Return To Work after stroke

Submission date	Recruitment status	Prospectively registered
26/08/2010	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
23/09/2010	Completed	Results
Last Edited	Condition category	Individual participant data
04/10/2017	Circulatory System	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Study website

 $http://www.clahrc-ndl.nihr.ac.uk/our-themes/clinical-themes/stroke-rehabilitation/return-to-work-after-stroke_20$

Contact information

Type(s)

Scientific

Contact name

Dr Kate Radford

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

10025

Study information

Scientific Title

Return To Work after stroke: a feasibility randomised controlled trial (RCT) and economic analysis

Acronym

RTW

Study objectives

This investigation aims to work with people with stroke and their employers to develop a model of vocational rehabilitation for people with recent stroke, define and cost the components of this model of vocational rehabilitation and establish the most appropriate measures of 'intangible' benefit (quality of life, well-being, self efficacy, stroke impact) for this intervention so that the intervention can be evaluated formally in a randomised controlled trial using both cost-effectiveness and cost benefit as outcomes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Leicestershire, Northamptonshire and Rutland Research Ethics Committee 1, 19/05/2010, ref: 10 /H0406/21

Study design

Single-centre single-blind randomised feasibility clinical trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Can be found at http://www.clahrc-ndl.nihr.ac.uk/our-themes/clinical-themes/stroke-rehabilitation/return-to-work-after-stroke_20

Health condition(s) or problem(s) studied

Stroke

Interventions

Stroke specific vocational rehabilitation (intervention arm):

The interventional arm involves an individually tailored process of case management, liaison, guidance and counselling, coaching, mentoring and occupational therapy delivered on a one to

one basis by our research occupational therapist. The total contact will vary between clients depending on their specific difficulties and clinical needs but we would generally expect less than 10 sessions per client. The vocational rehabilitation intervention is based on a developing evidence base - with good quality research previously conducted employing this approach to the treatment of clients with other long term neurological conditions and we are now testing this approach's efficacy as applied to supporting stroke survivors.

Treatment as usual (control arm):

The treatment as usual arm involves full and active participation in NHS, Social services, or 3rd sector provision just as the patient would receive anyway irrespective of trial participation.

Follow up for both arms is at 3 and 6 months only.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

- 1. Occupational status (working or not, hours worked and current income band)
- 2. Benefit status

Measured by postal questionnaire, sent to participants at 3 months and 6 months from the point of trial registration.

Secondary outcome measures

Standardised measures of:

- 1. Mood
- 2. Instrumental ADL (NEADL)
- 3. Disability
- 4. Stroke severity
- 5. Quality of life
- 6. Work
- 7. Participation (Sydney Psychosocial Reintegration Scale)
- 8. Cognitions

Measured by postal questionnaire, sent to participants at 3 months and 6 months from the point of trial registration.

Overall study start date

15/07/2010

Completion date

31/05/2012

Eligibility

Key inclusion criteria

- 1. People of working age, either sex
- 2. Living in Derby cities and Southern Derbyshire Health Communities

- 3. Have suffered a stroke
- 4. Were working or in full time education at stroke on-set

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

52

Key exclusion criteria

- 1. People not of working age
- 2. People not living in the catchment area
- 3. People who have not had a diagnosis of stroke confirmed
- 4. People who were not in full time education or working at the on-set of their stroke

Date of first enrolment

15/07/2010

Date of final enrolment

31/05/2012

Locations

Countries of recruitment

England

United Kingdom

Study participating centre University of Nottingham

Nottingham United Kingdom NG7 2RH

Sponsor information

Organisation

University of Nottingham (UK)

Sponsor details

Research Innovation Services Kings Meadow Campus Lenton Lane Nottingham England United Kingdom NG7 2NR

Sponsor type

University/education

Website

http://www.nottingham.ac.uk/ris/

ROR

https://ror.org/01ee9ar58

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Collaboration for Leadership in Applied Health Research and Care - Nottinghamshire, Derbyshire and Lincolnshire (CLAHRC NDL)

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