ISRCTN58449011 https://doi.org/10.1186/ISRCTN58449011

Improving primary care after stroke: testing a new stroke service

Submission date
03/04/2017

Recruitment status
No longer recruiting

Registration date
06/04/2017

Overall study status
Completed

Last Edited
10/08/2022

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A stroke is a serious condition where the blood supply to a part of the brain is cut off, usually by a blood clot blocking an artery (ischaemic stroke) or a bleed (haemorrhagic stroke). Stroke affects around 33 million people worldwide and is the second leading cause of death. Acute (hospital based) management of stroke has substantially improved over the years meaning more stroke survivors are living in the community. Therefore there is greater need for community based services that address the longer term needs. The range and availability of services for stroke survivors living in the community vary greatly across the UK. Research suggests that survivors experience unmet emotional, social and information needs, and many do not have their health and social care needs reviewed beyond the first six months. More effective long-term care could be achieved with a regular review of post-stroke needs, and by providing information through a direct contact for stroke in the GP Surgery. To address this, a new General Practice based model of care for stroke has been developed. The aim of this study is to assess how well the new model works when introduced at a single Practice.

Who can participate?
Adults who have had a stroke.

What does the study involve?
The new model of care is introduced into the participating practice. This involves five components. The first is to offer patients a structured review of post-stroke needs based on a checklist. The second is to provide patients with the opportunity to call a healthcare professional within their General Practice to talk about stroke and to gain information about the condition (Direct Point of Contact; DPoC). Thirdly, a meeting between General Practice staff, hospital and community based specialists (e.g. stroke physician, physiotherapists, occupational therapists) is arranged to help improve communication between healthcare services. Fourthly, comprehensive information about local services for stroke (service mapping) is made available to the General Practice who will sign post stroke survivors to relevant services. Finally, General Practice staff receive training in the components of the model. Information about patients' attendance at the review, calls made to the DPoC, additional workload, and any problems introducing the new care components is collected throughout the study. This is done by reviewing patients' records and through discussion with Practice staff at the end of the study. Before and 3 months after their

review, patients receive questionnaires about general well-being, ability to access health information, and satisfaction with the new service to complete.

What are the possible benefits and risks of participating?
The proposed model of care has not been evaluated and therefore its benefits are unknown. However, patients participating in the pilot study will have opportunities to have their questions about stroke answered by a Practice Nurse, talk about their needs with a Practice Nurse during an extended post-stroke review, and learn about local services which they may find useful. Additionally, participants will be contributing to research which could shape the future long-term provision of care for stroke survivors in General Practice and in the community. There are no notable risks involved with participating. Patients are also free to come with an informal caregiver to the review. Direct point of contact is offered as an additional, opt-in service component which patients are free to use at their discretion.

Where is the study run from?
The study is run from University of Cambridge and takes place in a single local General Practice in Cambridgeshire (UK)

When is the study starting and how long is it expected to run for?
August 2016 to February 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
1. Dr Ricky Mullis
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Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT03353519

Protocol serial number
33634

Study information

Scientific Title
Improving Primary Care After Stroke (IPCAS): a pilot of a cluster randomised controlled trial

Acronym
IPCAS

Study objectives
The aim of this pilot study is to:
1. Assess feasibility of the new model of care
2. Gather feedback from participants (both health care professionals and patients) to inform further iteration of the model prior to testing in a randomised controlled trial
3. Collect data to inform the feasibility and design of the subsequent trial

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - Edgbaston Research Ethics Committee, 17/03/2017, ref: 17/WM/0104

Study design
Non-randomised; Interventional; Design type: Process of Care, Education or Self-Management, Management of Care

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Primary Care, Primary sub-specialty: Stroke; UKCRC code/ Disease: Stroke/ Cerebrovascular diseases

Interventions
At baseline, patients will be sent an information pack and baseline questionnaires inviting them to the study by the General Practice. Consent to participate will be given by returning the consent form and study questionnaires. Once consent is gained, participants will be invited to a structured review by their General Practice and receive a checklist of post-stroke needs which they will fill in and bring to the review (approximately 2-4 weeks from consenting). Participants will return a satisfaction questionnaire following the review. They will receive follow-up questionnaires 6 months from the study start date in the practice (date of initial mail-out). Patients will be able to use DPoC throughout the lifetime of the study in their General Practice (6 months).

The new model of care incorporates a multi-factorial package of service aimed at providing a review of patient needs, a contact for patients in general Practice for queries related to stroke, improved communication between the different care services, and increased awareness of and access to national and local community and charity provided services.

Specifically, the intervention will comprise the following components:
1. A structured review of patient needs: this will be performed by a Practice Nurse (PN) as part of the regular annual review. The review will be based on three key needs identified by a patient prior to the review on a 15-item checklist
2. A direct point of contact for stroke survivors and carers at the GP surgery: patients will be able to call the Practice to ask questions about their stroke. A PN will call them back to sign post services and/or provide information and advice about specific issues.
3. Improved communication between General Practice staff and specialist services: a one-off meeting between General Practice staff, hospital stroke services, and the community neurorehabilitation team. The aim will be to: (1) introduce General Practice staff to community / hospital services for stroke (referrals), (2) facilitate further contact across services, (3) discuss referral criteria and routes into the services.
4. Service mapping for stroke related needs: a catalogue of stroke (and other relevant) services in participating localities and information on how to access them will be provided to the general practice.
5. Training for General Practice staff: an overview of stroke and stroke related long-term needs will be presented, followed by discussion of 3-4 vignettes based on items from the stroke review checklist.

Intervention Type
Other

Primary outcome(s)
Feasibility will be assessed as:
1.1. The recruitment rate will be recorded as percent of eligible patients invited who consent to

the study
1.2. The uptake rate to the intervention will be recorded as:
1.2.1. Percent of consented patients who attend the annual review by the end of the intervention (by 6 months) and
1.2.2. The number of times the DPoC was contacted by 6 months
1.3. Percent of fully completed baseline and follow-up questionnaires by 6 months

Key secondary outcome(s))
1. Feasibility is further assessed by recording:
1.1. Reasons why people are not reviewed will be recorded in patient medical records and reviewed at 6 months
1.2. Additional workload for the Practice associated with the model will be recorded based on patient medical records: The length of the reviews (mean, standard deviation; SD) and the number of times each patient is seen
1.3. The overall number of referrals made by 6 months
1.4. Call durations to the DPoC (mean, SD)
2. Acceptability is assessed using information on barriers and facilitators about the uptake to the study, recorded during the debriefing meeting

Completion date
28/02/2018

Eligibility

Key inclusion criteria
1. Diagnosis of stroke
2. Has a good understanding of English
3. Has the capacity to provide written informed consent.
4. Age ≥ 18 years
5. Gender: both males and females

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
1042

Key exclusion criteria

1. Patients with a history of transient ischaemic attack (TIA) only
2. Bed-bound patients
3. People unable to provide written informed consent due to mental illness or cognitive impairment
4. Patients considered by the GP to be unsuitable for example: terminal illness
5. Living in residential care

Date of first enrolment
09/07/2017

Date of final enrolment
16/08/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Cambridge
Primary Care Unit
Department of Public Health and Primary Care
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Sponsor information

Organisation
NHS Cambridgeshire and Peterborough CCG

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Ricky Mullis (r.mullis@medschl.cam.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/01/2019	15/08/2019	Yes	No
Protocol article		18/08/2019	09/08/2022	Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes