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Improving clinical stroke care using a stroke collaborative approach

Submission date	Recruitment status	[_] Prospectively registered
11/04/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/04/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/01/2015	Circulatory System	

Plain English summary of protocol

Background and study aims
Affecting over 100, 000 people per year in the UK alone, stroke can result in long-term disability or death. At the time of this study, mortality remained unacceptably high, with stroke outcomes in the North West of England amongst the worst in Europe.
The primary aim of the study was to understand whether participation in a group learning environment increased compliance to stroke care bundles compared to not taking part. A secondary aim was to understand if joining an established learning environment would give results at a faster pace.

Who can participate?
All hospitals in the North West of England that offered acute stroke services to patients living in the North West Strategic Health Authority (SHA) were asked if they wished to participate. 25 Hospital Trusts were assessed for eligibility and 24 Trusts took part in the study.

What does the study involve?
Participating hospitals in the North West of England were randomly allocated into two groups. One group used a quality improvement (QI) collaborative (the intervention group) to share the learning regarding compliance with the bundles and the other group carried on using the methods they were using at that time (the control group). In the first year of the study, the two groups used the different systems. In the second year of the study both groups used the QI collaborative system. The intervention group worked with the control group to help them learn the new system.

What are the possible benefits and risks of participating?
Risks: We did not anticipate any risks to organisations or individuals from this study. A minor risk was that data on performance was freely shared within organisations. Chief Executives were sent data on the performance of their stroke services on a 2-monthly basis. This information should already have been known to them as they will have been sent their data by the Royal College of Physicians (RCP) during the release of the Sentinel audit results. Performance of their hospital with respect to the study measures was therefore already publicly available via the RCP website and any current issue of poor performance was already known.
Data collection: All patient identifiable information were removed from the submitted files prior

to transfer to the Programme Management Office.
Potential benefits: Hospitals were given the opportunity to learn, free of charge with peers and experts in their clinical field. Teams had leadership support to make changes to their services for improvement. The study requirements for regular clinical audit required organisations to set up processes for regular data collection, which we anticipated would be sustained beyond the duration of the study, and which formed the basis for understanding the quality of care being offered and the opportunities for improvement. The RCP audit was run every two years and this study offered the opportunity to improve at pace. It was anticipated that participation in the QI collaborative would give each stroke unit the tools and techniques to sustain improved services in the future.

Where is the study run from?
The Stroke 90:10 study was co-ordinated by a Programme Management Office hosted at Salford Royal NHS Foundation Trust (UK).

When is study starting and how long is it expected to run for?
The study ran from January 2009 for 21 months until October 2010.

Who is funding the study?
Funding was provided by The Health Foundation (UK), with an extension granted in October 2010.

Who is the main contact?
Dr Maxine Power
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2008neuro12

Study information

Scientific Title
A cluster randomised controlled trial to determine the impact of participation in a quality improvement Breakthrough Series collaborative on adherence to a bundle of evidence based processes for stroke

Acronym
Stroke 90:10

Study objectives
Null hypotheses:
There will be no difference in adherence to a bundle of care for stroke patients between hospitals participating in a quality improvement programme and hospitals providing usual care.
There will be no difference in the National Sentinel Audit for Stroke scores between hospitals participating in a quality improvement programme and hospitals providing usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Tameside & Glossop Local Research Ethics Committee Manchester, 11 August 2008, ref: 08 /H1013/55

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not applicable as there was no direct patient involvement.

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

Interventions

During the two year programme a 10-month breakthrough series (BTS) cycle ran twice. At the start of the study, hospitals were randomly allocated to intervention or control. In the first year only the intervention teams participated in the collaborative. Control sites performed usual care to allow comparison between these sites and those initially participating in the improvement programme. All statistical comparisons were made at the end of year one. In the second year the intervention sites worked on improving bundle compliance to 95% using reliable care principles and acted as mentors for control hospitals invited to participate in the collaborative.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Adherence to the two bundles of processes and percentage of compliance to the bundles of care, known as all or none measurement.

Secondary outcome measures
Process measures: hospitals in the intervention were asked to conduct a retrospective audit of up to 20 sets of stroke notes from the 6 months preceding the commencement of the collaborative and monthly thereafter. Data abstraction was carried out in accordance with the RCP sentinel audit guidelines (http://www.rcplondon.ac.uk/resources/national-sentinel-stroke-audit). Hospitals were asked to obtain the following process measures:
- Time between admission and brain scan and the percentage of patients scanned within 24 hours
- Time between admission and delivery of 1st dose of aspirin and the percentage of patients receiving aspirin within 24 hours
- Percentage of patients receiving a swallow screen within 24 hours
- Percentage of patients weighed during their inpatient stay
- Percentage of patients assessed by a physiotherapist within 72 hours
- Percentage of patients assessed by an Occupational Therapist within 7 days
- Percentage of patients spending 50% or more of admission on an Acute Stroke Unit
- Percentage of patients receiving a mood assessment
- Percentage of patients with multidisciplinary team goals reviewed weekly
- Crude inpatient and 30 day mortality
- Length of stay
- 30-day readmission rate
- 30-day Modified Rankin (assessment of residual disability / functional outcome)

Overall study start date
01/01/2009

Completion date
01/10/2010

Eligibility

Key inclusion criteria
Hospitals were included if they offered acute stroke services to patients living in the North West Strategic Health Authority (SHA).

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
25 NHS Trusts

Key exclusion criteria
Hospitals admitting fewer than 100 eligible patients per year, or unable to commit a dedicated team for participation, were excluded.

Date of first enrolment
01/01/2009

Date of final enrolment
01/10/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
3rd Floor Mayo Building
Salford
United Kingdom
M6 8HD

Sponsor information

Organisation
Salford Royal NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/019j78370

Funder(s)

Funder type
Charity

Funder Name
This study was funded by The Health Foundation, UK, (Registered Charity: 286967)

Funder Name
Grant Ref: 1358 / 5200

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2014		Yes	No