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Synopsis

Early stroke specialist vocational rehabilitation for REturn To work After stroKE: a synopsis from the RETAKE RCT

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Published May 2026
DOI: 10.3310/LAKP6585

Abstract

Background: Return to work is achieved by < 50% stroke survivors. Evidence on support for return to work is lacking.
Objective: To determine whether Early Stroke Specialist Vocational Rehabilitation is more clinically effective and cost-effective at supporting return to work 12 months after stroke than usual care.
Design and methods: Pragmatic, observer-blind, multicentre superiority randomised controlled trial with embedded health economic evaluation. Participants were individually randomised, 5 : 4, to receive occupational therapy-led Early Stroke Specialist Vocational Rehabilitation + usual care. Questionnaire follow-up at 3, 6 and 12 months post randomisation. Mixed-methods process evaluation explored intervention experience, fidelity, compliance and implementation.
Setting: Twenty-one NHS stroke services in England and Wales.
Participants: Patients with new stroke within 12 weeks, aged ≥ 18, in paid/unpaid work at stroke onset. People not intending to return to work excluded.
Intervention: Occupational therapists assessed stroke impact on participants and their job; co-ordinated NHS/employer/other stakeholders' support; negotiated job accommodations, monitored return to work and explored alternatives if return to work were unfeasible. Usual care involved NHS rehabilitation provided by community teams and medical follow-up.

This synopsis should be referenced as follows:
Radford K, Wright-Hughes A, Clarke D, Phillips J, Holmes J, Powers K, *et al.* Early stroke specialist vocational rehabilitation for return to work after stroke: a synopsis from the RETAKE RCT. *Health Technol Assess* 2026;**30**(31):1–64. https://doi.org/10.3310/LAKP6585

Main outcome measures: Primary outcome: self-reported return to work for ≥ 2 hours/week 12 months post randomisation. Secondary outcomes: mood, functional ability, participation, productivity, work self-efficacy, health-related quality of life, confidence, mortality, carer strain, cost–consequences, COVID-19 impact.
Results: Between 1 June 2018 and 7 March 2022, 583 participants [mean age 54 years (standard deviation 11.1), 69.0% male, mean 29.9 days (standard deviation 20.0) post stroke, 452 (82.8%) ischaemic stroke] were randomised to Early Stroke Specialist Vocational Rehabilitation (n = 324) or usual care (n = 259). Primary and secondary outcome data were available for 454 (77.9%) and 316 (54.2%) participants, respectively. Intention-to-treat analysis showed no statistically significant difference in return to work between groups at 12 months [165/257 (64.2%) Early Stroke Specialist Vocational Rehabilitation vs. 117/197 (59.4%) usual-care, adjusted odds ratio 1.12 (95% confidence interval 0.8 to 1.87), p = 0.3582]. Similar proportions of adverse events occurred in both groups [40/241 (16.6%) attended accident and emergency, 24/244 (9.1%) hospital admissions, 6/266 (2.3%) work accidents at 12 months]. Exploratory subgroup analyses indicated Early Stroke Specialist Vocational Rehabilitation potentially benefits older people (60+), and those with two or more post-stroke impairments.
Health economic outcomes were consistent with primary clinical outcomes. Analysis using multiple imputation, adjusting for age, sex, utility or cost at baseline and site found Early Stroke Specialist Vocational Rehabilitation had higher costs [incremental cost £1337 (95% confidence interval −1113 to 3787) and slightly more favourable incremental quality-adjusted life-years of 0.019 (95% confidence interval −0.012 to 0.051)].
Early Stroke Specialist Vocational Rehabilitation was valued by participants and service managers. In contrast, usual-care participants reported limited or no vocational rehabilitation and poor communication. Intervention compliance was achieved for 244 (75.3%) participants. Mentor support for occupational therapies appeared to increase fidelity.
Limitations: Most participants had mild–moderate stroke, unlike our feasibility evaluation which informed the sample size (powered to detect an absolute 13% difference in return to work). More people return to work than anticipated. There was significant loss to follow-up for primary, secondary and health economic outcomes. Employers proved difficult to recruit and engage.
Conclusions: REturn To work After stroKE was unable to demonstrate an effect or cost effect of Early Stroke Specialist Vocational Rehabilitation on return to work 12 months post randomisation. The COVID-19 pandemic influenced employer behaviour, and remote working diluted Early Stroke Specialist Vocational Rehabilitation mechanisms in a predominantly mild–moderate sample, many of whom were able to self-navigate return to work.
Future work: Research is needed to confirm Early Stroke Specialist Vocational Rehabilitation benefits in people marginalised by age or post-stroke impairment, and determine what interventions benefit younger stroke survivors.
Funding: This synopsis presents independent research funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme as award number 15/130/11.
A plain language summary of this synopsis is available on the NIHR Journals Library Website https://doi.org/10.3310/LAKP6585.

Introduction

Rationale and background

This report details the work undertaken to establish the clinical effectiveness of an Early Stroke Specialist Vocational Rehabilitation (ESSVR) intervention designed to support return to work (RTW) after stroke, delivered in addition to usual NHS rehabilitation (Usual Care) when compared to usual care (UC) alone. Economic and process evaluations embedded in the trial are also described.

Early Stroke Specialist Vocational Rehabilitation is a vocational rehabilitation (VR) intervention that combines conventional occupational therapy (OT) with case co-ordination.[1,2] It is delivered by an occupational therapist (OT) with expertise in stroke and additional training in VR. ESSVR involves (1) assessing the impact of stroke on the person and their job; (2) educating stroke survivors, their employers and families about stroke impact on work, and strategies to lessen impact (e.g. memory aids, fatigue management); (3) work preparation, including opportunities to practice work skills using work simulation tasks; and (4) liaison with employers [including line managers, work-based occupational health (OH) and human resources] and employment advisors to plan and monitor a phased RTW and negotiate job, role and environmental accommodations to lessen the impact of stroke. ESSVR involves crossing organisational boundaries between health and workplace services, interactions between multiple health and social care and employment service stakeholders, is individually tailored, and requires behaviour change by the patient, their family and employer.

The development and process of ESSVR are described in Radford *et al.*[2] and elsewhere.[3,4]

There has been growing interest in the effectiveness and economic case for VR for a number of conditions, including

stroke, traumatic brain injury, musculoskeletal disorders and cancer, across countries, particularly Norway and the UK.[5–8]

Objectives

Primary objective

To establish whether ESSVR plus UC was more effective than UC alone at improving participants' self-reported work (≥ 2 hours per week) outcomes 12 months after randomisation.

Secondary objectives

Secondary objectives (measured across 3, 6 and 12 months post randomisation time points) were:

- To establish whether the intervention improves participants' self-reported work-related outcomes, mood, functional ability, participation, health-related quality of life, self-efficacy, post-stroke confidence and carer burden.
- To establish if the intervention changes overall health [including accident and emergency (A&E) visits, inpatient admissions, outpatient visits and primary care use including medications] and social care resource use.
- To measure resource use and estimate costs for participants in the ESSVR plus UC group compared to the UC alone group.
- To estimate the quality-adjusted life-years (QALYs) for participants in the ESSVR plus UC group compared to the UC alone group.
- To establish the economic value of the ESSVR intervention with UC compared to UC alone over the time frame of the trial.
- To assess the impact of COVID-19 on trial participants.

Internal pilot objectives

In an internal pilot, we also assessed whether study recruitment and follow-up rates meet the pre-defined progression criteria thresholds after 6 months of recruitment.

Process evaluation

The aim of the process evaluation was to measure fidelity to the ESSVR intervention and understand the social and structural context in which the intervention was delivered and to identify factors that might influence the quality of implementation in the wider NHS.

The objectives were to:

1. Ascertain intervention dose.
2. Describe the content of UC and ESSVR.
3. Describe levels of adherence to the ESSVR intervention.
4. Understand the delivery of UC and ESSVR.
5. Determine OTs competency to deliver ESSVR.
6. Describe participating sites.
7. Understand professionals' experiences of being trained to deliver the intervention.
8. Understand experiences of delivering the intervention.
9. Understand the social and structural factors, which support or act as barriers to the implementation of the intervention.
10. Understand participants' experience of being supported to RTW after stroke.
11. Identify potential contaminants.

Methods for data collection and analysis

Trial protocol

The proposed trial and process evaluation are published as two separate protocols.[9,10] It was prespecified that the REturn To work After stroKE (RETAKE) study's findings would be divided into separate clinical, economic evaluation and process evaluation publications.

Design

REturn To work After stroKE was a pragmatic, multicentre, researcher-blinded, individually randomised controlled, partially nested, superiority trial of OT-led ESSVR versus UC conducted in 21 NHS stroke services across England and Wales (including hyper acute stroke and stroke rehabilitation units). An internal pilot in eight sites assessed recruitment after 6 months and follow-up after a further 6 months. Embedded economic evaluation comparing costs and QALYs from an NHS and Personal Social Services (PSS) perspective and process evaluations exploring fidelity, the social and structural context, and implementation of the intervention are reported.

Eligibility

Eligible participants were aged 18 years or over, admitted to hospital with new stroke, and in work at the stroke's onset. Participants had to have capacity to provide informed consent and have sufficient proficiency in English to contribute to data collection. Participants with language barriers due to stroke were still eligible. Participants who were not intending to RTW following their stroke were excluded. Participants were invited to nominate a carer to take part in the study. Carers were eligible if they were the main informal caregiver providing the participant with support a minimum of once per week. They had to be able to give informed consent to participate and have

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sufficient proficiency in English to contribute to data collection. Written informed consent was obtained from all participants. Potential participants were provided with an information sheet and had the opportunity to ask questions of a researcher prior to consent. Participants were free to withdraw from the study at any time without giving reasons and without prejudicing their care.[9] Stroke services were eligible as study sites if they were able to deliver ESSVR. Services that routinely provided well-defined VR for stroke survivors within 12 weeks of their stroke were excluded. Registered OTs experienced in delivering specialist stroke rehabilitation in community rehabilitation setting were preferred when recruiting RETAKE OTs; however, there were no strict inclusion/exclusion criteria.

Randomisation and masking

Participants were randomly assigned to receive ESSVR or UC sequentially, using a 5 : 4 allocation ratio to account for the partially nested design of the study, with participants nested within therapists in the ESSVR group. Allocation was via a computer-generated minimisation programme incorporating random element to ensure treatment groups were well balanced by site, participant age (< 55, ≥ 55) and stroke severity [derived from EuroQol-5 Dimensions (EQ-5D) mobility question, the picture naming and executive tasks from the Oxford Cognitive Screen (OCS)]. Participants and therapists were aware of treatment allocation, whereas researchers were masked to enable unbiased follow-up.

Procedures

Early Stroke Specialist Vocational Rehabilitation training was delivered by experienced OTs from the central RETAKE team during a 2-day face-to-face training package which included provision and review of the ESSVR manual, clinical scenarios, case studies and delivery of the intervention within the trial context. After 6 months of experience delivering ESSVR, they attended a 1-day refresher training day. RETAKE OTs' competency was assessed via case vignettes at the end of their initial and refresher training sessions, and after 12 months experience of delivering ESSVR through review of case notes. OTs identified as needing support were offered additional training and mentoring. RETAKE OTs were assigned an expert mentor who facilitated monthly group mentoring sessions to provide support, share best practice and support fidelity.

Early Stroke Specialist Vocational Rehabilitation was delivered by specially trained RETAKE OTs using a case-co-ordination model of early intervention VR over up to 12 months post randomisation. ESSVR was individually tailored according to participants' needs, their preferences and employment context.

REturn To work After stroKE OTs' adherence to the ESSVR manual and intervention delivery was monitored via mentoring records,[11] content case report forms (CRFs) and routine treatment records. A fidelity checklist was applied using retrospective review of one randomly selected stroke participant's ESSVR record per OT.[12]

Usual care was offered to participants in both trial arms according to routine rehabilitation services available at each site. RETAKE OTs were restricted from providing any treatment to UC participants to prevent contamination.

Occupational therapists were trained in ESSVR over 2 days, face to face, led by two VR OT experts. They were given an intervention manual and stroke and VR resources[10] to support intervention delivery. We recorded demographic and practice history details, including post-qualification experience in stroke rehabilitation and VR, self-reported VR knowledge and research experience. Prior to the training, OTs were sent a case vignette, including six questions about supporting a stroke survivor back to work. The purpose was to determine the OTs' pre-training knowledge of VR, to enable trainers to tailor training to the OTs' needs. The same vignette was then used as a case study during the training, to navigate the OTs through the ESSVR process and familiarise them with CRFs for documenting the intervention. The Chief Investigator provided an overview of the trial, supporting evidence and led a workshop on contamination. OTs attended a 1-day refresher training 6 months later and participated in monthly group mentoring sessions led by an assigned VR OT expert mentor (described in Craven *et al.*, 2021).[11]

Data collection

Treatment data on ESSVR content, duration and dose were recorded by the RETAKE OTs on CRFs and with the participants' routine treatment records. Questionnaires were administered by post or online at baseline and 3, 6, and 12 months post randomisation. Priming calls, initial and reminder letters/e-mails, and Short Message Service (SMS) prompts were sent to maximise data return; two-way SMS text messages were sent to non-responders to confirm work status only, followed by a telephone call to offer support and/or collect the data over the telephone or to arrange face-to-face home visit. Primary outcome data were collected retrospectively where possible from non-responders towards the end of the overall trial follow-up period.

Outcomes

The primary outcome was self-reported RTW at 12 months post randomisation. Self-reported RTW was also measured at 3 and 6 months post randomisation.

Other secondary outcomes, measured at 3, 6 and 12 months post randomisation (unless stated otherwise), included RTW with the same employer, hours worked, days in work, mood [measured by the Hospital Anxiety and Depression Scale (HADS)], functional ability [measured by the Nottingham Extended Activities of Daily Living (NEADL)], social participation [measured by the Community Integration Questionnaire (CIQ) social and productivity scores only at 12 months], work self-efficacy [measured by a single question from the work ability index (WAI)], confidence [measured by the Confidence after Stroke Measure (CASM) only at 12 months], health-related quality of life [measured using the EuroQol-5 Dimensions, five-level version (EQ-5D-5L)] and healthcare resource use (measured by a bespoke resource use questionnaire). UC data for the 12-month period post randomisation was self-reported by participants' health and social resource care use. Adverse events included death, as reported by site, and hospital attendances and work accidents collected by self-report at 3, 6 and 12 months post randomisation.

Sample size

We estimated that a sample size of 760 participants (340 control, 420 intervention) would provide 90% power to detect a 13% absolute difference in the proportion of people in work at 12 months, at the two-sided 5% significance level, allowing for 20% loss to follow-up. This calculation assumed 26% in the control arm as per the feasibility study, clustering in the intervention arm only, an average cluster size of 11 participants per therapist, an intraclass correlation of 0.03, and a coefficient of variation in cluster size of 0.68 to account for a varying number of participants per therapist. Due to the impact of the COVID-19 pandemic, the sample size target was reduced to 582 participants (308 ESSVR and UC; 274 UC) to provide 80% power at the 5% significance level, to detect the same difference as originally planned, with updated cluster size assumptions of an average cluster size of 7 participants per therapist.

Statistical analysis

All clinical analyses were conducted in SAS® version 9.4 (SAS Institute Inc., Cary, NC, USA) (SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc. in the USA and other countries. ® indicates USA registration) according to the intention-to-treat population as described in the statistical analysis planpre-specified in advance of analysis. A single, final analysis of outcomes (including all data collected during the internal pilot) was conducted. All statistical testing was performed at the 5% significance level unless otherwise specified.

The primary outcome was analysed using a generalised logistic mixed-effects regression model, adjusting for site, age, sex, mobility, OCS picture naming and executive mixed score using a partially nested model to account for clustering of outcomes in the intervention arm due to therapist effects. Missing data patterns were explored and multiple imputation via chained equations with 50 imputations was used to impute missing values, and the results of identical analyses performed on each of the imputed data sets were combined using Rubin's rules. Results were expressed as adjusted odds ratio (OR) with 95% confidence intervals (CIs) and *p*-values. Continuous secondary outcomes were analysed using a generalised linear mixed-effects regression model adjusted for the same covariates and respective baseline score. Sensitivity analyses of participants with complete data were compared with analyses using multiple imputations. Assumptions were checked for all regression models using residual plots. Exploratory analysis was undertaken on the primary outcome to understand the impact of participant compliance using a complier-average causal effect (CACE) analysis and to explore moderating subgroup effects.

Descriptive statistics were used to report the flow of participants through the trial according to Consolidated Standards of Reporting Trials and to report safety data. The Trial Steering Committee and Trial Management Group reviewed accumulating safety data at agreed intervals throughout the trial.

Economic evaluation

The purpose of an economic evaluation is to inform decisions. The health benefits and harms, healthcare costs and other valuable effects are considered within a framework that makes best use of available clinical evidence.[13] The methods were pre-specified in advance of analysis in a Health Economic Analysis Plan (HEAP); see *Report Supplementary Material 1*. The within-trial economic evaluation was performed using the individual patient-level data collected and followed published guidelines for economic evaluation of healthcare interventions, as appropriate.[13–17] In line with the NICE reference case,[16] the economic evaluation takes an NHS and PSS perspective in the base case, although data on wider costs, including employment services [Department for Work and Pensions (DWP) perspective], time off work for family/carers and out-of-pocket costs (participant perspective) were also collected for secondary analysis.

As pre-specified in the HEAP, it was decided that cost–utility analysis to give an incremental cost per QALY would only be conducted if there was found to be a statistically significant clinical benefit and the assumptions of multiple imputation (missing at random) held.

To avoid the potential for double counting, the base-case resource use and costs were taken from patient-reported data only. This was the case for OT-intervention costs, except for training and mentoring costs, which were not participant specific and collected via CRFs. Mean [standard deviation (SD)] resource use and cost per participant were estimated for each randomised group. Mean difference (95% CI) in resource use and cost per participant between groups (ESSVR plus UC vs. UC alone) was presented.

Analyses were conducted in Stata MP 18 (StataCorp LP, College Station, TX, USA). To estimate the primary outcome for the health economic evaluation, the utility score from the EQ-5D-5L was used to estimate QALYs for the trial period using linear interpolation and area under the curve analysis, adjusting for baseline utility.[18] Mean (SD) utility at each time point and mean (SD) QALYs per participant per randomised group were presented and mean difference (95% CI) in utility at each time point and QALYs between groups (ESSVR plus UC vs. UC alone) were estimated.

Missing data are common in randomised controlled trials (RCTs) and a particular issue for economic evaluations where costs and outcomes are a composite of extensive data collected at multiple time points. This can lead to bias and lack of precision.[19] The level of missing resource use and EQ-5D data was reported, and the frequency and pattern of missing data were examined, following the approach adopted by Faria *et al.*[19] Multiple imputation was conducted by randomised allocation (ESSVR or UC) and where possible, in line with methods used in the clinical analysis.

Costs and outcomes were presented descriptively as a cost–consequence analysis, breaking it down by sector/perspective (primary care, secondary care, social services). Further methodological details are available in Pyne *et al.*[20]

Process evaluation

The mixed-methods process evaluation included longitudinal case studies (in a randomly selected 5% of cases), which involved non-participant observations, analysis of intervention records, following completion and semistructured interviews with stroke survivor participants at three time points (within 6 weeks, and at 6 and 12 months following recruitment), their nominated carers, employers and treating OTs. Treating OTs, carers and employers were interviewed once, 12 months after recruitment.

Semistructured interviews with an additional randomly selected 5% of participants were conducted to identify differences in ESSVR or UC delivery on participants' experiences over time.

Additional interviews with OTs delivering ESSVR were conducted with OTs during year 1 of the trial to explore views of training, the intervention, and organisational and social factors influencing intervention delivery. Mentors were interviewed in the same time frame to explore their perspectives on supporting RETAKE OTs to deliver ESSVR and on organisational and social factors influencing delivery. NHS staff supporting or managing OTs delivering ESSVR were also interviewed. Details of the eligibility criteria and consent procedures for each of the embedded studies are reported in Radford[9] and Clarke.[21]

During the pandemic we conducted an additional interview study to understand the impact of the pandemic on stroke survivors' ability to work and RTW from the perspectives of stroke survivors and employers. We focussed on the self-employed and participants employed in leisure, catering and service industries most adversely impacted by the pandemic. We interviewed their employers and others drawing on established clinical academic links and partnerships with employers and industry.[22]

Fidelity assessment focused on whether the intervention was delivered as intended (i.e. dose, sequence and scope) and participants' experiences of ESSVR and how it was adapted to context and tailored to the individual (explored qualitatively). We developed a 27-item fidelity checklist based on the logic model (see *Appendix 1*) and ESSVR intervention process and guided by the Conceptual Framework for Implementation Fidelity (CFIF).[23] We applied it to complete case records (intervention CRFs and OT records) for one randomly selected stroke participant per treating OT and used it to measure OT adherence to ESSVR and identify factors (fidelity consistent and inconsistent) affecting adherence. Associations between therapists' experience, knowledge, engagement in mentoring and intervention fidelity were explored using regression models.[24,25] More details on the development of the fidelity checklist are reported elsewhere.[12]

We also surveyed OTs about their experience and knowledge of stroke and VR prior to ESSVR training and explored relationships between OT and participant attributes and fidelity[24] to ESSVR, and to stroke survivor RTW outcomes using linear and logistic regression analyses.

Occupational therapists received monthly mentoring to support ESSVR delivery. The amount of mentoring each OT received was recorded in mentoring CRFs.

Occupational therapists' competence to deliver ESSVR was assessed immediately following initial and 6-month ESSVR training using questions based on case vignettes depicting

novel RTW after stroke scenarios and model answers supplied by VR experts. Responses were assessed using criteria based on intervention process knowledge (40%), clinical reasoning (50%) and written communication skills (10%) and mapped to a rubric identifying OTs as highly competent (≥ 70%), competent (50–69%) or needing additional support (≤ 49%). At 12 months post training, the clinical records of one randomly selected participant per OT were assessed by a VR expert OT. The competency assessment process and results are reported more fully elsewhere.[25]

To calculate the dose, duration and frequency of the ESSVR intervention, we recorded the total time spent delivering ESSVR including face-to-face contact, liaison with patients, employers, and other stakeholders by letter/phone, administration and travel (see *Appendix 4*, *Table 9* and Radford *et al.*[2]).

To describe and understand UC, we used self-reported resource use data from follow-up questionnaires, NHS therapy records and participant interviews in the embedded case studies.[21,26]

To measure contamination, we included a contamination workshop during training for the OTs involved in delivering the ESSVR intervention. We also identified contamination risks in sites, prior to site opening, OTs reported contamination risks and actual contamination during monthly meetings with mentors embedded in the trial team and sought advice on managing risk. We used CRFs to document (1) whether RETAKE OTs delivered intervention to UC participants, (2) actual contaminants/risks and documented how they were managed. Telephone site surveys with principal investigators (PIs) before, at 6 and 12 months after opening identified service developments potentially impacting on the intervention.

All process evaluation data collection was informed by the intervention logic model which identifies the core components of the ESSVR intervention (see *Appendix 1*) and underpinned by Normalisation Process Theory (NPT)[46] and the CFIF.[23]

The data collection methods and sources are described in detail in the protocols[9,10] and summarised in *Appendix 2*, *Table 8*.

Appendix 3 illustrates the research pathway showing the links between the different elements of the process evaluation.

We used descriptive content analysis to describe existing stroke services and VR provision and identify contamination risk at participating sites.

Case-study participants were described using International Classification of Functioning, Disability and Health[27] and NPT informed categories.[28]

Descriptions of UC in intervention records and interview data were analysed thematically.[29]

Observational and interview data were transcribed verbatim, coded in QSR NVivo v12 (QSR International, Warrington, UK) (QSR International Pty Ltd. Nvivo (Version 10, 2014), then imported into a Framework matrix for comparison within and across cases and sites.[30] Qualitative data were analysed independently, then jointly by two experienced qualitative researchers using an inductive approach to develop broad themes, which were then mapped to NPT constructs and ESSVR components. Iterative testing of interpretations occurred through discussion with the wider research team and patient and public involvement (PPI) members.

The COVID-19 substudy used thematic analysis,[31] drawing on Bury's (1982) theory of biographical disruption to examine and interpret the data.[32]

Synthesis of qualitative and quantitative data: At the end of the trial, we synthesised quantitative and qualitative data related to fidelity, participant experiences of RTW support and descriptions of UC. Comparing findings across related data sets and identifying areas of dis/agreement helped to explain the findings, which are reported more fully elsewhere.[21]

More detailed description of the analytic and synthesis methods for the process evaluation can be found in Trusson *et al.* and Clarke *et al.*[21,26]

Papers being synthesised

Radford KA, Wright-Hughes A, Clarke D, Phillips J, Holmes JA, Powers K, *et al.*, On behalf of the RETAKE Research group. Effectiveness of early vocational rehabilitation versus usual care to support RETurn to work After stroKE (RETAKE): a pragmatic, parallel arm multi-centre, randomised-controlled trial). *Int J Stroke* 2024. https://doi.org/10.1177/17474930241306693.[33]

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Results summary

Clinical effectiveness of Early Stroke Specialist Vocational Rehabilitation

The trial results were submitted to the *International Journal of Stroke*.[33] Between 1 June 2018 and 7 March 2022, 3672 patients were screened, and 583 participants were randomly assigned to ESSVR (n = 324) and UC (n = 259) as per the revised target sample size (see *Figures 1* and *2*). Recruitment was paused between 31 March and 1 August 2020, during the COVID-19 pandemic. Most participants were recruited pre-COVID (76.3%) and 28.5% were recruited at least 12 months pre-COVID, while 12.3% were recruited during and 11.3% after the UK Coronavirus Job Retention (furlough) scheme applied.

Baseline characteristics (*Table 1*) were well balanced across trial arms. Participants were mostly male (400, 69.0%), White (453, 83.7%), well educated (405, 71.3% to higher or further education) with a mean age 54 years (SD 11.1) and working in a mix of blue- and white-collar work (276, 50.9% vs. 266, 49.1% respectively). Participants were mostly ischaemic stroke survivors (452, 82.8%), recruited a median 28 days post stroke [interquartile range (IQR) 13–44] having spent a median 4 days in hospital (IQR 2–10). Half had no impairments in mobility, cognitive or expressive language, indicative of a mostly mild–moderate severity, and half had no comorbidities known to affect work including cardiac complications, mental health problems, seizures, musculoskeletal conditions and diabetes.

The intervention commenced in 309/324 (95.4%) participants allocated to the intervention arm, 244 (75.3%) complied with the intervention (18 withdrew – 3 before commencing the intervention, 24 dropped out, 4 discontinued for other reasons, 22 were missing data), and participants attended a median 7 (IQR 4–12) sessions. The median time to commence the intervention was 9 (IQR 6–13) days post randomisation and 38 (IQR 23–56) days post stroke. Of those commencing the intervention, 246 (82.3%) participants had at least one session at home, 67 (22.4%) at work, 31 (10.4%) in the community, 243 (81.3%) via telephone/videocall and 52 (17.4%) in the hospital; 119 (40.3%) consented to the therapist contacting their employer, employer contact was made for 109 (36.8%) and 74 (25.0%) had an in-person or online visit with their employer.

All follow-up ceased on 20 June 2023, with 454 (77.9%) participants (257/324, 79.3% in ESSVR, 197/259, 76.1% in UC) completing 12-month primary outcome data (68.5% via full questionnaire, 11.9% via SMS, 19.6% via retrospective questionnaire). Greater loss to follow-up occurred for secondary outcomes; 182/324 (56.2%) participants in ESSVR and 134/259 (51.7%) in UC returned full 12-month questionnaires, and carer burden was available for only 37/71 (52.1%) participants in ESSVR and 17/66 (25.8%) in UC. Participants lost-to-follow-up (at any time point) had less favourable baseline characteristics on impairments, length of hospital stay, stroke type, confidence, anxiety, depression, functional ability, and were more likely to have been recruited pre-COVID in hospital, female, older, non-White ethnicity, in blue-collar roles, not in paid employment, not in a relationship, living alone and without a recruited carer. Where primary outcome data were available, participants missing secondary outcomes were also less likely to have returned to work. Results also indicated differential missing data patterns by arm on impairments, community integration, length of hospital stay, recruitment pre-COVID, age, gender, marital status and work status.[33]

Eligibility violations occurred in four (< 1%) participants (two per arm). Contamination was recorded for four (1.5%) UC participants who were seen at least once in UC by a RETAKE OT in error. Researchers were unblinded for 18/324 (5.6%) participants in ESSVR and 10/259 (3.9%) in UC. Withdrawals from questionnaires, receipt of SMS texts, process evaluation and access to records/routine data occurred in 18/324 (5.6%) participants in ESSVR and 17/259 (6.6%) in UC. Five (< 1%) participants died within the 12-month follow-up period (one in ESSVR and four in UC).

On the primary outcome at 12 months, 282/454 (62.1%) participants reported to have returned to work, 165/257 (64.2%) in ESSVR and 117/197 (59.4%) in UC, with equal proportions of participants on a graded RTW. The adjusted OR (1.12, 95% CI 0.75 to 1.68, p = 0.5678) of

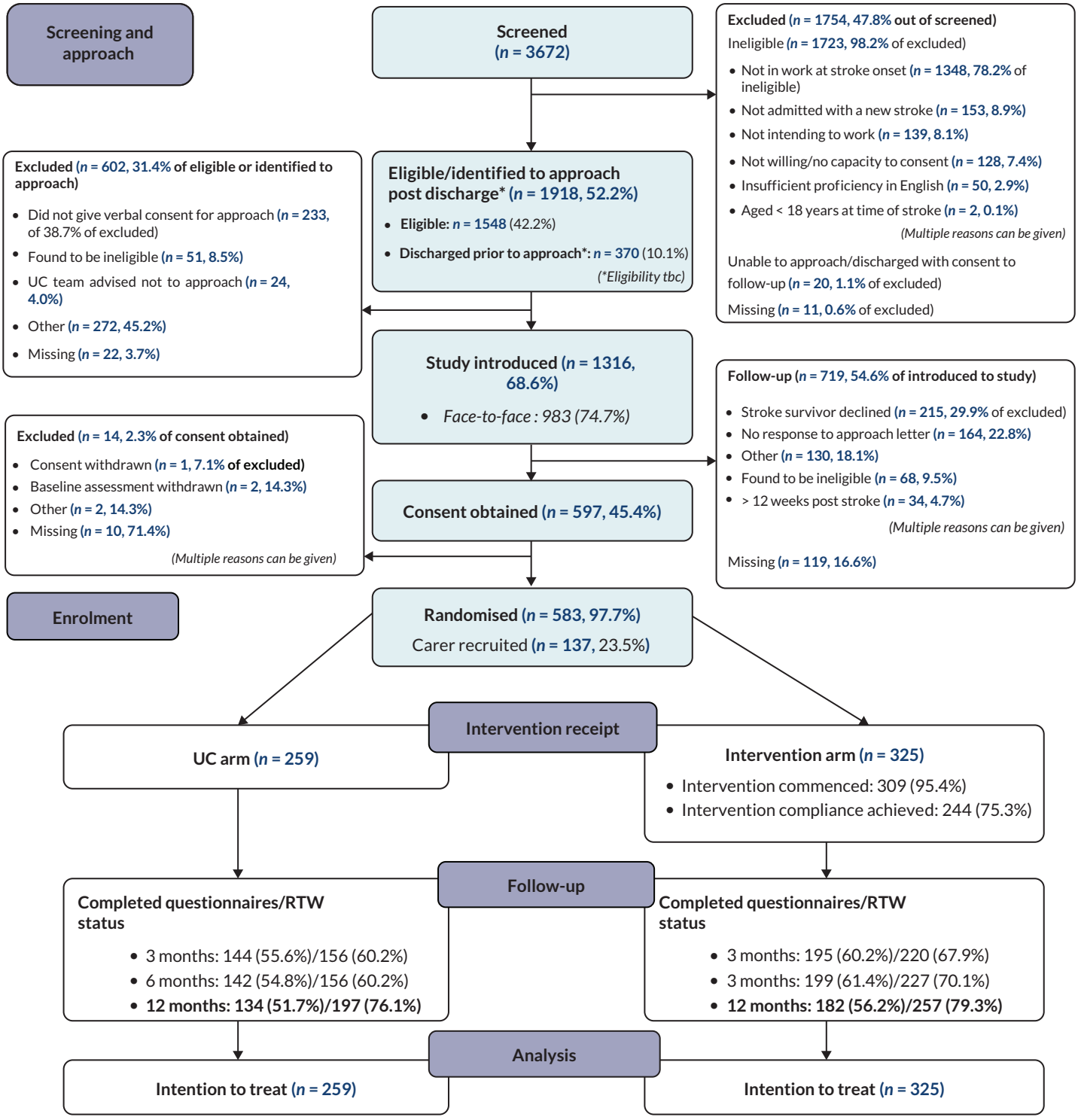

FIGURE 1 Consolidated Standards of Reporting Trials flow diagram. Reproduced with permission from Radford *et al.*[33] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) licence, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: https://creativecommons.org/licenses/by/4.0/. The text below includes minor additions and formatting changes to the original text.

RTW in ESSVR versus UC provided no evidence that ESSVR plus UC was superior to UC (*Table 2*). Younger participants (OR 0.97 per additional year, 95% CI 0.96 to 0.99, $p = 0.0120$), those with better mobility (OR 1.43, 95% CI 1.20 to 1.72, $p < 0.0001$) and cognition (OR 1.09, 95% CI 1.02 to 1.16, $p = 0.0081$) were more likely to RTW. Adjusted OR of RTW in ESSVR versus UC were similar at 3 (OR 1.02, 95% CI 0.65, 1.60, $p = 0.9283$) and 6 (OR 1.00, 95% CI 0.65 to 1.52, $p = 0.9884$) months. Sensitivity analysis of complete data at 12 months (OR 1.22, 95%

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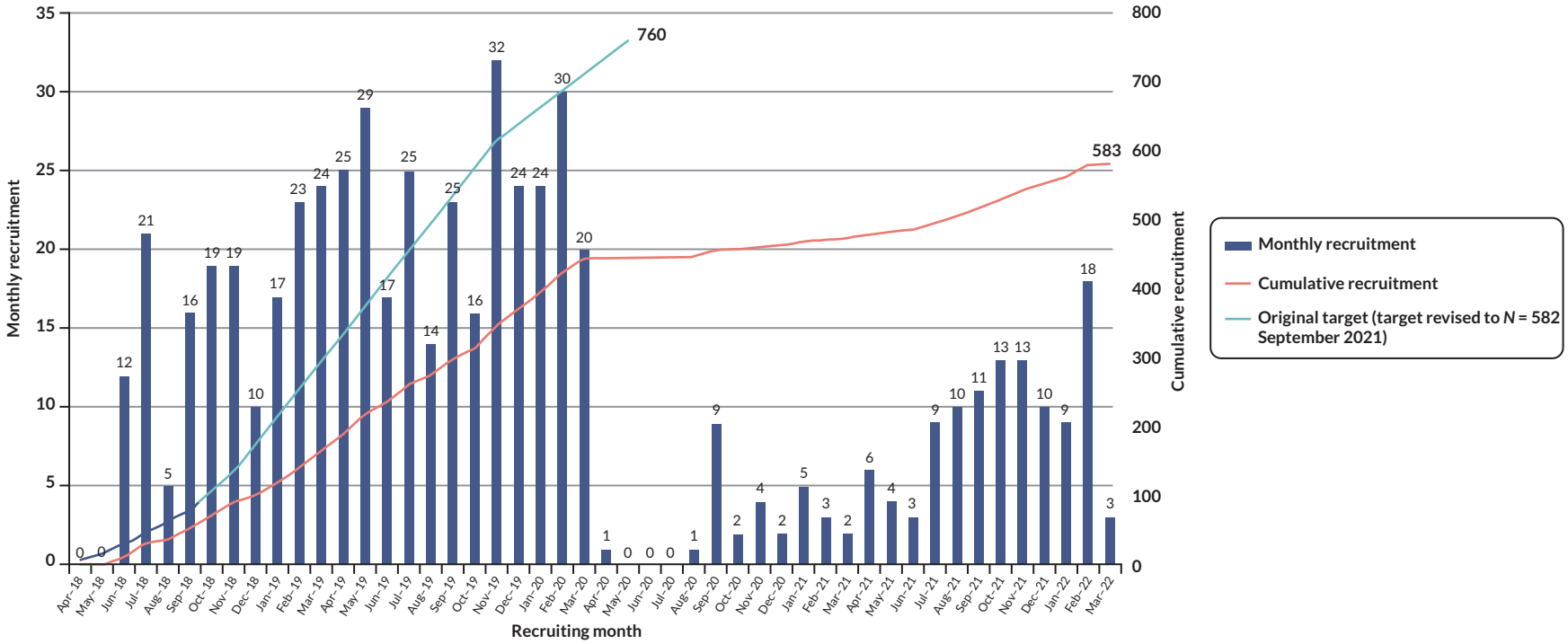

FIGURE 2 Monthly recruitment rate. SSNAP, Sentinel Stroke National Audit Programme.

DOI: 10.3310/LAKP6585

TABLE 1 Baseline characteristics

	ESSVR (plus UC) (*n* = 324)	UC (*n* = 259)	Total (*n* = 583)
Recruitment period, n (%)			
Pre-COVID < *31 March 2020*	248 (76.5%)	197 (76.1%)	445 (76.3%)
During furlough scheme < *30 September 2021*	38 (11.7%)	34 (13.1%)	72 (12.3%)
Post furlough > *30 September 2021*	38 (11.7%)	28 (10.8%)	66 (11.3%)
Location of assessment, n (%)			
Hospital	152 (47.6%)	121 (47.8%)	273 (47.7%)
Home	165 (51.7%)	130 (51.4%)	295 (51.6%)
Age, mean (SD)	53.7 (10.48)	54.3 (11.88)	54.0 (11.12)
Ethnicity, n (%)			
White	254 (84.1%)	199 (83.3%)	453 (83.7%)
Black	19 (6.3%)	23 (9.6%)	42 (7.8%)
Asian	13 (4.3%)	12 (5.0%)	25 (4.6%)
Mixed	2 (0.7%)	2 (0.8%)	4 (0.7%)
Other ethnic group	14 (4.6%)	3 (1.3%)	17 (3.1%)
Living with another person, n (%)	244 (75.5%)	203 (79.0%)	447 (77.1%)
Married, living with or in a long-term relationship, n (%)	212 (65.8%)	183 (71.2%)	395 (68.2%)
Carer recruited, n (%)	71 (21.9%)	66 (25.5%)	137 (23.5%)
Highest education, n (%)			
Higher education qualification	129 (40.8%)	108 (42.9%)	237 (41.7%)
Further education qualification	93 (29.4%)	75 (29.8%)	168 (29.6%)
Job collar type, n (%)			
Blue collar	156 (51.5%)	120 (50.2%)	276 (50.9%)
White collar	147 (48.5%)	119 (49.8%)	266 (49.1%)
In paid employment/self-employed pre-stroke, n (%)	301 (94.7%)	234 (94.4%)	535 (94.5%)
Pre-stroke working hours in paid/self-employment, mean (SD)	38.3 (12.88)	37.7 (12.65)	38.1 (12.78)
Type of stroke, n (%)			
Subarachnoid haemorrhage	8 (2.6%)	1 (0.4%)	9 (1.6%)
Intracerebral haemorrhage	48 (15.5%)	37 (15.6%)	85 (15.6%)
Ischaemic stroke	253 (81.9%)	199 (84.0%)	452 (82.8%)
Length of hospital stay (days), median (IQR)	4.0 (2.0–10.0)	4.0 (2.0–10.0)	4.0 (2.0–10.0)
Time from stroke to randomisation (days), median (IQR)	28.0 (112.0–46.0)	29.0 (13.0–42.0)	28.0 (13.0–44.0)
Comorbidities, n (%)			
Cardiac complications	65 (20.1%)	64 (24.9%)	129 (22.2%)

continued

TABLE 1 Baseline characteristics (*continued*)

	ESSVR (plus UC) (*n* = 324)	UC (*n* = 259)	Total (*n* = 583)
Mental health problems	29 (9.0%)	26 (10.1%)	55 (9.5%)
Seizures	6 (1.9%)	6 (2.3%)	12 (2.1%)
Musculoskeletal conditions	54 (16.7%)	39 (15.2%)	93 (16.0%)
Diabetes	59 (18.3%)	40 (15.6%)	99 (17.1%)
None	165 (51.1%)	130 (50.6%)	295 (50.9%)
Post-stroke impairments, n (%)			
None	161 (49.7%)	134 (51.7%)	295 (50.6%)
One	131 (40.4%)	95 (36.7%)	226 (38.8%)
Multiple	32 (9.9%)	30 (11.6%)	62 (10.6%)
Post-stroke impairment, n (%)			
Mobility (EQ-5D mobility score[a])	119 (36.7%)	91 (35.1%)	210 (36.0%)
Aphasia (OCS picture naming score[b])	53 (16.4%)	48 (18.5%)	101 (17.3%)
Cognitive (OCS mixed score[c])	32 (9.9%)	21 (8.1%)	53 (9.1%)
None	161 (49.7%)	134 (51.7%)	295 (0.6%)

a Mobility impairment defined as moderate or severe problems in walking about or unable to walk about on the EQ-5D-5L mobility item.
b Aphasia impairment defined as a score of 3 out of 4 or less on the OCS picture naming task (based on scores ≤ 5th centile of normative data in the OCS user manual indicating impairment on expressive language).
c Cognitive impairment defined as a score of 4 out of 13 or less on the OCS executive mixed task (based on scores ≤ 5th centile of normative data in the OCS user manual indicating impairment on task switching/attention).

Source
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CI 0.79 to 1.90, $p = 0.3698$) did not change the overall trial conclusion. While results were relatively consistent with the primary multiply imputed analysis, the complete case analysis showed a larger estimated treatment effect, further supporting the validity of our primary analysis using multiple imputation to appropriately account for the observed pattern of informative missing data.

On secondary RTW outcomes in participants who had returned to work at 12 months (see *Table 2*), 41/103 (39.8%) ESSVR versus 24/75 (32.0%) UC participants reported a change in working hours, of whom the mean weekly hours were reduced in ESSVR (28.4, SD 11.65) compared to UC (31.5, SD 11.71). A similar pattern was observed at 3 and 6 months but with a decreasing proportion of participants with changes in working hours and increased working hours over time. At 12 months, more ESSVR participants (22/98, 22.4%) reported having taken time off due to their stroke over the past 3 months compared to UC (14/72, 19.4%), and 13/103 (12.6%) ESSVR versus 9/76 (11.8%) UC participants reported a change in role.

Secondary outcomes not pertaining to work status (*Table 3*) were largely similar, with small differences between trial arms and provided no evidence that ESSVR was superior to UC. However, participants tended to have slightly improved outcomes in UC compared to ESSVR, and UC participants reported statistically significantly better functional ability [NEADL: MD −3.37 (95% CI −6.26 to −0.48), $p = 0.0230$] and carer burden [MSCI: MD 2.52 (95% CI 0.63 to 4.41), $p = 0.0095$] at 12 months in multiply imputed analyses. Statistically significant effects were not observed at other time points, or in complete case sensitivity analysis in which estimates fluctuated considerably according to the method of handling missing data, and should be interpreted with caution given substantial loss to follow-up.[33]

There were no related and unexpected severe adverse events. Self-reported safety outcomes were similar for both groups. At 12 months, 40/241 (16.6%) participants had attended A&E, 24/244 (9.1%) had been admitted to hospital and 6/266 (2.3%) had experienced work accidents over the previous 3 months.

TABLE 2 Primary and secondary RTW outcomes

	3 months			6 months			12 months		
	ESSVR (*n* = 324)	**UC (*n* = 259)**	**Total (*n* = 583)**	**ESSVR (*n* = 324)**	**UC (*n* = 259)**	**Total (*n* = 583)**	**ESSVR (*n* = 324)**	**UC (*n* = 259)**	**Total (*n* = 583)**
Primary outcome available	220 (67.9%)	156 (60.2%)	376 (64.5%)	227 (70.1%)	156 (60.2%)	383 (65.7%)	257 (79.3%)	197 (76.1%)	454 (77.9%)
Primary outcome: RTW, n (%)									
Yes	133 (60.5%)	95 (60.9%)	228 (60.6%)	152 (67.0%)	108 (69.2%)	260 (67.9%)	165 (64.2%)	117 (59.4%)	282 (62.1%)
No	87 (39.5%)	61 (39.1%)	148 (39.4%)	75 (33.0%)	48 (30.8%)	123 (32.1%)	92 (35.8%)	80 (40.6%)	172 (37.9%)
Missing	104	103	207	97	103	200	67	62	129
OR (95% CI), *p*-value	**1.02 (0.65 to 1.60), *p* = 0.9283**			**1.00 (0.65 to 1.52), *p* = 0.9884**			**1.12 (0.75 to 1.68), *p* = 0.5678**		
Retuned as part of									
Graded RTW							35 (33.7%)	26 (34.7%)	
Supported work							2 (1.9%)	0 (0.0%)	
None							28 (26.9%)	31 (41.3%)	
Other							39 (37.5%)	18 (24.0%)	
Missing							61	42	
Secondary outcomes:	**In those reporting *RTW* at follow-up**								
Stroke impacted participants' work status[a]	103/113 (91.2%)	73/85 (85.9%)	176/198 (88.9%)	78/127 (61.4%)	54/89 (60.7%)	132/216 (61.1%)	51/105 (48.6%)	34/77 (44.2%)	85/182 (46.7%)
Hours									
Change in working hours, *n*/*N* (%)	66/108 (61.1%)	39/80 (48.8%)	105/188 (55.9%)	59/124 (47.6%)	33/87 (37.9%)	92/211 (43.6%)	41/103 (39.8%)	24/75 (32.0%)	65/178 (36.5%)
If yes, current working hours, mean (SD)	18.3 (12.24), *n* = 51	20.3 (12.15), *n* = 35	19.1 (12.17), *n* = 86	19.9 (11.11), *n* = 31	24.2 (8.90), *n* = 18	21.5 (10.47), *n* = 49	28.4 (11.65), *n* = 33	31.5 (11.71), *n* = 15	29.4 (11.64), *n* = 48
Pre-stroke working hours, mean (SD)	41.2 (12.04), *n* = 118	37.3 (12.89), *n* = 78	39.7 (12.50), *n* = 196	38.7 (12.45), *n* = 135	38.5 (12.89), *n* = 94	38.6 (12.61), *n* = 229	39.0 (11.77), *n* = 145	39.3 (10.78), *n* = 103	39.1 (11.35), *n* = 248

continued

This synopsis should be referenced as follows: Radford K, Wright-Hughes A, Clarke D, Phillips J, Holmes J, Powers K, *et al.* Early stroke specialist vocational rehabilitation for return to work after stroke: a synopsis from the RETAKE RCT. *Health Technol Assess* 2026;**30**(31);1–64. https://doi.org/10.3310/LAKP6585

DOI: 10.3310/LAKP6585

TABLE 2 Primary and secondary RTW outcomes (*continued*)

	3 months			6 months			12 months		
	ESSVR (*n* = 324)	UC (*n* = 259)	Total (*n* = 583)	ESSVR (*n* = 324)	UC (*n* = 259)	Total (*n* = 583)	ESSVR (*n* = 324)	UC (*n* = 259)	Total (*n* = 583)
Days worked									
Have had to take time off, *n*/*N* (%)	91/111 (82.0%)	61/83 (73.5%)	152/194 (78.4%)	42/124 (34.4%)	31/85 (36.5%)	73/207 (35.3%)	22/98 (22.4%)	14/72 (19.4%)	36/170 (21.2%)
If yes, weeks taken off, mean (SD)	10.2 (4.30), *n* = 78	10.3 (5.97), *n* = 54	10.2 (5.02), *n* = 132	6.7 (5.91), *n* = 32	5.9 (5.04), *n* = 23	6.3 (5.52), *n* = 55	13.5 (15.78), *n* = 15	7.8 (8.26), *n* = 11	11.1 (13.22), *n* = 26
Role									
Changed role, *n*/*N* (%)	12/102 (11.8%)	9/75 (12.0%)	21/177 (11.9%)	12/122 (9.8%)	15/87 (17.2%)	27/209 (12.9%)	13/103 (12.6%)	9/76 (11.8%)	22/179 (12.3%)

a Over the past 3 months.

Source

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TABLE 3 Secondary outcomes[a]

	Baseline			3 months			6 months			12 months		
	ESSVR (*n* = 324)	**UC (*n* = 259)**	**Total (*n* = 583)**	**ESSVR (*n* = 324)**	**UC (*n* = 259)**	**Effect (95% CI), *p*-value**	**ESSVR (*n* = 324)**	**UC (*n* = 259)**	**Effect (95% CI), *p*-value**	**ESSVR (*n* = 324)**	**UC (*n* = 259)**	**Effect (95% CI), *p*-value**
Questionnaire returned				195 (60.2%)	144 (55.6%)	339 (58.1%)	199 (61.4%)	142 (54.8%)	341 (58.5%)	182 (56.2%)	134 (51.7%)	316 (54.2%)
Mood:* HADS – *anxiety, mean (SD)	6.6 (4.38), *n* = 314	7.0 (4.65), *n* = 247	6.8 (4.50), *n* = 561	7.5 (4.86), *n* = 179	7.4 (4.45), *n* = 127	**0.43 (−0.48 to 1.34), *p* = 0.3518**	6.5 (4.74), *n* = 180	6.7 (4.44), *n* = 127	**0.60 (−0.32 to 1.53), *p* = 0.2000**	6.8 (5.01), *n* = 155	7.2 (4.56), *n* = 104	**0.24 (−0.71 to 1.20), *p* = 0.6174**
Normal (0–7), *n* (%)	187 (59.6%)	134 (54.3%)	321 (57.2%)	96 (53.6%)	64 (50.4%)	160 (52.3%)	109 (60.6%)	76 (59.8%)	185 (60.3%)	92 (59.4%)	62 (59.6%)	154 (59.5%)
Mild (8–10), *n* (%)	67 (21.3%)	56 (22.7%)	123 (21.9%)	36 (20.1%)	32 (25.2%)	68 (22.2%)	33 (18.3%)	23 (18.1%)	56 (18.2%)	25 (16.1%)	15 (14.4%)	40 (15.4%)
Moderate (11–14), *n* (%)	45 (14.3%)	39 (15.8%)	84 (15.0%)	31 (17.3%)	24 (18.9%)	55 (18.0%)	25 (13.9%)	21 (16.5%)	46 (15.0%)	24 (15.5%)	21 (20.2%)	45 (17.4%)
Severe (15–21), *n* (%)	15 (4.8%)	18 (7.3%)	33 (5.9%)	16 (8.9%)	7 (5.5%)	23 (7.5%)	13 (7.2%)	7 (5.5%)	20 (6.5%)	14 (9.0%)	6 (5.8%)	20 (7.7%)
Mood:* HADS – *depression, mean (SD)	6.1 (3.94), *n* = 311	6.2 (4.18), *n* = 247	6.1 (4.04), *n* = 558	6.3 (4.38), *n* = 179	5.9 (3.98), *n* = 127	**0.40 (−0.49 to 1.29), *p* = 0.3772**	5.9 (4.28), *n* = 180	5.6 (4.14), *n* = 128	**0.56 (−0.36 to 1.48), *p* = 0.2305**	5.7 (4.59), *n* = 158	5.4 (4.13), *n* = 105	**0.58 (−0.40 to 1.56), *p* = 0.2416**
Normal (0–7), *n* (%)	201 (64.6%)	156 (63.2%)	357 (64.0%)	108 (60.3%)	86 (67.7%)	194 (63.4%)	119 (66.1%)	90 (70.3%)	209 (67.9%)	114 (72.2%)	78 (74.3%)	192 (73.0%)
Mild (8–10), *n* (%)	68 (21.9%)	50 (20.2%)	118 (21.1%)	40 (22.3%)	21 (16.5%)	61 (19.9%)	35 (19.4%)	18 (14.1%)	53 (17.2%)	19 (12.0%)	15 (14.3%)	34 (12.9%)
Moderate (11–14), *n* (%)	32 (10.3%)	31 (12.6%)	63 (11.3%)	20 (11.2%)	18 (14.2%)	38 (12.4%)	17 (9.4%)	17 (13.3%)	34 (11.0%)	16 (10.1%)	9 (8.6%)	25 (9.5%)
Severe (15–21), *n* (%)	10 (3.2%)	10 (4.0%)	20 (3.6%)	11 (6.1%)	2 (1.6%)	13 (4.2%)	9 (5.0%)	3 (2.3%)	12 (3.9%)	9 (5.7%)	3 (2.9%)	12 (4.6%)
Functional ability: NEADL, mean (SD)	61.4 (12.21), *n* = 315	62.5 (11.04), *n* = 252	61.9 (11.71), *n* = 567				54.9 (13.08), *n* = 179	56.3 (11.92), *n* = 129	**−1.05 (−3.96 to 1.86), *p* = 0.4755**	54.3 (13.20), *n* = 157	57.9 (10.75), *n* = 109	**−3.37 (−6.26 to −0.48), *p* = 0.0230**
Participation: CIQ-R Social Integration, mean (SD)	7.1 (1.89), *n* = 315	7.1 (1.92), *n* = 250	7.1 (1.90), *n* = 565							6.0 (2.24), *n* = 153	6.5 (2.16), *n* = 109	**−0.36 (−0.86 to 0.13), *p* = 0.1493**

continued

This synopsis should be referenced as follows: Radford K, Wright-Hughes A, Clarke D, Phillips J, Holmes J, Powers K, *et al.* Early stroke specialist vocational rehabilitation for return to work after stroke: a synopsis from the RETAKE RCT. *Health Technol Assess* 2026;**30**(31):1–64. https://doi.org/10.3310/LAKP6585

DOI: 10.3310/LAKP6585

TABLE 3 Secondary outcomes[a] (*continued*)

	Baseline			3 months			6 months			12 months		
	ESSVR (*n* = 324)	**UC (*n* = 259)**	**Total (*n* = 583)**	**ESSVR (*n* = 324)**	**UC (*n* = 259)**	**Effect (95% CI), *p*-value**	**ESSVR (*n* = 324)**	**UC (*n* = 259)**	**Effect (95% CI), *p*-value**	**ESSVR (*n* = 324)**	**UC (*n* = 259)**	**Effect (95% CI), *p*-value**
Participation: CIQ-R productivity, mean (SD)	5.6 (1.18), *n* = 285	5.6 (1.22), *n* = 234	5.6 (1.20), *n* = 519							4.3 (2.04), *n* = 149	4.6 (2.03), *n* = 106	**−0.40 (−0.82 to 0.01), *p* = 0.0571**
Self-efficacy: WAI, mean (SD)	3.7 (3.00), *n* = 311	3.6 (3.07), *n* = 246	3.6 (3.03), *n* = 557	5.0 (3.14), *n* = 182	5.4 (3.13), *n* = 127	**−0.44 (−1.06 to 0.17), *p* = 0.1551**	6.0 (2.71), *n* = 180	6.2 (3.07), *n* = 129	**−0.27 (−0.84 to 0.30), *p* = 0.3537**	6.2 (3.08), *n* = 154	6.6 (2.82), *n* = 111	**−0.45 (−1.18 to 0.28), *p* = 0.2226**
Post-stroke confidence: CASM, mean (SD)	51.0 (13.09), *n* = 312	50.9 (12.83), *n* = 236	50.9 (12.97), *n* = 548							51.2 (15.42), *n* = 149	52.0 (13.89), *n* = 104	**−0.79 (−3.64, 2.06), *p* = 0.5837**
Carer burden: MSCI,[b] mean (SD)	9.0 (6.08), *n* = 67	8.5 (6.23), *n* = 61	8.7 (6.13), *n* = 128	8.3 (6.47), *n* = 37	7.7 (6.01), *n* = 24	**−0.27 (−2.08 to 1.54), *p* = 0.7681**	7.5 (6.68), *n* = 38	6.2 (5.37), *n* = 18	**0.87 (−1.59 to 3.32), *p* = 0.4858**	8.1 (6.08), *n* = 37	3.9 (4.31), *n* = 17	**2.52 (0.63 to 4.41), *p* = 0.0095**

a Effects (95% CI) represent the mean difference between treatment groups, ESSVR–UC, estimated using linear regression adjusted for covariates, baseline value, therapist random effect, using multiply imputed data to account for missing data. HADS-A and HADS-D scores range from 0 to 21, where a higher score indicates more severe anxiety and depression respectively. NEADL scores range from 0 to 66, where higher scores indicate greater independence. CIQ-R Social Integration score ranges from 0 to 10, and productivity score 0–7, with higher scores indicating a greater degree of community integration. WAI scores range from 0 to 10, where higher values indicate better work ability. CASM Score ranges from 0 to 81, with higher scores indicating a higher level of confidence. MCSI scores range from 0 to 26, where higher scores indicate a higher level of strain on carers.

b MCSI is a carer rather than participant measure, *n* = 71 and *n* = 66 carers were recruited in the ESSVR and UC arms, respectively. Missing data were imputed for recruited carers where applicable using a reduced imputation model based on covariates, outcome and baseline values only.

Source

Exploratory analysis

In pre-specified subgroup analyses, there was good evidence of a differential treatment effect on the primary outcome according to participants' age (interaction $p = 0.0239$). Older participants were more likely to benefit from ESSVR compared to younger participants; older participants were less likely to RTW in UC but not ESSVR (*Figure 3*). There was also some evidence according to level of post-stroke impairment (interaction $p = 0.0239$) such that participants with more post-stroke impairment were more likely to benefit from the intervention.

On the primary 12-month outcome, 135/201 (67.2%) intervention compliers versus 30/56 (53.6%) intervention non-compliers reported to have returned to work; however, there was no change in conclusions in both CACE and analysis excluding non-compliers, thereby confirming the primary intention-to-treat analysis.

Health economic evaluation

Results of the economic are presented in full elsewhere.[20]

The proportion of missing data, by trial period, is reported in *Table 4*.[20] It can be seen that, as is common, missingness increases over time such that by 12 months only 57/324 (18%) ESSVR participants and 28/259 (11%) UC participants had complete resource use data. In the ESSVR group, 103/324 (32%) and 64/259 (25%) had complete utility data, enabling 12-month QALY scores to be estimated. In terms of outcomes, at all time points (3, 6 and 12 months) except baseline, more than 40% of data are missing as measured by complete EQ-5D-5L scores/utility scores. Consequently, complete case analysis for total QALYs gave a high proportion of missing data (71%). Missing data were imputed, with further details of the model used available in Pyne *et al.*[20]

At baseline, resource use from all perspectives was similar between the treatment groups. From a primary care perspective over the 12-month follow-up period, although those in ESSVR had more OT, physiotherapist, general practitioner (GP), district nurse and healthcare assistant appointments, they had slightly less counsellor, speech and language therapy (SLT), social worker and rehabilitation assistant appointments. The number of secondary care outpatient visits was similar between groups, but inpatient stays were slightly more frequent in UC.

Unit costs (in UK£ 2021–2) used to value resource use, together with their sources[34–40] and assumptions are presented in *Table 5*.[20] Given the level of missing data, multiple imputation adjusting for age, sex, utility or cost at baseline and site showed that the intervention was more expensive [incremental cost £1337 (95% CI −1113 to 3787)]. This contrasts with the complete case analysis based on small numbers ($n = 57$ ESSVR group, $n = 28$ UC group) which found ESSVR cheaper −£223 (95% CI −£3508 to £3062). Logistic regression for missingness for costs found treatment allocation was a statistically significant predictor of missing data, meaning that data were more likely to be missing for those in the UC arm, explaining why the costs in the imputed analysis change direction and magnitude.

Table 6 presents the unadjusted and adjusted mean (SD) and mean (95% CI) difference in outcomes and costs over 12 months. Utility score at baseline was similar between groups (0.589 ESSVR vs. 0.590 UC) and improved slightly in both groups, based on available case data, over the 12 months. The incremental QALYs, based on these utility scores, and using multiple imputation with adjustment (age, sex, baseline utility and site) was 0.021 (95% CI −0.011 to 0.052) compared to 0.014 (95% −0.050 to 0.078) using complete data only. The incremental cost using multiple imputation with adjustment (age, sex, baseline costs and site) was £1282 (95% CI −£933 to £3497). It should be noted though that due to the increasing proportion of missing data at each time point, the complete case results are based on < 1/3 of patients randomised (32% in the ESSVR group and 25% in the UC group).

It can be seen that health economic outcomes were in line with the primary clinical outcome, where the analysis using multiple imputation and adjusting for age, sex, utility or cost at baseline and site showed that the intervention was unlikely to be cost-effective, that is not good value for the costs involved, compared with other demands on healthcare resources.

Process evaluation

Participating sites were purposively selected for VR naivety to avoid contamination. Twenty of the 78 who initially expressed interest in participating in RETAKE were selected. However, four did not open to recruitment because there were too few OTs (ETCs; two sites), problems securing excess treatment costs (one site) and two that were due to open when the pandemic hit, did not open after the initial UK lockdown and recruitment pause. The 16 sites, which included 21 NHS, acute and community trusts, were from all 7 regions of England and 1 in Wales. Site surveys at baseline indicated none had a structured early VR pathway.

Sixty OTs were trained and 48 delivered the ESSVR intervention between February 2018 and April 2022, supported by 6 mentors experienced in stroke and VR.

DOI: 10.3310/LAKP6585

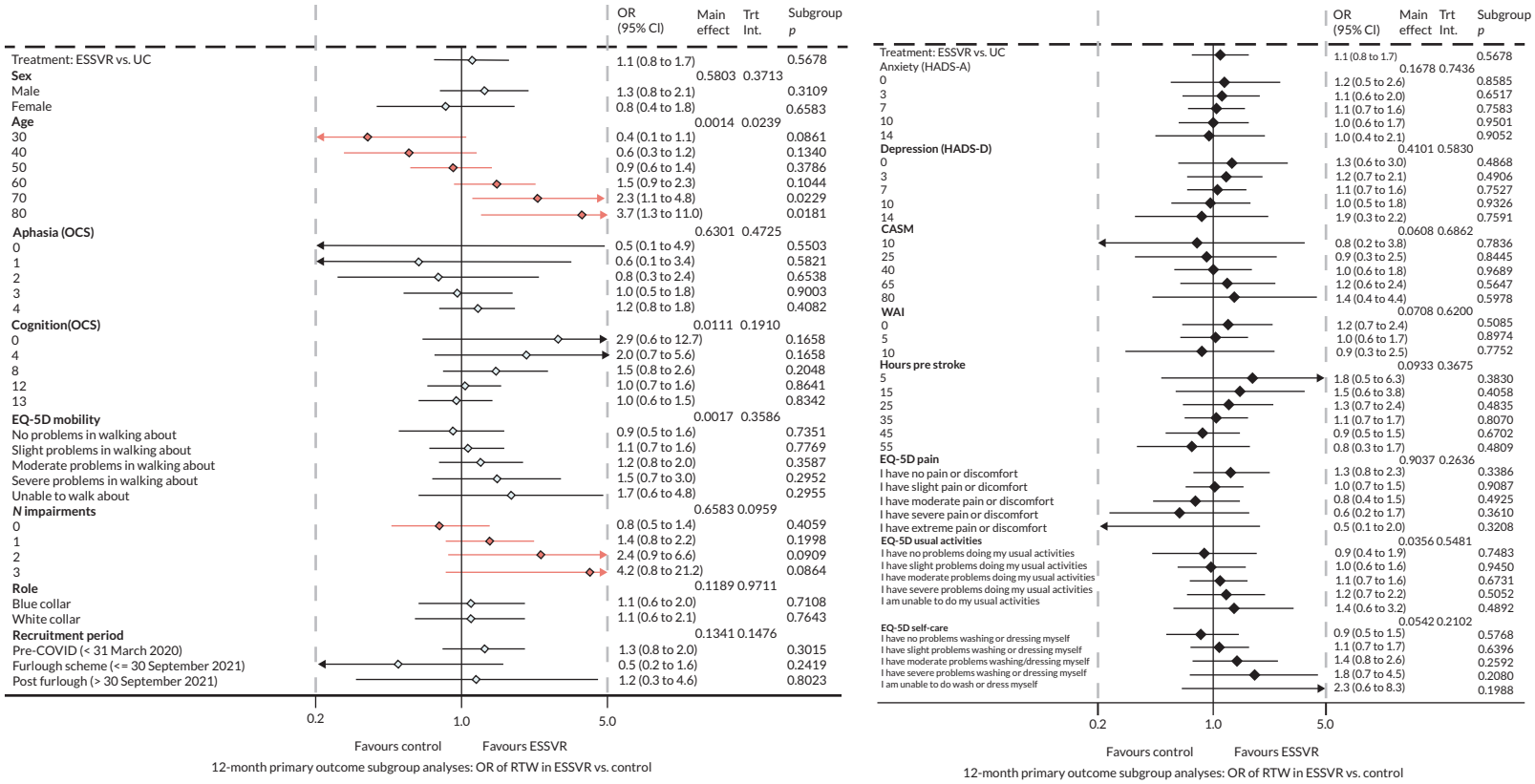

FIGURE 3 Forest plot depicting exploratory subgroup analyses. Reproduced with permission from Radford *et al.*[33] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) licence, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: https://creativecommons.org/licenses/by/4.0/. The figure includes minor additions and formatting changes to the original text.

TABLE 4 Proportion of missing values (survivor data)

Variable	ESSVR + UC (*N* = 324)	UC only (*N* = 259)	Total (*N* = 583)
Baseline variables			
Treatment allocation	0	0	0
Age	0	0	0
Sex	1/324 (0.3%)	2/259 (0.8%)	3/583 (0.5%)
Utility score at baseline	9/324 (2.8%)	14/324 (4.3%)	23/583 (3.9%)
Resource use at baseline[a]	108/324 (33%)	74/259 (29%)	182/583 (31%)
Cost variables			
Resource use at 3 months[a]	189/324 (58%)	167/259 (64%)	356/538 (61%)
Resource use at 6 months[a]	213/324 (66%)	190/259 (73%)	403/583 (69%)
Resource use at 12 months[a]	242/324 (75%)	210/259 (81%)	452/583 (78%)
Outcome variables for health-related quality of life			
Utility score at 3 months	133/324 (41.0%)	116/259 (44.7%)	249/583 (42.7%)
Utility score at 6 months	135/324 (41.7%)	126/259 (48.7%)	261/583 (44.8%)
Utility score at 12 months	157/324 (48.5%)	137/259 (52.9%)	294/583 (50.4%)
Outcomes for cost–utility analysis			
Total costs	267/324 (82%)	231/259 (89%)	498/583 (85%)
Total QALYs	221/324 (68.2%)	195/259 (75.3%)	416/583 (71.4%)

a Includes NHS/PSS resource use: community-based Healthcare Practitioner (HCP) appointments, outpatient appointments, inpatient stays, A&E attendance, prescription medication use and stroke-related equipment.

Source

TABLE 5 Unit costs table (Great British pounds, 2021–2)

Cost item	Unit cost (£)	Assumptions
Intervention		
ESSVR training: workshop facilitator (per hour)	75[34]	Principal occupational therapist (more experienced)
ESSVR training: workshop attendance (per hour)	47[34]	Community occupational therapist (local authority)
ESSVR training: competency assessment (per hour)	47[34]	Community occupational therapist (local authority)
ESSVR mentoring: facilitator (per hour)	75[34]	Principal occupational therapist (more experienced)
ESSVR mentoring: attendance (per hour)	47[34]	Community occupational therapist (local authority)
ESSVR face-to-face contact (per hour)	47[34]	Community occupational therapist (local authority)
Primary care appointments (per visit)		
OT	99[35]	Adult one-to-one session
GP	35[34]	Surgery consultation lasting 9.22 minutes. Inc direct staff costs. Exc qualifications

continued

TABLE 5 Unit costs table (Great British pounds, 2021–2) (*continued*)

Cost item	Unit cost (£)	Assumptions
Practice nurse	15[34,41]	Surgery consultation lasting 15.5 minutes. Inc direct staff costs. Exc qualifications
District nurse	54[35]	Adult, face-to-face session
Case manager	77[35]	Other therapist, adult, one-to-one
Counsellor	77[35]	Other therapist, adult, one-to-one
SLT	128[35]	Adult, one-to-one
Physiotherapist	73[35]	Adult, one-to-one
Social worker	112[34,41]	40-minute appointment. Inc direct staff costs. Exc qualifications
Rehabilitation assistant	131[35]	Stroke community rehabilitation team
Healthcare assistant	14[34,36,42]	Face-to-face day-time week price. 30- minute visit based on majority
Walk-in centre	82[35]	NHS walk-in centres: weighted average of all entries.
Other	35[34]	Based on a GP (common) visit (as above)
Secondary care: outpatient appointments (per visit)		
Consultant	185[35]	Average of all consultant-led
Psychiatrist	231[35]	Liaison psychiatry service
Physiotherapist	100[35]	Physiotherapy service
SLT	188[35]	SLT service
Nurse	76[35]	Other specialist nursing, adult, face-to-face
Stroke team	302[35]	Stroke medicine service
OT	99[35]	Occupational therapist, adult, one-to-one
Radiologist	117[35]	
Ophthalmologist	142[35]	
Cardiac and pulmonary tests	41[35]	
Blood tests	7[35]	
Other	165[35]	
Secondary care: inpatient stays		
Neurology ward	533[35]	
Other ward	1038[35]	
A&E	242[35]	
Prescription medications		
Various (average cost)	4[43]	Assume one prescription per month, applied 'cost per item'. If ambiguous, used most prescribed closest match.
Social services resources		
Stroke- related equipment	Not applicable	
Wider resources: out-of-pocket		
Employment services	49[8]	Assume costs are same as disability employment advisor[8]
Time off work (hourly)	18[44]	

TABLE 5 Unit costs table (Great British pounds, 2021–2) (*continued*)

Cost item	Unit cost (£)	Assumptions
Unpaid carer (hourly)	18[45]	
Wider resources: out-of-pocket		
Employment and Support Allowance (ESA)	91[46]	
Personal Independence Payment (PIP)	73[46]	
Universal Credit	393[46]	
Statutory Sick Pay (SSP)	117[46]	
Other	73[46]	

TABLE 6 Participant mean (SD) and mean (95% CI) difference in costs (£, NHS/PSS) and outcomes over 12 months (available case, unless stated otherwise)

	Mean ± SD (*n*)	Mean ± SD (*n*)	
	ESSVR + UC (*N* = 324)	UC (*N* = 259)	Mean difference (95% CI)
Costs (unadjusted)[a]			
Total at baseline	481 ± 3596 (216)	703 ± 3385 (185)	−222 (−912 to 467)
Total at 3 months	2568 ± 6281 (135)	4468 ± 14,057 (92)	−1899 (−4608 to 810)
Total at 6 months	1150 ± 2246 (111)	1602 ± 4033 (69)	−452 (−1376 to 472)
Total at 12 months	1065 ± 2694 (82)	1213 ± 4586 (50)	−148 (−1401 to 1104)
Total trial period	4754 ± 6733 (57)	7832 ± 7961 (29)	−3077 (−7818 to 1663)
Total trial period inc. intervention	5145 ± 6733 (57)	7832 ± 7961 (29)	−2686 (−7426 to 2055)
Costs (adjusted)[b]			
Total trial period inc. intervention (MI)	(324)	(259)	1282 (−933 to 3497)
Utility score/QALYs (unadjusted)	ESSVR + UC (*N* = 324)	UC (*N* = 259)	
Utility score (EQ-5D-5L) at baseline	0.589 ± 0.285 (315)	0.590 ± 0.308 (245)	−0.001 (−0.050 to 0.049)
Utility score (EQ-5D-5L) at 3 months	0.632 ± 0.261 (191)	0.669 ± 0.248 (143)	−0.037 (−0.092 to 0.019)
Utility score (EQ-5D-5L) at 6 months	0.679 ± 0.238 (189)	0.677 ± 0.256 (133)	0.002 (−0.052 to 0.057)
Utility score (EQ-5D-5L) at 12 months	0.674 ± 0.267 (167)	0.682 ± 0.264 (122)	−0.007 (−0.070 to 0.055)
12-month QALY score	0.699 ± 0.189 (103)	0.685 ± 0.227 (64)	0.014 (−0.050 to 0.078)
QALYs (adjusted)[b]			
12-month QALY score (MI)	(324)	(259)	0.021 (−0.011 to 0.052)

MI, multiply imputed data.
a Includes NHS/PSS resource use: community-based HCP appointments, outpatient appointments, inpatient stays, A&E attendance, prescription medication use and stroke-related equipment.
b Seemingly unrelated regression analysis with costs. Adjusted for age, sex, utility/costs at baseline and site.

Source
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Twelve never delivered any intervention and almost 1/3 (32%) left. Reasons included changed job (*n* = 9), maternity leave (*n* = 3) and personal reasons (*n* = 7). Fourteen were lost to the study when five sites that paused during the first national lockdown did not re-open. The mean time OTs were involved in RETAKE was 25 months (range 4–60 months). Of the 60 OTs trained, only 10 remained in the study from site opening to study ending.

Early Stroke Specialist Vocational Rehabilitation was successfully delivered; the intervention commenced in 95.4% of allocated participants with compliance achieved in 75.3%. It commenced a median 38 days (IQR 23–56, range 6–139) post stroke and continued for ≤ 12 months. Participants attended a median 7 intervention sessions (IQR 4–12, range 0–37), with discharge a median 10.3 months (IQR 5.5–12, range 0–15.4) post randomisation. Participant adherence was good. There was little difference between the number of sessions offered (median 8, IQR 4–13) and attended (median 7.0, IQR 4–12). However, the intervention delivery mode and focus differed slightly from that in the feasibility trial with most intervention sessions delivered via telephone/videocall (51.7%), in participants' homes (35.9%) or workplaces (6.4%) and most of the time spent on dealing with current issues (46%) compared to (16%) in the feasibility trial, and more spent on fatigue management and providing informal psychological support. OT contact with employers only occurred for 109 (36.8%) participants and employer visits occurred for 74 (25.0%). Further details of the intervention delivered are reported in Radford *et al*. and *Trusson* et al.[2,26] and summarised in *Appendix 4*, *Table 9*.

Twenty-six participants (15 ESSVR, 11 UC were included in longitudinal case studies. An additional 18 participants (8 ESSVR and 10 UC) were interviewed once. Nineteen OTs, 6 mentors and 19 service managers were interviewed.

Implementation fidelity was measured for one randomly selected ESSVR participant for 39 of the trained OTs [21 were not assessed because they left the study prior to delivering any intervention due to changes in study site capacity (14), changed job (4), were on long-term illness (2) or maternity leave (1) and the intervention records could not be retrieved]. Overall, OTs delivered ESSVR with acceptable fidelity (mean: 79%; SD: 19). However, fidelity to individual ESSVR components ranged widely from 13% to 100%. Components requiring stakeholder involvement, for example employer engagement or supporting family members, were delivered with lower rates of fidelity than those centred on the stroke survivor. Some components could not be delivered, for example where there was no employer or engagement was not permitted. Deliverability of components ranged from 10% to 100%. The findings suggest some OTs struggled with or resisted crossing service boundaries to engage employers or families. OTs may need additional training on how to engage stroke survivors' employers. Findings are reported more fully elsewhere[25]

Mentor support for OTs appeared to increase fidelity.[24] In a small, embedded study exploring OT attributes and their impact on fidelity,[24] we found that only OT engagement in mentoring was significantly associated with fidelity (OR = 0.29, 95% CI = 0.05–0.53, $p < 0.05$). We also observed that increased fidelity (OR = 1.06, 95% CI = 1.01–1.1, $p = 0.01$) and increasing years of stroke rehabilitation experience (OR = 1.17, 95% CI = 1.02–1.35) were significantly associated with positive stroke survivor RTW outcomes. This suggests providing OTs with mentoring support as an implementation facilitation strategy may have increased fidelity to ESSVR delivery, which, in turn, may have positively influenced stroke survivor RTW outcomes. The results also suggest that OTs with more experience of stroke rehabilitation were better able to support stroke survivors to RTW. However, this was an exploratory study, and further research is needed to confirm these findings. Up-skilling OTs to deliver complex interventions, such as ESSVR, may require mentoring support in addition to training to ensure fidelity.[24,25]

Competency

Sixty OTs were assessed following initial training, and 38 following refresher training and at 12 months. Fourteen OTs left the study before delivering any intervention due to changes in study site capacity, four left the study due to staff turnover (*n* = 4), were on long-term sick (*n* = 2) or maternity leave (*n* = 1) or ill on the day of training (*n* = 1) (*Figure 4*). At 12 months, we were unable to obtain intervention records for three OTs, who left the study or could not access offices during the COVID-19 pandemic. Additionally, five intervention records contained insufficient information to assess competency because the participant disengaged (*n* = 2), or the OT was ill (*n* = 1) or redeployed during the pandemic (*n* = 2).

Most OTs were identified as competent or highly competent at each time point (75%, 97%, 95%); see *Table 7*.[21] However, 25% needed additional support following initial training, suggesting training alone may be insufficient to prepare OTs to deliver ESSVR. OTs with prior VR experience were 30% more likely to be rated as competent following initial training [OR= 1.3, CI 95% = (1.01 to 1.67)]. Two OTs identified as needing support at 12 months had replaced others lost to the trial during the pandemic; each treated two or fewer participants. Ratings of 'highly competent' were unrelated to OT demographic, stroke rehabilitation

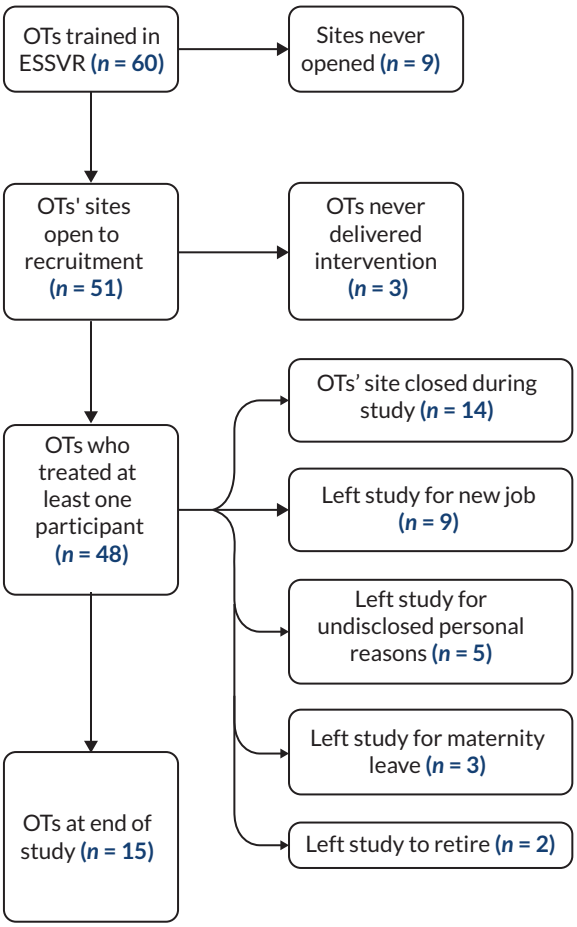

FIGURE 4 Occupational therapist retention and reasons for leaving the study.

or VR experience and added little value. Further details of this study are reported elsewhere.[47]

Case-study findings

When compared to UC, participants who experienced ESSVR described a different type of support, which was longer in duration, started early after stroke, was co-ordinated and included employer liaison and workplace adjustments where appropriate. ESSVR was valued by participants. In contrast, UC participants reported support lasting 2–8 weeks, which was largely focused on restoring functional ability with limited or no RTW support from healthcare professionals. They described feeling abandoned, struggling to find RTW information, advice and support, poor communication, and a lack of co-ordination between rehabilitation providers.[26]

Early Stroke Specialist Vocational Rehabilitation participants particularly valued the length of ESSVR intervention, OT advocacy, employer liaison and ongoing workplace monitoring. The qualitative data also indicated that individual participants' lived experiences of their post-stroke impairments differed from objective measures of stroke severity used in the trial.

Interviews with UC participants suggested that employers were facilitating RTW and implementing workplace adjustments, including a phased return, flexible working, home-based working and alternative roles.[21,22,26]

The case studies hinted at mixed experience of the OTs working with OH services. OH services did not always work with RETAKE OTs towards the shared goal of RTW. This might explain some of the challenges with employer engagement and fidelity inconsistency observed in the quantitative intervention data and fidelity assessment. Service managers indicated ESSVR would enhance post-stroke services.[21,26]

The impact of COVID-19 on workability and REturn To work After stroKE

Interviews with nine predominantly mild stroke survivors and five employers suggest pandemic-related changes to working practices positively influenced workability and RTW for stroke survivors employed in roles where home-based working was possible. Furlough also enabled more time for recovery and re-establishing work–life balance, following stroke. ESSVR helped stroke survivors manage

TABLE 7 Competency ratings across the three time points

	OTs in study at time of assessment	Number of OTs assessed	Needs support *n* (% of those assessed)	Competent *n* (% of those assessed)	Highly competent *n* (% of those assessed)
T1	60	60	15 (25%)	45 (75%)	0 (0%)
T2	48	38	1 (3%)	33 (87%)	4 (11%)
T3	48	40	2 (5%)	28 (70%)	10 (25%)

Source
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the impact of stroke and adapt to new ways of living and working.

Following the pandemic, remote working, enabled by videoconferencing technology, has become a culturally accepted 'norm'. It may benefit stroke survivors aiming to RTW by reducing the need to travel, mitigating the disruption stroke causes to lives and post-stroke identities. However, less is understood about the longer-term impact for people with more severe stroke and cognitive impairment, those whose jobs cannot be worked from home or who may be digitally excluded. Moreover, the challenges of balancing work with a post-pandemic home life, particularly for women, and the implications of homeworking on stroke survivors' social participation and mental health warrant further investigation.[22]

Contamination

Of the 48 OTs delivering intervention to 271 participants in 16 sites between July 2018 and June 2021, only 5 incidents of contamination were reported. Mentoring records identified a range of contamination risks including storing intervention records at trial sites; students/therapy assistants/UC therapists ascertaining intervention details when accompanying trial OT visits; trial participants potentially sharing intervention details in therapy groups and waiting areas and policy promoting VR service development.

Identifying potential risks routinely during OT mentoring helped to inform strategies to prevent contamination. Contamination training and mentor support to manage risks contained contamination in this complex intervention trial.

Discussion and interpretation

In stroke survivors working at stroke onset, we found no quantitative evidence of benefit of ESSVR over UC in self-reported RTW, mood, functional ability, social participation, work self-efficacy, post-stroke confidence or carer burden. These findings are in a predominantly male (69%, in line with UK stroke registry data),[48] young (mean age 54 years) and mild to moderate sample of stroke survivors; in the context of delivery during a pandemic when work practices changed across the UK; and some limitations in intervention fidelity to components involving employer and family engagement.

Although 5% more ESSVR participants returned to work for at least 2 hours per week, compared to UC (64.2% vs. 59.4%) at 12 months this was not statistically significant in primary imputed or complete case sensitivity analysis. The control arm had higher RTW rates than expected, more than double that observed in our feasibility trial (26%). This may be due to the participants' case-mix, the effects of the pandemic, and more recent evidence suggesting much higher RTW rates (5, 6), particularly in younger stroke survivors, expecting to RTW. This lack of effect was reflected in the health-related qualify of life results presented in the economic evaluation, which showed no significant difference in QALY scores at 12 months between groups.

In contrast to the feasibility trial, where 37% of participants sustained a moderate or moderate to severe stroke, half the RETAKE participants had no or only mild residual impairments in mobility, cognitive or expressive language and few had comorbidities such as mental health or musculoskeletal problems or cardiac conditions that might impact on their ability to work. Only 11% had more than one impairment, indicative of a mild–moderate severity sample. Participants were also predominantly male, White, well educated, and half were employed in white-collar roles. All of which are significant predictors of RTW.[49–51] It is possible that these stroke survivors are capable of self-advocating and navigating RTW without intensive ESSVR support, particularly if employed in a role that can be adjusted to accommodate home-based working and/or flexible hours.

Our exploratory subgroup analyses suggested ESSVR was more effective in older people and those with greater impairment, particularly cognitive and mobility impairments, suggesting ESSVR may benefit people disadvantaged by age and impairment. However, further research is required to confirm these exploratory findings and could aid in providing targeted ESSVR to those most in need and unlikely to RTW in UC.

In participants who returned to work, a greater proportion of ESSVR participants reported changes in working hours and taking time off compared to UC, suggesting that ESSVR might influence RTW in a role with reduced hours. This may reflect the age- and stroke-related impairments in those who successfully returned to work with ESSVR. However, it is also consistent with an intervention that seeks to ensure work is stable and balance is achieved between work and the other aspects of the stroke survivor's life. Financial stability may be achieved by supplementing the reduction in working hours with state benefits. Findings that a higher proportion of ESSVR participants received support from benefits advisors and were claiming state benefits at all time points would support this. However, further research is needed to understand how such changes support sustainable work in the longer term.

Our finding that participants tended to have slightly improved outcomes in UC compared to ESSVR on secondary outcomes, particularly 12-month functional ability and carer burden in which statistically significant effects were observed, should be interpreted with caution. Improvements largely represented very small effect sizes < 0.2[52] and were less reliable than findings from the primary RTW outcome due to higher levels of missing data (> 50%).

Interpretation of the economic evaluation results should be considered cautiously, in light of the degree of missing data. The economic evaluation found that, accounting for missing data using multiple imputation, ESSVR is unlikely to offer value for money from an NHS, public sector or participant perspective over a 12-month time frame and as delivered in this trial. These results mirrored the clinical findings and may be indicative of participants having less severe strokes and RTW rates being higher than that observed in the feasibility study. Resource use data were more likely to be missing in the UC arm and this was important in this analysis. Nevertheless, the economic evidence indicates the scale of resources used in the aftermath of a stroke from different perspectives and the impact on health-related quality of life.

Separate to our quantitative findings, our process evaluation found ESSVR was valued by participants and differed from UC, which was typically poorly co-ordinated with poor communication between rehabilitation providers, involved little or no RTW support and lasted less than 8 weeks.[21,22,26] Participants particularly valued the continuity of support, employer engagement and emotional support. Intervention length, which extended way beyond UC, provided opportunities for monitoring and feedback both on the RTW process and participants' post-stroke recovery. This reassured participants as they started to rebuild their life after stroke, mitigating against some of the life disruption caused by stroke and the pandemic.[22]

Key factors underpinning the perceived value of ESSVR for stroke survivors who received it were the case-co-ordination approach to early and individually tailored VR, written and verbal communication with participants and employers, employer engagement in planning RTW and stroke-specialist mediation in workplace adjustments.[21] These were consistent with the predicted mechanisms of action of ESSVR outlined in our pre-trial logic model.[2] In addition, mentor support for OTs appears to have been integral to effective ESSVR delivery.[24]

The process evaluation findings showed that stroke service providers, including OTs and service managers, wanted and felt it was important to provide VR for this younger cohort of stroke survivors who were already working. They saw it as a necessary improvement on existing VR provision and in line with the National Guideline for Stroke[53] and NHS policy directives for VR and RTW services in Integrated Stroke Delivery Networks[54] for England and Wales. OTs and employers also perceived ESSVR to be better than UC and indicated ESSVR would enhance post-stroke services.

Strengths and limitations

Despite challenges recruiting to multicentre stroke trials[55–57] and a global pandemic, this first, large, powered, UK trial of ESSVR recruited to our revised target to achieve 80% power, and almost 80% follow-up for our primary RTW outcome at 12 months.

Trial inclusion criteria were broad, aiming to support RTW irrespective of age, or whether work was paid or unpaid. This is consistent with the government's aim to provide equitable health care, NHS England's tiered model,[54] increases in the state pension age,[58] and recognises the contribution of voluntary work to the economy, the value of good work to health and well-being and its meaning in people's lives (8). Including people over 65 years was strongly advocated by PPI.

Early Stroke Specialist Vocational Rehabilitation was codeveloped with expert service users and providers following Medical Research Council (MRC) guidance.[59] We drew on stroke survivors lived experience, mapped, and explored the delivery content[60] and tested ESSVR in a feasibility trial.[4] The intervention features and mechanisms were consistent with best available evidence and clinical guidelines at the time,[61–63] indicating the need for early intervention, employer engagement and work-directed interventions combining education and coaching.[61] In RETAKE, compliance was good and fidelity acceptable. However, there were some limitations to OTs crossing service boundaries to engage employers or families suggesting additional training may be necessary, both in how to engage with employers as well as how to overcome barriers to engagement, for example, encouraging participants to consent to employer engagement, as only 119 (40.3%) participants permitted employer engagement. Interviews with OTs in the process evaluation highlighted that where engagement happened it was valued by participants, OTs and employers, although some OTs struggled to work with OH providers in larger companies or encountered conflicting advice.[22]

While the OTs were trained to engage with employers, and where permitted, most did. However, there were

fidelity inconsistencies,[25] with employer visits in only 25% of participants and particular challenges in engaging with OH.[2] Moreover, the fact that only 40% of participants granted permission to engage raises two questions. How do we better train OTs (1) to engage with employers and (2) encourage stroke survivors to permit this.

Challenges in employer engagement is a recurrent theme in the VR literature[8,64–66] Training for OTs and other health-based VR professionals in how to frame themselves as a resource for the employer, build relationships with employers and act as knowledge brokers and intermediaries at the intersection between the 'health' and 'employment' worlds may be the key to overcoming these challenges.[65,67]

In an exploratory qualitative study based on interviews and field notes from meetings with job agents, employers and jobseekers in a Norwegian demand-led VR approach called Ripples in the Water (RiW),[67] job agents functioned as knowledge brokers, who connected the discourses of 'welfare' (knowledge about traditional social work expressed in talk about jobseekers' resources and limitations as well as in their individualised and holistic approach to VR) and 'market' (employer), building relationships with employers and reframing VR using market discourse to 'match-make' between what the jobseeker has to offer and employer's production needs. To succeed, job agents had to overcome intrinsic differences between the discourses and speak and act in ways that encompassed both.[67]

Similarly, studies on job specialists' roles in Supported Employment[68,69] suggest job specialists' function between 'supply and demand', which requires competency and skills in individually tailored, empathetic support of jobseekers and competence in building relationships with employers and consumers, advocacy, communication skills and teamwork.[70,71]

While the context of job retention interventions differs from that of supported employment or RiW, where agents or employment specialists are trying to leverage work placements, equipping OTs with translation and brokering strategies and skills that improve their collaboration with and understanding of employers, including building relations, negotiation and coaching, and the confidence to use market discourse to communicate in a language that resonates with employers,[67,72] may help them to negotiate employer access, engage with employers and broker reasonable adjustments and workplace accommodations.

Further research should identify optimal engagement strategies, explore engagement from the employees and employers' perspective, including employers' willingness to support accommodations and identify and test interventions targeting the employer.

Limitations

Participants were indicative of a mild–moderate severity sample, suggesting we struggled to recruit people with more severe stroke. While we provided training and support to recruiting Clinical Research Network (CRN) staff, fewer than a fifth of recruited participants had aphasia and < 10% were cognitively impaired. High staff turnover,[82] repatriation of people with more severe stroke to local hospitals and the use of pre-recorded training resources following the pandemic may have contributed, and interviews with recruiting teams highlighted varied perceptions regarding the appropriateness of recruiting patients 'early after stroke'.

By supporting participants to complete outcome measures by telephone, supplementing questionnaires with SMS, and retrospective targeted data collection, we achieved almost 80% complete data for our primary outcome. However, full questionnaire completion was low with secondary outcomes missing (or only partially available) for more than half the sample. Those lost to follow-up also tended to represent a more severe sample, including those with communication impairments and with differential missing data patterns by arm, thus contributing to variability in treatment effect estimates across analyses approaches and making comparison between groups unreliable on secondary outcomes. Efforts were made by the research team to maintain participant engagement at each follow-up through letters, e-mails, telephone calls, text messages and face-to-face where necessary. Our secondary RTW measures and resource-use questionnaires were in retrospect overly long and complex. Reducing questionnaire length or collecting data via other means (for instance, via medical records) may have improved completion and follow-up rates. However, attempts were made to do this during the feasibility trial, but some community rehabilitation services still maintained paper records and where electronic, different systems were used by different primary care services making this impractical at the point of funding. However, future studies should consider this, to reduce the data collection burden and missing data. Efforts were also made to obtain aggregated non-identifiable data on work status via the DWP; however, contractual issues meant obtaining these data was not possible.

Further data collection limitations meant we could not explore the effect of contract type or flexible working in relation to outcomes and would recommend future data

collection include employment on zero hours contracts and ability to work remotely. A cross-sectional approach to work post stroke, rather than on changes to or since prior questionnaires may have yielded more reliable and complete data. The National Institutes of Health Stroke Scale for quantifying stroke severity was not collected; therefore, we used the number of impairments according to mobility, aphasia and cognition to quantify stroke severity.

Our measurement of UC relied largely on participant self-report. In our health economic evaluation, UC resource use was measured over the 12-month period post randomisation. However, only 57/324 (18%) ESSVR participants and 28/259 (11%) UC participants had complete resource use data and missingness increased with time, as questionnaire completion rates declined. Future studies should explore alternative, less burdensome methods, including routinely collected data and/or focus on likely cost-drivers.

The process evaluation also set out to describe UC content and understand how it was delivered in a series of randomly selected cases. This drew on a combination of participant interviews, Sentinel Stroke National Audit Programme data (where available) and participants' self-reported resource use data. However, most case study participants were recruited and treated before the pandemic, possibly reflecting different experiences of UC between case study participants and UC reported in health economic data. It is also possible that these observed differences reflect changes in UC practice in the lifetime of the trial.[53,74,75]

Most of the qualitative interviews conducted as part of the process evaluation related to pre pandemic intervention delivery. This may have limited our understanding of how participants experienced ESSVR and how this affected RTW in participants recruited during and after the furlough period when most intervention was delivered online.[33]

Initiation of sites was slow due to delays in Health Research Authority permissions and securing ETCs, following the introduction of a new Excess Treatment Cost model in 2018.

The pandemic was the greatest limitation. It changed the healthcare and employment contexts in which ESSVR was delivered and the meaning of work in people's lives.[76] It emerged at a critical point in RETAKE, impacting recruitment, intervention delivery, data collection and follow-up. RETAKE paused to recruitment 1 week after the first UK COVID-19 lockdown was mandated and the furlough scheme introduced (supporting employers to retain and pay staff while businesses were closed), having recruited 76.3% of our final sample across 21 sites but with trial completed in 28.5% participants.

Government directives to 'protect the NHS' led to redeployment of several of the 60 trained RETAKE OTs to COVID-19 activity. Routine procedures and non-COVID research were de-prioritised. Some stroke rehabilitation services were reconfigured. Following the initial lockdown, 5 sites closed, and 20 OTs were unable to continue delivering the trial intervention.

While the trial was intended for face-to-face delivery, we rapidly re-designed trial processes and training resources to support remote recruitment and delivery of ESSVR. Fewer intervention sessions were delivered in-person post COVID while delivery online or by phone increased substantially and there was increased difficulty engaging employers – a core underlying mechanism of ESSVR.[2] The focus of ESSVR also changed. Most time was spent addressing current issues, ~50% of sessions[2] versus 16% in the feasibility trial, with more time spent on fatigue management and informal psychological support. This was possibly in response to disruption caused to people's lives,[22] heightened anxiety,[77,78] limited access to NHS services[79] and COVID-19 symptoms, such as fatigue, possibly compounding that related to stroke.[80,81]

Early Stroke Specialist Vocational Rehabilitation is a complex intervention and dependent on the delivery context.[59] It relies on VR-trained OTs crossing service boundaries within and between health and the employment sector; however, the pandemic changed the employment context. The impact of COVID-19 infection on ability to work[82] led to an NHS England-led nationwide initiative to develop resources for NHS healthcare professionals to support RTW following COVID-19 infection.[83] This possibly equipped OTs with VR skills that were transferable to stroke. Widespread implementation of telehealth across the NHS, changed rehabilitation delivery, raising concerns about digital exclusion.[84] UC became more accessible for people with fewer disabilities, and those conversant in and with access to technologies.

Efforts to minimise COVID-19 spread and lockdown measures[85] also necessitated home-based working and led to widespread implementation of videoconferencing software and flexible working practices. Efforts to facilitate remote working and support employees during lockdowns, coupled with heightened awareness of pandemic-related health inequity[86] and labour shortages,[87] may have expedited employer awareness of equality, diversity and inclusion (EDI)[88] and their experience of implementing reasonable adjustments and RTW plans for people with

disabilities. These changes compromised core intervention mechanisms (employer engagement and education, cross-boundary working, negotiating reasonable adjustments). Home-based working also mitigated against the disabling effects of neurological fatigue exacerbated by travelling to work and reduced the length of the working day.[22] People with other long-term health conditions such as multiple sclerosis, and inflammatory arthritis reported increased productivity.[89,90]

These pandemic-related disruptions have changed rehabilitation delivery irreversibly, making interventions like VR more accessible for some, while simultaneously raising concern about digital exclusion,[84] particularly for stroke survivors with cognitive and communication impairments and older people who may be less conversant in and with limited access to technology. Clinicians and future research should reflect on the influence of these changes on the delivery, underlying mechanisms and effectiveness of VR models in different populations.

The pandemic increased the length of the trial to over 5 years. In this time, new guidelines[53,74] advocating the need for VR, highlighted the need for 'early intervention', and the Stroke Sentinel National Audit Programme, introduced VR-specific questions to its audit, influencing changes in clinical practice.[91]

Take-home message(s)

This first definitive RCT of a stroke specialist VR intervention found no significant effect of ESSVR on RTW for most of the participants in this trial.

We trained 60 OTs across 16 sites to deliver ESSVR. While it was successfully deployed and participants, OTs, service managers and employers valued it, the global COVID-19 pandemic changed the world of work (irreversibly for some types of job), the meaning of work in people's lives[76] and healthcare delivery beyond anything that could have been anticipated in the trial lifetime. This reduced the effectiveness of key ESSVR mechanisms (employer engagement, negotiating reasonable adjustments, such as home-based working and flexible hours), and the overall effectiveness of the ESSVR intervention and impacted our primary outcome.

The trial was impacted by the global COVID-19 pandemic. This impacted recruitment, intervention and UC delivery and participants lives, affecting data collection, and follow-up. It resulted in patterns of missing data that possibly reflect early retirement (affected by the change in meaning of work in people's lives) and the discriminatory effect of the pandemic on people of Black and minority ethnic ethnicity. We recruited a sample with less severe stroke than in the feasibility trial. Most participants in this trial had few residual disabilities, indicative of mild–moderate stroke. While they needed help to rebuild their lives, and valued the ESSVR support in returning to work, pandemic enabled changes to the nature of work, which meant that not everyone who received it needed ESSVR.

The pandemic impacted our primary outcome 'work'. Employers enabled flexible, home-based working and introduced technology that advantaged disabled people, including stroke survivors in UC, 59% of whom returned to work. It also advantaged people in managerial and professional roles with less face-to-face contact, who are more likely to be home-based post pandemic. Clinical services also changed, introducing VR earlier, and telerehabilitation, which benefitted people with intact cognitive and communication abilities, reducing the ESSVR effect.

Exploratory analysis identified that people more disadvantaged in their ability to RTW appeared to benefit from ESSVR. They included older people, and those with more impairments (across domains of mobility, communication and cognition) consistent with moderate and severe stroke. These people are at risk of becoming work disabled and may need ESSVR to address biopsychosocial barriers to RTW or find work alternatives. However, the possibility of bias resulting from missing data on the exploratory analysis cannot be excluded.

Patient and public involvement

Involvement of PPI is reported following Guidance for Reporting Involvement of Patients and the Public 2 short form headings.[92]

Aim

The aim of PPI in every aspect of the study was to ensure that the voices of stroke survivors were integral to the research, such that the results would be of direct benefit to them.

Methods

We worked with PPI representatives from intervention development, during piloting, feasibility testing and grant preparation, through to dissemination.

For RETAKE our seven-strong PPI group met 6-monthly throughout the trial. Members included people with a range of stroke severity and stroke-related disability, including two people with aphasia. One person had sustained an

acquired brain injury. All were working prior to onset in a range of public, charitable and private sector roles and included a medical doctor, a solicitor, a lorry driver and publican, an architect, a self-employed marketing manager, an IT consultant and an academic. Three were women (one Black). The group included people who had and had not returned to work.

Involvement included considerations around research design (two PPI member co-applicants), development and iteration of participant information resources, research management (two members joined the Trial Management Group) and troubleshooting (as members of the Trial Steering Committee), interpretation of the data and writing and dissemination of the findings.

Results of patient and public involvement input

In total, 14 meetings were held, 5 in person and 9 online. Examples of how PPI shaped the research are documented in the 'You Said, We Did' table (see *Appendix 5*, *Table 11*) mapped to UK Standards for Public Involvement standards for PPI involvement.[93]

Involvement included helping to define 'work' and 'voluntary work', as part of our primary outcome definition, developing and evaluating all patient-facing materials, including aphasia-friendly recruitment materials, codevelopment of interview topic guides for trial participants and OTs and Providing case studies for use in OT training and competency assessment.

During trial setup a new ETC payment model was introduced but no guidance on how to implement it was provided to the CRN or NHS for 7 months. This caused huge delays, as NHS Trusts' research and development (R&D) managers and therapy managers were reluctant to engage with the trial until reassurance could be offered that ETCs would be reimbursed. One PPI member wrote directly to Directors of the National Institute for Health and Care Research (NIHR), NHS England, Health and Social Care and the leads for the NIHR CRN to explain the impact these changes were having on the trial. She received a prompt response, which assisted us in explaining the new system to clinical, CRN and R&D colleagues and research teams at sites.

Overcoming challenges with recruitment. For example, providing resources and narratives to assist recruiters who were reluctant to approach people with severe stroke. Assisting in the design of new materials to promote follow-up, for example, including a 'patient journey leaflet' and 'Thankyou cards'. They advised on data capture and optimising follow-up by helping to shorten the follow-up questionnaire booklet. They also advised on communicating with participants during the pandemic. They told us to provide participants with contact numbers for the trial team and introduce a participant newsletter to let participants know what was happening and advise them about changes to data collection methods, when we moved to telephone data collection, when the Clinical Trials Research Unit was closed.

Patient and public involvement members assisted in our variation to contract request, advised on the content of trial newsletters and one member helped to codevelop a trial website (www.retake.org.uk/), which served as a repository for outputs.

During the pandemic and in the final stages of the trial, PPI members helped in crafting motivational messages for the NHS OTs and site teams to encourage recruitment.

In the latter stages of the study, two members got involved in related VR studies for people with communication impairments with overseas OT collaborators, one has joined an NIHR grant panel and two are involved in a bid for a first UK stroke rehabilitation platform trial for people with stroke-related emotional difficulties.

At all stages, interim findings were presented to PPI members and their comments shaped our interpretation prior to publication and/or dissemination. Key members have coauthored publications and contribute to writing up.

Reflections

Patient and public involvement had an overwhelmingly positive influence on the RETAKE trial. Their suggestions for improving follow-up (reducing the questionnaire booklet, introducing named contacts and numbers, thank you cards, participant newsletters) helped to achieve the near 80% response and ensure participants in both trial arms remained engaged. Their suggested appeals targeting UC participants ensured a more balanced response. However, despite their support and resources for recruiting participants with aphasia and more severe stroke, a predominantly mild–moderate sample and only 17% of people with aphasia were recruited. Future studies might consider involving PPI in the recruitment and training of CRN staff deployed to recruit to rehabilitation trials.

Most PPI members were retired, White professionals previously employed in white collar or qualified worker roles. We had no employer representatives. Although we recruited PPI through numerous networks and user groups, finding and involving people who are currently working,

from lower socioeconomic groups, blue-collar roles and more diverse cultural backgrounds proved challenging. Doing so might have ensured a more diverse sample in this trial, for example, by translating and preparing recruitment materials in different languages, formats and a variety of media, or ensuring greater diversity in staff involved in recruitment and the involvement of interpreters. Involving a PPI employer and seeking their advice on employer recruitment might have ensured more employers were recruited for interview in the process evaluation, and the challenges of OT–employer engagement during intervention delivery overcome.

Other stroke rehab trials have successfully recruited people with more severe stroke including communication impairments by involving skilled healthcare professionals, such as SLT in recruitment.[94] Our feasibility trial, which recruited 37% of people with moderate or severe stroke, involved an OT who was able to explain the study and describe the intervention to potential participants.[4] It is possible that CRN deployed staff were unprepared or unable to do this.

Our planned approach to PPI involvement included the more conventional aspects of planning for recruitment, ensuring participant-facing materials and data collection tools were fit for purpose, and seeking feedback on findings and outputs. However, most PPI input was in response to challenges arising during the trial, including the response rate and a global pandemic, while anticipating issues (e.g. poor response rates) and consulting PPI on how to avoid them is preferable, for example, involving PPI in the selection of outcome measures to reduce questionnaire burden, during bid development. Our flexible approach to involvement and our PPI members' ability and willingness to adapt and respond to issues and challenges contributed to the successful delivery of this large, complex trial.[95]

Equality, diversity and inclusion

The study enrolled 583 stroke survivors in the main RETAKE trial from 21 sites in England and Wales. A total of 69% were men and 15.6% were of non-White ethnicity (4.1% not stated); 80.3% of participants were of White ethnicity (Office for National Statistics ethnic group descriptors). This is consistent with the proportion of female stroke survivors of working age in population-based registry studies exploring RTW in the UK and Sweden[48,51] and systematic reviews of VR after stroke.[96,97,98] The mean age of participants in RETAKE [54 (SD 11.1)] is also consistent with UK and Swedish registry data (53.4 years and 53 years, respectively).[48,49] The mean age of stroke participants in other VR intervention studies varies widely by design and context.[97]

In UK stroke population registry data,[48] 31.8% were women and 46% of non-White ethnicity suggesting under-representation of working-age stroke survivors of non-White ethnicity in RETAKE. Only one participant in our feasibility trail was Black.[4] Ethnicity is not reported in the only other published trial of a post-stroke VR intervention.[99]

Despite the spread and geographical diversity of sites, training for recruiting teams, an inclusive approach and additional resources for recruiting people with a range of stroke severities, most (66%) participants in RETAKE had only one or no residual impairments in cognition, mobility or communication, indicative of a mild–moderate stroke sample. Most participants were also well educated (54% held a higher degree). Intention to RTW was also an inclusion criterion, increasing the possibility of recruiting motivated stroke survivors who believed they could return (factors indicative of RTW).[51] Therefore, less is known about RTW in people with more severe stroke, living in areas of deprivation, blue-collar workers, people who are less well educated or other social determinants of health and work inequality.

Ninety-nine participants (17.3%) had aphasia; while fewer than one-third anticipated in acute stroke[100] and less than the proportion recruited in the feasibility trial (26%), it is greater than the 14.4% observed in UK registry data for people working prior to stroke[48] and far greater than the 1.5% included in most RCTs examining stroke interventions.[101] Studies investigating interventions to support RTW in people with aphasia are sparse. In a systematic review of RTW after stroke,[97] only one study reported the proportion of participants with aphasia,[102] making this one of very few and the largest VR trials to include participants with aphasia. However, in exploratory subgroup analyses, ESSVR appeared to be less effective for people with aphasia, than UC, indicating a need for further research into VR interventions in this population.[33]

A smaller proportion (8.2% vs. 50%) of RETAKE participants had visual impairment than in the feasibility trial, possibly reflecting the mild–moderate sample and differences in screening measures.

In the embedded process evaluation, case study participants and the additional 5% of participants interviewed were randomly selected from participants in the main trial; therefore, similar imbalances were seen.

There were also imbalances in follow-up data collection. Those lost to follow-up also tended to represent a more

severe sample, including those with communication impairments and there were differential missing data patterns by arm, including greater loss to follow-up in people of non-White ethnicity in the intervention arm (check), thus contributing to variability in treatment effect estimates.

Guidance for improving inclusion of underserved groups in research[103,104] was not published when this trial was designed. Therefore, we did not formally assess the impact of EDI imbalances within the research team. It is possible that inherent biases exist in recruitment teams, who are mostly White and female.

It is also possible that post-pandemic turnover of NHS staff[88] and the use of pre-recorded training slides were inadequate in the context of this trial. More in-person, cultural and stroke competency focused training[105,106] for local PIs and recruitment teams, involving the CI and PPI members, together with recruitment materials codeveloped with underserved communities, may have resulted in greater buy-in of clinical teams[95] and a more diverse sample. Further research is also needed to explore the potential for recruitment bias by non-experts in an area of expert clinical care.

Future trials should also monitor recruitment for inclusivity and representation regularly during the recruitment period, so that efforts can be made to address disparities in real time.

Impact and learning

Despite the impact of a global pandemic and complexity of large rehabilitation trial, RETAKE successfully recruited to the revised target and adapted to unexpected issues, including site closures and loss of a substantial number of the treating OTs. This success reflects the robust design, the expertise, flexibility and resilience of the trial team and the support of our advisory networks, including our PPI members and the Trial Steering Committee.

The key impact and learning from RETAKE are that better research infrastructure and multiple, well-defined recruitment strategies are needed to support the delivery of any large-scale complex rehabilitation stroke trial. For stroke VR trials this should include the involvement of healthcare professionals experienced in stroke in recruitment, and providing more specialist training for recruitment teams in how to recruit people of non-White ethnicity, people with severe stroke, people with communication impairments and people with poor health literacy, lower incomes and blue collar workers, to ensure that trial participants reflect the wider working age stroke population.

The trial team's significant learning on how to train and support OTs to deliver a highly individualised, complex intervention with fidelity, including assessment of fidelity and competency, and the use of mentoring as an implementation facilitation strategy, will inform future projects and trial designs.

Learning from the therapist capacity and ETC payment issues faced in RETAKE has enabled the trial team to develop flexible processes for the recruitment and contracting of OTs to deliver the trial intervention, which have informed other trials and will be implemented from the outset in any future research.

Learning from this trial, in future trials we would:

- Involve more PPI at the design stage to select outcome measures, creatively design resource use questions and reduce length to ease participant burden.
- Involve PPI in training recruiting teams and introduce cultural competency training for all research and recruiting team members, to raise awareness of socioeconomic and educational barriers to research participation, which threaten recruitment, follow-up and generalisability of research findings.
- Further explore the assessment of work and other outcomes using routinely collected Hospital Episode Statistics and DWP and registry-based data.

Real-world impact/potential impact

The trial raised awareness of the need to support stroke survivors in a RTW, influencing changes in policy and clinical guidelines, prompting the development of an NHS England eLearning resource for NHS staff for supporting stroke survivors in a RTW.[83]

Two of the research assistants (Powers and Craven) on this study have completed PhDs; one exploring fidelity within RETAKE, and the other has worked with stroke survivors and employers to codevelop an eHealth Toolkit for self-managing RTW after stroke. This is due to be tested in a feasibility study.

Of the 60 OTs trained in ESSVR, some have continued to work with us on subsequent NIHR-funded VR trials (OPAL and ROWTATE), including involvement in mentoring or training others to deliver VR interventions. Based on their experience, recommendations to encourage patients to permit and therapists to engage with employers can be found in *Appendix 7*.

Collaborations/further funding/future work

This work has led to future collaborations between RETAKE team members (KR, AF) and VR trialists in Hong Kong and Australia.

Implications for decision-makers

The incidence of stroke in people under the age of 65 is rising, making returning to work an increasingly important outcome of rehabilitation.

Rehabilitation has not traditionally been designed to meet the needs of stroke survivors wishing to RTW, and there remains limited available evidence for the efficacy of interventions to promote RTW in this population.

This world first definitive trial of VR following stroke adds considerably to the body of literature on VR, more than doubling the number of stroke survivors enrolled in VR trials to date.

Our process evaluation suggests that in an ideal world ESSVR should be offered to all stroke survivors, employed at stroke onset, as usual NHS stroke rehabilitation does little to address RTW. However, where resources are limited, our findings suggest ESSVR should potentially be targeted at older patients and patients with greater post-stroke impairment. However, further research is needed to confirm this finding. A less intensive VR intervention may better suit younger patients who have little residual disability and are able to self-advocate post stroke.

This is a rapidly developing field with several trials underway testing different models of VR following stroke. A review is needed that identifies the effectiveness of different VR models and the effectiveness of different interventions for different stroke populations, for example people with aphasia and those with more severe stroke, and which identifies the differential effectiveness of intervention components to guide implementation.

Funding mechanisms are needed that enable a joined-up (health and social care and employment) approach to investigating the effectiveness of interventions targeting RTW or job retention, along with longitudinal studies that enable assessment of the clinical and cost-effectiveness of interventions over time, particularly for more severe stroke. Data-enabled and smart trial designs may offer ways of exploring the effectiveness of different VR approaches simultaneously in different stroke populations.

Research recommendations

Research for people with more stroke-related impairment is the top priority, supported by our recruitment of a relatively mild to moderate severity sample, no evidence of an overall beneficial effect ofVR, and exploratory findings suggesting more promising results in patients with greater levels of impairment. Longer follow-up studies are also needed, given the time taken to recover from stroke and the possibility that ESSVR might have had benefits beyond 12 months deserves further exploration.

Secondly, research is needed to better understand the challenges surrounding employer engagement and stroke survivors' reluctance to permit this, alongside research evaluating strategies to address these challenges: For example, interventions directly targeting the employer, such as training to enhance employer knowledge of and marketing strategies to engage employers in discussions about the benefits of employing people with disabilities; training to equip OTs with the language and skills to market these benefits and those of the intervention to the patient and the employer and training in brokerage, for example of work placement and work-based learning opportunities such as placements and job-shadowing for stroke survivors unable to return to an existing job.

Thirdly, research is needed in how to maximise resource-use data capture in this patient population across relevant sectors to reduce participant data collection burden and ensure equity of follow-up. This is particularly important, since if ESSVR is found to be effective for certain groups, for example more severe stroke survivors, understanding its cost-effectiveness over a longer period is essential before widespread implementation.

As the clinical results suggest there may be benefit from ESSVR for older and more severely affected stroke survivors, further research exploring value-for-money in these subgroups would be worthwhile. Also, the economic value of a more light-touch approach, for example a self-guided online toolkit to aid RTW for those experiencing mild to moderate strokes, would also be worthwhile. This is particularly pertinent given that the UK is currently experiencing rising numbers of economically inactive individuals aged > 50 years due to long-term illness.[82]

In addition, development, agreement and further piloting of core outcome sets for work-related outcomes and the use of routine data would increase follow-up rates and encourage completion and interpretability of self-report outcomes.

Further secondary analysis could explore therapist learning effects, site experience, and a holistic view of outcomes through joint modelling of RTW with secondary outcomes of mood, functional ability, social participation, work self-efficacy and post-stroke confidence.

Although trial findings indicate that most mild–moderate stroke survivors were able to independently navigate RTW, our process evaluation suggests this is not always the case. Most participants in this study were White, 54% had degree level education and only 146 (25%) were aged < 43 years. More research is needed to understand social and health inequalities that affect work and access to VR and the needs of younger, less well-educated stroke survivors and people of non-White ethnicity, particularly given greater loss to follow-up in Black and minority ethnic groups in this study.

We also recruited relatively few people with aphasia and follow-up was equally challenging in these groups. Further research is needed to better understand how best to support people with post-stroke communication impairment and those with severe stroke in returning to work.

Factors affecting RTW are not limited to the biological impact of stroke. Psychological, socioeconomic and workplace-related factors also determine outcome success.[70,107] Further research is needed to explore the known employment-related (relationship with the line manager, employer size, manual job) psychological and social factors known to affect stroke survivors' RTW. to provide additional insights into the barriers. Moreover, research is also needed to match the stroke survivor's needs to a type or level of support and to determine the effectiveness of different interventions for people of different ages with different needs, for example, resource facilitation[108,109] or self-management interventions[110–112] and eHealth interventions[113,114] for people with less stroke-related impairment or those preferring to navigate RTW without professional help.

The challenges surrounding employer engagement in particular warrant further research, including the effectiveness of strategies directly targeting the employer.

Further research is also needed to explore the value of cultural and stroke competency-based training and PPI involvement in training for non-experts in an area of expert clinical care to address recruitment bias in complex rehabilitation trials.

Conclusions

The quantitative findings from this first definitive RCT of a stroke-specialist VR intervention found no evidence of benefit of ESSVR on RTW. While we trained 60 OTs across 21 sites to deliver ESSVR successfully, and participants, OTs, service managers and employers valued it, the pandemic changed the world of work irreversibly, as well as healthcare delivery beyond anything that could have been anticipated in the trial lifetime. It changed the meaning of work in people's lives, increasing rates of early retirement, and had a discriminatory effect on people of Black and minority ethnic ethnicity. This compromised key ESSVR mechanisms compared to UC, the overall effectiveness of the intervention, our primary outcome, and trial delivery.

Qualitative interviews found that participants needed help to rebuild their lives after stroke, and valued ESSVR support in returning to work. However, pandemic-enabled changes to the workplace meant that not everyone who received it needed ESSVR.

Exploratory subgroup analysis found that people who were more disadvantaged in their ability to RTW appeared to benefit. They included older people, those with more impairments, particularly in mobility and cognition who remain at risk of becoming work disabled and may need support to overcome the biopsychosocial barriers to RTW or find work alternatives. Further research is needed to confirm these findings post pandemic.

Early Stroke Specialist Vocational Rehabilitation plus UC, as delivered in the trial for this population, does not appear to offer value for money over a 12-month time horizon and as delivered in this trial. Further research to explore if there may be benefits for certain groups, in particular those with more severe disability, would be of value.

Additional information

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Acknowledgements

We would like to thank our patient and public engagement partners, the occupational therapists involved in delivering ESSVR, the Leeds Clinical Trials Research Unit staff: Marissa Arfan, Richard Brindle, Andrew Carter, Marie Chenery, Alison Fergusson, Joseph Hill and Tom Morris; Mentors, Jane Terry, Ruth Tyerman, Jo Hurford, and Yash Bedekar; Research Assistants, Rachel Chambers, Sara Clarke, Abigail Statham, Kristina Kroller and Rebecca Lindley; Our Trial Steering Committee members and chairs, Professors Peter Langhorne, Helen Rogers and Alison Hammond and principally the participants.

Patient data statement

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it is important that there are safeguards to make sure that they are stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation

Data-sharing statement

Data supporting this work are available on reasonable request. All requests will be reviewed by relevant stakeholders, based on the principles of a controlled access approach. Requests to access data should be made to CTRU-DataAccess@leeds.ac.uk in the first instance.

Ethics statement

Research Ethics Committee approval was obtained from the East Midlands – Nottingham 2 Research Ethics Committee on 5 February 2018 (Ref: 18/EM/0019).

Information governance statement

The collaborating institutions are committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679.

Under the Data Protection legislation, the University of Nottingham and the University of Leeds are the joint Data Controllers, and you can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for our Data Protection Officer here:

www.nottingham.ac.uk/utilities/privacy/privacy.aspx; https://ctru.leeds.ac.uk/privacy-cookies/how-we-use-personal-data/

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/LAKP6585.

Primary conflicts of interest: Kate Radford, Audrey Bowen, Amanda Farrin, Christopher McKevitt, Caroline Watkins were awarded NIHR Health Technology Assessment (HTA) grant funding (15/130/11) for the RETAKE Trial. Kate Radford, Katie Powers, Audrey Bowen, Julie Phillips, Amanda Farrin, Alexandra Wright-Hughes, Ellen Thompson, David Clarke, Diane Trusson, Kristelle Craven, Christopher McKevitt, Caroline Watkins, Rory O'Connor, Jain Holmes, Sarah Pyne, Helen Risebro, Rory Cameron, Tracey Sach and Florence Day were paid a proportion of their salary from the NIHR HTA grant funding the RETAKE trial to undertake this study.

Kate Radford and Jain Holmes were unpaid advisors to NHS England in the development of a toolkit for NHS professionals to support RETurn to work After stroKE. Jain Holmes was Chair of the Royal College of Occupational therapists Specialist Section Work from 2019- present. Jain Holmes received royalty payments for a book, 'Vocational Rehabilitation' published in 2007. Jain Holmes reports grant funding from RCOT. Kate Radford was a member of the HTA Clinical Evaluation and Trials panel between 2017 and 2021. Kate Radford received funding from NIHR, EPSRC, Elisabeth Casson Trust, Ossie Newell Foundation, MRFF. Amanda Farrin Received grants from NIHR HTA, EME, PGfAR, HS&DR, NIHR/MRC and received funding as an NIHR Senior Investigator from 2021. Amanda Farrin was also a member of the HTA Clinical Evaluation and Trials panel until November 2018, the NIHR Clinical Trials Unit Standing Advisory Committee until 2022 and the NIHR COVID Prophylaxis Platform Study in Care Homes Funding Committee in 2020. Amanda Farrin was also independent statistician on one NIHR Data Monitoring and Ethics Committee and one BHF-funded Trial Steering Committee. Alexandra Wright-Hughes reports other grant funding from NIHR. Alexandra Wright-Hughes was a committee member for the Yorkshire and Northeast Regional Advisory Committee for NIHR Research for Patient Benefit, protocol editor for the journal Trials, and an unpaid independent statistician on four Data Safety Monitoring or Advisory Boards for NIHR-funded studies. Caroline Watkins reports other grant funding from NIHR. Caroline Watkins was Implementation Lead for the NIHR ARC NWC and participated in two NIHR HTA Data Monitoring and Ethics Committees and two NIHR Trial Steering Committees. Audrey Bowen received funding from Wellcome Trust, Stroke Association, NIHR. Rory J O'Connor reports other grant funding from NIHR. Rory J O'Connor is a Clinical Member of the Clinical Reference Group on Rehabilitation, Disability and Spinal Cord Injury, NHS England. Florence Day reports other grant funding from NIHR.

Department of Health and Social Care disclaimer

This publication presents independent research commissioned by the National Institute for Health and Care Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, MRC, NIHR Coordinating Centre, the Health Technology Assessment programme or the Department of Health and Social Care.

This synopsis was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

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This synopsis should be referenced as follows:
Radford K, Wright-Hughes A, Clarke D, Phillips J, Holmes J, Powers K, *et al.* Early stroke specialist vocational rehabilitation for return to work after stroke: a synopsis from the RETAKE RCT. *Health Technol Assess* 2026;**30**(31):1–64. https://doi.org/10.3310/LAKP6585

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- Martin Coult

Occupational therapist mentors:

- Julie Phillips
- Jain Holmes
- Ruth Tyerman
- Yash Bedekar
- Jo Hurford

Trial registration

This trial is registered as ISRCTN12464275.

Funding

This synopsis presents independent research funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme as award number 15/130/11.

This synopsis provided an overview of the research award *RETurn to work After stroKE (RETAKE).* For more information about this research please view the award page (https://fundingawards.nihr.ac.uk/award/15/130/11).

About this synopsis

The contractual start date for this research was in July 2017. This article began editorial review in July 2024 and was accepted for publication in July 2025. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The Health Technology Assessment editors and publisher have tried to ensure the accuracy of the authors' article and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this article.

List of supplementary material

Report Supplementary Material 1
Health Economic Analysis Plan for the RETAKE trial

Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/LAKP6585).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

The supplementary materials (which include but are not limited to related publications, patient information leaflets and questionnaires) are provided to support and contextualise the publication. Every effort has been made to obtain the necessary permissions for reproduction, to credit original sources appropriately, and to respect copyright requirements. However, despite our diligence, we acknowledge the possibility of unintentional omissions or errors and we welcome notifications of any concerns regarding copyright or permissions.

List of abbreviations

A&E	accident and emergency
CACE	complier-average causal effect
CASM	Confidence after Stroke Measure
CFIF	Conceptual Framework for Implementation Fidelity
CIQ	Community Integration Questionnaire
COVID-19	coronavirus disease 2019
CRF	case report form
CRN	Clinical Research Network
CTRU	Clinical Trials Research Unit

EDI	equality, diversity and inclusion
EQ-5D	EuroQol-5 Dimensions
EQ-5D-5L	EuroQol-5 Dimensions, five-level version
ESSVR	Early Stroke Specialist Vocational Rehabilitation
ETC	excess treatment cost
GP	general practitioner
HADS	Hospital Anxiety and Depression Scale
HEAP	Health Economic Analysis Plan
MRC	Medical Research Council
NEADL	Nottingham Extended Activities of Daily Living scale
NIHR	National Institute for Health and Care Research
NPT	Normalisation Process Theory
OCS	Oxford Cognitive Screen
OH	occupational health
OT	occupational therapist
PI	principal investigator
PPI	patient and public involvement
PSS	Personal Social Services
QALY	quality-adjusted life-year
RCT	randomised controlled trial
R&D	research and development
RETAKE	REturn To work After stroKE
RiW	Ripples in the Water
RTW	return to work
SLT	speech and language therapy
SMS	Short Message Service
UC	usual care
VR	vocational rehabilitation
WAI	work ability index

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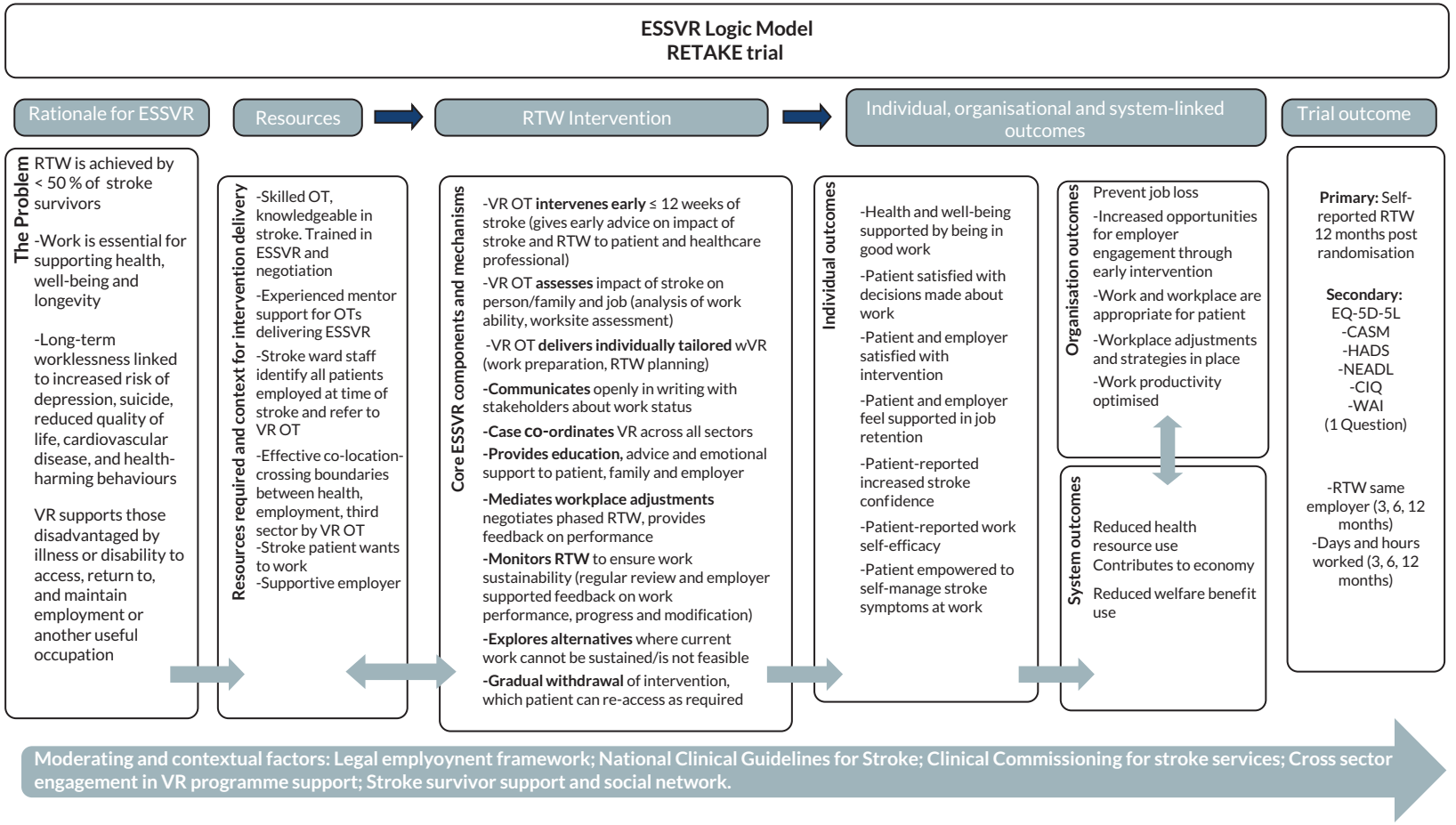
Appendix 1 Early Stroke Specialist Vocational Rehabilitation Logic Model



This synopsis should be referenced as follows: Radford K, Wright-Hughes A, Clarke D, Phillips J, Holmes J, Powers K, *et al.* Early stroke specialist vocational rehabilitation for return to work after stroke: a synopsis from the RETAKE RCT. *Health Technol Assess* 2026;**30**(31);1–64. https://doi.org/10.3310/LAKP6585

Appendix 2 REturn To work After stroKE process evaluation research questions and data sources

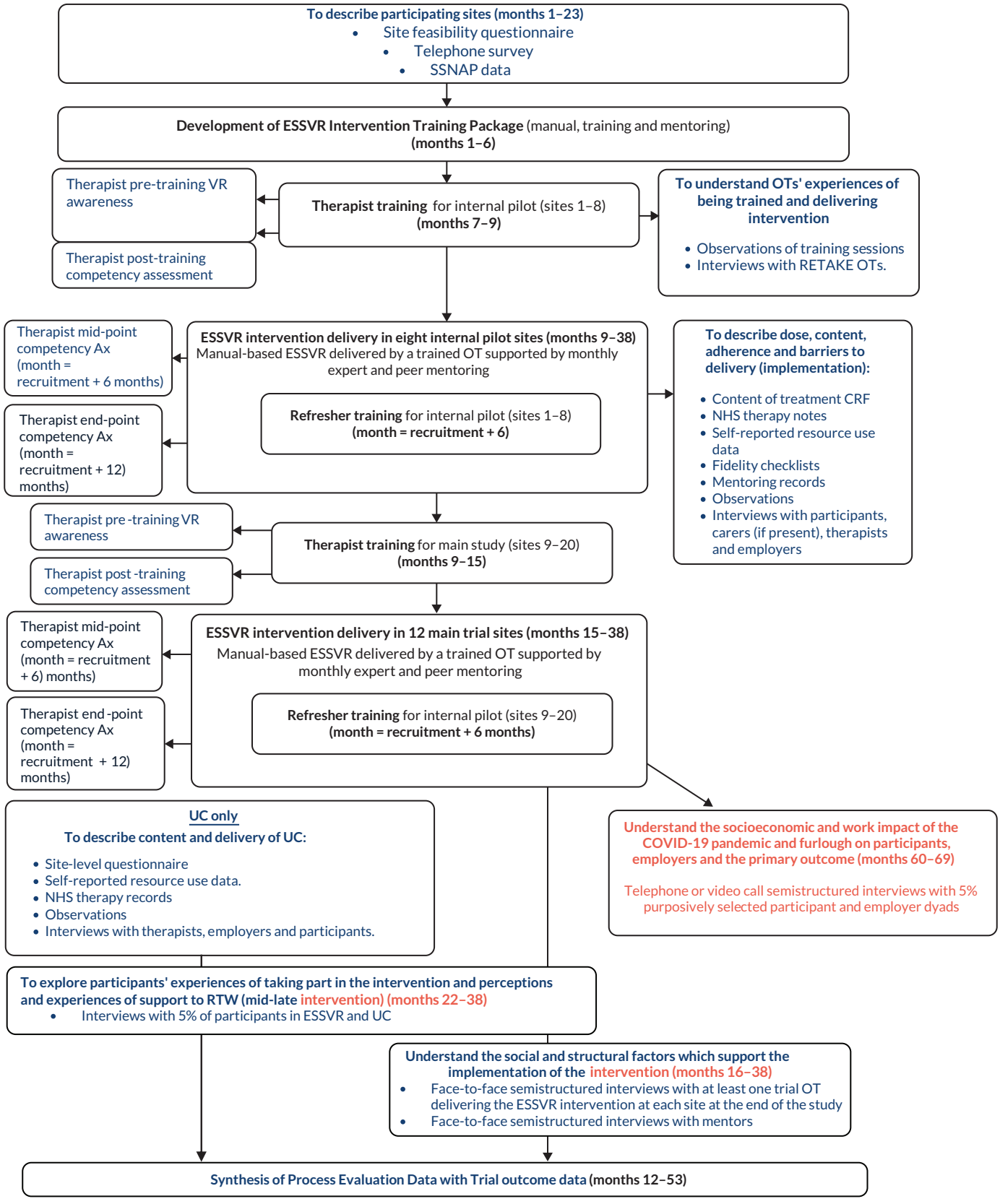
TABLE 8 RETurn to work After stroKE process evaluation research questions and data sources

Aims	Research questions	Data source(s)	Method(s)	Time point
Measure fidelity to the intervention	What is the intervention dose, intensity and duration?	• Intervention content CRFs	Quantitative	Months 3–45
	What is the (reported) content of the ESSVR intervention?	• Intervention content CRFs.	Quantitative and qualitative	Months 3–45
	What is the content of UC?	• NHS therapy records.		
		• Stroke survivor-reported resource use data.		Months 12–45
		• Stroke survivor carer and OT interviews		Months 12–36
	Was the intervention delivered with fidelity?	• Fidelity checklist	Quantitative and qualitative	Months 3–45
	What factors affect implementation fidelity?	• Intervention content CRFs	Quantitative	Months 12–18
	Are RETAKE OTs competent to deliver the ESSVR intervention?	• Mentoring records		Months 1–8 and as new OTs join the trial and 6 and 12 months post training.
		• RETAKE OT interviews		
		• Individual OT performance in assessed vignettes at baseline and 6 months		
		• RETAKE OT case record reviews at 12 months post training		
Understand the social and structural context which may influence intervention implementation and future embedding in practice settings.	What is the context for intervention delivery?	• Site survey at baseline, mid-point and end-of-intervention delivery	Quantitative and qualitative	Months 1, 18 and 36* *later time point for end-of-intervention delivery where sites recruit beyond the COVID-19 extension.
	What services are in place for supporting patients in RTW?	• Site survey at baseline, mid-point and end-of-intervention delivery	Quantitative and qualitative	As above.
	What are the staffing levels at sites?	• Site survey at baseline, mid-point and end-of-intervention delivery	Quantitative and qualitative	As above
	Potential for contamination: Are there proposed or actual VR service developments or changes in practice in place/planned at site?	• Site survey at baseline, mid-point and end-of-intervention delivery	Quantitative and qualitative	As above.
		• NHS staff interviews		
	What are the RETAKE OTs' perceptions of training and mentoring to deliver the intervention?	• Observations at training sessions	Qualitative	Months 1–8 and as new OTs join the trial.

TABLE 8 RETurn to work After stroKE process evaluation research questions and data sources (*continued*)

Aims	Research questions	Data source(s)	Method(s)	Time point
	How do OTs experience delivering the intervention?	• RETAKE OT interviews	Qualitative	Months 12–18
		• Observations of ESSVR sessions		Months 12–18
		• RETAKE OT interviews		Months 12–45
		• Mentoring records		
	What are the social and structural factors supporting or acting as barriers to intervention implementation?	• Observations of UC and ESSVR sessions	Qualitative	Months 1–8
		• RETAKE OT interviews		Months 12–18
		• UC therapist interviews		Months 12–18
		• NHS staff interviews		Months 12–24
		• Mentor interviews		Months 6–8
	How do participants' experience being supported to RTW after stroke?	• Stroke survivor interviews	Qualitative	Months 12–24
		• Carer interviews		Months 12–24
		• Employer interviews		Months 12–24
To understand the impact of the pandemic on stroke survivors' work ability and RTW **support from the perspectives of stroke survivors and employers.**	How do stroke survivors and employers perceive the impact of the pandemic on post-stroke RTW support	• Stroke survivor interviews	Qualitative	Months 12–45
		• Employer interviews		

Appendix 3 Research pathway showing the links between each element of the process evaluation



SSNAP, Sentinel Stroke National Audit Programme.

Appendix 4 Description of the Early Stroke Specialist Vocational Rehabilitation intervention delivered in the REturn To work After stroKE Trial following Template for Intervention Description and Replication

TABLE 9 Description of the ESSVR intervention delivered in the RETAKE trial following Template for Intervention Description and Replication

	Description
Brief Name	Early Stroke Specialist Vocational Rehabilitation (ESSVR)
WHY Describe any rationale, theory, or goal of the elements essential to the intervention.	**Goal and Rationale**The aim of ESSVR was to support stroke survivors to RTW and prevent job loss by reducing the impact of stroke on workability. Drawing on employment law and the Equality Act (2010)[115] to prevent disability discrimination, the OT negotiates 'reasonable adjustments' with employers to modify the stroke survivor's job and accommodate stroke disability. Individually tailored work-related physical and cognitive rehabilitation (strategies to lessen stroke impact, for example fatigue management, activities to prepare the person to RTW and self-management education increase the stroke survivor's ability to work. **The rationale for** ESSVR is described more fully elsewhere[96] The underlying programme theory was based on the following underlying assumptions: • *If* we implement an early 'VR pathway' for stroke, *then* work is seen as a health outcome by stroke rehabilitation teams, and their confidence, knowledge and skills in VR are increased and conflicting advice is prevented. The patient is aware and knows how to (re) access available support; early barriers to RTW are identified, for example environmental (job type), personal. Rehabilitation teams share a philosophy of rehabilitation to support RTW **[Mechanism: Early Intervention, Multidisciplinary Team Working]** • *If* we identify people who are employed at the time of stroke and refer to an OT trained in VR (VR OT) for information/advice/support regarding RTW, *then* this will increase opportunities for RTW and prevent job loss; prevent people falling into service gaps and ensure work needs are met. [**Mechanism: Early Identification of work needs; Identifying Stroke Impact]** • *If we* teach OTs basic skills in VR (how to evaluate jobs and assess work capability, match the injury-related disabilities to job demands; how to communicate and engage with employers, and other employment sector stakeholders, to go into the workplace and how to negotiate reasonable adjustment and a phased RTW), *then* they will have the confidence, knowledge and skills to support stroke survivors in a RTW **[Mechanisms:** VR **Upskilling, colocation; Employer engagement and education, Accommodating stroke disability at work]** • *If the* OT provides early (within 12 weeks of stroke) assessment, education and advice on the impact of stroke and RTW, *then* the impact of the stroke on the job role will be identified and individual goals set to inform a VR plan. Persons requiring psychological support are identified and referred for support, resulting in improved physical and mental health and financial well-being. **[Mechanisms: Identifying Stroke Impact, Early intervention, Early identification of work needs, Vocational goal setting, Timely psychological support]** • *If the* OT delivers individually tailored, case-co-ordinated VR, educates employers about stroke and negotiates a phased RTW and workplace accommodations, and monitors ongoing work ability, *then* the person will be able to cope with work, resulting in reduced sickness absence and sustainable employment. **[Mechanisms: Individual Tailoring; Accommodating stroke disability at work, case-co-ordination, colocation, Employer Engagement and education, Responsiveness: Multidisciplinary Team Working]**
WHAT Materials: **Procedures**: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	**Materials:** **Training** Training comprised 2 days of face-to-face teaching delivered by the RETAKE training team (four OTs experienced in VR and research) followed by 1-day refresher training after 6 months. Training was supported by monthly telephone/online peer mentoring facilitated by an OT experienced in stroke and VR. More details of the training and mentoring are reported in Radford *et al.* 2026 (this publication) and Clarke *et al.* 2024[21] and elsewhere.[11] OTs were given an 'ESSVR Intervention manual' (available on request from the authors) detailing the intervention rationale, objectives, process, content and forms for use in documenting ESSVR delivery. Example RTW plans, graded RTW planning session and work review letters, GP and employer letters, discharge letters and OH reports were also included together with a list of other useful resources (below). The manual was sent to therapists 2 weeks before the training and used to navigate them through the ESSVR intervention process and familiarise them with its contents and resources. during training. Mentors were members of the training team; three were also post-doctoral researchers. The purpose of mentoring was to ensure implementation and fidelity to the intervention process by discussing implementation challenges and sharing best practice. Prior to training, OTs were signposted to papers relating to the feasibility trial and sent a case vignette, requiring written responses to six questions. This enabled the trainers to ascertain the OTs pre-training VR knowledge. The same case study was used to teach the ESSVR process during the training. Details of the training and resources are reported elsewhere.[11,21,25]

continued

TABLE 9 Description of the ESSVR intervention delivered in the RETAKE trial following Template for Intervention Description and Replication (*continued*)

	Description
	Resources included: For OTs • Employment and Support Allowance (ESA) supporting letter and guide to completing ESA (2012). Accessible via www.nawra.org.uk/wordpress/wordpress/wp-content/uploads/2012/03/Completing-the-ESA50.pdf (nawra.org.uk) • Allied Health Professions Fitness for Work Report (RCOT). Accessible via www.rcot.co.uk/practice-resources/standards-and-ethics/ahp-health-and-work-report • AHP (Allied health Professions Federation) Health and Work Report: Guidance for AHP practitioners on the use and completion of the Report. Accessible via www.ahpf.org.uk/files/Guidance-on-completion-of-AHP-Health-and-Work-Report.pdf (ahpf.org.uk) • Graded RTW planning leaflet (RETAKE Trial specific) • Tailored Adjustments Plan (Business Disability Forum, 2020). Accessible via https://businessdisabilityforum.org.uk/knowledge-hub/resources/tailored-adjustments-plan/ Paid access to members only • Work Ability Support Scale (WSS) (Fadyl J, McPherson KM, Schulter P, Turner-Stokes L., 2014) [21]. Accessible via www.kcl.ac.uk/cicelysaunders/resources#WorkabilitySupportScale • WSS Detailed work questionnaire. Accessible via www.kcl.ac.uk/nmpc/assets/rehab/tools-wss-work-questionnaire.pdf • WSS Brief work questionnaire and job-matching, no longer available online • The City of Toronto S Job Demands Analysis and Job Match System (Lucas, 2017). Accessible via; https://silo.tips/download/the-city-of-toronto-s-job-demands-analysis-and-job-match-system • Beginners Guide to Benefits. Accessible via www.turn2us.org.uk/Benefit-guides/Beginner-s-Guide-to-Benefits/Checking-benefit-entitlement • Good work for good health: The difference occupational therapy makes (RCOT, 2019). Accessible via ILSM Work report A4 7pp D7.pdf (rcot.co.uk) For Employers • Employees with Executive Functioning Deficits. Job Accommodation Network. Accessible via https://askjan.org/disabilities/Brain-Injury.cfm • Accommodation and Compliance Series: Employees with Speech-Language Impairment. Job Accommodations Network, (2019). Accessible via https://dysphonia.org/wp-content/uploads/2019/07/JAN-Job-accomadation-suggestions.pdf • Job accommodations for people with stroke. Job Accommodations Network. Accessible via https://askjan.org/disabilities/Stroke.cfm#spy-scroll-heading-0 • A complete guide to stroke for Employers, Stroke Association. Accessible via www.stroke.org.uk/resources/complete-guide-stroke-employers • Information Pack: Work After Stroke – Information for Employers, Different strokes. Accessible via https://differentstrokes.co.uk/wp-content/uploads/2018/10/3.-Work-After-Stroke-Employers-Guide-.pdf For stroke survivors • Information Pack: Work After Stroke – Information for Family & Friends. Different Strokes. Accessible via https://differentstrokes.co.uk/wp-content/uploads/downloads/2.%20Work%20After%20Stroke%20-%20Family%20and%20Friends.pdf • A complete guide to work and stroke. Stroke Association. Accessible via www.stroke.org.uk/sites/default/files/publications/a_complete_guide_to_work_and_stroke.pdf • Driving after a Stoke guide. Stroke Association. Accessible via www.stroke.org.uk/stroke/life-after/driving • Stroke in people of working age. Stroke Association, 2014 (no longer available).

TABLE 9 Description of the ESSVR intervention delivered in the RETAKE trial following Template for Intervention Description and Replication (*continued*)

	Description
	• Tailored Adjustments Plan (Business Disability Forum, 2020). Accessible via https://businessdisabilityforum.org.uk/knowledge-hub/resources/tailored-adjustments-plan/ Paid access to members only **Additional resources provided ad hoc during mentoring** **Advisory services** • ACAS – Advisory, Conciliation and Arbitration Service – provides support in assisting employment disputes including those related to disability management: www.acas.org.uk • Citizens Advice Bureau: www.citizensadvice.org.uk/ • Disability Law Service: https://dls.org.uk/ • Disability Rights UK: http://disabilityrightsuk.org/ • Equality and Human Rights Commission: www.equalityhumanrights.com/ **Occupational health** • Occupational Health Advisory Service – Fit for Work service. No longer available as service has been discontinued by the Department of Work and Pensions. Replaced by Support with employee health and disability. Accessible via www.support-with-employee-health-and-disability.dwp.gov.uk/support-with-employee-health-and-disability • Commercial Occupational Health Provider Association – no longer available • NHS Health at Work: www.nhshealthatwork.co.uk/support-for-business.asp • Society of Occupational Medicine: www.som.org.uk/ • Safe Effective Quality Occupational Health Service: www.seqohs.org/ **Government advice** • Find a job service: www.gov.uk/jobsearch • Jobcentre Plus: www.gov.uk/contact-jobcentre-plus • Specialist employability service: www.gov.uk/government/publications/specialist-employability-support-statistics-information-note/specialist-employability-support-background-information-note • Access to Work: www.gov.uk/access-to-work • Allied Health Professions Fitness to Work Report info: www.ahpf.org.uk/AHP_Advisory_Fitness_for_Work_Report.htm • Fit Note: www.gov.uk/government/collections/fit-note • Statutory sick pay: www.gov.uk/employers-sick-pay • The Employer's Charter Department for Business Innovation and Skills: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/32147/employerscharter.pdf • Touchbase: DWP news about work, working age benefits, pensions and services. Accessible via: www.gov.uk/government/publications/touchbase-dwp-news-about-work-working-age-benefits-and-services **Benefits and debt issues** • Benefits and Work: www.benefitsandwork.co.uk/ • National Debtline: www.nationaldebtline.org/ • Debt Advice Foundation: www.debtadvicefoundation.org/ **Equipment advice:** • Ability Net: www.abilitynet.org.uk/

continued

TABLE 9 Description of the ESSVR intervention delivered in the RETAKE trial following Template for Intervention Description and Replication (*continued*)

	Description
	• Disabled Living Foundation (now called Living made easy): https://livingmadeeasy.org.uk/
	Guidelines:
	• UK Vocational Rehabilitation Association standards of practice: https://vrassociationuk.com/resources/vra-standards-practice/
	• British Society of Rehabilitation Medicine: www.bsrm.org.uk/publications/publications
	• Vocational Assessment and rehabilitation after acquired brain injury (2004)[116]
	• Vocational Assessment and Rehabilitation for People with Long-Term Neurological Conditions: Recommendations for Best Practice (2010)[117]
	• Vocational Rehabilitation: BSRM brief guidance (2021)[118]
	• Health and Safety Executive managing sickness absence and return to work – obsolete now called Managing sick leave and return to work: www.hse.gov.uk/sicknessabsence/
	• British Occupational Health Research Foundation Rehabilitation after Illness or Injury: www.bohrf.org.uk/rehabilitation/
	Career advice/Job searching:
	• Indeed (recruitment company): www.indeed.co.uk
	• Civil Service job search: www.civilservicejobs.service.gov.uk/csr/index.cgi
	• The Guardian Jobs (recruitment company): http://jobs.theguardian.com/
	• NHS Jobs: www.jobs.nhs.uk/
	• CharityJob (third sector/NGO recruitment): www.charityjob.co.uk/
	• What Color Is Your Parachute: A Practical Manual for Job-Hunters & Career-Changers: www.jobhuntersbible.com/
	• Jobs Go Public (public sector recruitment): www.jobsgopublic.com/searches/new
	Vocational rehabilitation/rehabilitation:
	• MS Trust: mstrust.org.uk/search?s=work
	• MS Society: www.mssociety.org.uk/care-and-support/everyday-living/working-and-ms
	• Headway: www.headway.org.uk/about-brain-injury/individuals/practical-issues/returning-to-work-after-brain-injury/
	• Reasonable adjustments, Job Accommodation Network: https://askjan.org/
	• British Association of Supported Employment: http://base-uk.org/
	• Goal Attainment Scaling (GAS) in Rehabilitation: www.kcl.ac.uk/cicelysaunders/resources/toolkits/gas-overview
	Volunteering
	• The National Council for Voluntary Organisations: www.ncvo.org.uk/ncvo-volunteering
	• Do-it role search: www.doit.life/
	Fitness/health information
	• Exercise guides from the NHS: www.nhs.uk/Livewell/fitness/Pages/free-fitness.aspx
	• CEA (UK Cinema Association) card: www.cinemauk.org.uk/key-issues/disability-and-access/cea-card/
	• Local walk for health schemes: www.walkingforhealth.org.uk/walkfinder/ -

TABLE 9 Description of the ESSVR intervention delivered in the RETAKE trial following Template for Intervention Description and Replication (*continued*)

	Description
	Transport and travel • DVLA (driver vehicle licensing authority): www.gov.uk/government/organisations/driver-and-vehicle-licensing-agency • Stroke and driving: www.gov.uk/stroke-and-driving • Assessing fitness to drive: a guide for medical professionals: www.gov.uk/guidance/assessing-fitness-to-drive-a-guide-for-medical-professionals • Bus pass entitlement: www.gov.uk/apply-for-disabled-bus-pass Informed by our literature review, clinical guidelines[2,4,116,117,119] and our earlier studies,[2,8,120,121] ESSVR was designed as a case co-ordination model of individually tailored VR delivered in addition to usual NHS rehabilitation. It involved early intervention and ongoing support for community-dwelling stroke survivors for up to 12 months post randomisation.[2] ESSVR was delivered in four stages (*Figure 5*). The initial three-stage intervention process (early recovery, graded RTW, job retention) is described below and elsewhere.[10] The ideal situation of the OT and ESSVR's relationship with other services depicted is described elsewhere,[2] A fourth stage, 'discharge', was added to the model following fidelity assessment in the RETAKE trial.[25] **Stage one** involved assessment of the impact of the stroke on the stroke survivor, their job, role and responsibilities, and a job demands analysis (OTs were introduced to different tools during training, but none were prescribed). This was followed by goal setting, work preparation including strategies to lessen the impact of stroke (e.g. self-management, fatigue management and preparing the stroke survivor for RTW), work simulation activities (tailored to the person and their job role), and education for stroke survivors, their families and employers. Participants were encouraged to keep workplace communication channels open. **Stage two** involved planning and implementing a phased RTW. This involved negotiating a realistic time frame and possible reasonable adjustments with employers, a worksite visit, and providing information and education to employers about the effects of stroke, its impact on the individual and the job, including how job demands might affect performance/productivity. The OT case-co-ordinated the rehabilitation across all sectors and liaised with NHS health care, employers and other workplace service providers such as OH to reduce overlap and ensure consistency in RTW aims. They liaised directly or indirectly (by letter/e-mail) with employers, where permitted by stroke survivor participants, to recommend workplace adjustments, and provide mediation or advocacy if difficulties arose. **Stage three** took place during the RTW and involved monitoring the RTW through regular reviews. The focus was on sustaining work. The OT (and line manager, if involved) offered feedback on progress/productivity and suggested workplace and role modifications as needed. Monitoring and review continued for up to 12 months according to need and complexity and was gradually withdrawn. Where RTW was unsuccessful, stage 3 also involved considering other work alternatives. Throughout stages 1–3, participants received informal psychological support from OTs. Emerging issues were dealt with flexibly and referrals made for more formal support as required. **Stage four** was the discharge process. The OT communicated in writing with the stroke participant, family and employer, providing information on how to re-access ESSVR (if discharged before 12 months post randomisation), or information on- or referral/signposting to other available support (if discharged at 12 months post randomisation) if required. The intervention was delivered in addition to the participant's usual stroke rehabilitation. This varied depending on local provision and individual participants' needs. The OT liaised with healthcare professionals providing UC to agree roles and ensure VR was provided by the RETAKE OT. RETAKE **intervention delivery summary.** Of 324 participants allocated to the intervention, 309 (95.4%) commenced the intervention with a total 2945 sessions recorded. Across all sessions attended, a median of 3 (IQR 1–4, range 1–14) of a maximum 16 intervention components were delivered in each session (*Figure 6*). **Of stage 1 intervention components,** almost half of all sessions addressed current issues [1275 (45.8%) sessions in 282 (95.3%) participants], while work preparation [1092 (39.3%) sessions in 258 (87.2%) participants], fatigue management [903 (32.5%) sessions in 230 (77.7%) participants, psychological [713 (25.6%) sessions in 195 (65.9%) participants] and physical components [601 (21.6%) sessions in 191 (64.5%) participants] were all addressed in over a fifth of sessions.

continued

TABLE 9 Description of the ESSVR intervention delivered in the RETAKE trial following Template for Intervention Description and Replication (*continued*)

	Description
	Stage 2 intervention components, RTW with and without direct employer contact were delivered in 305 (11.0%) and 739 (26.6%) of sessions in 107 (36.1%) and 204 (68.9%) participants, respectively. Overall, OT contact with the employer took place for 109 (36.8%) participants, a median of 39 days (IQR 21–83, range 3–379) after the first session, and an employer visit took place for 74 (25.0%), a median of 49 days (IQR 28–119, range 9–420) after the first session.
	Stage 3 intervention components, monitoring job retention and job redirection were delivered in 584 (21.0%) and 114 (4.1%) of sessions, in 175 (59.1%) and 45 (15.2%) participants, respectively.
	At stage 4, of those who commenced the intervention, 35 (11.3%) were referred for ongoing rehabilitation at the point of intervention discharge, of whom most were referred to other healthcare services (24, 68.6%), with < 10 participants referred to each of social care services, employer services, or voluntary organisations. Only three participants re-engaged with the intervention after initial discharge and within 12 months of randomisation. Discharge dates indicated that 294 (95.1%) of 309 participants who commenced the intervention were discharged from the intervention.
WHO PROVIDED	The intervention was delivered by qualified HealthCare Professions Council (HCPC) registered OTs, recruited from 16 sites and 21 NHS Trusts in England and Wales. OTs were embedded in a range of services, including acute, community and the independent sector. They were recruited if they had experience of working with people with stroke and/or other neurological conditions and community rehabilitation experience. Some had prior VR experience.
For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	Sixty OTs were trained (see Radford *et al.*, Clarke *et al.* and Craven)[10,11,21] between 19.2.18 and 10.11.21 in 17 separate 2-day and 7 one-day refresher training sessions; data were available for 58; 49 were involved in ESSVR delivery with 48 delivering the majority of sessions for at least one RETAKE participant (median 6 participants, up to a maximum 16 participants). This included one mentor who stepped in when an OT was redeployed during the pandemic. Demographic and other characteristics of the OTs involved in ESSVR delivery can be found in Radford *et al.*[2]
	While intended to be in groups of 4–6 OTs, mentoring for the *N* = 48 main OTs, sessions comprised a median of two (range 1–3) OTs to mentor and the median number of sessions attended was 13 (IQR 8–20).
HOW	ESSVR was delivered face-to-face or via telerehabilitation (videoconference or phone call) on a 1-to-1 basis, with additional time spent in liaison (letters, phone and videoconference calls) with patients, employers, family or other stakeholders. It was intended that most Stage 3 progress monitoring was by telephone.
WHERE	Of 324 participants allocated to ESSVR, 309 (95.4%) commenced the intervention. Of those with available data (*n* = 299), most intervention sessions were delivered via telerehabilitation (*n* = 1414, 51.7% sessions for *n* = 243, 81.3% participants), in participants' homes (*n* = 982, 35.9% sessions for *n* = 246, 82.3% participants) or workplaces (*n* = 175, 6.4% sessions for *n* = 67, 22.4% participants). Other locations included hospital (*n* = 112, 4.1% sessions for *n* = 52, 17.4% participants) and community settings (*n* = 53, 1.9% sessions for *n* = 31, 10.4% participants).
WHEN and HOW MUCH.	The intervention commenced a median 38 days (IQR 23–56, range 6–216) post stroke [median 9 days post randomisation (range 0–198, IQR 6–13)] and continued for up to 12 months following randomisation. Reasons for delayed first visit included delayed therapist training, unable to make contact initially, RETAKE e-mail errors (*n* = 2), neurosurgery (*n* = 1), OT annual leave and large RETAKE caseload.
	Duration and frequency of sessions were determined by individual participant's needs and the OT. Participants attended a median of seven intervention sessions (IQR 4–12, range 0–37), with discharge from ESSVR at a median 10.3 months (IQR 5.5–12.0, range 0–15.4) post randomisation. The number and frequency of sessions and intervention duration for all participants are shown in *Figure 7*.
	In 189 participants reported to have RTW during intervention delivery, a median of 4 sessions (IQR 2–17, range 1–25) were attended prior to RTW of a total median 9 (IQR 6–15, range 1–37).
	A detailed summary of the intervention received can be found in Radford *et al.* 2024.[2]
TAILORING	The ESSVR intervention was tailored in duration and frequency according to individual need over 12 months. This is illustrated by the wide-ranging number of sessions, components delivered and time per participant (see supplementary File 10, *Table 5* and *6* in Radford *et al.*[2] and *Figure 2* and *3*) and by referrals made for other services in 35 cases (12.4%), including healthcare (26 cases), social care in 3 cases, ongoing employment services (4), voluntary organisations (8) or other (3).

TABLE 9 Description of the ESSVR intervention delivered in the RETAKE trial following Template for Intervention Description and Replication (*continued*)

	Description
If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when and how.	In the fidelity analysis, we found that stroke-, family-, work- and socioeconomic-related factors impacted whether certain individual ESSVR components could be delivered, requiring RETAKE OTs to tailor and individualise ESSVR delivery.[25] Qualitative data suggested very little differences between intervention delivery across sites or the need for site-specific tailoring.
MODIFICATIONS	During the COVID-19 pandemic, ESSVR was adapted for online delivery and additional training in how to deliver ESSVR remotely was offered to the OTs. However, only 11/17 OTs involved in the trial following the pandemic-related recruitment pause attended this training. In some sites, OTs continued to visit participants at home wearing personal protective equipment (PPE) in accordance with local NHS Trust protocols. There were 1100 sessions (65.5%) delivered face-to-face pre COVID, with the remaining 579 (34.5%) sessions pre COVID delivered by telephone or online. During the furlough period, there was a shift to non-face-to-face sessions, with 585 (82.6%) sessions delivered by telephone or online during this time period and only 123 (17.4%) delivered face-to-face. Post-furlough period, once the lockdown restrictions had eased, showed a slightly lower proportion of non-face-to-face sessions (71.6% *n* = 250), with 99 (29.3%) sessions delivered face-to-face.
HOW WELL	The intervention was reported as completed for 172 (56%), and intervention compliance achieved for 244 (75.3%) participants. Of 135 (44%) where the intervention was reported as not completed, 44 (32.6%) had reached the full 12 months maximum input, 22 (16.3%) had a mutually agreed ending of the intervention and 6 (4.4%) had a therapist-led discontinuation and were classed as compliant, while 18 (13.3%) withdrew from the intervention, 24 (17.8%) became uncontactable, 12 (8.9%) did not commence, and the reason was other or unknown for 9 (6.6%) participants, all of whom were classed as non-compliant. Participant adherence was good. There was little difference between the number of sessions offered [mean 9.6 (SD 7.46), range 0–39] and attended [mean 9.0 (SD 7.16), range 0–37]; however, 24 (7.8%) participants who commenced the intervention became uncontactable, 18 (5.8%) withdrew, 9 (2.9%) did not attend all planned sessions for other or missing reasons, and 17 (5.5%) were missing all intervention data. A total of 244 (75.3%) participants were therefore classed as compliant and 80 (24.7%) as non-compliant. The average duration based on the time from randomisation to last session was a median 8 months (IQR 3.4–11.4, range 0–17). It started early, as intended, a median 38 days (IQR 23–56, range 6–139) post stroke and continued for up to 12 months following randomisation. OT contact with employers only occurred for 119 (40%) participants and an employer visit took place for 74 (25.0%) participants. Twenty-six per cent of participants did not consent for OT contact with their employer and 10.2% preferred to self-manage their RTW (*Table 10*), making it difficult for OTs to mediate timing of the participant's RTW, employment role or workplace adjustments, or monitor RTW[21]
Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	ESSVR was delivered with fidelity; 309 (95%) participants commenced the intervention as planned and had at least one session. Reasons for the intervention not commencing were participant withdrawal (3), unable to contact (3), other or missing reasons. Fidelity assessment data indicate that components involving other stakeholders (e.g. the stroke survivors' family, other healthcare providers, and employers) were delivered with lower rates of fidelity than those centred on the stroke survivor. Fidelity results are reported more fully elsewhere.[25] Interview data suggest contextual factors affecting intervention delivery were self-employment (in some cases, participants returned to work very early due to financial pressures and/or to ensure continuation of their business, either prior to OT involvement or against OT advice) and conflicting advice between employment-based OH services, who act on behalf of the employer and the advice of the OT. Other factors included more severe stroke and participants enduring including mobility, cognitive or communication impairments problems that could not be accommodated in the workplace.[21,26] At an organisational level, problems including poor inter-organisational communication and increased travel time and costs arose where the OTs were employed by a different NHS Trust to that responsible for providing UC. Having more than one OT involved in ESSVR provision facilitated opportunities for peer support and workload sharing.[21,26] Further details pertaining to the intervention delivery are reported elsewhere.[2]

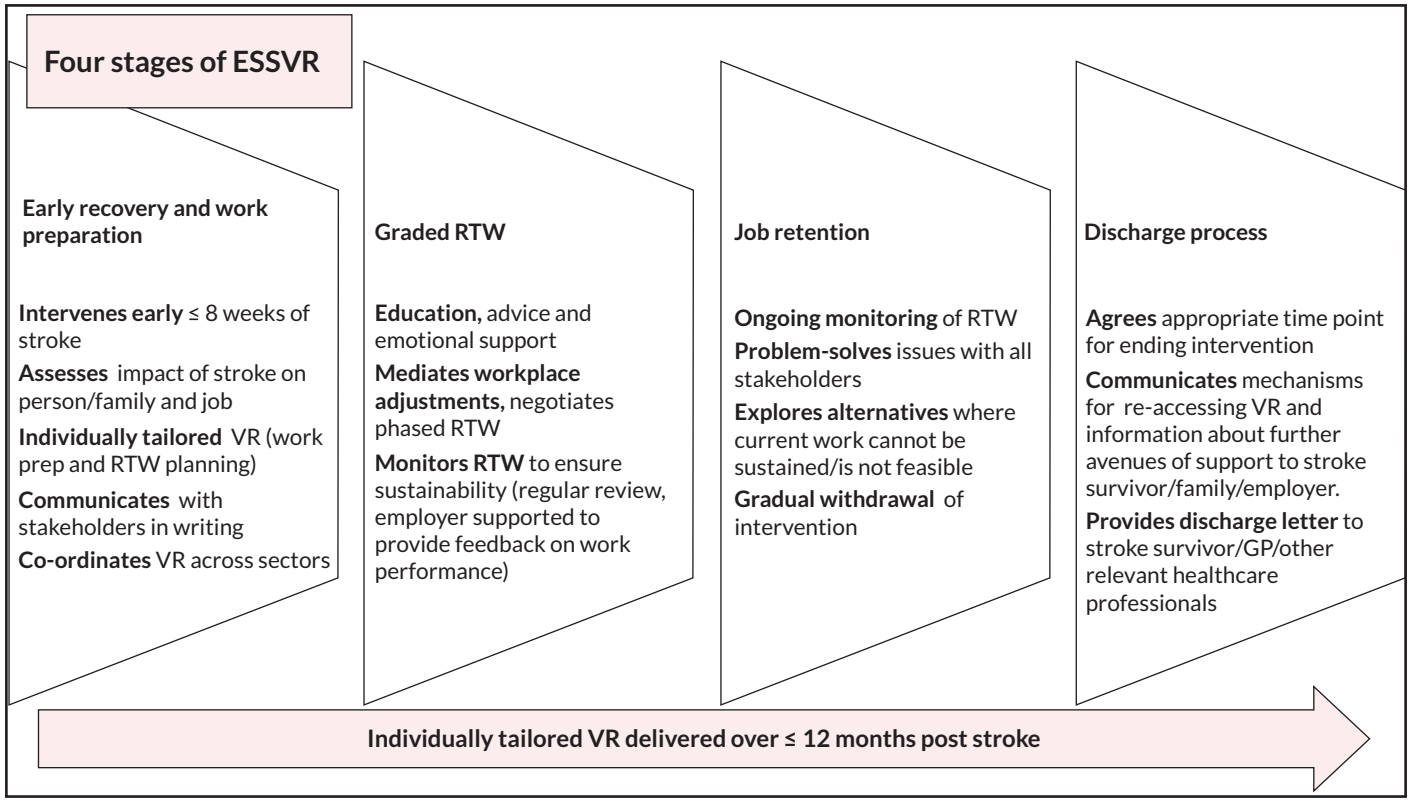


FIGURE 5 The four stages of the ESSVR intervention process.

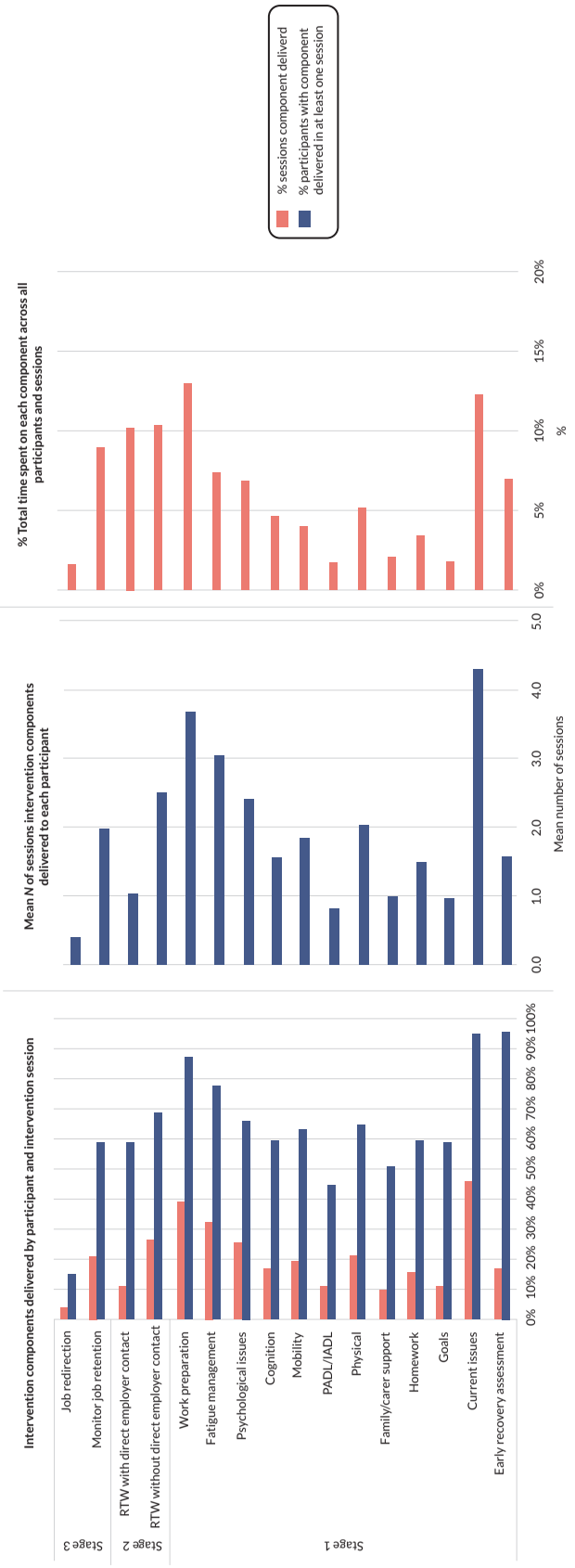


FIGURE 6 Intervention component delivery summary bar chart. IADL, instrumental activities of daily living; PADL, personal activities of daily living.

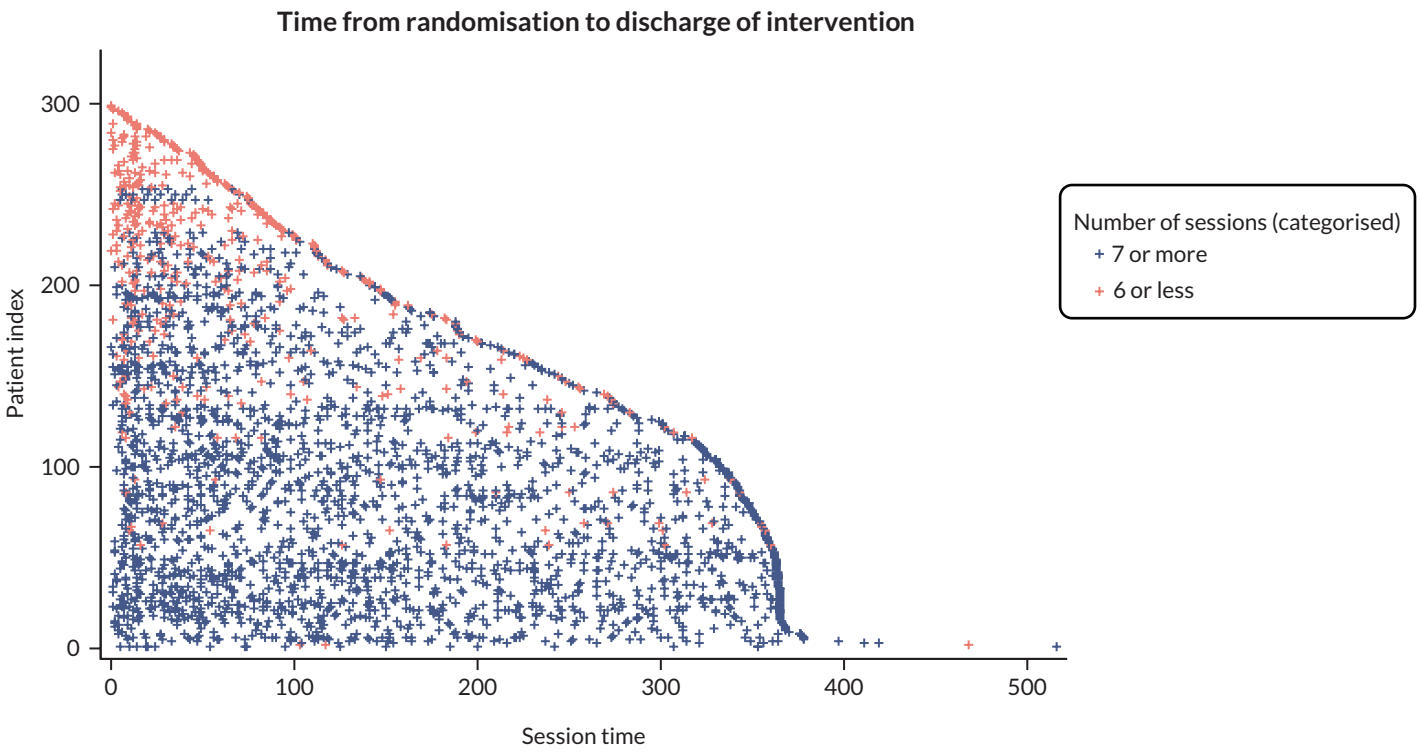


FIGURE 7 Duration of intervention (days).

TABLE 10 Employer engagement (of those commencing intervention)

	Total (*n* = 309)
Participant consented to contact employer	
Yes	119 (40.3%)
No[a]	79 (26.8%)
N/A – no employer	10 (3.4%)
N/A – self-employed	57 (19.3%)
N/A – employer liaison self-managed by participant	30 (10.2%)
Missing	15
Contact with employer took place	
Yes	109 (36.8%)
No	187 (63.2%)
Visit with employer took place	
Yes	74 (25.0%)
No	222 (75.0%)
Time from first session to first contact with employer (days)	
Mean (SD)	68.0 (72.63)
Median (range)	39.0 (3.0–379.0)
IQR	21.0–83.0
N	109

TABLE 10 Employer engagement (of those commencing intervention) (*continued*)

	Total (*n* = 309)
Time from first session to first visit with employer (days)	
Mean (SD)	85.0 (84.92)
Median (range)	49.0 (9.0–420.0)
IQR	28.0–119.0
N	74

a No reasons for lack of contact were provided. CRF options were: participant furloughed due to COVID-19, participant has been made redundant due to COVID-19, employer is currently closed due to COVID-19. This question was introduced post COVID-19, and no other reasons were provided.

Appendix 5 'You said, we did' summary of patient and public involvement contributions

TABLE 11 'You said, we did' summary of PPI contributions

Inclusive opportunities 'Offer public involvement opportunities that are accessible and that reach people and groups according to research needs'		
We asked	**You said**	**We did**
For a diverse group of people from around the UK with different types of strokes, a range of stroke-related impairments and experience of working in different sectors and roles, including white- and blue-collar work. We also wanted to include the perspectives of people who had/had not returned to work.	Yes – we are seven stroke/acquired brain injury survivors from London, Portsmouth, Derbyshire, Northern Ireland. Three of us are women. Six are White and one is Black. We have a range of stroke-related difficulties, resulting from communication, mobility and cognitive impairments. One of us is a wheelchair user. Four of us returned to work after stroke, two attempted unsuccessfully to RTW. Prior to stroke we worked in a variety of private, public and charitable sector roles, including white (medical, architect, solicitor, academic professor) and skilled (IT consultant, market research) and semi-skilled blue-collar (lorry driver, publican) roles. One of us was self-employed.	We agreed an easily accessible place to meet pre-COVID that was wheelchair accessible. The group met at an accessible venue in London. Met at midday to avoid travelling at rush hour. Paid travel + attendance expenses, provided lunch. Provided help with participating in virtual meetings during and after the COVID-19 pandemic.
For people with stroke and/or acquired brain injury	We are seven representatives with different experiences (length of time since onset and severity) of stroke/acquired brain injury	We involved people who were mobile, those with mobility problems, including one wheelchair user, two people with aphasia, people who experience fatigue, executive problems and those with post-stroke comorbidity, for example mood problems, epilepsy
For people who experience stroke while working	Between us, there is an IT expert, an architect, medical consultant, solicitor, publican, self-employed marketing specialist.	We involved people with a variety of post-stroke work experiences, that is, unable to RTW, those who lost their job(s), found new work, remained in work, returned to work and then had to stop work, people who were/are job seeking.

continued

TABLE 11 'You said, we did' summary of PPI contributions (*continued*)

We asked	You said	We did
Working together 'Working together in a way that values all contributions, and that builds and sustains mutually respectful and productive relationships'		
Individuals to contribute as co-applicants to the study, be on the Trial Management Group, the Trial Steering Committee and the PPI group	It would be helpful if we could meet together, rather than be involved in different aspects of the study – to share our thoughts and support each other. Some PPI members were involved in designing and planning the trial from the outset.	Budgeted for and arranged a PPI group to be held 2x yearly throughout the study.
For case studies to be used in the competency assessments for the OTs we trained to deliver the intervention.	You can use us as case examples. We will share our own stories.	We used these 'case examples' when designing the OT competency assessments.
For advice as the recruitment team were hesitant about approaching participants with severe stroke and talking about work.	Work would be on participants' minds. PPI members said that they would have been upset not to be asked to be part of the study. Professionals cannot presume they know what is best for people.	We created crib sheets for how to approach and explain the study to people with severe stroke and top tips for people involved in recruitment. We asked them to give everyone a chance to participate, irrespective of stroke severity.
Help with writing, presenting and accepting the PPI abstract prize at the UK Stroke Forum 2019	Yes. A member of the PPI attended the Stroke Forum to receive the first prize	We won first prize in the UKSF Patient, Carer and Public category for our abstract, 'Patient, Carer, Public Involvement (PCPI) in the RETurn to work After stroKE (RETAKE) Trial' UK Stroke Forum December 2019.
We asked for input into commenting about the findings + writing up + ideas for future research	We are very willing to comment as and when we can	We presented emerging findings to PPI members at PPI, and TMG meetings and asked for feedback. We circulated abstracts, posters and papers, invited coauthorship and asked for feedback in different ways.
Support and learning 'Offer and promote support and learning opportunities that build confidence and skills for public involvement in research'		
For help with deciding the primary outcome.	A minimum of 2 hours of work per week would be a meaningful outcome for participants in the study.	We agreed this as the primary outcome for the study.
For help with deciding what constituted volunteering as this was an inclusion criterion for the study and was causing confusion for recruiters.	You sent us your views, many of which were based on your personal experiences of volunteering and running volunteer services.	This helped us define clearly what we classed as volunteering as inclusion criteria.
Did the logic model make sense?	Yes, but added suggestions to the wording to make it more easily understood.	Produced a lay version of the logic model
Comments on abstracts produced for UKSF, WFNR, OPYRSIS	You did not know what a poster was.	We shared examples and you gave feedback on all posters and outputs.
Communications 'Use plain language for well-timed and relevant communications, as part of involvement plans and activities'		
For opinions on all participant-facing information, including the questionnaire.	The questionnaire was too long – shorten and simplify it. Don't use terms such as mild, moderate or severe stroke.	We shortened and simplified the questionnaire and changed the vocabulary
You to test our online questionnaire.	Yes, of course. It works.	Rolled out the online questionnaire to RETAKE participants.

TABLE 11 'You said, we did' summary of PPI contributions (*continued*)

	We need aphasia-friendly recruitment materials.	We produced aphasia-friendly recruitment materials.
	The lay public need to know about the study. It needs to be shared on social media and information sent to the Stroke Association, Different Strokes, Headway and OTs working in stroke rehabilitation	We produced a quarterly newsletter and distributed it widely as suggested.
For help with sending e-mails to OTs to help with recruitment in last month, participants who have not responded at 12 months and for those who have never responded.	Yes, and produced wording for e-mails and simplified letters.	Sent e-mails from the PPI group directly to the RETAKE OTs saying how useful PPI members would have found the RETAKE intervention. Simplified letters for non-responding participants.
Impact 'Seek improvement by identifying and sharing the difference that public involvement makes to research'		
We asked	**You said**	**We did**
	Participants should be given longer than 4 weeks to decide to be in the study	We changed our criteria so participants could have up to 8 weeks to decide to participate in the study
	You wanted participants to be able to self-refer to the OTs after discharge up to 12 months post randomisation.	We incorporated this into the study design.
For help with increasing follow-up response rates	We needed simple information leaflets to help participants understand where they were in their RETAKE journey.	• Produced some instructional information to send with the questionnaires
	• An opportunity to complete the questionnaire by phone + have a pre-specified and recognised phone number	• Increased our capacity to phone participants
	• A short response to the phone call of essential information	• Identified the key questions we want answered
	• Send out a participant newsletter	• Obtained a specific RETAKE phone + sent newsletter with phone number on it and reiterated importance of returning questionnaires and alerted people to the fact that they would be phoned
For suggestions in securing the ETCs	You wrote to the NIHR and NHS leads and representatives and key decision-makers to tell them about the impact of the ETC model on this and other similar rehabilitation trials.	We said thank you as this was helpful and greatly helped with sorting out this issue. A revised model of ETC payments was introduced, which has helped in a subsequent study.
Help with fighting for an extension to the study due to the disruption caused by the COVID-19 pandemic.	A PPI member wrote a letter of support; others commented on it or endorsed the comments.	Sent the letter in support of our variation to contract request and obtained the additional funding.
Governance 'Involve the public in research management, regulation, leadership and decision making'		
We asked	**You said**	**We did**
That you freely express your opinions and respect others' opinions	Do not worry – we will!	We aimed to make being part of the PPI group and the meetings a place where members felt respected, where everyone opinions were valued and acted upon. All members had the e-mail and the phone number of a research team member to contact (JP) if needed.

continued

TABLE 11 'You said, we did' summary of PPI contributions (*continued*)

	One year is not long enough for the intervention	We trained the RETAKE OTs to list unmet needs when they discharge participants so that we can better understand the intervention and which and whose needs remain unmet.
For help for another researcher (overseas collaborator) for her study on aphasia and RTW	Yes, of course we will help	Two PPI members helped with this
		Used what we learnt from this group to influence how to involve PPI members in future research
For comments regarding the RETAKE webpage	Use different wording, change the font to Arial, Geneva or Tahoma and increased font size.	These comments will be incorporated into the updated website design
Miscellaneous – ideas not covered by the six standards		
We asked	**You said**	**We did**
	We need a big conference for the participants and OTs to disseminate the results as they will not be able to access journals and so on	We had not initially planned or budgeted for that but think it is an excellent idea so have set aside some money to do this
	Talk about the study at the Stroke Assembly, as that is for lay people as well as the UK Stroke Forum Conference, which is largely for professionals	We have not done that yet but hope to that when we have some findings to present
	We want a follow-up study as this intervention has lifelong effects	Unfortunately, we do not have permission to contact participants after the study has ended but this is a great suggestion.

Appendix 6 Publications, conference papers, seminars and so on resulting from this study

Papers under review

Radford KA, Grant MI, Holmes JA, Phillips J, Powers K, Chambers RL, *et al*. Development and description of the Early Stroke Specialist Vocational Rehabilitation (ESSVR) intervention delivered in the RETurn to work After stroKE (RETAKE) Trial. *Health Technol Assess* 2026; in press.

Trusson D, Powers K, Radford K, Bowen A, Craven K, Farrin A, *et al*. Exploring stroke survivor and employer experiences of return-to-work support within the context of the COVID-19 pandemic. *Front Sociol* 2026; under review.

Powers K, das Nair R, Farrin A, De Dios Perez B, Radford K. Do therapist attributes impact patient outcomes within studies of complex rehabilitation interventions? A systematic review. Submitted to *Phys Ther Rehabil J*.

Powers K, das Nair R, Farrin A, Radford K. Assessing fidelity to Early Stroke Specialist Vocational Rehabilitation. Submitted to *Trials*.

Papers Published

2025

Trusson D, Powers K, Radford K, Bowen A, Craven K, Holmes J, *et al*., On behalf of the RETAKE Research Group. Experiences of support to return to work: longitudinal case-studies from the RETurn to work After stroKE (RETAKE) trial [published online ahead of print March 26 2025]. *Health Technol Assess* 2025. https://doi.org/10.3310/WRKS9661

Pyne S, Sach TH, Cameron R, Risebro H, Wright-Hughes A, Thompson E, *et al*.; RETAKE research group. Cost consequences analysis of early vocational rehabilitation compared with usual care for stroke survivors. *Clin Rehabil* 2025;**39**:161–73. https://doi.org/10.1177/02692155241299372

2024

Thesis

Powers KE. *Exploring the Impact of Individual-Level Attributes on Fidelity and Return-to-Work Outcomes in a*

Complex Rehabilitation Trial. Doctoral Thesis, University of Nottingham 2024.

Radford KA, Wright-Hughes A, Clarke D, Phillips J, Holmes JA, Powers K, *et al.*, On behalf of the RETAKE Research group†. Effectiveness of early vocational rehabilitation versus usual care to support RETurn to work After stroKE (RETAKE): a pragmatic, parallel arm multi-centre, randomised-controlled trial). *Int J Stroke* 2024. https://doi.org/10.1177/17474930241306693.[47]

Clarke DJ, Powers K, Trusson D, Craven K, Phillips J, Holmes J, *et al.* The RETurn to work After stroKE (RETAKE) trial: findings from a mixed-methods process evaluation of the Early Stroke Specialist Vocational Rehabilitation (ESSVR) intervention. *PLOS ONE* 2024;**19**:e0311101. https://doi.org/10.1371/journal.pone.0311101.

De Dios Pérez B, Merchan J, Powers K, Craven K, Holmes J, Phillips J, et al. How does Mentoring Occupational Therapists Improve Intervention Fidelity in a randomised controlled trial? A realist evaluation. *BMC Med Res Methodol* 2024;**24**:142. https://doi.org/10.1186/s12874-024-02269-4

2023

Powers KE, das Nair R, Phillips J, Farrin A, Radford KA. Exploring the Association between Individual-Level Attributes and Fidelity to a Vocational Rehabilitation Intervention within a Randomised Controlled Trial. *Int J Environ Res Public Health* 2023;**20**:4694. https://doi.org/10.3390/ijerph20064694

2022

Powers K, Clarke S, Phillips J, Clarke S, Cripps R, Holmes JA, *et al.* Developing an implementation fidelity checklist for a vocational rehabilitation intervention. *Pilot Feasibility Stud* 2022;**8**:234. https://doi.org/10.1186/s40814-022-01194-x

Radford KA, McKevitt C, Clarke S, Powers K, Phillips J, Craven K, *et al.* RETurn to work After stroKE (RETAKE) Trial: protocol for a mixed-methods process evaluation using normalisation process theory. *BMJ Open* 2022;**12**:e053111. https://doi.org/10.1136/bmjopen-2021-053111

2021

Craven K, Holmes J, Powers K, Clarke S, Cripps RL, Lindley R, *et al.* Embedding mentoring to support trial processes and implementation fidelity in a randomised controlled trial of vocational rehabilitation for stroke survivors. *BMC Med Res Methodol* 2021;**21**:203. https://doi.org/10.1186/s12874-021-01382-y

2020

Radford KA, Craven K, McLellan V, Sach TH, Brindle R, Holloway I, *et al.* An individually randomised controlled multi-centre pragmatic trial with embedded economic and process evaluations of early vocational rehabilitation compared with usual care for stroke survivors: study protocol for the RETurn to work After stroKE (RETAKE) trial. *Trials* 2020;**21**:1010. https://doi.org/10.1186/s13063-020-04883-1

Abstracts

2024

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Appendix 7 Employer Engagement – Top Tips for Occupational Therapists

1. Consent from the participant

a. **Be confident** in explaining your role and experience in liaising with employers.
b. Highlight that employers value your intervention and why.
c. Highlight the importance of the **employer understanding** their health condition so that they can support and adjust work as needed.
d. Provide **reassurance** that you will never share information with the employer that the participant has not agreed to or seen first.
e. Remind them of the **Equality Act.**

2. Communication with the employer

a. Discuss the pros and cons of you versus the participant contacting the employer and arranging visits.
b. **Put all communication in writing** – use e-mail to summarise conversations/meetings.
c. If visiting in person, always attend with the participant (employee).
d. Be the person who takes control of the communication, if possible, for example, sending summaries of meetings.

e. Be proactive and share regular updates before they are asked for.
f. Always smile and always thank the employer for their time and considerations.

3. Helpful phrases

a. My role includes liaising with (participant), their medical team/treating professionals and their employer to plan a suitable return to work, to monitor their return and provide ongoing advice as needed.
b. **Thank you** for your continued support.
c. If you have any **queries or concerns**, please let me know.
d. (Participant) is **determined** to get back to work and I am supporting them to **achieve** this.
e. (Participant) is eager to return in the new year, but timings and plans for a phased return to work would be good to discuss with yourself prior to this to **ensure that it is successful**.
f. I will be supporting (participant) in their recovery and their aim in getting back to work as soon as possible.
g. I look forward **to working with you both** as needed.