

# Training Caregivers after Stroke (TRACS)

<b>Submission date</b> 30/01/2007	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/04/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/10/2013	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.tracstrial.co.uk>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

470772, G0501807

# Study information

## Scientific Title

Training Caregivers after Stroke (TRACS): a cluster randomised controlled trial of a structured training programme for caregivers of in-patients after stroke

## Acronym

TRACS

## Study objectives

The hypothesis for TRACS, based on results from a previous single centre study, is that a competency based caregiver-training programme (The London Stroke Carer Training Course, LSCTC) should improve patient outcomes in patients with disabling stroke. The study aims to evaluate the clinical and cost effectiveness of the training programme (LSCTC) by embedding it in usual practise to test the wider generalisability in settings where the population, health and social care provision differ.

Please note that as of 19/03/2008 this record was extensively updated. All changes are shown under the relevant fields with the date of change noted as 19/03/2008. Please also note that the anticipated start and end dates of this trial have been updated to the dates mentioned below.

The previous trial dates were as follows:

Previous anticipated start date: 01/04/2007

Previous anticipated end date: 31/10/2010

Please note that as of 08/02/10 this trial has been extended from 31/10/10 to 31/08/11

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Favourable ethical opinion received from the Leeds (West) Research Ethics Committee on 2nd February 2007. Ref: 07/Q1205/12

## Study design

Pragmatic multicentre cluster randomised controlled trial with blinded follow-up

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## 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**

Disabling Stroke

## **Interventions**

Current interventions as of 19/03/2008:

This is a cluster, randomised, controlled trial and aims to recruit 900 patients and caregivers in 36 stroke rehabilitation units. The intervention developed by Kalra and colleagues is known as the London Stroke Carer Training Course (LSCTC) and comprises a number of carer training sessions, competency assessment and one follow up session after discharge. The multidisciplinary teams (MDTs) in the units randomised to the intervention group will be trained to deliver the LSCTC, whilst those randomised to the control group will continue to provide usual care as per the National Guidelines.

Stroke rehabilitation units randomised to the control group will continue to provide usual care as per the National Guidelines for Stroke.

Previous interventions:

Stroke units will be randomised into intervention or control groups using the stratification factors of geographical site and quality of care.

Caregivers of inpatients in stroke rehabilitation units randomised to the intervention group will receive the London Stroke Carer Training Course (LSCTC) programme. Caregivers will receive 3-5 caregiver training sessions (depending on need) lasting 30-45 minutes, competency assessment and one home visit. Multidisciplinary teams in these stroke units will be trained to deliver the intervention.

Stroke rehabilitation units randomised to the control group will continue to provide usual care as per the National Guidelines for Stroke.

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome measure**

Current primary outcome measure(s) as of 19/03/2008:

Patient: Nottingham Extended Activities of Daily Living (NEADL)

Caregiver: Caregivers Burden Scale

Primary outcomes are measured at six months after recruitment.

Previous primary outcome measure(s):

The primary outcome is Nottingham Extended Activities of Daily Living (NEADL) for patients at 6 months after recruitment.

## **Secondary outcome measures**

Current secondary outcome measure(s) as of 19/03/2008:

Patient:

1. Hospital Anxiety and Depression Scale (HADS) (mood)
2. Euro-quality of life (EQ-5D) (health state)
3. Barthel Index (activities of daily living)
4. Death
5. Institutionalisation
6. Re-admission
7. Stroke Impact Scale (functional ability and health related quality of life)
8. Costs based on Client Service Receipt Inventory

Caregiver:

1. Compliance with intervention
2. Frenchay activities index (social restriction)
3. HADS
4. EQ-5D
5. Death
6. Hospitalisation
7. Institutionalisation
8. Costs based on Client Service Receipt Inventory

Secondary outcomes measured at the final follow up at 12 months.

Previous secondary outcome measure(s):

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

1. Hospital Anxiety and Depression Scale (HADS) (mood)
2. EQ - 5D (health state)
3. Barthel Index (activities of daily living)
4. Stroke Impact Scale (functional ability and health related quality of life)
5. Costs based on the Client Service Receipt Inventory (CSRI)
6. Death
7. Institutionalisation
8. Re-admission

The Nottingham Extended Activities of Daily Living (NEADL) at 12 months is also a patient secondary outcome measure to assess whether any intervention effect is sustained.

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

1. Compliance with the intervention (LSCTC, measured by number of training sessions, time taken, competencies signed off)
2. Caregivers Burden Scale
3. Frenchay activities index (social restriction)
4. HADS (mood)
5. EQ-5D (health state)
6. Death
7. Hospitalisation
8. Institutionalisation

**Overall study start date**

18/02/2008

**Completion date**

31/08/2011

# Eligibility

## Key inclusion criteria

Current inclusion criteria as of 19/03/2008:

Stroke Rehabilitation Units:

A stroke rehabilitation unit will be defined according to the definition provided by the Royal College of Physicians of London for the National Sentinel Stroke Audit 2004 by the presence of 4 /5 of the following criteria:

1. Consultant physician with responsibility for stroke
2. Formal links with patient and caregiver 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

Patient:

1. Patient has a confirmed primary diagnosis of new stroke
2. Is medically stable
3. Is likely to return home but with residual disability
4. Have a caregiver available, defined as the main person, other than health, social or voluntary care provider, helping with activities of daily living and/or advocating on behalf of the patient
5. Written informed consent/caregiver assent and caregiver consent will be obtained prior to any trial specific procedures

Caregiver:

1. Caregiver is willing and able to provide support after discharge
2. Fulfils the trial definition of a caregiver

Previous inclusion criteria:

Stroke Rehabilitation Units:

A stroke rehabilitation unit will be defined according to the definition provided by the Royal College of Physicians of London for the National Sentinel Stroke Audit 2004 by the presence of 4 /5 of the following criteria:

1. Consultant physician with responsibility for stroke
2. Formal links with patient and caregiver 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

An additional criterion will be that the majority of patients on the unit will have a diagnosis of stroke.

Patients with the following characteristics are eligible for this trial:

1. Have a confirmed primary diagnosis of new stroke
2. Are medically stable (defined as sitting out of bed for at least four hours per day)
3. Are likely to return home but with residual disability (defined as a modified Rankin score of  $\geq 3$ )
4. Have a caregiver available, defined as the main person, other than health, social, or voluntary care provider, helping with activities of daily living and advocating on behalf of the patient, who has no notable disability (defined as a modified Rankin score of 0-2) and who is willing and able

to provide support after discharge

5. Written informed patient consent/relative assent and caregiver consent will be obtained prior to any trial specific procedures

### **Participant type(s)**

Patient

### **Age group**

Not Specified

### **Sex**

Not Specified

### **Target number of participants**

900 patients and caregivers

### **Key exclusion criteria**

Current exclusion criteria as of 19/03/2008:

1. If discharge is planned within one week of admission to the stroke rehabilitation unit (insufficient time to instigate the intervention)
2. If the patient is in need of palliative care
3. If the patient or caregiver were registered to the trial on a previous admission

Previous exclusion criteria:

1. If discharge is planned within 96 hours of admission to the stroke rehabilitation unit (insufficient time to instigate the LSCTC)
2. If the patient has a concurrent illness requiring, or likely to require, palliative care
3. If the patient or caregiver was registered to the trial on a previous admission

### **Date of first enrolment**

18/02/2008

### **Date of final enrolment**

31/08/2011

## **Locations**

### **Countries of recruitment**

England

United Kingdom

### **Study participating centre**

**Academic Unit of Elderly Care and Rehabilitation**

Bradford

United Kingdom

BD9 6RJ

# Sponsor information

## Organisation

University of Leeds (UK)

## Sponsor details

Faculty of Medicine and Health  
Research Office, Room 7.11  
Level 7, Worsley Building  
University of Leeds  
Claredon Way  
Leeds  
England  
United Kingdom  
LS2 9NL

## Sponsor type

University/education

## ROR

<https://ror.org/024mrx33>

# Funder(s)

## Funder type

Government

## Funder Name

Medical Research Council (UK)

## Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## 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?
<a href="#">Results article</a>	results	01/10/2013		Yes	No
<a href="#">Results article</a>	results	21/12/2013		Yes	No