



*Caring for today  
Researching for tomorrow  
Working for change*

The logo for LoTS care, consisting of the text "LoTS care" in a sans-serif font. "LoTS" is in white on a blue background, and "care" is in blue on a white background. The "LoTS" and "care" are separated by a white oval shape that tapers at the ends.

**LoTS care**

**Stroke system of care trial**

A cluster trial evaluation of a patient  
and carer-centred system of  
longer-term stroke care

# Who's who?



- **Chief investigator:**

Professor Anne Forster, Academic Unit of Elderly Care and Rehabilitation, Bradford Institute for Health Research.

- **Co-investigators:**

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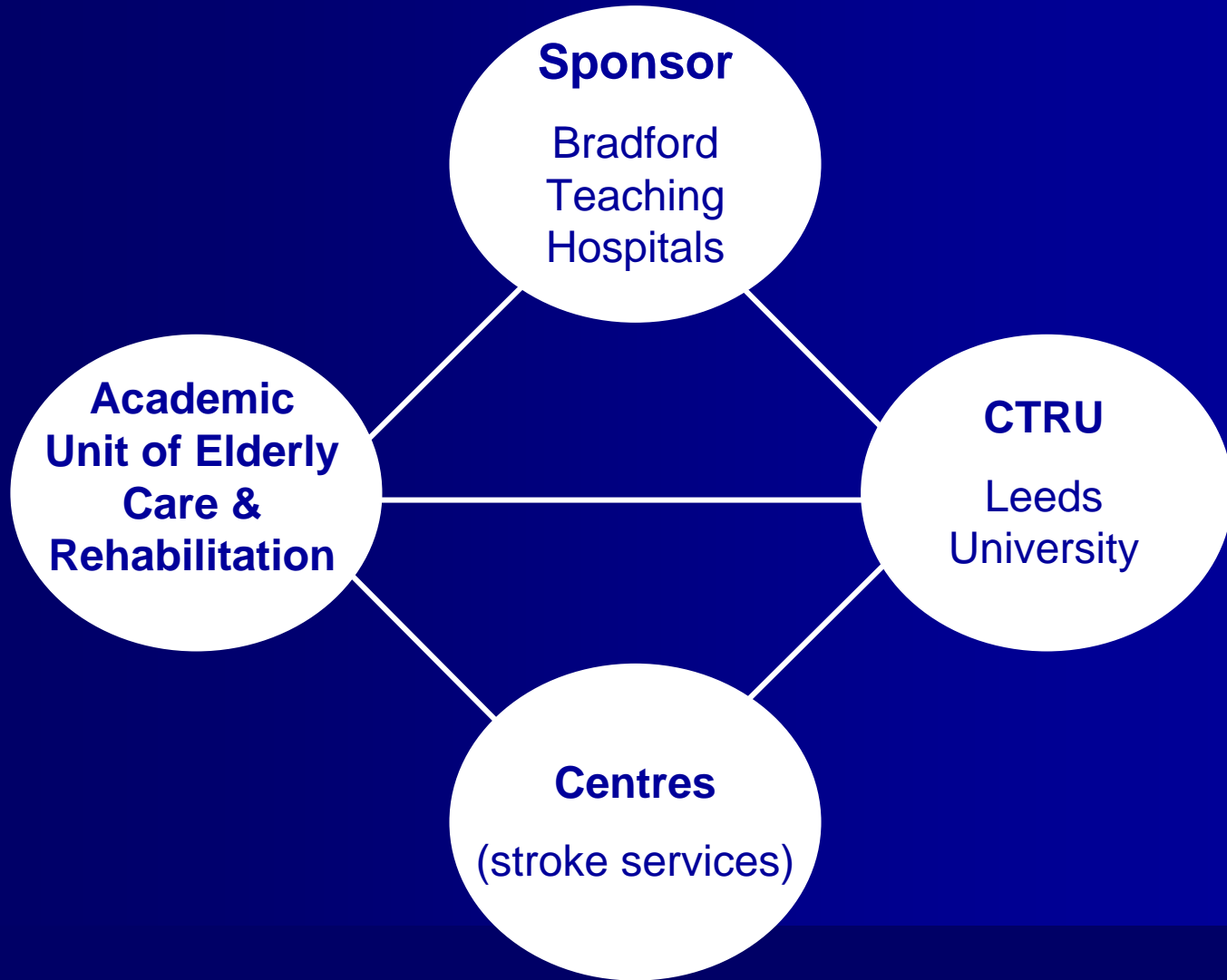


# Who is involved?



- **Funders:** NIHR Programme Grant & TSA
- First NIHR stroke rehabilitation programme grant to be awarded
- The trial is part of a programme of research to improve longer-term outcomes of stroke patients living in the community
- A very exciting & prestigious study to be involved with!

# Who is involved?



# Background



- Longer-term recovery is poor for many stroke patients
- Patients depressed and housebound
- Carers stressed and anxious

# Development work

Review of qualitative  
research

Review of  
quantitative  
research

Interviews with  
patients and carers



Identification of patient and  
carer longer term problems (16)



System of Care

# System of Care

## Structured Assessment

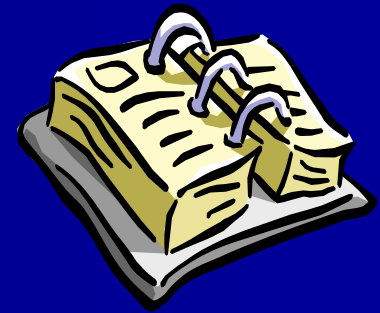
(focussed on patient and carer centred problems following a stroke)



highlights patients' and carers' problems



Reference Guides  
(Treatment algorithms)



Action Plans

# Feasibility Study



- 47 patients/ 21 carers were recruited
- Professionals found it easy to use and helpful
- Feedback further refined system

# Study Aim



- To evaluate the clinical and cost effectiveness of our new system of care, on psychological and functional outcomes of stroke patients living in the community.

# Objectives

- **Primary Objective:**
  - Improved psychological outcomes for patients
- **Secondary Objectives:**
  - Improved functional outcomes for patients
  - Improved psychological and functional outcomes for carers
  - Assess if the system of care is cost-effective

# Methods



- Multi-centre, cluster randomised controlled trial of 800 stroke patients and their carers
- The system of care will be delivered by stroke care co-ordinators (SCCs)

## Are you a stroke care co-ordinator (SCC)?

We have defined an SCC as follows, however other titles may be in use.

- A registered health profession with documented experience in stroke care
- Undertakes a community based liaison or co-ordinating role for stroke patients
- In regular contact with patients and co-ordinate a range of longer-term care inputs on their and their carers' behalf (e.g. signposting, carrying out assessments etc)
- Works within a stroke service

# Service Eligibility

- Encompass primary and secondary care over a geographical area within the UK
- A stroke service must have a **stroke unit**, defined (at least 4 out of 5) as follows:
  - Consultant physician with responsibility for stroke
  - Formal links with patient and carer organisations
  - Multidisciplinary meetings at least weekly to plan patient care
  - Provision of information to patients about stroke
  - Continuing education programmes for staff

# Service Randomisation

- This is a **CLUSTER** randomised trial, so the service will be randomised not the individual patients
- Services will be randomised to either:

## Intervention

SCCs will deliver  
our new  
system of care  
to assess patients

OR



## Control

SCCs will deliver  
their usual care

# What will it involve?

What will happen to my working practice if...

I'm randomised to the **INTERVENTION**

- You will deliver our new system of care to **ALL** your patients

I'm randomised to the **CONTROL?**

- You will continue to deliver your usual assessments

Your patients will be approached by a researcher to take part in the study i.e. to complete questionnaires

# SCC Training



If randomised to the **INTERVENTION**:

- SCCs will need to attend 2 national training days:
  1. Training in delivering the system of care
  2. Training in the research procedures

If randomised to the **CONTROL**:

- SCCs will need to attend 1 national training day:
  1. Training in the research procedures

Travel expenses will be provided

# Patient Recruitment

- Carried out by independent researchers
- Research nurse will:
  - Assess patients
  - Explain the trial to patients
  - Take informed consent
  - Collect baseline data

# Outcomes

- Outcomes of the trial will be evaluated by a questionnaire pack:
  - at baseline
  - posted to patients and carers after 6 months
  - posted to patients and carers after 12 months
- Postal questionnaire packs will be co-ordinated centrally by the CTRU

# Outcomes

- Patient questionnaire pack contains:
  - General health questionnaire (GHQ12)
  - Frenchay activities index (social activities)
  - Barthel index (activities of daily living)
  - EQ-5D (health state)
  - Stroke Impact Scale
  - Longer-term unmet needs in stroke (LUNS)
  - Costs based on Client Service Receipt Inventory
- Carer questionnaire pack contains:
  - Caregivers burden scale
  - General health questionnaire (GHQ12)
  - Satisfaction

# Patient Eligibility

## Inclusion criteria:

- Have a confirmed primary diagnosis of stroke
- Are referred to a SCC on discharge home from hospital or within 6 weeks of stroke
- Are still waiting for their first SCC assessment visit
- Provide written informed consent or carer assent

## Exclusion criteria:

- Unlikely to survive for more than 3 months
- Are being discharged to a residential or nursing home
- Have been previously registered to the trial

# Carer Eligibility



## Inclusion criteria:

- Identified by the patient as the informal carer who provides them with practical support on at least a weekly basis

## Exclusion criteria:

- If their patient does not consent to the trial

# Methods



- **Multi-centre:** we aim to recruit 40 SCC from around the UK
- Approx. 20 patients/carers per service
- Recruitment over 12 months: approx. 1-2 patients per month per service