

A cluster randomised trial evaluation of a patient-and carer-centred system for longer term stroke care (LoTS care)

The LoTS-Care trial is a national randomised trial to evaluate a new approach to delivering longer-term support for stroke patients and their carers in the community. The trial is working with community stroke care co-ordinators (SCC's) and community stroke teams around the UK.

Community stroke care co-ordinators (SCC's) and community stroke teams:

Registered health care professionals who are in regular contact with stroke patients organising community care inputs on their behalf (e.g. signposting, carrying out assessments).

Cluster Randomisation

Participating SCC's and teams will be randomised into either the intervention or control groups at the beginning of the trial. Half of them will be allocated to the intervention group and the other half into the control group.

Intervention: We have developed a system of care based on the up-to-date evidence, which provides treatment guidance following patient and carer assessments. SCC's allocated to the intervention group will be trained in the new system of care and will use it as a supportive tool to help them assess and co-ordinate patient care in the community.

Control: Stroke care co-ordinators and community stroke teams continue to deliver their current practice.

Patients and Carers

The trial aims to recruit 800 patients (with and without their carers). Researchers will recruit patients who are referred to SCC's/teams and will obtain written informed consent/carer assent.

The inclusion criteria for both patients and are broad to be as inclusive as possible:

Patients:

- Have a confirmed primary diagnosis of new stroke
- Living at home
- Are referred to an SCC on discharge home from hospital or within 6 weeks of stroke if not admitted to hospital
- Are still waiting for their first SCC assessment visit
- Provide written informed consent or carer assent
- Do not have a poor prognosis

Carers:

- Informal carer who provides the patient with practical support on a weekly basis
- Provide written informed consent

Objectives:

The LoTS care trial aims to evaluate whether our new system of care improves psychological and functional outcomes in patients and carers living at home in the community when compared to usual practice. An economic analysis of the new system of care will also be conducted.

The outcomes of the trial will be assessed using questionnaire packs completed by consenting patients and their carers (if they have one) when they are recruited into the trial and 6 & 12 months later when questionnaire packs will be posted to their homes from the central trial office.

ISRCTN: 67932305

Ethics Approval: This trial was approved by Leeds (West) Research Ethics Committee (Ref: 08/H1307/43)

For further information, please contact:

www.lotscare.co.uk

Anne Forster (Chief Investigator), Tel: 01274 383406, Email: a.forster@leeds.ac.uk

Kirste Mellish (Programme Manager), Tel: 01274 382815, Email: kirste.mellish@bradfordhospitals.nhs.uk

Katie Shorter (LoTS-Care Trial Manager), Tel: 01274 383407, Email: katie.shorter@bradfordhospitals.nhs.uk