ISRCTN12464275 https://doi.org/10.1186/ISRCTN12464275

Return to Work After Stroke (RETAKE)

Submission date	Recruitment status	[X] Prospectively registered
26/02/2018	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/03/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/12/2024	Circulatory System	

Plain English summary of protocol

Background and study aims
Every year 110,000 people in England have a stroke, 25% of which are of working age. For many, a primary goal is to return to work, yet fewer than 50% of those working at stroke onset do. Being in work benefits personal finances, mood, lifestyle and relationships. Current rehabilitation after stroke aims to help people to be able to live independently, but does not focus on helping them back into work. Vocational Rehabilitation (VR) involves helping people find work, prevent job loss and support career progression despite disability. Early Stroke Specialist Vocational Rehabilitation (ESSVR) seeks to lessen the impact of stroke by assessing the patient's role as a worker and finding acceptable strategies to overcome problems.

Who can participate?
Stroke survivors aged 18 and over who were employed at stroke onset and their carers (if applicable)

What does the study involve?
Participants are randomly allocated to receive ESSVR or usual care. ESSVR is delivered by a stroke specialist occupational therapist who is trained to assess the impact of the stroke on the participant and their job; coordinate appropriate support from NHS, employer and other stakeholders; negotiate workplace adjustments, monitor return to work and explore alternatives where current work is not feasible or cannot be sustained. It is tailored to individual needs. Usual care is the usual NHS rehabilitation provided by the usual care team, which may involve outpatient/community physio, speech or occupational therapy, psychology, and medical follow-up. The intervention lasts for as long as is needed up to 12 months. Participants are followed up by postal/online questionnaire at 3, 6 and 12 months. The success of ESSVR is measured by the number of stroke survivors who are in employment (paid or unpaid) for a minimum of 2 hours at 12 months. Changes in mood, physical function, community integration, quality of life, work self-efficacy, post-stroke confidence, the number of NHS services needed for participants, changes in the numbers and types of negative events participants experience (for example admission to hospital) are also measured.

What are the possible benefits and risks of participating?
This study aims to improve rehabilitation services for people in employment who have had a

stroke. It is hoped that this study will help to support people who have had a stroke in returning to work. No disadvantages or risks are expected. Any appointments are arranged at times to suit the participants.

Where is the study run from?
University of Leeds (UK)

When is the study starting and how long is it expected to run for?
July 2017 to May 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Florence Day, f.day1@leeds.ac.uk or retake@leeds.ac.uk

Contact information

Type(s)
Scientific

Contact name
Ms Florence Day

ORCID ID
http://orcid.org/0000-0003-0306-5558

Contact details
Clinical Trials Research Unit
Leeds Institute of Clinical Trials Research
University of Leeds
Leeds
United Kingdom
LS2 9JT
+44 (0)113 343 1672
f.day1@leeds.ac.uk

Type(s)
Scientific

Contact name
Dr Kate Radford

ORCID ID
http://orcid.org/0000-0001-6246-3180

Contact details
Division of Rehabilitation and Ageing
School of Medicine
Faculty of Medicine and Health Sciences
Leeds

United Kingdom
LS2 9JT
+44 (0)115 8230226
kate.radford@nottingham.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
37304

Study information

Scientific Title
Early vocational rehabilitation compared with usual care for stroke survivors: an individually randomised controlled multi-centre pragmatic trial with embedded economic and process evaluations

Acronym
RETAKE

Study objectives
Every year 110,000 people in England have a stroke, 25% of which are of working age. For many, a primary goal is to return to work yet fewer than 50% of those working at stroke onset do. Being in work benefits personal finances, mood, lifestyle and relationships. Current rehabilitation after stroke aims to help people to be able to live independently, but does not focus on helping them back into work. Vocational Rehabilitation (VR) involves helping people find work, prevent job loss and support career progression despite disability.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands – Nottingham 2 Ethics Committee, 22/01/2018, ref: 18/EM/0019

Study design
Randomized; Both; Design type: Treatment, Complex Intervention, Rehabilitation, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Stroke

Interventions
This study will involve 760 stroke survivors (420 ESSVR plus usual care, 340 usual care alone), who are employed at stroke onset, and their carers (if applicable). Two occupational therapists from 20 UK hospitals will receive training in the Early Stroke Specialist Vocational Rehabilitation (ESSVR). ESSVR seeks to lessen the impact of stroke by assessing the patient's role as a worker and finding acceptable strategies to overcome problems. ESSVR is individually tailored to participants' needs, starting within eight weeks of stroke, with dose and intensity as needed.

The Early Stroke Specialist Vocational Rehabilitation (ESSVR) model (intervention) will be compared to a usual care (control) group:

Intervention group: ESSVR will be delivered by a stroke specialist occupational therapist (OT) who is trained to assess the impact of the stroke on the participant and their job; coordinate appropriate support from NHS, employer and other stakeholders; negotiate workplace adjustments, monitor return to work and explore alternatives where current work is not feasible or cannot be sustained. It will be tailored to individual needs.

Usual care (UC) group: Usual NHS rehabilitation provided by usual care team. This may involve outpatient/community physio-, speech- or occupational- therapy, psychology, medical follow-up.

The intervention will commence within 2 weeks of randomisation and last for as long as is needed up to 12 months post-randomisation. Participants will be followed up by postal/online questionnaire at 3, 6 and 12 months post-randomisation. The success of ESSVR will primarily be measured by the number of stroke survivors who are in employment (paid or unpaid) for a minimum of 2 hours at 12 months post-randomisation. Secondary outcomes will also include changes in mood, physical function, community integration, quality of life, work self-efficacy, post-stroke confidence, the number of NHS services needed for participants, changes in the numbers and types of negative events participants experience (for example admission to hospital).

Intervention Type
Other

Primary outcome measure
Self-reported return to work of at least 2 hours per week at 12 months post randomisation. This may be a return to a pre-stroke job or a new job. This will be recorded as a positive response to the question: 'Are you currently in work(paid or unpaid) for at least 2 hours per week?'; Timepoint (s): 12 months post-randomisation

Secondary outcome measures
All secondary outcomes are measured at 3, 6 and 12 months:
1. Work-related outcomes: return to work with same employer, number of hours worked, number of days in work
2. Mood, assessed using the Hospital Anxiety & Depression Scale (HADS) anxiety and depression scores
3. Physical function, assessed using the Nottingham Extended Activities of Daily Living scale (NEADL) summary score
4. Social participation, assessed using the Community Integration Questionnaire (CIQ) social and productivity scores
5. Work self-efficacy, measured using a single question from the work ability index
6. Health-related quality of life, measured using the EuroQoL 5 dimension health questionnaire, 5 level (EQ-5D-5L)
7. Health and social care resource use and wider resource use (e.g. productivity, personal or carer costs): self reported A&E attendances, hospital admission/readmission, number of work accidents, overall health and social care resource use, measured using a bespoke patient completed resource use questionnaire
8. Post-stroke confidence, measured using the Confidence after Stroke Measure (CaSM) summary score

Process Evaluation
Intervention compliance and how the intervention is experienced and understood by providers and recipients, and the organisational implications of embedding and sustaining the intervention in preparation for wider NHS roll-out. Measured using an embedded mixed-methods process evaluation using a range of methods including observations, qualitative interviews with participants, carers, service providers and employers, non-participant observation in sites, document analysis (case records and intervention proformas) and care mapping in a random sample of cases (up to 5% of participants in both ESSVR and UC)

Internal Pilot (8 Sites)
Recruitment rates at 4 – 6 months post randomisation and follow-up rates after 12 months post-randomisation, to assess whether they meet the predefined progression criteria thresholds

Overall study start date
01/07/2017

Completion date
31/05/2023

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Admitted to hospital with new stroke (all severities)
3. In work at stroke onset (including self-employed, paid or unpaid)
4. Willing and have capacity to provide informed consent to participate in the study
5. Have sufficient proficiency in English to contribute to the data collection required for research

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 582; UK Sample Size: 582

Total final enrolment
583

Key exclusion criteria
Not intending to work

Date of first enrolment
01/04/2018

Date of final enrolment
07/03/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Leeds
United Kingdom
LS2 9JT

Sponsor information

Organisation
University of Nottingham

Sponsor details
c/o Ms Angela Shone
East Atrium
Jubilee Conference Centre

Triumph Road
Nottingham
England
United Kingdom
NG8 1DH

Sponsor type
University/education

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 15/130/11

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/06/2024

Individual participant data (IPD) sharing plan
De-identified individual participant data datasets generated and/or analysed during the current study will be available upon request from the Clinical Trials Research Unit, University of Leeds (contact CTRU-DataAccess@leeds.ac.uk in the first instance). Data will be made available at the end of the trial, i.e. usually when all primary and secondary endpoints have been met and all key analyses are complete. Data will remain available from then on for as long as CTRU retains the data.

CTRU makes data available by a 'controlled access' approach. Data will only be released for legitimate secondary research purposes, where the Chief Investigator, Sponsor and CTRU agree that the proposed use has scientific value and will be carried out to a high standard (in terms of scientific rigour and information governance and security) and that there are resources available to satisfy the request. Data will only be released in line with participants' consent, all applicable laws relating to data protection and confidentiality, and any contractual obligations to which the CTRU is subject. No individual participant data will be released before an appropriate agreement is in place setting out the conditions of release. The agreement will govern data retention, usually stipulating that data recipients must delete their copy of the released data at the end of the planned project.

The CTRU encourages a collaborative approach to data sharing and believes it is best practice for researchers who generated datasets to be involved in subsequent uses of those datasets. Recipients of trial data for secondary research will also receive data dictionaries, copies of key trial documents and any other information required to understand and reuse the released datasets.

The conditions of release for aggregate data may differ from those applying to individual participant data. Requests for aggregate data should also be sent to the above email address to discuss and agree on suitable requirements for release.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	pilot	22/04/2020	30/01/2020	Yes	No
Protocol article	protocol	09/12/2020	11/12/2020	Yes	No
Protocol article	Protocol for process evaluation	15/03/2022	18/03/2022	Yes	No
Other publications	checklist for measuring implementation fidelity	02/11/2022	04/11/2022	Yes	No
HRA research summary			28/06/2023	No	No
Results article		29/11/2024	02/12/2024	Yes	No
Results article	Nested economic evaluation	05/12/2024	11/12/2024	Yes	No