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Return To Work after stroke

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

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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