ISRCTN49208824 https://doi.org/10.1186/ISRCTN49208824

Training Caregivers after Stroke (TRACS)

Submission date 30/01/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 30/04/2007	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 29/10/2013	**Condition category** Circulatory System	[_] 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

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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 >=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
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Sponsor information

Organisation
University of Leeds (UK)

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Sponsor type
University/education

ROR
https://ror.org/024mrxd33

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?
Results article	results	01/10/2013		Yes	No
Results article	results	21/12/2013		Yes	No