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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

Registration date
09/05/2008

Overall study status
Completed

Last Edited
13/07/2015

Condition category
Circulatory System

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.lotscare.co.uk/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Quality of life

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

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

Secondary outcome measures
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

Overall study start date
01/06/2008

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
800 patients (and carers if applicable)

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
England

United Kingdom

Study participating centre
Bradford Institute for Health Research
Bradford
United Kingdom
BD9 6RJ

Sponsor information

Organisation

Bradford Teaching Hospitals NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.bradfordhospitals.nhs.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)

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

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	01/12/2014		Yes	No
Results article	results	01/08/2015		Yes	No