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The RETurn to work After stroKE (RETAKE) Trial: protocol for a mixed-methods process evaluation using normalisation process theory

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2 3	1	TITI F
4 5	1	
6 7 8	2	The RETurn to work After stroKE (RETAKE) Trial: protocol for a mixed-methods
9 10	3	process evaluation using normalisation process theory
11 12 13	4	
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44 45	17	references)
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19 ABSTRACT

Objectives

This mixed-method process evaluation underpinned by Normalisation Process Theory (NPT) aims to measure fidelity to the intervention, understand the social and structural context in which the intervention is delivered, and to identify barriers and facilitators to intervention implementation.

25 Setting

Return to Work after Stroke (RETAKE) is a multi-centre individual patient
randomised controlled trial to determine whether Early Stroke Specialist Vocational
Rehabilitation (ESSVR) plus usual care is a clinically and cost-effective therapy to
help people return to work after stroke, when compared with usual care alone. This
protocol paper describes the embedded process evaluation.

31 Partic

Participants and outcome measures

Intervention training for therapists will be observed and use of remote mentor support reviewed through documentary analysis. Fidelity will be assessed through participant questionnaires and analysis of therapy records, examining frequency, length and content of ESSVR sessions. Therapists' attitudes towards evidence-based practice, their competency to deliver the intervention and identification of potential sources of contamination will also be evaluated. Longitudinal case studies incorporating non-participant observations will be conducted with a proportion of intervention and usual care participants. Semi-structured interviews will be completed with stroke survivors, carers, occupational therapists, mentors, service managers and employers. Analysis of qualitative data will draw on thematic and

3 4	42	Framework approaches. Analysis of quantitative data focused on intervention fidelity
5 6 7	43	will include regression models and descriptive statistics.
8 9 10	44	Conclusions
11 12 13	45	Large trials of complex rehabilitation interventions often lack empirical data needed
14 15	46	to provide context for interpreting trial outcomes. Embedded process evaluations are
16 17	47	vital to understanding factors impacting on, and potentially influencing, trial results.
18 19 20	48	The process evaluation will also identify professional and organisational implications
20 21 22	49	of embedding and sustaining an ESSVR intervention in post-stroke rehabilitation
23 24 25	50	services.
26 27 28	51	Trial registration
29 30	52	Registration number: ISRCTN: 12464275
31 32	53	
33 34 35 36	54	
37 38 30	55	KEYWORDS
40 41	56	Return to work, stroke, vocational rehabilitation, occupational therapy, complex
42 43	57	intervention, process evaluation, randomised controlled trial, mixed-methods,
44 45 46	58	qualitative, Normalisation Process Theory, Consolidated Framework for
47 48	59	Implementation Fidelity
49 50 51	60	
52 53 54	61	STRENGTHS AND LIMITATIONS OF THIS STUDY
55 56 57	62	A mixed-methods theory-driven process evaluation will generate detailed
57 58 59 60	63	findings to assist in interpreting the results of a pragmatic, multi-centre

Page 4 of 38

BMJ Open

64	individual patient randomised controlled trial of a complex vocational
65	rehabilitation intervention, which crosses the work/health divide.
66	This is one of the most comprehensive multi-site, multi-component, multi-
67	stakeholder perspective process evaluations embedded in a stroke
68	rehabilitation trial, involving detailed assessment of implementation fidelity,
69	therapist competency to deliver the trial intervention, contamination logging
70	and exploration of social and structural influences on intervention provision in
71	post-stroke rehabilitation services.
72	 Longitudinal case studies with intervention and usual care will capture
73	participant experiences of providing and experiencing the intervention
74	including those of employers.
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70	BACKGROUND
70	BACKGROUND
79	Approximately 100,000 people in the UK suffer from a stroke every year,[1] and
80	around 1 in 4 are of working age.[2] Returning to work after a stroke is a major goal
81	for stroke survivors, contributing to social identity, emotional and financial wellbeing,
82	and conferring a sense of purpose and has benefits for the individual, the individual's
83	family and the economy.[3] Despite this, only half of working age stroke survivors
84	make a successful return to meaningful work, and they are two to three times more
85	likely to be unemployed eight years after their stroke than the general population.[1]
86	Although impairments in the stroke survivor's physical, cognitive and communication
87	abilities can affect this, [4, 5] social and environmental factors such as personal and

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employer beliefs and attitudes, job type and organisation size and the benefits
system also play an important part.[6, 7]

Vocational rehabilitation (VR) is defined as whatever helps someone with a health
problem to return to, or remain in, work and includes both work *and* work-related
education.[8] It involves helping people find work, helping those who are in work but
having difficulty, as well as supporting career progression in spite of illness or
disability. The primary aim is to optimise work participation.[9] Existing research
suggests that VR may help stroke survivors return to their previous job or find new
work,[10, 11] however trials to date involve small samples in non-UK settings.

RETAKE is a multi-centre individual patient randomised controlled trial (RCT) which 99 aims to determine the clinical and cost-effectiveness of an Early Stroke Specialist 100 101 Vocational Rehabilitation (ESSVR) intervention in addition to usual NHS rehabilitation on stroke survivors' return to work at 12 months post-randomisation, 102 compared to NHS rehabilitation alone.[12] Acceptability and utility were assessed in 103 104 a feasibility trial.[13] ESSVR combines conventional occupational therapy (OT) with case coordination and is intended for delivery in the community as often as required 105 by individuals, as determined by a stroke specialist OT with additional VR training. 106 ESSVR includes the following: (a) assessing stroke impact on the person and their 107 job; (b) educating individuals, employers, and families about stroke impact on work. 108 109 and strategies to lessen impact (e.g. memory aids, fatigue management); (c) work preparation, including opportunities to practice work skills; and (d) liaison with 110 employers to plan and monitor a phased return to work (RTW). 111 112

Page 6 of 38

Failure to implement evidence-based stroke rehabilitation interventions in clinical practice may result in unnecessary suffering and disability.[14, 15] Trialists must consider future implementation in the real world when designing clinical trials, paying particular attention to the context for intervention delivery and factors likely to influence its uptake and use.[16] This is especially true for trials of complex rehabilitation interventions, which comprise multiple interacting components, and target a number of different organisational levels, making them particularly challenging to implement. An embedded process evaluation provides for an in-depth exploration of factors influencing the implementation of complex interventions. The Medical Research Council (MRC) argue for a systematic approach to designing and conducting process evaluations, drawing on clear descriptions of intervention theory and the identification of key process guestions.[17] Mixed-method approaches to process evaluation are increasingly common and consistent with the MRC framework's emphasis on exploring and understanding the important relationship between context, mechanisms and implementation. Theory driven process evaluations are recommended alongside complex intervention trials to measure what is delivered. These measurements include fidelity (whether the intervention was delivered as intended), dose (the quantity of intervention implemented), and "reach" of interventions to understand how the intended audience interacts with the intervention.[17] Alongside a focus on fidelity, in-depth qualitative exploration of participants' experiences of an intervention, and of the social and structural context in which an intervention is provided, are essential elements of process evaluation of complex interventions. This ensures any adaptations made to tailor intervention to the individual and/or differing contexts, which might undermine fidelity can be

Page 7 of 38

1 2

3 4	138	evaluated. Understanding and reporting how the intervention (including training and
5 6	139	support, communication and management structures) is delivered is important for
7 8 9	140	replication in clinical practice.[17] Such evaluation aims to reduce the chance of
10 11	141	discounting effective interventions (Type II error) or erroneously attributing outcomes
12 13	142	to treatment effectiveness, when interventions are not delivered as intended (Type III
14 15	143	Errors).[18 - 21] The approach is designed to improve trial design and knowledge
16 17 18	144	translation interventions enhancing clinical implementation and reducing research
19 20	145	waste.[22, 23]
21 22	146	
23 24 25	147	This paper reports the protocol for the process evaluation embedded in the RETAKE
26 27	148	trial.
28 29	149	
30 31 32	150	
33 34 35 36	151	AIMS AND OBJECTIVES
37 38 39	152	Aims
40 41	153	To determine OTs competency to deliver the ESSVR intervention, measure fidelity
42 43	154	to the ESSVR intervention and understand the social and structural context in which
45 46	155	the intervention is delivered and identify factors which may influence the quality of
47 48	156	implementation.
49 50 51	157	
52 53 54 55	158	Objectives
56 57 58	159	Fidelity measurement and competency assessment will
59 60	160	1. Ascertain intervention dose
		Dego 7 of 26

1 2		
2 3 4	161	2. Describe content of usual care and ESSVR
5 6	162	3. Describe levels of adherence to the ESSVR intervention
7 8 9	163	4. Understand the delivery of Usual Care and ESSVR.
10 11 12	164	5. Determine OTs competency to deliver ESSVR
13 14 15	165	Social and structural context will include
16 17	166	6. Describe participating sites.
18 19	167	7. Understand professionals' experiences of being trained to deliver the intervention.
20 21 22	168	8. Understand experiences of delivering the intervention.
23 24	169	9. Understand the social and structural factors which support the implementation of
25 26	170	the intervention.
27 28 29	171	10. Understand participants' experience of being supported to return to work after
30 31	172	stroke.
32 33	173	11. Identify potential contaminants
34 35 26	174	
30 37 38	175	
39 40 41 42 43	176	METHODS
44 45 46	177	Design
47 48	178	Embedded theory-driven mixed-methods process evaluation incorporating qualitative
49 50	179	and quantitative methods. The process evaluation will draw on the intervention logic
51 52	180	model developed by the Trialists (Figure 1) and will be underpinned by Normalisation
55 55	181	Process Theory (NPT), an implementation theory built on four constructs
56 57	182	(coherence, cognitive participation, collective action and reflexive monitoring) each
58 59 60	183	informed by four components.[24] NPT will be used in the development of data

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184	collection tools (interview topic guides and observation checklists) and as a		
185	sensitising lens in qualitative data analysis and interpretation. NPT constructs will		
186	underpin the process evaluation and provide insights into the implementation and		
187	integration of the	e intervention into particip	pating stroke services. This will include how
188	the intervention i	is received, understood,	implemented and how it could be
189	normalised into t	he current healthcare sy	stem (see Table 1).
190			
191			
192	Figure 1. The ESSVR logic model.		
193			
194	Table 1: Norma	alisation Process Theor	ry (Adapted from May et al, 2015)
	NPT constructs	Components	Explanation
	Coherence	 Differentiation Communal specification Individual specification Internalisation 	The sense making work that people do individually and collectively when faced with implementing changes to existing working practices. This would include differentiating new practices from existing work and thinking through not only the perceived value and benefits of desired/planned changes but also what
			work will be required of individual people in a setting to bring about these changes.

ive ation	 Initiation Enrolment Legitimation Activation 	The work that people need to do to engage with and commit to a new set of working practices. This often requires bringing together those who believe in and are committed to making changes happen. This also involves people working together to define ways to implement and sustain the new working practices.

	Collective Action	 Interactional workability Relational integration Skill set workability Contextual integration 	The work that will be required of people to actually implement changes in practices, including preparation and/or training of staff. Often this entails rethinking how far existing work practices and the division of labour in a setting will have to be changed or adapted to implement the new practices. This requires consideration of not only who will do the work required, but also the skills and knowledge of people who will do the work and the availability of the resources they need to enact and sustain the new working practices.
	Reflexive monitoring	 Systematisation Communal appraisal Individual appraisal Reconfiguration 	Peoples' individual and collective on- going informal and formal appraisal of the usefulness or effectiveness of changes in working practices. This involves considering how the new practices affect the other work required of individuals and groups and whether the intended benefits of the new working practices are evident for the intended recipients and staff.
195			E:
196	In addition, the C	Conceptual Framework fo	r Implementation Fidelity (CFIF) (Figure 2)
197	will guide collect	ion and analysis of quant	itative data.[25] The CFIF outlines the
198	components and	variables that make up a	and affect intervention fidelity and explains
199	how they relate t	o each other. Adherence	includes content and dose (frequency,
200	coverage and du	ration) of the delivery.[25	5]
201 202	Figure 2. Assess	ment of fidelity and facto	rs moderating ESSVR delivery in
203	accordance with	the Conceptual Framewo	ork for Implementation Fidelity.[25]
204			
205	Eligibility criter	ia	

2 3 4	206	Stroke survivors that meet the following criteria will be considered eligible to
5 6	207	participate in the process evaluation:
/ 8 9	208	 Age ≥18 years.
10 11	209	Admitted to hospital with new stroke (all severities).
12 13	210	 In work at stroke onset (including self-employed, paid or voluntary).
14 15 16	211	• Willing and have capacity to provide informed consent to participate in the study.
17 18	212	• Have sufficient proficiency in English to contribute to the data collection required
19 20 21	213	for research.
22 23	214	Potential participants who do not intend to return to work will be excluded.
24 25 26 27	215	
28 29	216	Inclusion criteria for carers of potential participants:
30 31	217	 Nominated carer of consenting participant.
32 33	218	 Willing and have capacity to provide informed consent to participate in the
35 36	219	study.
37 38	220	Have sufficient proficiency in English to contribute to the data collection
39 40	221	required for research.
41 42 43	222	
44 45 46	223	Informed Consent
47 48 49	224	Potential participants will be provided with an information sheet and be provided the
50 51	225	opportunity to ask questions of a researcher prior to consent. Written informed
52 53	226	consent will be obtained from all participants. When a participant is randomised to
54 55 56	227	the case study element, a researcher will contact the participant to gain consent for
57 58	228	interview and observations. Consent will be reaffirmed at the start of interviews. This
59 60	229	process will be the same for carer, employer, OT and NHS staff interviews. For

1 2		
2 3 4	230	employer interviews, additional consent to contact the employer will be requested
5 6 7	231	from the case study participant before the employer is contacted.
7 8 9 10	232	
11 12 13	233	Patient and Public Involvement Statement
14 15 16	234	Stroke survivors are involved in all stages of the research cycle.
17 18 19	235	Design and development.
20 21	236	Two stroke survivors are co-applicants on the grant and assisted in identifying the
22 23	237	research questions, designing the study and developing the trial protocol.
24 25 26	238	Delivery.
27 28	239	Two PPI are members of the Trial Steering Committee, and two are members of the
29 30	240	Trial Management Group. Additionally, our RETAKE PPI (Patient & Public
31 32	241	Involvement) group, which has six members, meets quarterly. Examples of the work
33 34	242	achieved by the PPI group to date are:
35 36	243	Helping define the primary outcome and defining 'voluntary work' which is
37 38	244	included in the definition of the primary outcome.
39 40	245	Evaluating all patient facing material including aphasia friendly recruitment
41	246	material.
42 43	247	 Co-development of interview topic guides for trial participants and
44 45	248	occupational therapists.
46 47	249	Overcoming problems with recruitment. For example, resources and
48	250	narratives to assist recruiters in approaching people with severe stroke.
49 50	251	 Assisting in the design of new materials to promote follow up e.g. including a
51 52	252	'patient journey leaflet' and Thankyou cards.
53	253	Helping reduce the length of follow-up questionnaires.
54 55	254	 Advising on communicating with participants during the pandemic.
56 57	255	Changes to the Excess Treatment Cost payment models during trial, caused
58 50	256	problems for the study. One PPI member wrote directly to Directors of the
60		

Page 13 of 38

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59 60 BMJ Open

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2 3	257	NIHR. NHS Englar	nd. Health and Socia	I Care and the leads for	the NIHR	
4 5	258	Clinical Research I	Network to explain th	e impact that these cha	naes on the	
6	250	trial She received	a prompt response	which was extremely h	eloful to the	
/ 8	239			which was extremely h		
9	260	research team. Th	is has assisted us in	explaining the new syst	em to clinical	
10 11	261	colleagues and res	searchers in the Trus	ts.		
12	262	 Co-Development of 	of a trial website and	trial newsletters.		
13 14						
15	263	The PPI group will also be	e involved in writing u	up and presenting study	findings.	
16 17						
17	264					
19						
20 21						
22	265	Data Collection				
23 24	266	The presses evelvetion of				
24 25	266	The process evaluation w	an employ qualitative	and quantitative metho	as to address	
26 27	267	the research questions. T	able 2 illustrates the	relationship between th	e process	
28 29 30	268	evaluation aims, research questions, data sources and data collection methods. The				
31 32	269	following section describes each data source in more detail.				
33 34	270					
35 36	271	Table 2: RETAKE proce	ss evaluation resea	irch questions and dat	ta sources	
37 38	272					
39 40	273					
41 42		Aims	Research	Data Source(s)	Method(s)	
43			questions		A 11 1	
44 45			What is the	Intervention	Quantitative	
43 46			intervention dose,	content case		
47			duration?			
48			What is the		Quantitative	
49 50			content of the	content CRFs	and	
50		Measure fidelity to	RETAKE	 NHS therapy 	qualitative	
52		the intervention	intervention?	records	.1	
53				Stroke		
54			What is the	survivor-		
55 56			content of usual	reported		
57			care?	resource use		

data.

		•	Stroke survivor carer and OT interviews	
0	Was the intervention delivered with fidelity? What factors affect implementation fidelity? (context, adherence, moderating factors)	•	Fidelity checklist, Intervention content CRFs Mentoring records, RETAKE OT interviews	Quantitative and qualitative
Determine RETAKE OT competency	Are the RETAKE OTs competent to deliver the RETAKE intervention?		Individual OT performance in assessed vignettes at baseline and 6 months RETAKE OT case records at 12 months post training	Quantitative
Understand the social and structural context and identify factors which may influence intervention	What is the context for intervention delivery? What are the existing stroke pathways?	•	Site survey at baseline, mid- point and end of intervention delivery	Quantitative and qualitative
quality (enablers and barriers, contextual factors associated with	What services are in place for supporting patients in return to work?	•	Site survey at baseline, mid- point and end of intervention delivery	Quantitative and qualitative
variations in outcome across the intervention groups, factors supporting	What are the staffing levels at the site?	•	Site survey at baseline, mid- point and end of intervention delivery	Quantitative and qualitative

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implementation into routine practice).	Are there any proposed VR service developments or changes in practice in place/ planned at site? What are the RETAKE OTs' perceptions of the training and mentoring to deliver the intervention?	 Site survey at baseline, mid- point and end of intervention delivery NHS staff interviews Observations at training sessions RETAKE OT interviews 	Quantitative and qualitative Qualitative
	How do the RETAKE OTs experience delivering the intervention?	 Observations of ESSVR sessions RETAKE OT interviews Mentoring records 	Qualitative
	What are the social and structural factors supporting intervention implementation?	 Observations of usual care and ESSVR sessions RETAKE OT interviews Usual Care therapist interviews NHS Staff interviews Mentor interviews 	Qualitative
	How do participants' experience being supported to return to work after stroke	 Stroke survivor interviews Carer interviews Employer interviews 	Qualitative
Identify potential contaminants.	What factors threaten the success of the trial?	 Training delivery Mentoring records Site survey at baseline, mid- point and end 	Quantitative and qualitative

of intervention delivery • NHS staff interviews • RETAKE OT interviews • Stroke Participant
interviews

275 Intervention content Case Report Forms (CRFs)

Initial Session CRFs (one per participant) record the Intervention start date and whether this occurred within 8 weeks of stroke. Participant Summary CRFs record the number of sessions attended out of those proposed and whether there was an agreed ending for the OT led return to work support. To ascertain intervention dose and describe intervention content, data will be extracted from intervention CRFs for all participants (see Table 3). Therapists record each intervention session against pre-defined components, on an 'Intervention content CRF'. These data will be used to identify which components of the intervention were delivered, to what extent therapists adhered to the intervention process described in the RETAKE manual, and to what extent participants adhered to the intervention. For case study participants only, content data will be cross-referenced with the OT's clinical case notes and additional data extracted to explain how the RETAKE intervention interacts with usual care and other services such as employment services. Describing usual care

To describe the content of the intervention and of usual care, resource use questions
 pertaining to participants' use of health and social care services over the previous
 three months will be completed by all participants at three, six and twelve months

Page 17 of 38

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2 3	293	post-randomisation as part of follow-up. This data will be used to describe the
4 5 6	294	content of usual care, and in case study participants (n=38) will be triangulated with
7 8	295	therapists' clinical notes and participant interview transcripts.
9 10 11 12 13	296	Therapist competency assessment
14 15	297	Following attendance at a two-day, manualised face-to-face training session with VR
16 17	298	expert trainers and again at refresher training six months later, retake OTs
18 19 20	299	competence will be assessed using vignettes depicting novel RTW after stroke
21 22	300	scenarios. Model answers developed by the training team will be used to measure
23 24	301	competence using criteria based on knowledge of the intervention process (40%),
25 26 27 28 29 30 31 32 33 34 35 36	302	clinical reasoning (50%) and written communication (10%). Scores will be mapped to
	303	a rubric identifying OTs as highly competent (≥70%), competent (50-69%) or needing
	304	additional support (≤49%). After 12 months of delivering the intervention RETAKE
	305	OTs competence will be reassessed by evaluating the intervention delivered in a
	306	random selection of completed intervention case records (one participant per
37 38	307	RETAKE OT) against the trainer's expert opinion.
39 40 41 42 43 44	308	
45 46 47	309	Fidelity
48 49	310	To assess implementation fidelity a range of data collection methods informed by the
50 51 52	311	CFIF will be used (see Table 3).[25]
53 54 55	312	Fidelity Checklist
56 57	313	A fidelity checklist based on the RETAKE intervention logic model (see Figure 1) and
58 59 60	314	RETAKE intervention process and components will be applied to complete case
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315 records (Content of Intervention CRFs, RETAKE OT case notes and Initial Session

CRFs) from a random selection of stroke participants randomised to receive the

317 RETAKE intervention (one per treating RETAKE OT). This will be used in measuring

318 adherence to the RETAKE process and identifying factors affecting adherence.

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1 2 3

Table 3. CFIF led data extraction for Fidelity Assessment:

Fidelity Measure	CFIF	Measurement	Data for	Time point
	Construct*	tool	extraction	
Frequency	Adherence	Initial Session	Intervention	One CRF
	and	Case Report	start date and	per
Duration	moderating	Forms (CRFs)	end date	participant
	factors		Number of	at Initial
		~~	proposed and	session.
		Participant	sessions	
		Summary CREs	Whathar there	ner
		Summary OK S	was an agreed	per
		L.	ending for OT	completed
			return to work	throughout
			support	intervention
				delivery
Intensity (time	Adherence	Intervention	Time spent (in	One
spent per		content CRF	minutes) on VR	completed
session)			activities per	following
Dose (number of			session	every
sessions)				intervention
		OT clinical		session
		records	Description of	
		(RETAKE+	intervention	In case
		Usual Care)	delivered in	study
			each session	participants.
Therapist	Adherence	Fidelity	Components	Applied to
adherence	and	Checklist	delivered,	one
Factors affecting	moderating		factors affecting	randomly
adherence	factors		delivery	selected
			RETAKE	completed
				case per
			tollowed Y/N	

1 2						
3 4 5 6 7 8 9 10 11 12		Real time therapist adherence Factors affecting adherence	Adherence and moderating factors	Mentoring CRFs	Mentor's concerns about adherence Factors affecting intervention delivery Potential	Completed monthly by mentors
13 14 15 16 17 18 19 20 21		Barriers and enablers to intervention delivery	Moderating factors	Interviews with RETAKE Therapists	solutions Factors affecting intervention delivery Potential	In a random selection of cases during intervention delivery at
22 23 24			0		solutions (developed by OT)	3, 6 and 12 months
24 25 26 27 28 29 30 31 32 33		Acceptability of the intervention Barriers and enablers to intervention delivery	Moderating factors	Interviews with stroke participants, carers, employers and NHS staff	Acceptability of intervention Factors affecting delivery Potential solutions to barriers	Throughout intervention delivery in case studies
34 35	322	Key; *CFIF Adhere	ence includes i	ntervention content	, dose, coverage, i	frequency and
36 37 38	323	duration of interve	ntion; CFIF Mo	derating factors inc	cludes participant	
39 40	324	responsiveness, in	ntervention con	nplexity, strategies	to facilitate implem	entation,
41 42	325	quality of delivery,	recruitment, a	nd context.		
43 44 45 46	326					
47 48 49	327	Mentor interviews	and records			
50 51 52	328	Mentoring records				
52 53 54	329	Following training,	each treating	OT will be assigned	a mentor with ext	ensive
55 56	330	knowledge and ex	perience of voo	cational rehabilitatio	on. Mentoring will t	ake place
57 58 50	331	monthly via teleco	nference in sm	all groups (four to s	six therapists) and	serve as an
60	332	intervention impler	mentation supp	ort mechanism. RE	TAKE OTs will be	able to
				Page 19 of 36		

discuss any difficulties they are experiencing, ask questions and share best practice with other OTs and their mentor. This process will also facilitate communication between the trial team and enable barriers to implementation and contamination risks to be reported. Key discussion points will be recorded by mentors using a mentoring record form for each session. These records, along with all email correspondence between mentor and mentees will be collected for qualitative content analysis.

Mentor Interviews

Semi-structured interviews will be conducted by two research assistants (SC and
KC) with all mentors (n=6) to explore their experiences of supporting RETAKE OTs
to deliver the intervention, and ascertain their views of organisational, social and
other factors contributing to or affecting delivery of the intervention.

346 Social and structural context

347 Site survey

To describe participating sites and identify potential contaminants, sites will be asked to complete a questionnaire by telephone at three time points; prior to recruitment, halfway through, and at the end of the intervention period. This will contribute to understanding contextual influences through capturing data on existing stroke care pathways and resources (including staff and services) available for supporting participants in a return to work. It will also identify potential contamination risks associated with proposed or planned VR service developments or changes in practice that may influence trial outcomes.

Page 20 of 36

Therapist training

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358	Non-participant observations
359	To understand OT's experiences of being trained to deliver the intervention, a
360	research assistant (RC) will observe up to four training sessions delivered by the
361	training team. A checklist will be developed using NPT constructs to guide
362	observations. Non-participant observations aim to identify; whether therapists
363	understand the intervention and their role in implementation, whether they think the
364	RETAKE intervention can be integrated into existing practice and any contextual
365	factors affecting the trial.
366	
367	To describe adherence to the intervention, a researcher will observe up to three
368	sessions for each case study participant in the intervention and usual care arms of
369	the trial. Non-participant observations will be conducted using prompts for structured
370	observation and unstructured field notes.[26] Participant selection for inclusion the
371	case study element is described below.
372	
373	Interviews with Occupational Therapists
374	Semi-structured interviews will be conducted by a research assistant (RC) with a
375	minimum of one OT per site following their initial RETAKE training to explore their
376	experience of training, the mentoring process and their confidence in intervention
377	delivery. OT's views of the intervention, barriers and facilitators to implementation,
378	and any organisational or social factors impacting on delivery will also be explored.
379	Interviews will take place following training and be repeated at two additional time-

Page 21 of 36

3 4	380	points: mid-way through the RETAKE intervention delivery and at the end of the
5 6	381	study.
/ 8 9	382	
10 11	383	Case studies
12 13	384	Longitudinal case studies will be used to map the care received by RETAKE and
14 15 16	385	usual care participants to develop a more detailed understanding of participants'
17 18	386	(stroke survivors, carers, employers) and RETAKE OTs experiences of support for
19 20 21	387	RTW. A 5% subset of participants from both arms of the trial (total n=38) will be
21 22 23	388	randomly selected and invited to participate in the case study element of the process
24 25	389	evaluation.
26 27 28	390	
28 29 30 31	391	i) Case study interviews
32 33	392	Semi-structured interviews will be conducted by two research assistants (SC and
34 35 26	393	KC) with case study participants at three time points: three, six, and twelve months
36 37 38	394	post-randomisation, about their experiences and views of and adherence to the
39 40	395	RETAKE intervention and the support they received to return to work. The case
41 42	396	study participants' carers (if nominated), their employers (where participant consent
43 44 45 46	397	is obtained) and the OTs providing support for RTW will be interviewed.
47 48 40	398	NHS staff interviews
49 50 51	399	To further understand the social and structural factors which influence the
52 53	400	implementation of the intervention, interviews will be conducted with up to two (n=34
54 55	401	in total) NHS staff involved in the management, commissioning or delivery of stroke
56 57 58	402	rehabilitation within each trial site. Participating staff will be chosen using a mixture
59 60	403	of purposive and snowball sampling. This will based on a full range of trial sites,

2 3 4	404	staff knowledgea	ble about the implement	tation of the intervention at the	ir site, and		
5 6	405	staff knowledgea	ble about the decision-n	naking process relating to wide	er roll-out.		
7 8 9	406						
10 11 12 13	407	Additional particip	oant interviews				
13 14 15	408	An additional ran	dom 5% of study partici	pants will be invited to participa	ate in semi-		
16 17	409	structured intervie	ews at the end of the int	ervention period. These interv	iews will		
18 19	410	explore participar	nts' experience of the int	tervention as well as their perc	eptions and		
20 21 22	411	experiences of re	turning to work.				
22 23 24 25	412						
23 26 27 28 29 30 31 32	413	All qualitative interviews will be conducted using a topic guide informed by NPT.					
	414	Examples of question topics and how they relate to the four NPT constructs are					
	415	shown in Table 4. Topic guides will be presented to the RETAKE Public and Patient					
32 33 34	416	Involvement (PPI) group for comment pri	or to use. All interviews will be	audio		
35 36	417	recorded and trar	nscribed in full.				
37 38	418						
39 40 41	419	Table 4: Examples of question topics related to NPT constructs					
41 42 43 44 45 46 47 48		Normalisation Process Theory Constructs	NHS Staff/ therapist interview topics (some may also arise in informal feedback during training observations)	Stroke Participant interview topics (some may also arise in intervention / usual care observations)	Employer interview topics		
48 49 50 51 52 53 54 55 56 57 58 59 60		Coherence	How do staff describe the intervention? How is the intervention similar to/different from usual care? Who would (most) benefit from the	RTW support received: similarities/differences between control and intervention participants	Experience of liaising with the therapist and/or participant on RTW issues		

	intervention?
Cognitive	Do staff see
participation	value/potential in th
	intervention?
	Have they found the
	training and
	experience a
	worthwhile
	investment of time?
	investment of time :
	Do they feel they
	have the
	competence/
	resources to deliver
	the intervention
	effectively?
	9
Collective	How compatible is
action	the intervention with
	the existing stroke
	care pathwav?
	.
	What other RTW
	services/resources
	exist locally? How
	does this intervention
	compare/compleme
	those services?
	Describe working
	relationships with
	those services.
	1
	Support from
	Support from managers and
	Support from managers and colleagues during th
	Support from managers and colleagues during th intervention period
Reflexive	Support from managers and colleagues during th intervention period Perceived effects o
Reflexive monitoring	Support from managers and colleagues during th intervention period Perceived effects of patients (& carers)
Reflexive monitoring	Support from managers and colleagues during th intervention period Perceived effects of patients (& carers)
Reflexive monitoring	Support from managers and colleagues during th intervention period Perceived effects of patients (& carers)
Reflexive monitoring	Support from managers and colleagues during th intervention period Perceived effects of patients (& carers) Views on time/resources
Reflexive monitoring	Support from managers and colleagues during th intervention period Perceived effects of patients (& carers) Views on time/resources invested in delivery
Reflexive monitoring	Support from managers and colleagues during th intervention period Perceived effects of patients (& carers) Views on time/resources invested in delivery vs impact
Reflexive monitoring	Support from managers and colleagues during th intervention period Perceived effects of patients (& carers) Views on time/resources invested in delivery vs impact

ognitive articipationDo staff see value/potential in the intervention?What were their expectations? Did patients (& carers) value the intervention?Expectations of the processes: liaising with therapist/patie and patient's RTWHave they found the training and experience a worthwhile investment of time?How did they respond to the therapists' suggestions?(Prior) experience i supporting RTW for people with disabilitiesDo they feel they have the competence/Do they feel they sessions and ultimatelyDid they feel they had the ability/resources/confidence to progress through the sessions and ultimatelyHave the competence/	nt n
resources to deliver the intervention effectively? Context in which participant received RETAKE/acted on suggestions: social, financial, health state, access to opportunities	r
ollective ctionHow compatible is the intervention with the existing stroke care pathway?How did participants accommodate the intervention sessions/follow up actions?Views on who is responsible /roles is supporting RTWWhat other RTW services/resources exist locally? How does this intervention compare/complement those services.How did they manage/are they managing their RTW (if applicable)?Views on who is responsible /roles is supporting RTWFinancial implicationsFinancial implicationsFinancial implicationsSupport from managers and colleagues during the intervention periodSupport from managers and colleagues during the intervention periodFinancial implications	n ns
eflexive nonitoringPerceived effects on patients (& carers)Perceived effects of RETAKE/other RTW 	efit sor efit

25 of 38	BMJ Ope	en	
	make it possible to roll out the interventionRE be inter effectively? (changes plat to intervention; changes in services/resources needed for delivery)	TAKE and what could improved? (content of ervention sessions/work ins, timing, relationship h therapist)	with therapist/participant? What further information/support would they have liked – at what time?
420			
421	Data Analysis		
422	Quantitative analysis		
423	The dose, duration and frequency of the ESS	SVR intervention will be cal	culated using
424	data from completed CRFs in combination with	ith NHS therapy records. T	he total time
425	spent delivering the ESSVR intervention (face	e to face and non-face to f	ace contact
426	(liaison with the patient, employer and other s	stakeholders by letter/phor	ne),
427	administration and travel) will be identified. De	etails relating to the conter	nt of
428	intervention sessions will be extracted to iden	ntify whether core compone	ents of
429	ESSVR were delivered as intended (i.e. as sp	pecified in the intervention	manual and
430	logic model). Associations between therapist	attributes, contextual facto	ors and
431	intervention fidelity (measured by deviations f	from the RETAKE core pro	ocess) will be
432	explored using regression models. Analysis w	will be conducted using Sta	itistical
433	Package for the Social Sciences (SPSS) (ver	rsion 21.0 for Windows). In	addition, a
434	fidelity monitoring checklist will be used to che	eck whether the ESSVR p	rocess is
435	followed.		
436			
437	Describing Usual Care		
438	Data regarding rehabilitation delivered in Usu	al Care will be extracted fr	rom resource
439	use data in the follow-up questionnaires and	from NHS Therapy records	s in case
	Page 25 c	of 36	

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study participants randomised to Usual Care. These data will be used to inform the
cost of Usual Care for the economic evaluation and describe and understand usual
care provided during stroke rehabilitation in inpatient and community services.
Quantitative data analysis will be conducted using Statistical Package for the Social
Sciences (SPSS; Version 21.0 for Windows). Analysis of usual care data obtained
from NHS Therapy records is described below.

447 Qualitative analysis

Inductive (thematic analysis) and deductive (informed by NPT) approaches will be used guide data analysis and interpretation. Observational and Interview data will be transcribed verbatim and uploaded into QSR NVivo software for management. Descriptions of usual care in NHS Therapy records, observational field note data, including researcher reflections and interview data will be analysed thematically.[26] Framework analysis will be used with the case study data to facilitate within and between case analyses. Analysis of each data set will be conducted independently and then jointly by at least two study team members (SC, KC, KP) to corroborate themes and discuss any discrepancies. It will follow a standard approach of data familiarisation, line-by-line coding, development and refinement of broader conceptual explanatory categories and iterative testing of interpretation through participant feedback and discussions within the research team. Analysis will proceed iteratively with data collection to determine whether data saturation has been achieved; researchers will draw on the RETAKE logic model (Figure 1). Throughout the qualitative analysis, NPT will be used as a sensitising framework. Researchers will keep a set of interim summary notes documenting any reflexivity points and

 discussions with the wider process evaluation team. discussions with the wider process evaluations of complex stroke rehating the wider process evaluations of complex stroke rehating trials are still relatively few in number. [29-36] At present, despite the publication the MRC guidelines for process evaluation, [17] there is limited consensus of the MRC guidelines for process evaluation. 	al
 466 467 467 467 468 468 468 468 469 469 469 469 469 469 469 469 469 460 469 460 470 471 471	
 467 DISCUSSION 468 Process evaluations are increasingly embedded in trials of complex 469 interventions,[16] but published process evaluations of complex stroke rehat 470 trials are still relatively few in number.[29-36] At present, despite the publication 471 the MRC guidelines for process evaluation,[17] there is limited consensus of the mathematical structure of the mathematical struct	
 Process evaluations are increasingly embedded in trials of complex interventions,[16] but published process evaluations of complex stroke reha trials are still relatively few in number.[29-36] At present, despite the publica the MRC guidelines for process evaluation,[17] there is limited consensus of 	
 interventions,[16] but published process evaluations of complex stroke rehating trials are still relatively few in number.[29-36] At present, despite the publication the MRC guidelines for process evaluation,[17] there is limited consensus of the state of the state	
 trials are still relatively few in number.[29-36] At present, despite the public the MRC guidelines for process evaluation,[17] there is limited consensus of 	bilitation
$\frac{21}{22}$ 471 the MRC guidelines for process evaluation,[17] there is limited consensus of	ation of
	on how
 472 best to conduct these important studies, particularly in relation to complex 	
 interventions such as RETAKE, which cross the boundary between health interventions such as RETAKE, which cross the boundary between health 	and
 ²⁸ ²⁷ ²⁸ ²⁹ ⁴⁷⁴ ²⁹ ²⁰ ²¹ ²⁰ ²¹ ²¹ ²² ²³ ²⁴ ²⁵ ²⁵ ²⁶ ²⁷ ²⁸ ²⁹ <l< td=""><td></td></l<>	
$\frac{30}{31}$ 475 Balancing the need to gain greater understanding of contextual factors that	may
 476 affect trial outcomes with the realities of collecting more data than is neces 476 affect trial outcomes with the realities of collecting more data than is neces 	sary to
$\frac{34}{35}$ 477 describe the facilitators and barriers to implementation is a challenge for	
$\frac{37}{38}$ 478 researchers.[23] However, adopting a robust theoretical framework to und	erpin the
$\frac{39}{40}$ 479 process evaluation, pre-determining objectives that steer the data collection	n and
41 42 480 drawing on previous research mitigates this challenge.[29, 31, 34, 36] Usin	ga
44 45 481 mixed-methods approach and generating quantitative data to measure fide	ity and
46 47 482 adherence to the intervention protocol alongside site specific data and in-de	epth
48 49 483 qualitative data from a wide range of participants will ensure a focused but	
⁵¹ 484 comprehensive data set to support analysis of the trial outcomes.	
53 54 485	
The MRC guidelines identify that different approaches to managing proces	3
 487 evaluations are used.[17] In this study the process evaluation is led by a re 60 	searcher

Page 28 of 38

who is independent of the trial team. However, data will be collected and analysed by researchers who are also contributing to the trial data collection. The development of topic guides and interview schedules with the support of the process evaluation lead has been outlined above. In respect of the qualitative analysis the use of independent and then joint coding and development of themes, followed by review of emerging findings by the wider research team is designed to enhance the transparency and trustworthiness of the analytical process. Research reflexivity is encouraged and recorded in memo form and discussed by the wider research team in process evaluation review meetings every two months.

Rehabilitation interventions are frequently tailored to the participant and modified to suit the local context and resources. It is therefore important to monitor intervention delivery to ensure fidelity is maintained and any moderating factors are identified and addressed in real time to ensure robust trial outcomes. A unique feature of this trial is the use of mentoring for individual RETAKE OTs throughout intervention delivery in this study. Monitoring this process will enable any intervention modifications to be identified and documented in detail. Using NPT's constructs will help to identify vulnerable features of the implementation process with respect to the work involved in introducing and embedding the RETAKE intervention and the importance and influence of contextual factors on trial outcomes.

Investigating the implementation fidelity of a complex intervention offers insight into barriers and facilitators to delivery to inform future study design. It also yields valuable information regarding the 'core components' and 'active ingredients' of an intervention and any permitted modifications for clinical implementation.[37]

Page 28 of 36

BMJ Open

3 4	513	Understanding of the causal mechanisms of complex interventions is vital in being
5 6	514	able to deliver an effective intervention in other settings. This process evaluation will
7 8 9	515	measure these modifications and their effect on the intervention's fidelity while
10 11	516	providing the context in which to interpret the variation in outcomes on the
12 13	517	effectiveness of the trial.
14 15 16	518	
17 18	519	Ethics and dissemination
19 20	520	Ethics approval has been obtained through the East Midlands – Nottingham 2
21 22 23	521	Research Ethics Committee (REC) (Ref: 18/EM/0019) and the NHS Health
23 24 25	522	Research Authority.
26 27	523	
28 29 30	524	Availability of data and materials
31 32	525	No additional data will be made available.
33 34	526	
35 36 37	527	Competing interests
38 39	528	The authors declare that they have no competing interests.
40 41	529	
42 43 44	530	Funding
45 46	531	This study is funded by the NIHR HTA programme (ref: 15/130/11). The views
47 48 49	532	expressed herein are those of the authors, not necessarily the NIHR, the Department
50 51	533	of Health and Social Care, or the NHS.
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54 55 56	535	Authors' contributions
57 58	536	KR, CM, AFa, AB, ROC, MW, and CW conceived the study. KR, DJC, and CM
59 60	537	designed the process evaluation. KR, CM, DJC, SC, KC, JH, JP and KP
		Page 29 of 36

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Page 30 of 38

operationalized the process evaluation protocol. KR, JP, and JH designed the intervention. AS has the role of trial sponsor. IH, RB, and AFa devised the data management and statistical analysis plan. JS and JM acted as PPI collaborators to support plans for trial design/delivery, management, and dissemination of trial findings. VM and SH have responsibility for management of the trial. KR, SC and DJC drafted the manuscript; all other authors read and approved the final version. Authors' information ¹Associate Professor of Rehabilitation Research, Division of Rehabilitation, Ageing and Wellbeing, School of Medicine, B-Floor, Medical School Queen's Medical Centre, Nottingham NG7 2UH. ²Clinical Trials Research Unit (CTRU), Leeds Institute of Clinical Trials Research, Level 11 Worsley Building, University of Leeds, Leeds LS2 9JT. ³Health Economics Group, Room 2.37, Norwich Medical School, University of East Anglia, Norwich Research Park, Norwich NR4 7TJ, ⁴Lancashire Clinical Trials Unit, Lancashire Applied health Research Collaboration Hub, Brook Building, Room 429, University of Central Lancashire, Preston PR1 2HE. ⁵ Academic Department of Rehabilitation Medicine, Leeds Institute of Molecular Medicine, University of Leeds, Level D, Martin Wing, Leeds General Infirmary, Leeds LS1 3EX. 6Patient and Public Involvement Collaborator, Hampshire, UK. ⁷Different Strokes, Raphael House, Ilford, London IG1 1YT. 8Geoffrey Jefferson Brain Research Centre, The Manchester

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Page 34 of 38

BMJ Open

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BMJ Open

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Rationale for ESSVR	Resources	RTW Intervention	Individual, Organisatio Outo	onal and System linked omes	Trial ou
 Generation to work the standard by (GTW) is achieved by (GTW) is achieved by the standard by the	Association of the subscription of the subscri	 -YA OT Intervente saity 58 weeks of stroke, first optimiset ad hardhoever probasional) -Ar OT assesse impact of strake of proving strake saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits of the saits	-Health supported by -Patient satisfied with -Patient satisfied with work work -Patient satisfied with work -Patient & employer satisfied with -Patient & employer increased stroke confidence -Patient reports increased stroke confidence -Patient work	Provent job loss Increased apportunities for employee engagement by intervening early -Work & workplace is appropriate for patient -Workplace adjustments -Optimized productivity at work by patient -Reduced health resource usage -Reduced Welfare benefits use	Trial out measure -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost -Cost



Return-to-Work

Evaluation

Component analysis to identify essential components



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The RETurn to work After stroKE (RETAKE) Trial: protocol for a mixed-methods process evaluation using normalisation process theory

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1 TITLE

The RETurn to work After stroKE (RETAKE) Trial: protocol for a mixed-methods
process evaluation using normalisation process theory

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Page 1 of 34

Page 3 of 48

1 2 BMJ Open

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44	references)
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ABSTRACT

Objectives

This mixed-method process evaluation underpinned by Normalisation Process Theory (NPT) aims to measure fidelity to the intervention, understand the social and structural context in which the intervention is delivered, and identify barriers and facilitators to intervention implementation.

Setting

Return to Work after Stroke (RETAKE) is a multi-centre individual patient randomised controlled trial to determine whether Early Stroke Specialist Vocational Rehabilitation (ESSVR) plus usual care is a clinically and cost-effective therapy to facilitate return to work after stroke, compared with usual care alone. This protocol paper describes the embedded process evaluation.

Participants and outcome measures

Intervention training for therapists will be observed and use of remote mentor support reviewed through documentary analysis. Fidelity will be assessed through participant questionnaires and analysis of therapy records, examining frequency, duration and content of ESSVR sessions. To understand the influence of social and structural contexts, the process evaluation will explore therapists' attitudes towards evidence-based practice, competency to deliver the intervention and evaluate potential sources of contamination. Longitudinal case studies incorporating non-participant observations will be conducted with a proportion of intervention and usual care participants. Semi-structured interviews with stroke survivors, carers, occupational therapists, mentors, service managers and employers will explore their

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experiences as RETAKE participants. Analysis of qualitative data will draw on 69 70 thematic and Framework approaches. Quantitative data analysis will include 71 regression models and descriptive statistics. Qualitative and guantitative data will be independently analysed by process evaluation and Clinical Trials Research Unit 72 teams respectively. Linked data, e.g. fidelity and describing usual care will be 73 74 synthesised by comparing and integrating quantitative descriptive data with the 75 qualitative findings. 76 77 Ethics and dissemination Approval obtained through the East Midlands – Nottingham 2 Research Ethics 78 Committee (Ref: 18/EM/0019) and the National Health Service (NHS) Research 79 Authority. Dissemination via journal publications, stroke conferences, social media 80 and meetings with national Stroke clinical leads. 81 82 **Trial registration** 83 Registration number: ISRCTN: 12464275 84 85 **KEYWORDS** 86 87 Return to work, stroke, vocational rehabilitation, occupational therapy, complex 88 intervention, process evaluation, randomised controlled trial, mixed-methods, qualitative, Normalisation Process Theory, Consolidated Framework for 89 90 Implementation Fidelity 91

STRENGTHS AND LIMITATIONS OF THIS STUDY

A mixed-methods theory-driven process evaluation will generate detailed findings to assist in interpreting the results of a pragmatic, multi-centre individual patient randomised controlled trial of a complex vocational rehabilitation intervention, which crosses the work/health divide. This is one of the most comprehensive multi-site, multi-component, multi-stakeholder perspective process evaluations embedded in a stroke rehabilitation trial, involving detailed assessment of implementation fidelity, therapist competency to deliver the trial intervention, contamination logging and exploration of social and structural influences on intervention provision in post-stroke rehabilitation services. Longitudinal case studies with intervention and usual care will capture participant experiences of providing and experiencing the intervention including those of employers. The Covid19 pandemic limited researcher access to direct observation of face-to-face intervention delivery and employer interactions with stroke survivors in each site. Integration of interview data from different participant sources including stroke survivors and carers, occupational therapists and employers with available observational data is planned to address this limitation.

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BACKGROUND

Approximately 100,000 people in the UK suffer from a stroke every year,[1] and around 1 in 4 are of working age.[2] Returning to work after a stroke is a major goal for stroke survivors, contributing to social identity, emotional and financial wellbeing, and conferring a sense of purpose and has benefits for the individual, the individual's family and the economy.[3] Despite this, only half of working age stroke survivors make a successful return to meaningful work, and they are two to three times more likely to be unemployed eight years after their stroke than the general population.[1] Although impairments in the stroke survivor's physical, cognitive and communication abilities can affect this, [4-5] social and environmental factors such as personal and employer beliefs and attitudes, job type and organisation size and the benefits system also play an important part.[6-7]

Vocational rehabilitation (VR) is defined as whatever helps someone with a health problem to return to, or remain in, work and includes both work and work-related education.[8] It involves helping people find work, helping those who are in work but having difficulty, as well as supporting career progression in spite of illness or disability. The primary aim is to optimise work participation.[9] Existing research suggests that VR may help stroke survivors return to their previous job or find new work,[10-11] however trials to date involve small samples in non-UK settings.

RETAKE is a multi-centre individual patient randomised controlled trial (RCT) which aims to determine the clinical and cost-effectiveness of an Early Stroke Specialist Vocational Rehabilitation (ESSVR) intervention in addition to usual NHS rehabilitation on stroke survivors' return to work at 12 months post-randomisation, compared to NHS

rehabilitation alone.[12] Acceptability and utility were assessed in a feasibility trial.[13] ESSVR combines conventional occupational therapy (OT) with case coordination. The intervention commences within two weeks of randomization and lasts up to 12 months post-randomization. It is intended for delivery in the community as often as required by individuals, as determined by a stroke specialist OT with additional VR training. ESSVR includes the following: (a) assessing stroke impact on the person and their job; (b) educating individuals, employers, and families about stroke impact on work, and strategies to lessen impact (e.g., memory aids, fatigue management); (c) work preparation, including opportunities to practice work skills; and (d) liaison with employers to plan and monitor a phased return to work (RTW) (see Appendix I). The target number of participants for the trial is 760 participants (420 ESSVR and 340 usual care) from 20 UK hospitals and linked early supported discharge/community services. The RETAKE trial and embedded process evaluation commenced in June 2018 and will complete in March 2022. This period includes a funder approved extension of seven months necessitated by an unplanned pause in recruitment during the Covid19 pandemic.

Failure to implement evidence-based stroke rehabilitation interventions in clinical practice may result in unnecessary suffering and disability.[14-15] Trialists must consider future implementation in the real world when designing clinical trials, paying particular attention to the context for intervention delivery and factors likely to influence its uptake and use.[16] This is especially true for trials of complex rehabilitation interventions, which comprise multiple interacting components, and target a number of different organisational levels, making them particularly challenging to implement. An embedded process evaluation provides for an in-depth exploration of factors influencing the implementation of complex interventions.

Page 7 of 34

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2 3 4	165	
5 6	166	The Medical Research Council (MRC) argue for a systematic approach to designing
7 8 9	167	and conducting process evaluations, drawing on clear descriptions of intervention
10 11	168	theory and the identification of key process questions.[17] Mixed methods
12 13	169	approaches to process evaluation are increasingly common and consistent with the
14 15 16	170	MRC framework's emphasis on exploring and understanding the important
17 18	171	relationship between context, mechanisms and implementation. Theory driven
19 20	172	process evaluations are recommended alongside complex intervention trials to
21 22 23	173	measure what is delivered. These measurements include fidelity (whether the
24 25	174	intervention was delivered as intended), dose (the quantity of intervention
26 27	175	implemented), and "reach" of interventions to understand how the intended audience
28 29 30	176	interacts with the intervention.[17] Fidelity data are necessary to interpret
31 32	177	intervention outcomes, but despite an extensive literature supporting its importance,
33 34	178	fidelity is commonly under-reported in studies of complex rehabilitation interventions.
35 36 27	179	Whilst most trials of VR have not raised particular concerns about fidelity, ESSVR in
37 38 39	180	the RETAKE trial is an example of a particularly complex intervention that crosses
40 41	181	organisational boundaries, involves interactions between multiple stakeholders, is
42 43	182	highly individually tailored and requires behavioural change by the patient, their
44 45 46	183	family and employer. Therefore, in the process evaluation for the RETAKE trial we
47 48	184	have included specific methods to measure fidelity. Alongside a focus on fidelity, in-
49 50	185	depth qualitative exploration of participants' experiences of an intervention, and of
51 52 53	186	the social and structural context in which an intervention is provided, are essential
55 54 55	187	elements of process evaluation of complex interventions. This ensures any
56 57	188	adaptations made to tailor intervention to the individual and/or differing contexts,
58 59 60	189	which might undermine fidelity can be evaluated. Understanding and reporting how

2		
3 4	190	the intervention (including training and support, communication and management
5 6	191	structures) is delivered is important for replication in clinical practice.[17] Such
7 8 0	192	evaluation aims to reduce the chance of discounting effective interventions (Type II
9 10 11	193	error) or erroneously attributing outcomes to treatment effectiveness, when
12 13	194	interventions are not delivered as intended (Type III Errors).[18 - 21] The approach is
14 15	195	designed to improve trial design and knowledge translation interventions enhancing
16 17 18	196	clinical implementation and reducing research waste.[22-23]
19 20	197	
21 22	198	This paper reports the protocol for the process evaluation embedded in the RETAKE
23 24 25	199	trial.
26 27	200	
28 29	201	
30 31 32 33 34 35 36 37 38 39 40 41	202	AIMS AND OBJECTIVES
	203	Aims
	204	To measure fidelity to the ESSVR intervention and understand the social and
	205	structural context in which the intervention is delivered and identify factors which
42 43 44	206	may influence the quality of implementation.
45 46	207	
47 48		
49 50	208	Objectives
51 52 53	209	Fidelity measurement and competency assessment will
54 55 56	210	1. Ascertain intervention dose
57 58	211	2. Describe content of usual care and ESSVR
59 60	212	3. Describe levels of adherence to the ESSVR intervention

Page 9 of 34

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1 2						
- 3 4	213	4. Understand the delivery of Usual Care and ESSVR.				
5 6 7 8 9 10 11 12 13 14 15	214	5. Determine OTs competency to deliver ESSVR				
	215	Social and structural context will include				
	216	6. Describe participating sites.				
	217	7. Understand professionals' experiences of being trained to deliver the intervention.				
16 17	218	8. Understand experiences of delivering the intervention.				
18 19	219	9. Understand the social and structural factors which support or act as barriers to the				
20 21	220	implementation of the intervention.				
22 23 24	221	10. Understand participants' experience of being supported to return to work after				
25 26	222	stroke.				
27 28	223	11. Identify potential contaminants				
29 30	224					
31 32 33 34 35 36 37 38 39 40 41	225					
	226	METHODS				
	227	Design				
42 43	228	Embedded theory-driven mixed-methods process evaluation incorporating qualitative				
44 45 46	229	and quantitative methods. The process evaluation will draw on the intervention logic				
40 47 48	230	model developed by the Trialists (Figure 1) and will be underpinned by Normalisation				
49 50	231	Process Theory (NPT), an implementation theory built on four constructs				
51 52	232	(coherence, cognitive participation, collective action and reflexive monitoring) each				
53 54	233	informed by four components.[24] NPT will be used in the development of data				
55 56 57	234	collection tools (interview topic guides and observation checklists [see Table 1]) and				
58 59 60	235	as a sensitising lens in qualitative data analysis and interpretation. NPT constructs				



237 integration of the intervention into participating stroke services. This will include how

the intervention is received, understood, implemented and how it could be

239 normalised into the current healthcare system.

Table 1: Examples of question topics related to NPT constructs

Normalisation	NHS Staff/	Stroke Participant	Employer	
Process Theory	therapist	interview topics	interview topics	
Constructs and	interview topics	(some may also arise		
components	(some may also	in intervention / usual		
	arise in informal	care observations)		
	feedback during			
	training			
	observations)			
 Coherence: Differentiation Communal 	How do staff describe the intervention? How is the intervention similar	Experiences of RTW support received: similarities/differences between control and intervention participants	Experience of liaising with the therapist and/or participant on RTW issues	
specification				
 Individual 				
specification	Who would (most)			
 Internalisation 	benefit from the	6.		
	intervention?		-	
cognitive participation	Do staff see value/potential in the intervention?	What were their expectations? Did patients (& carers) value the intervention?	Expectations of the processes: liaising with therapist/patient and patient's RTW	
Enrolment	Have they found the			
LegitimationActivation	training and experience a worthwhile investment of time?	How did they respond to the therapists' suggestions?	(Prior) experience in supporting RTW for people with disabilities	
	Do they feel they have the competence/ resources to deliver the intervention	ability/resources/confidence to progress through the sessions and ultimately RTW?		
	effectively?	Context in which participant received RETAKE/acted on suggestions: social, financial, health state, access to opportunities		
Collective action Interactional	How compatible is the intervention with the existing stroke	How did participants accommodate the intervention sessions/follow	Views on who is responsible /roles in supporting RTW	
 workability Relational integration 	care pathway? What other RTW	up actions? How did they manage/are	Financial implications	
integration			J	

Page 11 of 34

2					
3		Skill set	services/resources	they managing their RTW	
4		workability	exist locally? How	(if applicable)?	
5			does this intervention		
6		 Contextual 	compare/complement	Financial implications	
7		integration	those services?	·	
8			Describe working		
9			relationships with		
10			those services.		
11					
12			Support from		
12			managers and		
13			colleagues during the		
14			intervention period		
15		Reflexive monitoring	Perceived effects on	Perceived effects of	Percentions of benefit
16		Renexive monitoring	nationts (& carers)	PETAKE/other PT\//	to
17		- Systematication	patients (& carers)	support	omployer/tutor/advisor
18		Systematisation	Viewe on	support	employentutor/advisor
19		Communal	time/resources	Views on time/resources	Porcontions of honofit
20		appraisai	interfesources	views of time/resources	te employee
21		Individual	invested in delivery	impact	to employee
22		appraisal	vsimpact	Impact	M/bot wee balsful
23		 Reconfiguration 			vvnat was neiptui
24		•	what is needed to	what was good about	about discussions
25			make it possible to	RETAKE and what could	with
25			roll out the	be improved? (Content of	therapist/participant?
20			intervention	intervention sessions/work	
2/			effectively? (Changes	plans, timing, relationship	What further
28			to intervention;	with therapist)	information/support
29			changes in		would they have liked
30			services/resources		– at what time?
31			needed for delivery)	<u> </u>	
32	241				
33					
34					
35	242				
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37					
38	2/13	Figure 1 The ESSVR	logic model		
39	243		logic model.		
40					
ло Л1	244	Column 2 of the logic	model identifies the	ore components of the L	
41	244	Column 3 of the logic			33VK
42					
43	245	intervention. A more d	etailed description of	f the development and fea	asibility testing of
44			·		, ,
45	240	the ESSI/D intervention	n haa haan nublisha	d proviously [12]	
46	246	The ESSAR Intervention	n has been publishe	a previously. [15]	
47					
48					
49	247				
50					
51					
52	248	In addition, the Conce	ptual Framework for	Implementation Fidelity (CFIF) (Figure 2)
52		-			
55	240	will quide collection on	d analysis of quantit	ative data [25] The CEIE	outlines the
54 55	249	will guide collection an	iu analysis of qualitit		
55					
56	250	components and varia	bles that make up a	nd affect intervention fidel	lity and explains
57		-			-
58					
59					
60					

3 4	251	how they relate to each other. Adherence includes content and dose (frequency,
5 6 7	252	coverage and duration) of the delivery.[25]
8	253	
9 10 11	254	Figure 2. Assessment of fidelity and factors moderating ESSVR delivery in
12 13	255	accordance with the Conceptual Framework for Implementation Fidelity.[25]
14 15 16	256	
17 18 19	257	Eligibility criteria
20 21	258	Stroke survivors that meet the following criteria for inclusion in the RETAKE trial will
22 23 24	259	be eligible to participate in the process evaluation:
25 26	260	• Age ≥18 years.
27 28 20	261	 Admitted to hospital with new stroke (all severities).
29 30 31 32 33	262	 In work at stroke onset (including self-employed, paid or voluntary).
	263	• Willing and have capacity to provide informed consent to participate in the study.
34 35 26	264	• Have sufficient proficiency in English to contribute to the data collection required
36 37 38	265	for research.
39 40	266	Potential participants who do not intend to return to work will be excluded. Potential
41 42 43	267	participants with a transient ischaemic attack will be excluded.
44 45	268	Inclusion criteria for carers of potential participants:
46 47 48	269	Nominated carer of consenting participant.
49 50	270	Willing and have capacity to provide informed consent to participate in the
51 52	271	study.
53 54 55	272	Have sufficient proficiency in English to contribute to the data collection
56 57	273	required for research.
58 59 60	274	

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Informed Consent

Potential participants will be provided with an information sheet and be provided the opportunity to ask questions of a researcher prior to consent. Written informed consent will be obtained from all participants. When a participant is randomised to the case study element, a researcher will contact the participant to gain consent for interview and observations. Consent will be reaffirmed at the start of interviews. This process will be the same for carer, employer, OT and NHS staff interviews. For employer interviews, additional consent to contact the employer will be requested from the case study participant before the employer is contacted. OTs who will deliver the ESSVR intervention and mentors supporting these OTs will be recruited prior to intervention training. NHS staff involved in the management, commissioning or delivery of stroke rehabilitation in each site participating in the RETAKE trial will elie be recruited.

Sampling

For professional and patient interviews, as far as possible we will use a purposive sampling strategy to ensure diversity in terms of geographical location (e.g. urban vs rural centres), level of staff seniority and participant sociodemographic variables (including gender and socio-economic status). See Table 2 for the timepoints at which data collection is planned.

Patient and Public Involvement Statement

Stroke survivors are involved in all stages of the research cycle.

Design and development.

Page 14 of 34

3 4	299	Two stroke survivors are co-applicants on the grant and assisted in identifying the
5	300	research questions, designing the study and developing the trial protocol.
7 8 9	301	Delivery.
10 11	302	Two PPI are members of the Trial Steering Committee, and two are members of the
12 13	303	Trial Management Group. Additionally, our RETAKE PPI (Patient & Public
14 15	304	Involvement) group, which has six members, meets quarterly. Examples of the work
16 17 18	305	achieved by the PPI group to date are:
18 19	306	Helping define the primary outcome and defining 'voluntary work' which is
20 21	307	included in the definition of the primary outcome.
22 23	308	Evaluating all patient facing material including aphasia friendly recruitment
24	309	material.
25 26	310	Co-development of interview topic guides for trial participants and
27 28 29 30 31 32 33	311	occupational therapists.
	312	 Overcoming problems with recruitment. For example, resources and
	313	narratives to assist recruiters in approaching people with severe stroke.
	314	Assisting in the design of new materials to promote follow up e.g. including a
34 35	315	'patient journey leaflet' and Thankyou cards.
36	316	 Helping reduce the length of follow-up questionnaires.
37 38	317	 Advising on communicating with participants during the pandemic.
39 40	318	Changes to the Excess Treatment Cost payment models during trial, caused
41 42	319	problems for the study. One PPI member wrote directly to Directors of the
42	320	NIHR, NHS England, Health and Social Care and the leads for the NIHR
44 45	321	Clinical Research Network to explain the impact that these changes on the
46 47	322	trial. She received a prompt response which was extremely helpful to the
48	323	research team. This has assisted us in explaining the new system to clinical
49 50	324	colleagues and researchers in the Trusts.
51 52 53	325	 Co-Development of a trial website and trial newsletters.
54 55	326	A draft report on the process evaluation findings will be presented to the PPI group
56	327	for their consideration and comments prior to submission of the final report to the
58	328	funder and as part of planning publications and dissemination. The PPI group will be
59 60	329	involved in writing up and presenting study findings.

Page **15** of **34**

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3 4 5	330					
6 7 8	331	Data Collection				
9 10	332	The process evaluation	on will employ qua	litative and quantitati	ve methods t	to address
11 12 12	333	the research questior	ns. Table 2 illustrat	es the relationship be	etween the p	rocess
13 14 15	334	evaluation aims, rese	earch questions, da	ata sources and data	collection me	ethods. The
16 17	335	following section des	cribes each data s	ource in more detail.		
18 19 20	336					
21	337	Table 2: RETAKE pr	ocess evaluation	research question	s and data s	ources
22 23 24	338					
24 25		Aims	Research	Data Source(s)	Method(s)	Timepoint
26 27 28 29			questions What is the intervention dose, intensity and duration?	Intervention content case report forms (CREp)	Quantitative	Months 3-45
30 31 32 33 34 35			What is the (reported) content of the ESSVR intervention?	 Intervention content CRFs. NHS therapy records. 	Quantitative and qualitative	Months 3-45 Months 12-45
36 37 38 39 40 41 42 43		Measure fidelity to	content of usual care?	 Stroke survivor- reported resource use data. Stroke survivor carer and OT intoniowo 		Months 12-36
44 45 46 47 48		the intervention	Was the intervention delivered with fidelity?	Fidelity checklist, Intervention content CRFs	Quantitative and qualitative	Months 3-45
49 50 51 52			What factors affect implementation fidelity?	 Mentoring records, RETAKE OT interviews 		Months 12-18
53 54 55 56 57 58 59			Are RETAKE OTs competent to deliver the ESSVR intervention?	 Individual OT performance in assessed vignettes at 	Quantitative	Months 1-8 and as new OT join the trial and 6 and 12 months post

training.

		 baseline and 6 months RETAKE OT case record reviews at 12 months post training 		
	for intervention delivery?	 Site survey at baseline, mid- point and end of intervention delivery 	qualitative and qualitative	vionths 1, 18 and 36* *later timepoint for end of intervention delivery where sites recruit beyond the Covid19 extension.
	What services are in place for supporting patients in return to work?	 Site survey at baseline, mid- point and end of intervention delivery 	Quantitative and qualitative	As above.
Understand the social and	What are the staffing levels at sites?	 Site survey at baseline, mid- point and end of intervention delivery 	Quantitative and qualitative	As above
context which may influence intervention mplementation and future embedding in practice settings.	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 NHS staff interviews 	Quantitative and qualitative	As above.
	What are the RETAKE OTs' perceptions of training and mentoring to deliver the intervention?	 Observations at training sessions RETAKE OT interviews 	Qualitative	Months 1-8 and as new OT join the trial.
	How do OTs experience delivering the intervention?	 Observations of ESSVR sessions RETAKE OT interviews Mentoring records 	Qualitative	Months 12-18 Months 12-18 Months 12-45
	What are the social and structural factors supporting or acting as barriers to intervention implementation?	 Observations of usual care and ESSVR sessions RETAKE OT interviews 	Qualitative	Months 1-8 Months 12-18 Months 12-18
				10101113 12-24

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13 14	
15 16	
17 18	339
19 20	340
20 21 22	
23 24	341
25 26	342
27 28	343
29 30	344
31 32	3/15
33 34	246
35 36	346
37 38	347
39 40	348
41 42	349
43 44	350
45 46 47	351
48 49	352
50 51	353
52 53	354
54 55	355
56 57	255
58 59	356
60	257

	•	Usual Care therapist interviews NHS Staff interviews Mentor interviews		Months 6-8
How d particip experie suppor to worl stroke	o • pants' ence being rted to return • k after ? •	Stroke survivor interviews Carer interviews Employer interviews	Qualitative	Months 12-24 Months 12-24 Months 12-24

341 Intervention content Case Report Forms (CRFs)

To check on fidelity in terms of (early) intervention within two weeks of recruitment, initial Session CRFs (one per participant) record the Intervention start date and whether this occurred within 8 weeks of stroke. Participant Summary CRFs record the number of sessions attended out of those proposed and whether there was an agreed ending for the OT led return to work support. To ascertain intervention dose and describe intervention content, data will be extracted from intervention CRFs for all participants (see Table 3). Therapists record each intervention session against pre-defined components, on an 'Intervention content CRF'.[13] These data will be used to identify which components of the intervention were delivered, to what extent therapists adhered to the intervention process described in the RETAKE manual, and to what extent participants adhered to the intervention. For case study participants only, content data will be cross-referenced with the OT's clinical case notes and additional data extracted to explain how the RETAKE intervention interacts with usual care and other services such as employment services. Participants' consent includes permission for members of the trials team to access their therapy records. 357

Page 18 of 34

358 Describing usual care

To describe the content of the intervention and of usual care, resource use questions pertaining to participants' use of health and social care services over the previous three months will be completed by all participants at three, six- and twelve-months post-randomisation as part of follow-up. This data will be used to describe the content of usual care, and in case study participants (n=38) will be triangulated with therapists' clinical notes and participant interview transcripts.

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Page 21 of 48

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2 3 4 5	365	Fidelity
6 7	366	To assess implementation fidelity a range of data collection methods informed by the
8 9 10	367	CFIF will be used (see Table 3).[25]
11 12 13 14	368	
15 16 17	369	Therapist competency assessment
18 19 20	370	Following attendance at a two-day, manualised face-to-face training session with VR
20 21 22	371	expert trainers and again at refresher training six months later, retake OTs
23 24	372	competence will be assessed using OTs written responses to questions based on
25 26	373	vignettes depicting novel RTW after stroke scenarios. Model answers developed by
27 28 20	374	the training team will be used to measure competence using criteria based on
29 30 31	375	knowledge of the intervention process (40%), clinical reasoning (50%) and written
32 33	376	communication (10%). Scores will be mapped to a rubric identifying OTs as highly
34 35	377	competent (≥70%), competent (50-69%) or needing additional support (≤49%) (see
36 37 38	378	Appendix II). In addition, as mentors meet with mentees on a monthly basis, informal
39 40	379	monitoring of OT competency can occur. If required, action can be taken to
41 42	380	addresses issues of concern identified by mentor or mentee. After 12 months of
43 44	381	delivering the intervention RETAKE OTs competence will be reassessed by
45 46 47	382	evaluating the intervention delivered in a random selection of completed intervention
48 49	383	case records (one participant per RETAKE OT) against the trainer's expert opinion.
50 51	384	The trainer will review the selected case records against the intervention
52 53	385	mechanisms identified in the logic model and confirm whether the intervention
54 55 56	386	delivered is consistent with the intervention that would have been delivered by the
57 58 59 60	387	trainer as an expert return to work related occupational therapy.

Page 20 of 34

388					
389					
390	Fidelity Checklist				
391	A fidelity checklist	based on the F	RETAKE intervention	on logic model (see	Figure 1) and
392	RETAKE intervent	ion process an	d components will	be applied to comp	olete case
393	records (Content o	f Intervention (CRFs, RETAKE OT	case notes and Ir	iitial Session
394	CRFs) from a rand	om selection c	of stroke participant	s randomised to re	ceive the
395	RETAKE intervent	ion (one per tre	eating RETAKE OT). This will be used	I in measuring
396	adherence to the F	RETAKE proce	ss and identifying f	actors affecting ad	herence.
397					
398	Table 3. CFIF led	data extractio	on for Fidelity Ass	sessment:	
399					
	Fidelity Measure	CFIF	Measurement	Data for	Time point
	_	Construct*	tool	extraction	P
	Frequency	Adherence	Initial Session	Intervention	One CRF
	Duration	and	Case Report	start date and	per
	Duration	factors	Forms (CRFS)	Number of	at Initial
		luotoro		proposed and	session.
			_	attended	
			Participant	sessions	One CRF
			Summary CKFS	whether there	per
				ending for OT	completed
				return to work	throughout
				support.	intervention
					aelivery

2						
3		Intensity (time	A dherence	Intervention	Time spent (in	One
4			Autorenee	agentant CDE	minutes) on VD	completed
5		spent per		content CRF	minutes) on VR	completed
6		session)			activities per	following
7		Dose (number of			session	every
8		sessions)				intervention
a a				OT clinical		cossion
10				OT CIIIICai	5	56551011
10				records	Description of	
11				(RETAKE+	intervention	In case
12				Usual Care)	delivered in	studv
13					each session	narticinants
14						participants.
15		Therepiet	Adharanaa		Componente	Applied to
16		Therapist	Adherence	Fidelity	Components	Applied to
17		adherence	and	Checklist	delivered,	one
18		Factors affecting	moderating		factors affecting	randomly
19		adherence	factors		delivery	selected
20			laotoro			completed
21					RETARE	completed
22					process	case per
23					followed Y/N	RETAKE
24						OT
25						
26		Real time	Adherence	Mentoring	Mentor's	Completed
27		therapist	and	CRFs	concerns about	monthly by
28		adherence	moderating		adherence	mentors
20		Eactors affecting	factors		Factors	
30			1401013		offection	
21		adherence			anecting	
27					Intervention	
22 22					delivery	
22					-	
54 25					Potential	
35					adutiona	
30						
3/		Barriers and	Moderating	Interviews with	Factors	In a random
38		enablers to	factors	RETAKE	affecting	selection of
39		intervention		Therapists	intervention	cases
40		delivery		•	delivery	during
41		Gonvory				intervention
42					Detertial	
43					Potential	delivery at
44					solutions	3, 6 and 12
45					(developed by	months
46					ÓT) Í Í	
47		Accentability of	Moderating	Intorviowe with	Accentability of	Throughout
48		the intervention	feetere			intervention
49			Tactors	Stroke		
50		Barriers and		participants,	Factors	delivery in
51		enablers to		carers,	affecting	case
52		intervention		employers and	deliverv	studies
53		deliverv		NHS staff	Potential	
54		Gonvory			solutions to	
55						
56					parriers	
57	400	Key; *CFIF Adhere	ence includes i	ntervention content	, dose, coverage, f	requency and
58						

⁵⁹ 401 *duration of intervention; CFIF Moderating factors includes participant*

responsiveness, intervention complexity, strategies to facilitate implementation, quality of delivery, recruitment, and context. Mentor interviews and records Mentoring records Following training, each treating OT will be assigned a mentor with extensive knowledge and experience of vocational rehabilitation. Mentoring will take place monthly via teleconference in small groups (four to six therapists) and serve as an intervention implementation support mechanism. RETAKE OTs will be able to discuss any difficulties they are experiencing, ask questions and share best practice with other OTs and their mentor. This process will also facilitate communication between the trial team and enable barriers to implementation and contamination risks to be reported. Key discussion points will be recorded by mentors using a mentoring record form for each session. These records, along with all email correspondence between mentor and mentees will be collected for qualitative content analysis. Mentor Interviews Semi-structured interviews will be conducted by two research assistants (SC and KC) with all mentors (n=6) to explore their experiences of supporting RETAKE OTs to deliver the intervention, and ascertain their views of organisational, social and other factors contributing to or affecting delivery of the intervention.

424 Social and str	uctural context
--------------------	-----------------

To describe participating sites and identify potential contaminants, sites will be asked to complete a guestionnaire by telephone at three time points; prior to recruitment, halfway through, and at the end of the intervention period. This will contribute to understanding contextual influences through capturing data on existing stroke care pathways and resources (including staff and services) available for supporting participants in a return to work. It will also identify potential contamination risks associated with proposed or planned VR service developments or changes in practice that may influence trial outcomes. relie Therapist training Non-participant observations To understand OT's experiences of being trained to deliver the intervention, a research assistant (RC) will observe up to four training sessions delivered by the

training team. A checklist will be developed using NPT constructs to guide

observations. Non-participant observations aim to identify; whether therapists

441 understand the intervention and their role in implementation, whether they think the

442 RETAKE intervention can be integrated into existing practice and any contextual

443 factors affecting the trial.

53 444

To describe adherence to the intervention, a researcher will observe up to three
 sessions for each case study participant in the intervention and usual care arms of
 the trial. Non-participant observations will be conducted using prompts for structured

Page 24 of 34

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448	observation and unstructured field notes.[26] Participant selection for inclusion the
449	case study element is described below.
450	
451	Interviews with Occupational Therapists
452	Semi-structured interviews will be conducted by a research assistant (RC) with a
453	minimum of one OT per site following their initial RETAKE training to explore their
454	experience of training, the mentoring process and their confidence in intervention
455	delivery. OT's views of the intervention, barriers and facilitators to implementation,
456	and any organisational or social factors impacting on delivery will also be explored.
457	Interviews will take place following training and be repeated at two additional time-
458	points: mid-way through the RETAKE intervention delivery and at the end of the
459	study.
460	
461	Case studies
462	Longitudinal case studies will be used to map the care received by RETAKE and
463	usual care participants to develop a more detailed understanding of participants'
464	(stroke survivors, carers, employers) and RETAKE OTs experiences of support for
465	RTW. A 5% subset of participants from both arms of the trial (total n=38) will be
466	randomly selected and invited to participate in the case study element of the process
467	evaluation.
468	
469	i) Case study interviews
470	Semi-structured interviews will be conducted by two research assistants (SC and
471	KC) with case study participants at three time points: three, six-, and twelve-months
	Page 25 of 34
	 448 449 450 451 452 453 454 455 456 461 462 463 464 465 466 467 468 469 470 471

1 2		
3 4	472	post-randomisation, about their experiences and views of and adherence to the
5 6	473	RETAKE intervention and the support they received to return to work. The case
7 8 9 10 11 12	474	study participants' carers (if nominated), their employers (where participant consent
	475	is obtained) and the OTs providing support for RTW will be interviewed.
13 14 15	476	NHS staff interviews
16 17	477	To further understand the social and structural factors which influence the
18 19	478	implementation of the intervention, interviews will be conducted with up to two (n=34
20 21 22	479	in total) NHS staff involved in the management, commissioning, or delivery of stroke
22 23 24	480	rehabilitation within each trial site. Participating staff will be chosen using a mixture
25 26 27 28 29 30 31	481	of purposive and snowball sampling. This will be based on a full range of trial sites,
	482	staff knowledgeable about the implementation of the intervention at their site, and
	483	staff knowledgeable about the decision-making process relating to wider roll-out.
32 33 34	484	
35 36 37	485	Additional participant interviews
38 39	486	An additional random 5% of study participants will be invited to participate in semi-
40 41 42	487	structured interviews at the end of the intervention period. These interviews will
42 43 44	488	explore participants' experience of the intervention as well as their perceptions and
45 46	489	experiences of returning to work.
47 48 49	490	
50 51	491	All qualitative interviews will be conducted using a topic guide informed by NPT.
52 53 54	492	Examples of question topics and how they relate to the four NPT constructs are
55 56	493	shown in Table 1. Topic guides will be presented to the RETAKE Public and Patient
57 58	494	Involvement (PPI) group for comment prior to use. All interviews will be audio
59 60	495	recorded and transcribed in full.

Page 26 of 34

1 2 3 4 5	496	
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	497	Data Analysis
	498	Quantitative analysis
	499	The dose, duration and frequency of the ESSVR intervention will be calculated using
	500	data from completed CRFs in combination with NHS therapy records. The total time
	501	spent delivering the ESSVR intervention (face to face and non-face to face contact
	502	(liaison with the patient, employer and other stakeholders by letter/phone),
	503	administration and travel) will be identified. Details relating to the content of
24 25	504	intervention sessions will be extracted to identify whether core components of
26 27	505	ESSVR were delivered as intended (i.e., as specified in the intervention manual and
28 29 30	506	logic model). Associations between therapist attributes, contextual factors and
30 31 32	507	intervention fidelity (measured by deviations from the RETAKE core process) will be
33 34	508	explored using regression models. Analysis will be conducted using Statistical
35 36 27	509	Package for the Social Sciences (SPSS) (version 21.0 for Windows).
38 39	510	
40 41 42	511	Describing Usual Care
44 45	512	Data regarding rehabilitation delivered in Usual Care will be extracted from resource
46 47	513	use data in the follow-up questionnaires and from NHS Therapy records in case
48 49	514	study participants randomised to Usual Care. These data will be used to inform the
50 51 52 53 54 55 56 57 58 59	515	cost of Usual Care for the economic evaluation and describe and understand usual
	516	care provided during stroke rehabilitation in inpatient and community services.
	517	Quantitative analysis of these data will be conducted using Statistical Package for
	518	the Social Sciences (SPSS; Version 21.0 for Windows). Analysis of usual care data
60	519	obtained from NHS Therapy records is described below.

Page 27 of 34

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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35	520	
	521	Qualitative analysis
	522	Inductive (thematic analysis) and deductive (informed by NPT) approaches will be
	523	used to guide data analysis and interpretation. Observational and Interview data will
	524	be transcribed verbatim and uploaded into QSR NVivo software for management.
	525	Descriptions of usual care in NHS Therapy records, observational field note data,
	526	including researcher reflections and interview data will be analysed thematically.[27]
	527	Framework analysis will be used with the case study data. For each participant the
	528	interview data will be coded in NVivo and then imported into a Framework matrix for
	529	comparison both within the individual case (comparing views of stroke survivor,
	530	carer, OT and employer) and across cases and sites. Analysis will proceed
	531	iteratively with data collection to determine whether data saturation has been
	532	achieved; researchers will draw on the RETAKE logic model (Figure 1). Throughout
	533	the qualitative analysis, NPT will be used as a sensitising framework.
36 37 38	534	Analysis of each qualitative data set will be conducted independently and then jointly
39 40	535	by at least two study team members (SC, KC, KP) to corroborate themes and
41 42	536	discuss any discrepancies. It will follow a standard inductive approach of data
43 44 45	537	familiarisation, line-by-line coding and development of broad themes. Themes will
45 46 47	538	then be mapped to NPT constructs as part of development and refinement of
48 49	539	broader conceptual explanatory categories. Researchers will keep a set of interim
50 51	540	summary notes documenting any reflexivity points and connections between the
52 53 54	541	data with NPT and the logic model, to aid analytical discussions with the wider
54 55 56	542	process evaluation team. Iterative testing of interpretation will occur through
57 58	543	discussion with and feedback from the PPI group and discussions within the
59 60	544	research team.

Page 28 of 34

2 3 4 5	545	
6 7 8 9	546	Synthesis of qualitative and quantitative data
10 11 12	547	During the RETAKE trial the qualitative and quantitative data generated as part of
13 14	548	the process evaluation will be independently analysed by the process evaluation
15 16	549	team and the Clinical Trials Research Unit respectively. Data related to intervention
17 18 19	550	fidelity and description of usual care will be synthesised at the conclusion of the trial.
20 21	551	We will review and compare findings from related data sets, identify areas of
22 23	552	agreement and disagreement and develop explanations for the findings. Synthesis of
24 25 26	553	findings from both the quantitative and qualitative data generated will contribute
20 27 28	554	directly to the overall evaluation and explanation of the outcomes of the RETAKE
29 30	555	trial.
31 32 33	556	
34 35	557	Ethics and dissemination
36 37	558	Ethics approval has been obtained through the East Midlands – Nottingham 2
38 39 40	559	Research Ethics Committee (REC) (Ref: 18/EM/0019) and the National Health
41 42	560	Service Research Authority. The procedures for gaining informed consent have been
43 44	561	detailed above. Dissemination will be via journal publications, stroke and
45 46 47	562	rehabilitation focused conferences, newsletter articles, social media, presentations to
48 49	563	clinicians and stroke survivors and meetings with national clinical leads for the
50 51 52	564	Stroke Plan and the NHS Plan.
53 54	565	
55 56 57	566	Availability of data and materials
58 59 60	567	No additional data will be made available.

1 2		
- 3 4	568	
5 6	569	Competing interests
7 8 9	570	The authors declare that they have no competing interests.
10 11	571	
12 13 14	572	Funding
15 16	573	This study is funded by the NIHR HTA programme (ref: 15/130/11). The views
17 18	574	expressed herein are those of the authors, not necessarily the NIHR, the Department
19 20 21	575	of Health and Social Care, or the NHS.
22 23	576	
24 25 26	577	Authors' contributions
27 28	578	KR, CM, AFa, AB, ROC, MW, and CW conceived the study. KR, DJC, and CM
29 30	579	designed the process evaluation. KR, CM, DJC, SC, KC, JH, JP, TS, RC and KP
31 32 33	580	operationalized the process evaluation protocol. KR, JP, and JH designed the
34 35	581	intervention. AS has the role of trial sponsor. IH, RB, and AFa devised the data
36 37	582	management and statistical analysis plan. JS and JM acted as PPI collaborators to
38 39 40	583	support plans for trial design/delivery, management, and dissemination of trial
41 42	584	findings. VM and SH have responsibility for management of the trial. KR, SC and
43 44	585	DJC drafted the manuscript; all other authors read and approved the final version.
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Page 34 of 48

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2		
3	Appendix I	ESSVR Description (TIDieR)
4		
5	Brief Name	1a) Farly Stroke Specific Vocational Rebabilitation (FSSVR)
7	(Provide the	1b) The Return to Work after Stroke (RETAKE) trial
8	name or a	
9	phrase that	
10	describes the	
11	intervention.)	
12	WHY Describe	Rationale
13	any rationale,	
14	theory, or goal	Stroke is common (>100.000 strokes per annum in the UK) [1]. In spite of reperfusion therapy and
15	of the elements	secondary prevention outcomes remain poor - almost two-thirds of survivors leave hospital with a
16	essential to the	disability and a third experience depression and/or cognitive impairment. Stroke survivors of working
17	intervention.	and a time experience depression and/or cognitive impairment. Stroke survivors of working
18		age are 2-3 times more likely to be unemployed [1].
19		Increasingly, there is an expectation that existing health and social care nothways for stroke sumivers
20		increasingly, there is an expectation that existing health and social care pathways for stroke survivors
21		provide support for stroke patients intending to return to work [2-9]. Despite improvements in the
22		organisation of stroke rehabilitation services following discharge, many stroke survivors fail to access
23		this support because a) their work rehabilitation needs are not identified early after stroke b) many
24		have hidden disabilities such as visual or cognitive impairments and fatigue, which are missed in the
25		acute phase [10] and c) the criteria for referral to community rehabilitation are impairment based
20		rather than needs led, meaning that a person with unmet needs for work participation alone (rather
27		than a need for support from more than one healthcare professional e.g. Occupational Therapy and
20		Speech and Language Therapy) may be unable to access support. d) Not all community stroke services
30		provide rehabilitation that addresses work needs [11]. Where they do this may be time limited or fail
31		to engage with employers in the workplace, as supporting a return to work is not always seen as the
32		ich of health [9] Eurthermore stroke survivors themselves may not appreciate the true impact of the
33		stroke on their workability until they attempt to return to work [12]
34		Stroke off their workability until they attempt to return to work [12].
35		
36		Failure to provide this support, may lead to job loss, affecting physical, emotional, and imancial
37		wellbeing and quality of life [13,14]. Return to work is a recognised outcome of nearth interventions
38		[15]. Supporting people who develop health conditions to return to work is recommended in stroke
39		policy and clinical guidelines [3,4,5,7].
40		
41		The UK government has committed to reduce the employment gap (54% Vs 82%) between disabled
42		and non-disabled people. Its goal is to see one million more disabled people in work by 2027 [16].
43		
44		The Equality Act requires employers to make reasonable adjustments, to accommodate the person in
45		the workplace [17]. These adjustments may involve more breaks, reductions in working hours,
46		reduced responsibilities, increased supervision, flexible working patterns and working from home and
4/		help from other people or agencies, including rehabilitation.
48		
49		The 'theory of change underninning ESSVR'
50		
50		
52 53		Health based preparation and support for returning to work after stroke has typically been deficient
54		in meeting stroke survivors work needs. ESSVR was designed to bridge the gap between existing
55		stroke rehabilitation services, the employment and the voluntary sector in supporting stroke survivors
56		in a return to work [10] Tested in a single centre feasibility trial we found evidence to suggest that
57		that the intervention may have potential to support job retention at 12 months post stroke [18].
58		
59		The implicit theory of change on which ESSVR can be expressed as follows:
60		

2	
3	Stroke brings about physical and psychological impairments that are likely impact on the capacity to
4	return to and remain in work
5	
6	The children is identify words and combain the startic methods in the starting from startic combines and
7	The ability to identify work needs early in the stroke pathway is missing from stroke services and
8	vocational rehabilitation knowledge and skills gap is present in stroke rehabilitation services.
9	Implementing mechanisms for identifying stroke survivors who are employed at stroke onset;
10	educating the stroke care team about 'return to work' and teaching OTs with stroke specific
11	knowledge basic skills in vocational rehabilitation, disability discrimination, how to evaluate jobs and
12	assess work capability and match stroke survivor's abilities to job demands:
13	how to engage with employers, and other employment sector stakeholders, to go into the workplace
14	and how to engage with employers, and other employment sector stakeholders, to go into the workplace
15	and now to negotiate reasonable adjustment and phased return to work will enable stroke services to
16	support stroke survivors in a return to work.
17	
18	The logic model (Figure 1) has the following underlying assumptions;
19	
20	• If we implement an early 'VR nathway' for stroke then work is seen as a health outcome by stroke
21	if we implement an early VK pathway for stroke <i>then</i> , work is seen as a health outcome by stroke
22	renabilitation teams, conflicting advice prevented, increased confidence, knowledge and skills in VR,
23	patient aware of available support & how to access; Early barriers to RTW identified e.g. environmental
24	(job type), personal. Recognising work as an outcome of health interventions thus promoting a shared
25	philosophy of rehabilitation to support return to work [Mechanism: Early Intervention, Collective
26	Understanding
27	
28	• If we identify people who are employed at the time of stroke and refer to an Occupational Therapist
29	trained in VR (VR OT) for information/advice/ support re-return to work (RTW) then this will increase
30	connectivities for DTW 8, assumption loss provent people from folling into convice going and ensure
31	opportunities for RTW & prevent job loss; prevent people from failing into service gaps, and ensure
32	work needs are met. [Mechanism: Early Identification]
33	
34	• If we teach OTs basic skills in vocational rehabilitation (how to evaluate jobs and assess work capability,
35	match the injury related disabilities to job demands; how to engage with employers, and other
36	employment sector stakeholders, go into the workplace and how to negotiate reasonable adjustment
37	and a phased return to work) <i>then</i> they will have the confidence, knowledge and skills to support
38	stroke survivors in a return to work [Mechanism: VR Linskilling: Clinicians confident and empowered:
39	
40	Assessmentj
41	. If the OT provides early (within Queeks of studie) experiment, advection and advice on the impact of
42	ij the Or provides early (within 8 weeks of stroke) assessment, education and advice on the impact of
43	stroke & RIW, then the impact of the stroke on the job role will be identified to inform a vocational
44	rehabilitation plan. Persons requiring psychological support for mental health issues are identified and
45	referred for support, resulting in improved physical and mental health and financial wellbeing.
46	[Mechanisms: Assessment; Education Early intervention]
47	
48	• If the OT delivers individually tailored vocational rehabilitation, engaging with the employer to
49	negotiate workplace accommodations, a phased return to work, educating employers and monitors
50	ongoing work ability, then, the person will be able to cope with work, resulting in reduced sickness
51	absence and sustainable employment. [Mechanisms: Individual Tailoring: Accommodating stroke at
52	work, Colocation, Employer Engagement, communication
53	· · · · · · · · · · · · · · · · · · ·
54	
55	ESSVR is a biopsychosocial intervention informed by the International Classification of Function
56	(ICF) [19] and the 'Work Disability Arena' or Sherbrooke model [20]. It takes into consideration
57	the overall context of an individual. It identifies the level of functioning at the body, person and
58	societal level, as well as understanding the nersonal and environmental contextual factors that
59	may impade or enhance work participation
60	

	It aims to prevent job loss by drawing on employment law and the Equality Act (2010) (17) to prevent disability discrimination and ensure "reasonable adjustments" are negotiated with employers to reduce the impact of stroke disability by accommodating (modifying) the stroke survivor's job to enable a return to work. ESSVR also ensures patients are provided with appropriate individualised work-related physical and cognitive rehabilitation and self-management education to increase their ability to work.
WHAT	Materials:
Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL). Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	 Training: Occupational therapists are provided with an 'ESSVR Intervention manual' detailing the intervention content, its rationale and objectives, processes to be followed and forms for use in documenting ESSVR delivery in the trial. The manual included examples of return to work plans, sample graded RTW planning, session and work review letters, sample letters to GP, discharge letters, letter to employer, sample report for occupational health and a list of other useful resources (below). The manual was sent to therapist two weeks before the training and used during the training to navigate them through the ESSVR intervention process and familiarise them with its contents and resources. Resources included: For Occupational Therapists Employment and Support Allowance (ESA) Supporting letter and Guide to completing ESA (2012), See 50 9 eas50guide2012 (nawra.org.uk) Allied Health Professions Fitness For Work Report (RCOT), Accessible via https://www.rcot.co.uk/practice-resources/standards-and-ethics/ahp-health-and-work-report (Allied health Professions Federation). See; 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 Tailored Adjustments Plans - Business Disability Forum Work Ability Support Scale (WSS) (Fadyl J, McPherson KM, Schulter P, Turner-Stokes L., 2014) [21] Accessible via https://www.kcl.ac.uk/cicelysaunders/resources/tools/wss WSS Brief work questionnaire, Accessible via https://www.kcl.ac.uk/cicelysaunders/resources/tools/wss WSS Brief work questionnaire and jobe matching, Accessible via https://www.kcl.ac.uk/cicelysaunders/resources/tools/wss Tailored Adjustment PD and Bueston AnD S ANALYSIS AND JOB MATCH SYSTEM (Lucas, 2017), accessible via https://www.kcl.ac.uk/cicelysaunders/resources/tools/wss Tailored Net questionnaire and jobe matching, Acc
	 For Employers Employees with Executive Functioning Deficits (Job Accommodation Network 2018), Accessible via; Brain Injury (askjan.org) Accommodation and Compliance Series: Employees with Speech-Language Impairment (Job Accommodations Network, 2019) Accessible via JAN-Job-accomadation-suggestions.pdf (dysphonia.org)

1 2	
3 4 5 6 7 8 9 10	 Job accommodations for people with motor limitations from stroke (Morgantown, WV, Office of Disability Employment Policy, Job Accommodation Network, 2010) Accessible via Job accommodations for people with motor limitations from stroke - University of Missouri Libraries A complete guide to stroke for Employers (Stroke Association, 2019), See: f41cg_a_complete_guide_to_stroke_for_employers_v3_oct_2019.pdf, Information Pack -Work After Stroke - Information for Employers, (Different strokes, 2018) Available at: Work After Stroke (differentstrokes.co.uk)
11 12	For stroke survivors
13 14 15 16 17 18 19 20 21 22	 Information Pack Work After Stroke - Information for Family & Friends (Different Strokes, xxx year) Accessible via: Work After Stroke - Information for Family & Friends A_complete_guide_to_work_and_stroke.pdf See: Your rights at work after stroke Stroke Association, (Stroke Association, UK) Driving after a Stoke guide; (Stroke Association, 2021) See f02_driving_v_3.1_web_june_21.pdf (stroke.org.uk) Stroke in people of working age (Stroke Association, 2014), Accessible via: stroke_in_people_of_working_age.pdf Tailored Adjustments Plan (Business Disability Forum, 2020) Accessible via Tailored Adjustments Plans -
23	Business Disability Forum
24 25 26 27	Links provided to other Online Resources
28	Advisory services
29 30	 ACAS- Advisory, Conciliation and Arbitration Service- provides support in assisting employment disputes including these related to disability management: http://www.acas.org.uk/
31	 Citizens Advice Bureau: http://www.citizensadvice.org.uk/
32	 Disability Law Service: www.dls.org.uk
33	Disability Rights UK http://disabilityrightsuk.org/
34 35	Equality and Human Rights Commission http://www.equalityhumanrights.com/
36	Occupational Health Advisory Service Eit for Work offers free expert and importial advise to anyone
37	 Occupational Health Advisory Service – Fit for work offers free, expert and impartial advice to anyone looking for help with issues around health and work. You can browse our online resources, chat online
38	to a specialist advisor, email a question or call our free advice line on 0800 032 6235 (English) or 0800
39 40	032 6233 (Cymraeg). https://fitforwork.org/
41	Details of occupational health providers
42 43	Occupational health support can be very helpful in complex cases Occupational health services are
44	sometimes provided by NHS or local authority services. To find details of providers in your area,
45	contact:
46	Commercial Occupational Health Provider Association www.compa.co.uk NHS Health at Work www.nbsbealthatwork.co.uk/support-for-business.asp
47 48	 Society of Occupational Medicine www.som.org.uk
49	Safe Effective Quality Occupational Health Service (list of approved occupational health providers)
50	http://www.seqohs.org
51	Lab Cantes Diver
52 53	Job Centre Plus:
54	employment situations because of a disability or health condition. They can act as an advocate with
55	prospective employers if necessary, aiming to identify work solutions that will overcome or minimise
56	any difficulties related to an individual's disability in the work place. https://www.gov.uk/specialist-
57	employability-support
58 50	Welfare Benefits and Department for work and Pensions (DWP)
60	Benefits (Including Attendance Allowance, Employment Support Allowance, and Disability Living Allowance/Personal Independence Payment): https://www.gov.uk/browce/disabilities/bonefits
	Anowance/reisonarindependence raymenty. https://www.gov.uk/browse/disabilities/bellents

3	Access to Work information including contact details for all centres (for registration, the initial step for
4	clients wanting to use this scheme): https://www.gov.uk/access-to-work/overview
5	Bonofits and Work website offers advice to people to benefits. Some free information, fee for access to
6	Benefits and work website others advice to people repenetits. Some free information, ree for access to
7	additional support http://www.benefitsandwork.co.uk/
8	
9	Debt issues
10	 https://www.citizensadvice.org.uk/debt-and-money/
11	 https://www.nationaldebtline.org/
12	 http://www.debtadvicefoundation.org/
13	
14	Equipment advice:
15	 A huge range of IT accessibility info, assessments, resources: http://www.abilitynet.org.uk/
16	 Disabled Living Foundation: http://ww.dlf.org.uk
17	
18	Guidelines:
19	 Vocational Rehabilitation Association Guidelines- free to download upon registration:
20	https://vrassociationuk.com/
21	 BSRM Publications free to download- VR and long term conditions; VR Interagency guidelines:
22	 https://www.bsrm.org.uk/publications/publications
23	
24	Fit Note
25	AHP Fitness to Work Report info:
26	http://www.ahnf.org.uk/AHP_Advisory_Eitness_for_Work_Benort_htm
27	Fit Note info: https://www.gov.uk/government/collections/fit-note
28	• The Note mild. https://www.gov.uk/government/conections/in-hote
29	Managing cickness absence, disputes and sick new
30	• Managing sickness absence, disputes and sick pay
31	 Gov.uk - https://www.gov.uk/employers-sick-pay
32	
33	Ine Health and Safety Executive has provided guidance for employers and managers on managing
34	sickness absence and return to work.
35	 www.hse.gov.uk/pubns/priced/hsg249.pdf
36	
37	British Occupational Health Research Foundation has also developed guidance for managing sickness
38	absence and return to work. www.bohrf.org.uk/downloads/Managing_Rehabilitation-Guidance.pdf
39	
40	For questions about Statutory Sick Pay you can visit the HMRC website at
41	https://www.gov.uk/topic/business-tax/paye or call them on 08457 143143.
42	
43	The Employer's Charter helps employers understand what they can do in respect of a number of
44	issues.
45	www.gov.uk/government/uploads/system/uploads/attachment_data/file/32147/employerscharter.pdf
46	
47	 Touchbase: DWP news about work, working age benefits, pensions and services (DWP, 2015)
48	Accessible via: Touchbase: DWP news about work, working age benefits, pensions and services -
49	GOV.UK (www.gov.uk)
50	
51	Job search:
52	 https://www.gov.uk/jobsearch
53	 http://www.indeed.co.uk
54	 https://jobs.civilservice.gov.uk/company/nghr/jobs.cgi
55	 http://jobs.theguardian.com/
56	 http://www.jobs.nhs.uk/
57	 http://www.charityiob.co.uk/
58	 http://www.jobhuntershible.com/
59	 http://www.iobsgonublic.com/searches/new/
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	Stroke information
٠	Different strokes - https://differentstrokes.co.uk/ (for younger stroke pts)
٠	Stroke association https://www.stroke.org.uk
٠	VR general:
٠	MS Trust/Society and Headway - links to toolkits
٠	Job Accommodation Network https://askjan.org/
•	British Association of Supported Employment http://base-uk.org/
•	Volunteering associations
٠	https://www.ncvo.org.uk/ncvo-volunteering
•	https://do-it.org/
	Fitness/health information http://www.nhs.uk/Livewell/fitness/Pages/free-fitness.aspx
•	Cinema Exhibitor card https://www.cinemauk.org.uk/key-issues/disability-and-access/cea-card/
٠	If a person gets DLA, PIP or is registered blind, they can get this card and it entitles a free entry for another person
•	Local walk for health schemes http://www.walkingforhealth.org.uk/walkfinder/ -
	Transport
•	DVLA (driver vehicle licencing authority)
•	https://www.gov.uk/stroke-and-driving (patient information)
•	https://www.gov.uk/current-medical-guidelines-dvla-guidance-for-professionals
	Disabled bus pass
•	If not allowed to drive for a year due to their injury, they are entitled to a disabled bus pass
•	https://www.gov.uk/apply-for-disabled-bus-pass
•	Goal Attainment Scaling (GAS) in Rehabilitation system
	https://www.kcl.ac.uk/cicelysaunders/resources/tools/gas
Proced	ures:
Interve	ntion Delivery
ESSVR i	s an early, individually tailored, stroke specific job retention intervention. It adopts a problem- solving
and acc	some of the stroke survivor at work. It also aims to educate the person to self-manage the condition
at work	
It involv	 yes a trained vocational rehabilitation OT adopting a role as a case coordinator with a wider team of
healthc	are professionals employers family members and other agencies (e.g. occupational health and
employ	ment services, GPs, independent and voluntary sector services) to:
•	
	Assess the impact of the stroke on the patient, family and the patient's role as a worker/student and
	their ability to do their job/study course.
•	Assess the impact of the stroke on the patient, family and the patient's role as a worker/student and their ability to do their job/study course. Educate participants, employers/tutors and families about the effects of stroke and its impact on
•	Assess the impact of the stroke on the patient, family and the patient's role as a worker/student and their ability to do their job/study course. Educate participants, employers/tutors and families about the effects of stroke and its impact on work/education and find acceptable strategies to lessen the impact.
•	Assess the impact of the stroke on the patient, family and the patient's role as a worker/student and their ability to do their job/study course. Educate participants, employers/tutors and families about the effects of stroke and its impact on work/education and find acceptable strategies to lessen the impact. Monitor and assess the patient's work/educational goals.
•	Assess the impact of the stroke on the patient, family and the patient's role as a worker/student and their ability to do their job/study course. Educate participants, employers/tutors and families about the effects of stroke and its impact on work/education and find acceptable strategies to lessen the impact. Monitor and assess the patient's work/educational goals. Prepare people for work/education by establishing structured routines with gradually increased activity
• •	Assess the impact of the stroke on the patient, family and the patient's role as a worker/student and their ability to do their job/study course. Educate participants, employers/tutors and families about the effects of stroke and its impact on work/education and find acceptable strategies to lessen the impact. Monitor and assess the patient's work/educational goals. Prepare people for work/education by establishing structured routines with gradually increased activity levels and opportunity to practice work skills, e.g., structured computerised cognitive stimulation to
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• • •	Assess the impact of the stroke on the patient, family and the patient's role as a worker/student and their ability to do their job/study course. Educate participants, employers/tutors and families about the effects of stroke and its impact on work/education and find acceptable strategies to lessen the impact. Monitor and assess the patient's work/educational goals. Prepare people for work/education by establishing structured routines with gradually increased activity levels and opportunity to practice work skills, e.g., structured computerised cognitive stimulation to increase concentration, daily walks to increase physical stamina. Liaise with employers/tutors, employment advisors, student services and the healthcare team to advise about the effects of stroke and to plan and monitor a phased return to work. Alternatives to pre-injury employment are explored in cases where return to pre-existing employer is

The Occupational Therapist VR role involves, negotiating workplace accommodations, communicating with employers, offering advice and emotional to the patient, the patient's family and employer, and exploring work alternatives as required. The case-coordination role involves theRETAKE OT actively coordinating the RTW and input from relevant services from across all sectors (health, work, independent, voluntary, education), communicating with all involved stakeholders, such as the participants GP Department for Work and Pensions Services, welfare rights and employer organisations e.g. occupational health, GPs and voluntary sector services e.g. the stroke Association. The aim being to maximise the use of all locally available resources and ensure consistent advice and support for the patient.

ESSVR is a process (rather than a set of predetermined components) that is broken into 3 stages;

Stage 1: Early recovery and Work preparation: The OT intervenes early, within 8 weeks of stroke onset, to ensure work is on the agenda and jobs are not relinquished but kept open. Assessment of the individual, the impact of the stroke and a detailed job analysis and liaison with family members takes place at this stage. Plans are made to prepare the RETAKE participant for work return by providing advice and information to the participant and their family and advise medical/other rehab staff to encourage the participant not to make immediate decisions about work i.e. leaving work or going back too soon, which may jeopardise their RTW or job retention. The RETAKE participant is encouraged to keep the channels of communication with the workplace open and the RETAKE OT offers to mediate if difficulties arise. Activities are undertaken at home, relevant to work or simulated to build up the stamina and skills required to return to specific work tasks or roles. These include physical, cognitive or communication based activities depending on how the stroke has affected the RETAKE participant and the demands of their job. Liaison with any other services the person is receiving takes place to ensure there is no overlap and the approach to VR is smoothly coordinated.

Stage 2: Graded return to work: This involves planning, negotiating and implementing a phased return to work (RTW). This might involve a worksite visit, negotiation of realistic timing and identification of workplace adjustments/accommodations to optimise RTW. Liaison with Human Resources (HR), occupational health, other employer bodies and medical teams may also take place. Information and education is provided for employers to increase their understanding of the impact of the stroke on the RETAKE participant and how this might influence their ability to meet job demands. The participant receives feedback on their work performance during this stage. This may involve regular reviews, feedback on progress and supporting the employer to provide feedback on work performance, and the implementation of any modifications to the RTW plan or work role.

Stage 3: Job Retention: This involves monitoring the participant's RTW to ensure work stability and troubleshooting issues that may arise with all stakeholders (patient, employer, family, others) and gradually withdrawing support when the work situation is stable. However, participants and employers can re-access this support as required up to 12 months post randomisation. In some cases where work cannot be sustained or is unfeasible, work alternatives e.g. voluntary work, changes in job type, career are explored. In some cases the intervention may involve supporting retirement or medical withdrawal from work.

The intervention is delivered in addition to the stroke participant's usual stroke rehabilitation. This will vary depending on local provision and individual participants' needs. Therefore, the RETAKE OT liaises with health care professionals providing usual stroke rehabilitation to clarify and agree roles and ensure that any vocational rehabilitation is provided by the RETAKE OT.

The RETAKE OT works in partnership with other health, social care, charitable, employment and independent sector service providers in delivering the ESSVR. Any parallel rehabilitation or other wider services involved (e.g. other OTs, Social Services, Jobcentre Plus, Occupational Health, Different Strokes) are kept informed of the ESSVR process, the RETAKE participant's progress and the RETAKE OTs involvement. RETAKE OTs will refer to, liaise with and help participants to access any service they need, and attend DWP appointments or Occupational Health meetings with participants if required.

Assessment of the impact of the stroke on the person and the job may involve the use standardised assessments of function and impairment e.g. mobility and cognition, functional capacity evaluation, work needs, and detailed job analysis. Specific tools are not prescribed but rather introduced and resources signposted.

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4		For more detailed descriptions of the intervention delivered in the feasibility trial see
5		To more detailed descriptions of the intervention delivered in the redshinty that see,
6		Creat M. (2010) Developing delivering and evolution stroke an efficiency translation. A face it little and deviced
7		Grant M. (2016) Developing, delivering and evaluating stroke specific vocational renabilitation: A reasibility randomised
, o		controlled trial (Doctoral dissertation, University of Nottingham).
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9		Grant M, Radford K, Sinclair E, Walker M (2014) Return to work after stroke: recording, measuring, and describing
10		occupational therapy intervention. British Journal of Occupational Therapy, 77(9), 457–465.
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14		
15		
1J 16		
10		
17		
18	WHO PROVIDED	Intervention provider qualifications
19	For each	The intervention was delivered by qualified and HealthCare Professions Council (HCPC) registered occupational
20	category of	therapists (OTs).
21	intervention	
22	nrovidor (o g	Intervention provider background and experience
22		The OTe require survey of used in survey of the state of
∠⊃ 24	psychologist,	Ine UIS require experience of working with people with stroke and/or other neurological conditions and
24	nursing	community rehabilitation experience. Some may have vocational rehabilitation experience.
25	assistant),	\sim
26	describe their	The level of experience and suitability of the therapists recruited to deliver the intervention is assessed by the
27	expertise	Chief Investigator and OT mentors prior to training
28	background and	
29		- · · · · · · · · · · · · · · · · · · ·
20	any specific	I raining provided
21	training given.	The training comprised 2-days of face-to face teaching delivered by the RETAKE training team (4 OTs
31		experienced in vocational rehabilitation and research) followed by an additional day, 6 months later, supported
32		by monthly small group-based (4-6 OTs) telephone/ videocall mentoring from occupational therapists with
33		extensive experience in delivering vocational rehabilitation following stroke. The OT mentors were members of
34		the training team. Three members of the OT training team hald a DhD
35		the training team. Three members of the OT training team field if the the interpretion and each three the
36		The purpose of mentoring is to ensure implementation and fidelity to the intervention process through
50 27		discussion of difficulties and sharing of best practice with other OTs and their mentor.
3/		
38		Prior to training, occupational therapicts were signported to papers relating to the PETAKE feasibility trial
39		Filo to training, occupational therapists were signosted to papers relating to the RETARE reasoning that
40		mungs and were sent a KTW case study, which required them to provide written responses to 6 questions and
41		return to the training team prior to training. This enabled the expert trainers to ascertain the OTs pre-training
42		vocational rehabilitation knowledge. The same case study was used to teach the ESSVR process during the
/3		training.
11		
44	HOW	Mode of delivery
45	110 44	The intervention is delivered fore to fore or via televelocitization (video cell or chere cell) or a 4 to 4 to -i-
46		The intervention is delivered face-to-face of via telefenabilitation (video call of phone call) on a 1 to 1 basis.
47		
48		Other
49		Additional time is spent in liaison (letters, phone and video calls) with the patient, employer, family or other
50		stakeholders. Most progress monitoring in stage 3 is delivered by telephone
50		
51		
52		
53	WHERE	Where provided
54		The intervention is delivered in the community (mostly in the home or in the workplace). Other locations may
55		include the meeting room of a disability rights charity (120/) and a valuation ergonization is he beckgross control
56		include the meeting room of a disability rights charity (13%), and a voluntary organization jobs brokerage centre
57		(7%). In the reasibility trial almost hair of the participants were initially seen in hospital or in a stroke
50		rehabilitation unit.
20		
59		
60		

4 HOW MUCH. The intervention commences within 8 weeks of stroke and continues for up to 12 months following the initial session. The duration of intervention and frequency of contacts is determined by individual participant's need Based on feasibility trial data (Grant, 2014), two thirds of the OTS time will be spent delivering the intervention either face-to-face or in liaison with the participant and others. The other third is spent writing notes and reports or travelling to see participants at home or their work places. 11 Number of sessions and length 12 Based on feasibility trial data the estimated mean number of face-to face sessions per participant is 10 (SD 7, range 1-25) and average session length is one hour. People with more moderate and severe stroke may requimore sessions. 13 Frequency of sessions 14 More interventions sessions will be delivered at the outset of the intervention during stages 1 and 2 with less frequent interventions in stage 3, during progress monitoring once the participant has RTW. 14 TAILORING The ESSVR intervention will be tailored in duration and frequency according to individual need over a 12-month period. 15 TAILORING The ESSVR intervention will be tailored in duration and frequency according to individual need over a 12-month period. 16 The COVID-19 pandemic. In some sites OTs continued according to local NHS Trust protocols throughout the COVID-19 pandemic. In some sites OTs continued to visit participants at home wearing personal protective equipment, in others delivery was via telerehabilitation (online or telephone).	
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48 Adherence and Factors affecting adherence will be measured using an ESSVR fidelity checklist (Powers, in	
49 preparation) and recorded on mentoring CRFs during monthly mentoring sessions led by an experienced	
50 vocational rehabilitation OT. implementation barriers and contamination risks will be communicated to the tri	al
51 team, enabling barriers to be managed in real time.	
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53 Factors affecting intervention delivery will be recorded in Interviews with RETAKE Therapists, participants with	i
54 stroke, their employers and other NHS staff as part of a series of embedded case studies.	
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56 Actual: If	_
57 intervention	
58 adherence or	
59 fidelity was	
60 assessed,	

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 Appendix II RETAKE OT Competency Marking Rubric

Criteria	Needs support	Competent	Highly competent
	≤49% Demonstrates some understanding of ESSVR and its application in RETAKE. However, major deficits noted in VR knowledge, clinical reasoning and application. Requires additional individualised mentoring until next assessment.	50-69% Understands ESSVR with some evidence of misinterpretation in its application in RETAKE. Ad hoc monitoring via group mentoring until next assessment.	≥70% Fully understands ESSVR and its application in RETAKE.
Knowledge of intervention processes, timeframes & documentation (40% of total marks)	Most answers were missing the required ESSVR components.	Some answers were missing the required ESSVR components.	Few, if any of the required ESSVR components were missing in the answers.
Clinical reasoning – identification and analysis of salient work-related issues in the case study, to inform the design of an appropriate intervention (ESSVR) plan in the letter/report. (50% of total marks)	Limited identification of and/or limited analysis of work-related issues from the case study. None or few solutions for the work- related issues identified within the intervention plan(s). Significant gaps remain in problem-solving.	Some identification of and/or some analysis of work-related issues from the case study. A number of solutions for the work-related issues identified within the intervention plan(s) but a few gaps remain in problem-solving.	Identification and or analysis of all work-related issues from the case study. Comprehensive solutions for the work-related issues within the intervention plan(s).
Written communication of work issues. Appropriate use of lay language in letter/report to ensure if it is fit for purpose & likely to gain reader engagement. (10% of total marks)	Letter/report lacks logical structure. Limited focus of work issue(s) addressed. Overuse of medical terminology. Little use of lay language to communicate issues. Information conveyed in a manner less likely to engage recipient.	Case study letter/report reasonably well structured. Mostly focussed on the work issue(s) being addressed. Minimal use of medical terminology. Good use of lay language to communicate issues. Information conveyed in a manner may to engage recipient.	Case study letter/report very well structured. Report fully focussed on work issue(s) addressed. Issues communicated clearly in lay language and without any use of medical terminology. Information conveyed in a manner likely to engage recipient.