RETAKE: **RET**urn to work **A**fter stro**KE.** Pragmatic, multicentre RCT with internal pilot, cost-effectiveness evaluation and embedded process evaluation, comparing Early Stroke Specialist Vocational Rehabilitation (ESSVR) in addition to usual NHS Rehabilitation to usual NHS rehabilitation alone.

STUDY SUMMARY

SETTING: 20 acute stroke units with stroke rehab services.

POPULATION: Acute stroke: INCLUSION: Age >18; in paid/unpaid work pre-stroke; provision of consent.
EXCLUSION: People not intending to work; living > one hour from the Hospital of hospital admission; no capacity to consent.

HEALTH TECHNOLOGY: Up to 12 months manualised ESSVR, delivered by trained OTs (2 per site), starting within 8 weeks of stroke. ESSVR: early (acute stroke) specialist (stroke & VR specialist knowledge) health-based (by HS staff) mixed VR (work return & job retention) community-based case management (CM).

CONTROL: Usual NHS rehabilitation provided by UC team. May involve outpatient/community physio-,speech- or OT therapy, psychology, medical follow-up.

RANDOMISATION: Individually randomised within 6wks of stroke, via CTU, stratified by site, age, severity.

DATA COLLECTION: Baseline face-to-face assessment; postal follow-up at 3, 6 & 12m, maximised with phone/text prompts & phone interviews.

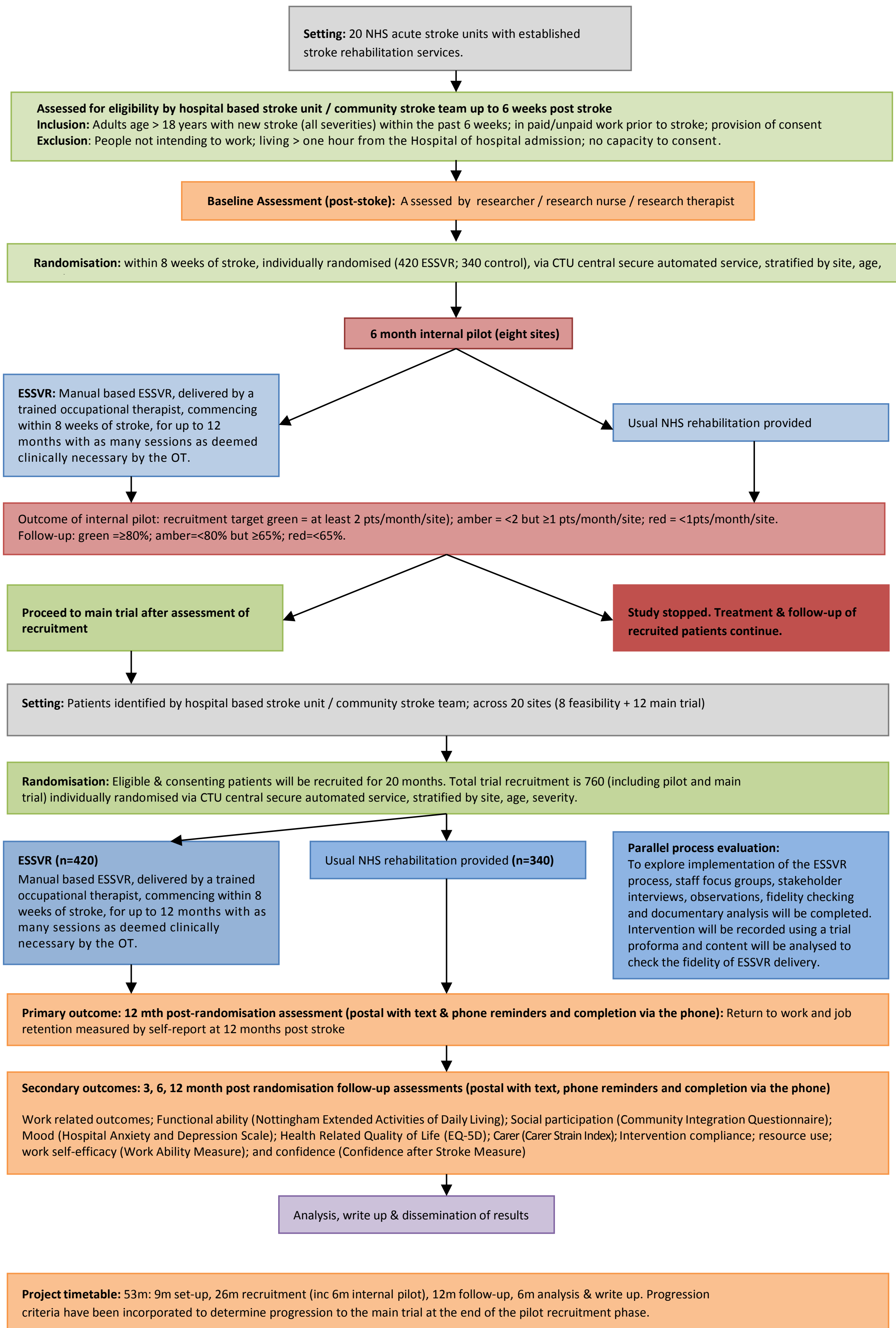
PRIMARY OUTCOME: Return to work & job retention (self-report at 12 m).

SECONDARY OUTCOMES: Work related outcomes; Functional ability (Nottingham Extended Activities of Daily Living); Social participation (Community Integration Questionnaire); Mood (Hospital Anxiety and Depression Scale); Health Related Quality of Life (EQ-5D); Carer (Carer Strain Index); Intervention compliance; resource use; work self-efficacy (Work Ability Measure); and confidence (Confidence after Stroke Measure)

ECONOMIC EVALUATION: Within trial cost-effectiveness and cost-utility analyses (NHS & PSS perspective); wider perspective reported separately.

PROCESS EVALUATION: Explore ESSVR implementation (intervention fidelity, content, adherence & deployment) and contextual factors linked to outcome variation across intervention & UC. To include analysis of routine process indicators (treatment records, mentoring feedback in ESSVR, resource use data from all participants) and focus groups & individual semi-structured interviews with stroke service users & NHS staff (manage, commission or deliver stroke rehabilitation)

SAMPLE SIZE: 760 (420 ESSVR; 340 control)


Setting: 20 NHS acute stroke units with established stroke rehabilitation services.
Assessed for eligibility by hospital based stroke unit / community stroke team up to 6 weeks post stroke
Inclusion: Adults age > 18 years with new stroke (all severities) within the past 6 weeks; in paid/unpaid work prior to stroke; provision of consent
Exclusion: People not intending to work; living > one hour from the Hospital of hospital admission; no capacity to consent.
Baseline Assessment (post-stroke): Assessed by researcher / research nurse / research therapist
Randomisation: within 8 weeks of stroke, individually randomised (420 ESSVR; 340 control), via CTU central secure automated service, stratified by site, age,
6 month internal pilot (eight sites)
ESSVR: Manual based ESSVR, delivered by a trained occupational therapist, commencing within 8 weeks of stroke, for up to 12 months with as many sessions as deemed clinically necessary by the OT.
Usual NHS rehabilitation provided
Outcome of internal pilot: recruitment target green = at least 2 pts/month/site); amber = <2 but ≥1 pts/month/site; red = <1pts/month/site.
Follow-up: green =≥80%; amber=<80% but ≥65%; red=<65%.
Proceed to main trial after assessment of recruitment
Study stopped. Treatment & follow-up of recruited patients continue.
Setting: Patients identified by hospital based stroke unit / community stroke team; across 20 sites (8 feasibility + 12 main trial)
Randomisation: Eligible & consenting patients will be recruited for 20 months. Total trial recruitment is 760 (including pilot and main trial) individually randomised via CTU central secure automated service, stratified by site, age, severity.
ESSVR (n=420)
Manual based ESSVR, delivered by a trained occupational therapist, commencing within 8 weeks of stroke, for up to 12 months with as many sessions as deemed clinically necessary by the OT.
Usual NHS rehabilitation provided **(n=340)**
Parallel process evaluation:
To explore implementation of the ESSVR process, staff focus groups, stakeholder interviews, observations, fidelity checking and documentary analysis will be completed. Intervention will be recorded using a trial proforma and content will be analysed to check the fidelity of ESSVR delivery.
Primary outcome: 12 mth post-randomisation assessment (postal with text & phone reminders and completion via the phone): Return to work and job retention measured by self-report at 12 months post stroke
Secondary outcomes: 3, 6, 12 month post randomisation follow-up assessments (postal with text, phone reminders and completion via the phone)
Work related outcomes; Functional ability (Nottingham Extended Activities of Daily Living); Social participation (Community Integration Questionnaire); Mood (Hospital Anxiety and Depression Scale); Health Related Quality of Life (EQ-5D); Carer (Carer Strain Index); Intervention compliance; resource use; work self-efficacy (Work Ability Measure); and confidence (Confidence after Stroke Measure)
Analysis, write up & dissemination of results
Project timetable: 53m: 9m set-up, 26m recruitment (inc 6m internal pilot), 12m follow-up, 6m analysis & write up. Progression criteria have been incorporated to determine progression to the main trial at the end of the pilot recruitment phase.