Site Questionnaire

Thank you for your interest in the RETAKE study. RETAKE is funded by the National Institute for Health Research Health Technology Assessment (NIHR HTA) and is led by Dr Kate Radford and colleagues at the Division of Rehabilitation and Ageing Rehabilitation, University of Nottingham and co-ordinated by the Leeds Institute of Clinical Trials Research (LICTR) at the University of Leeds.

The study is an individually randomised controlled trial of a return to work intervention, known as Early Stroke Specialist Vocational Rehabilitation (ESSVR), for stroke survivors intending to return to work. We aim to recruit a total of 760 participants from 20 sites over a total of 26 months. Although sites will be identified up front, site set-up will be staggered to accommodate a six month internal pilot; 8 sites will be included in the pilot and if the pre-defined progression criteria are met then the trial will continue and the additional 12 sites will begin recruitment. It is anticipated that each site will support an average recruitment rate of 2 participants per month, once recruitment rates stabilise. Around 440 participants will be randomly assigned to receive ESSVR plus usual care, and 320 to receive usual care only.

The ESSVR intervention has been developed to be delivered by NHS community based therapists familiar with delivering community rehabilitation programmes to stroke survivors. ESSVR is an individualised case coordinated approach to supporting job retention delivered over a total of 12 months, including home visits, work-site visits, telephone and email contact with patients discharged from hospital. Therapists identified by sites to deliver the intervention will receive full training at a time and location convenient for staff and the service. It is anticipated that a minimum of two therapists will be trained at each site to accommodate caseload and deliver the ESSVR intervention. All participants will receive unrestricted usual care provided by primary, community and social services.

The study will also include an embedded Process Evaluation to explore and understand the implementation of the intervention, and how it is experienced and understood by providers and recipients.

The attached questionnaire asks several questions about your current service which will enable us to ensure appropriate consideration of site specific set-up requirements and successful study delivery.

It is also important for us to consider readiness of each site to provide the RETAKE intervention. We believe factors which are important for successful implementation are as follows;

1. Engagement of service management at an appropriate level.
2. Enthusiastic therapy staff willing and able to support intervention delivery.
3. Dedicated time of appropriate staff.

*Please note that following confirmation of site selection an application for Excess Treatment Costs (ETCs) will be submitted to the relevant local CCG(s) to cover resource required for staff time (to support intervention).*

Following completion of this form we will arrange a suitable time to contact you by telephone to discuss the study further and address any questions or concerns you may have.

Dr. Kate Radford, Vicki McLellan and the RETAKE team!

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| **1.0 Site Details** | | |
| a. | Lead Site Name |  |
| b. | NHS Trust |  |
| c. | NIHR CRN Site Number |  |
| d. | Address | Postcode: |
| e. | R&D Contact Name |  |
| f. | R&D Email |  |
| g. | R&D Telephone |  |

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| **2.0 Service Structure** | | |
| *We are hoping to identify the current rehabilitation services for people (aged 18+) who are admitted to your hospital. This information is crucial to ensure appropriate approvals are obtained, and that appropriate training and information are disseminated to relevant teams to avoid recruitment barriers.* | | |
| **A.** | **Hospital wards** | |
| a1. | Please identify all medical wards that a person aged over 18 years might be transferred to following admission due to stroke. | |
| Ward Name |  |
| Type of Ward |  |
| Number of beds |  |
| Average length of stay |  |
| Av. No. of re-admissions |  |
| a2. | Are these teams aware of and supportive of study participation? |  |

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| **3.0 Service Delivery** | | |
| *We would like to understand what rehabilitation packages you currently offer to ensure there will be no conflicts with the proposed intervention. To ensure feasibility of intervention delivery within your service we would like to assess engagement of relevant teams and whether staff are willing and able to support intervention delivery.* | | |
| **A.** | **Therapy Services** | |
| a1. | What stroke rehabilitation services do you currently offer to people upon discharge from hospital? | *Please include details on the focus of rehabilitation, duration, and who is responsible for delivering the rehabilitation.* |
| a2 | Do any of these services already specialise in helping stroke survivors return to work? | Yes / No  If yes please indicate which one(s): |
| a3. | Do you anticipate any changes to services in the next 12 months? | Yes / No  Comments: |
| A4. | Do you feel your current practice would conflict with the study intervention?  (i.e. ≤ 12 months individually tailored support with return to work) |  |
| **B.** | **Therapy Team** | |
| b1. | Please provide an overview of your local management of therapy services  i.e. Head of Therapy Service, Managers of community/other therapy services |  |
| b2. | Please provide details of relevant therapy service management team  (as summarised in b1.) | Name:  Job Title:  Email: |
| Name:  Job Title:  Email: |
| Name:  Job Title:  Email: |
| Name:  Job Title:  Email: |
| Name:  Job Title:  Email: |
| b3. | Are all therapy management team members supportive of involvement in the study? | Yes / No |
| b4. | Do they feel your current team could support the study intervention? | Yes / No |
| b5. | Have you identified key staff able to support intervention delivery? | Yes / No  *Occupational Therapist with stroke specialist or neuro-rehabilitation knowledge. Sufficient to support 1 - 2 patients per month on a 12 month rehabilitation programme and complete associated therapy records.* |
| Therapist 1 | Name:  Email:  Grade:  FTE:  Employer: |
| Therapist 2 | Name:  Email:  Grade:  FTE:  Employer: |
| Therapist 3 | Name:  Email:  Grade:  FTE:  Employer: |
| Therapist 4 | Name:  Email:  Grade:  FTE:  Employer: |
| Other |  |
| b6. | Please provide details regarding turnover/rotation of therapy staff anticipated to support ESSVR delivery.  (i.e. G5/6 Community / Outpatient Therapists) |  |
| b7. | Will these staff members be supported to attend a training workshop as part of the ESSVR programme?  (approx. 2 days – delivered at/ near site, plus additional day 6 months later) | Yes / No  Comments: |
| b8. | Will these staff members be able to access ongoing training materials (webinars/discussion forums)? | Yes / No  Comments: |
| b9. | Will you be able to restrict staff trained in the intervention from treating any patients taking part in the study but not allocated to the intervention, should any referrals occur? | Yes / No  Comments: |
| To avoid contamination the occupational therapists delivering the intervention will be educated in contamination issues and asked not to discuss work issues in depth with usual care participants, in addition usual care participants will be treated by different therapists to reduce contamination. | |

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| **4.0 Research Infrastructure** | | |
| *We would like to understand what research staff you may have available to support the study, any additional research support required for research specific tasks, and determine training requirements during study set-up.* | | |
| a. | Do you have CRN supported studies at your site? | Yes / No  Comments: |
| b. | Do you have local Research staff in post available to support recruitment? | Yes / No |
| If yes, please provide additional details. | *Please include staff roles, grade, and FTE. Relevant contact details should be provided in the contacts section.* |
| c. | Do these staff members currently have access to all potential services? | Yes / No  Comments: |
| d. | Do you have local Research staff available to support research data collection? | Yes / No  Comments: |
| e. | Have these staff members received relevant training for working with stroke survivors? | Yes / No  Comments: |
| f. | Do Research staff have appropriate internet access to support research activities, such as randomisation? | Yes / No  Comments:  *(Internet Explorer version 9 or newer and Google Chrome version 37 or newer)* |
| g. | Do you have any concerns regarding supporting delivery of the study? |  |

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| **5.0 Study Specific Requirements** | | |
| *We would like to determine your sites ability to achieve required recruitment rates, including timings for set-up and availability to commence recruitment.* | | |
| **A1.** | **Study Population** | |
| a1. | How many stroke survivors come through your service per month/ per year? |  |
| a2. | Able to achieve monthly recruitment rate of 2 patients per month? | Yes / No  Comments: |
| **Inclusion criteria:**   * Age ≥18 years. * Admitted to hospital with new stroke (all severities). * In work at stroke onset (including self-employed paid or unpaid). * Intending to work. * Willing and able to give informed consent to participate in the study. | **Exclusion criteria**   * Not intending to work. * Lives ≥ one hour from the centre where admitted/treated. * Lack capacity to consent. |
| **B.** | **Other Trials, Research Projects or Local Initiatives** | |
| b1. | Is your stroke service/site currently involved in any stroke trials, stroke research projects or local initiatives?  *\*If yes, please list studies and the duration of your involvement. For local studies please give details of (a) what it is called, (b) what it involves, (c) what your involvement is and (d) the duration of the project.* | Yes\* / No |
| b2. | Is your stroke service/site intending to be involved in other stroke trials, stroke research projects or local initiatives in the foreseeable future?  *\*If yes, please list studies and the duration of your involvement. For local studies please give details of (a) what it is called, (b) what it involves, (c) what your involvement is and (d) the duration of the project.* | Yes\*/No |
| **C.** | **Timelines** |  |
| c1. | Do you have a preference on timelines for recruitment? | April 2018  *Overall recruitment period 26 months (April 18 – May 20)*  October 2018  *Overall recruitment period 20 months (Oct 18 – May 20)* |
| c2. | Will your site be able to fulfil requirements to achieve preferred timelines? | Yes / No  Comments:  *Consider approval process, training (including intervention specific), staffing.* |

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| **6.0 Site Contacts** | |
| *Please include any staff members relevant to study set-up and delivery* | |
| Principal Investigator | |
| Name |  |
| Role |  |
| Email |  |
| Co-Investigator | |
| Name |  |
| Role |  |
| Email |  |
| Researcher | |
| Name |  |
| Role |  |
| Email |  |
| Researcher | |
| Name |  |
| Role |  |
| Email |  |
| Therapy Services | |
| Name |  |
| Role |  |
| Email |  |
| Therapy | |
| Name |  |
| Role |  |
| Email |  |
| *Please add additional rows as required.* | |

**Thank you for taking your time to complete this form**.

Upon receipt of a completed questionnaire the RETAKE Chief Investigator will review the details provided and arrange a time to contact you to discuss the study in more detail and answer any questions you may have (please ensure the most appropriate person to contact to do this is listed below).

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| **Form completed by (print name)** | **Work address**  **Tel**  **Email** |
| **Position/job title** |
| **Trust/employer** |
| **Signature** | **Date** |

**Please return completed forms to:**

RETAKE study

Clinical Trials Research Unit

Leeds Institute of Clinical Trials Research

University of Leeds

Leeds

LS2 9JT

Or by email to: [RETAKE@leeds.ac.uk](mailto:HERO@leeds.ac.uk)