

Stroke system of care trial: a cluster randomised trial evaluation of a patient and carer-centred system of Longer-Term Stroke Care

Submission date 04/04/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/05/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/07/2015	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Anne Forster

Contact details
Academic Unit of Elderly Care and Rehabilitation
Bradford Institute for Health Research
Temple Bank House
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ
+44 (0)1274 383 406
a.forster@leeds.ac.uk

Additional identifiers

Protocol serial number
RP-PG-0606-1128

Study information

Scientific Title

Stroke system of care trial: a cluster randomised trial evaluation of a patient and carer-centred system of Longer-Term Stroke Care

Acronym

LoTS Care

Study objectives

The hypothesis for LoTS Care is that a system of care delivered by a Stroke Care Co-ordinator (SCC) to patients and carers living at home, in the community, will improve psychological and functional outcomes compared to usual SCC practice.

The primary objective of the trial is to determine whether the system of care improves psychological outcomes for patients requiring long term care at home.

The secondary objectives include:

1. Improved functional outcomes for patients requiring long-term support at home
2. Improved psychological and functional outcomes for carers of patients requiring long term support at home
3. Cost effectiveness

Ethics approval required

Old ethics approval format

Ethics approval(s)

Leeds (West) Research Ethics Committee, 09/05/2008, ref: 08/H1307/43

Study design

Pragmatic multi-centre cluster randomised controlled trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Stroke

Interventions

Stroke services will be randomised into intervention or control groups using the stratification factors of quality of the stroke unit; referral rate and SCCs working alone versus within a community multidisciplinary team.

SCCs in stroke services randomised to the intervention group will be trained to deliver a system of care centered on key problems identified as of central importance to stroke patients and their carers. The assessment schedule is presented in a manual comprising 16 questions (patient) and 11 questions (carer) representing the identified problem areas, linked to reference guides

containing educational text with algorithms of evidence based treatment options and associated patient carer action plans. Implementation of the assessment system is supported by a specific training programme.

SCCs in stroke services randomised to the control group will continue to deliver current community-based practice as determined by local policy and practice.

The SCC will undertake a primary assessment of patients (and carer if appropriate) using the system of care and instigate service responses, with additional follow-up and monitoring visits as appropriate to the needs of individual patients. Therefore there are no specified treatment times for either arms. Follow up of both the control and intervention arms of the patients (and carers if applicable) will be followed up at 6 and 12 months.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

General Health Questionnaire 12 (GHQ12) completed by the patient 6 months after recruitment

Key secondary outcome(s)

The secondary outcome measures for patients at 6 and 12 months are:

1. Frenchay Activities Index
2. Barthel Index
3. EQ-5D
4. Stroke Impact Scale
5. Longer-term Unmet Need in Stroke
6. Satisfaction
7. Death
8. Hospital re-admission
9. Institutionalisation
10. Total costs
11. Cost-effectiveness/cost-utility

The GHQ12 at 12 months is also a patient secondary outcome measure to assess whether any intervention effect is sustained.

The secondary outcome measures for carers at 6 and 12 months are:

1. GHQ12
2. Carer Burden Scale
3. Satisfaction
4. Death
5. Institutionalisation

Completion date

30/04/2012

Eligibility

Key inclusion criteria

The trial is evaluating a complex intervention delivered by the Stroke Care Co-ordinator (SCC) within a stroke service and eligibility criteria apply at three levels - the stroke service, the stroke unit and the SCC.

A stroke service will only be considered for inclusion in the trial if it includes a stroke unit which fulfils the Royal College of Physicians guidelines definition of a stroke unit, that is, by the presence of 4/5 of the following criteria:

1. Consultant physician with responsibility for stroke
2. Formal links with patient and carer organisations
3. Multidisciplinary meetings at least weekly to plan patient care
4. Provision of information to patients about stroke
5. Continuing education programmes for staff

Stroke Care Co-ordinators (SCC) will be eligible if they fulfill the following criteria:

1. A registered healthcare professional with documented experience in stroke care
2. Undertakes a community based liaison or co-ordinating role for stroke patients
3. Co-ordinates a range of longer-term care inputs on the patients' and carers' behalf (e.g., signposting, carrying out assessments)
4. Works within a stroke service as above

Patients with the following characteristics will be eligible for the trial:

1. Have a confirmed primary diagnosis of stroke
2. Are referred to a SCC on discharge home from hospital or within six weeks of stroke
3. Are still waiting for their first SCC assessment visit
4. Provide written informed consent or carer assent

All carers with the following characteristics are eligible for this study:

1. Identified by the patient
2. Eligible for this study
3. Provides the patient with practical support on at least a weekly basis

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Key exclusion criteria

Patients will be excluded from the trial if:

1. They are unlikely to survive for more than three months
2. Are being discharged to/resident in a nursing or residential home
3. Have been previously registered to the trial
4. They are taking part in other stroke research network adopted studies which involve 6- and 12-month follow-up questionnaires

Date of first enrolment

01/06/2008

Date of final enrolment

30/04/2012

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Bradford Institute for Health Research

Bradford

United Kingdom

BD9 6RJ

Sponsor information

Organisation

Bradford Teaching Hospitals NHS Foundation Trust (UK)

ROR

<https://ror.org/05gekvn04>

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

Funder Name

Stroke Association

Alternative Name(s)

TheStrokeAssociation, TheStrokeAssoc

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary****Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2014		Yes	No
Results article	results	01/08/2015		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes