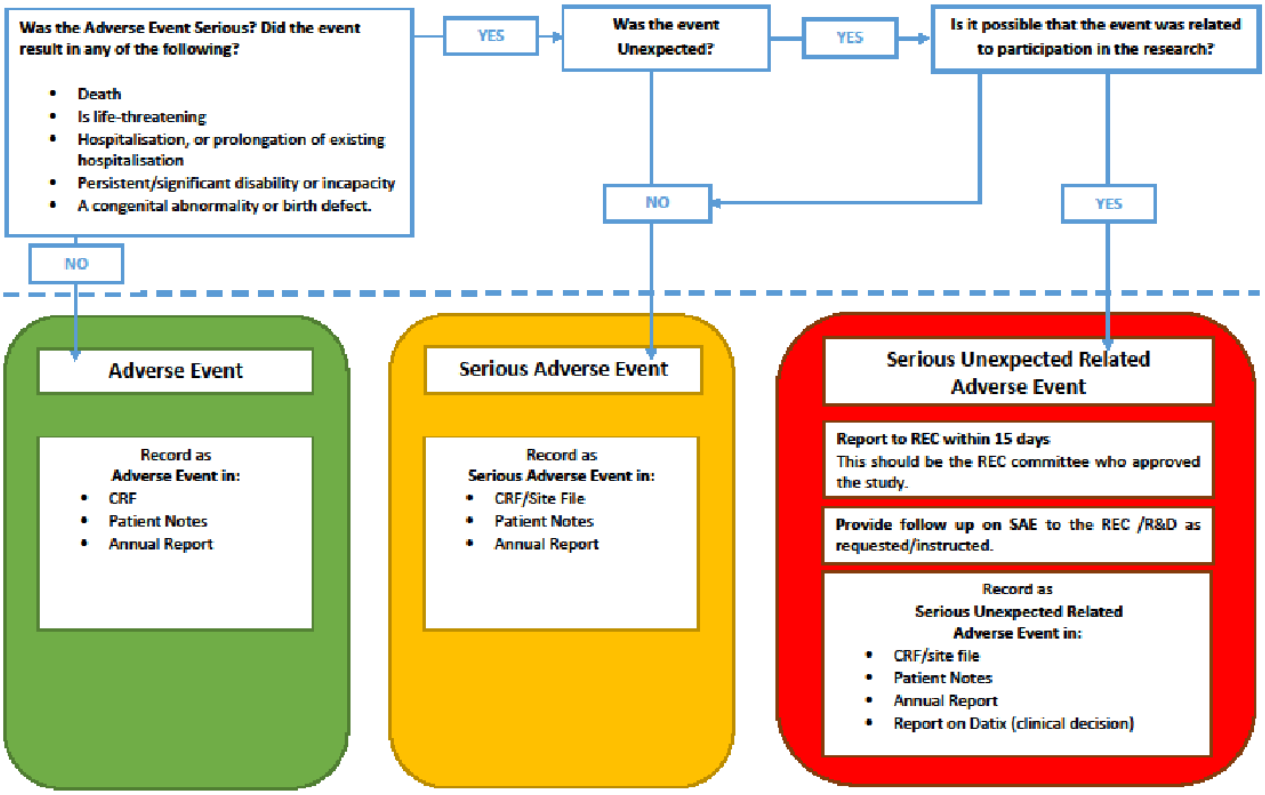
4. **Is there anything else which you feel is important for us to consider as researchers?**

APPENDIX 2

SAE Reporting Flow Diagram-Non CTIMPs

V2 22.10.21

SAE Reporting Flow Diagram- Non CTIMPs.



APPENDIX 3

Information with regards to Safety Reporting in Non-CTIMP Research

	Who	When	How	To Whom
SAE (related and unexpected)	Chief Investigator	-Report to Sponsor within 24 hours of learning of the event -Report to the MREC within 15 days of learning of the event	SAE Report form for Non-CTIMPs, available from NRES website.	Sponsor and MREC
Urgent Safety Measures	Chief Investigator	Contact the Sponsor and MREC Immediately Within 3 days	By phone Substantial amendment form giving notice in writing setting out the reasons for the urgent safety measures and the plan for future action.	Main REC and Sponsor Main REC with a copy also sent to the sponsor. The MREC will acknowledge this within 30 days of receipt.
Declaration of the conclusion *or* early termination of the study	Chief Investigator	Within 90 days (conclusion) Within 15 days (early termination) *The end of study should be defined in the protocol*	End of Study Declaration form available from the NRES website	Main REC with a copy to be sent to the sponsor
Summary of final Report	Chief Investigator	Within one year of conclusion of the Research	No Standard Format However, the following Information should be included:- Where the study has met its objectives, the main findings and arrangements for publication or dissemination including feedback to participants	Main REC with a copy to be sent to the sponsor