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# A trial to Evaluate an eXTended RehAbilitation service for Stroke patients (EXTRAS)

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| **Submission date**<br>08/08/2012 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>09/08/2012 | **Overall study status**<br>Completed | |
| **Last Edited**<br>01/06/2020 | **Condition category**<br>Circulatory System | |

**Plain English summary of protocol**

Background and study aims

One third of patients have long term disability after stoke but specialist stroke rehabilitation usually lasts no more than a few months. Patients who have on going rehabilitation needs once specialist stroke rehabilitation finishes may be referred to a range of other health care professionals or services, but most do not offer specialist stroke rehabilitation. One of the reasons that specialist stroke rehabilitation is not provided over a longer period is because it is not yet known if it is beneficial. This research project is a clinical trial to determine whether a new extended stroke rehabilitation service is beneficial to patients and carers.

Who can participate?

Adults aged over 18 with a new stroke who are being discharged from hospital after their stroke under the care of an Early Supported Discharge team. Carers of stroke patients may also participate. A carer is the main family member or friend, who will provide support after discharge. He/she may not necessarily live with the patient.

What does the study involve?

Stroke patients and carers who agree to participate in the trial will be randomly allocated to either receive a new extended stroke rehabilitation service or to continue with usual NHS care when routine specialist stroke rehabilitation (Early Supported Discharge) ends. The new extended stroke rehabilitation service will involve on going contact, usually by telephone, with a senior Early Supported Discharge (ESD) stroke therapist or nurse for 18 months after ESD finishes. The therapist/nurse will contact patients and carers at 1, 3, 6, 12 and 18 months after discharge from ESD to review their progress and rehabilitation needs. Rehabilitation goals will be agreed and the therapist/nurse will give advice on how to progress towards the goals. The advice may be verbal advice, for example, exercises to practice at home. Or, if required, referral for an additional period of therapy from a service which is available locally may be arranged. Usual NHS care following specialist stroke rehabilitation may involve referral to a range of rehabilitation services in accordance with local clinical practice. The effectiveness of the new extended rehabilitation service will be evaluated by comparing the health (e.g functional abilities and quality of life) of patients and carers who received the new service with those who received usual NHS care.

What are the possible benefits and risks of participating?
We do not know if providing a specialist stroke rehabilitation service over a longer period of time is beneficial. However, we do know that rehabilitation treatments early after stroke improve health and recovery. We believe that rehabilitation over a longer period of time may be beneficial, but this is not yet proven.

Where is the study run from?
The study is being run from Newcastle University, Newcastle upon Tyne, UK. Patients and carers from twelve or more NHS stroke services will be invited to take part.

When is the study starting and how long is it expected to run for?
Recruitment to the study will start on 01 January 2013 and end on 31 May 2015. Study follow up will end on 31 January 2017. The total duration of the study is 5 years.

Who is funding the study?
UK National Institute for Health Research - Health Technology Assessment Programme.

Who is the main contact?
Dr Lisa Shaw
Lisa.Shaw@ncl.ac.uk

# Contact information

### Type(s)
Scientific

### Contact name
Dr Lisa Shaw

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
12789

# Study information

### Scientific Title
A trial to Evaluate an eXTended RehAbilitation service for Stroke patients (EXTRAS)

### Acronym
EXTRAS

### Study objectives
To determine the clinical and cost effectiveness of an extended stroke rehabilitation service.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Newcastle and North Tyneside Research Ethics Committee, 25/06/2012, ref: 12/NE/0217

### Study design
Randomised interventional phase III study

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

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

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

### Interventions
Study intervention: An extended stroke rehabilitation service provided for 18 months following completion of routine specialist stroke rehabilitation (Early Supported Discharge). The extended stroke rehabilitation service will provide on-going contact with a senior ESD team member who will lead and coordinate further rehabilitation.

Study control: Usual care post Early Supported Discharge. Usual care may involve referral of patients to a range of rehabilitation services upon completion of ESD in accordance with local clinical practice.

### Intervention Type

Other

### Phase
Phase III

### Primary outcome measure
Nottingham Extended Activities of Daily Living Scale at 24 months post randomisation.

### Secondary outcome measures
For patients: health status (Oxford Handicap Scale), quality of life (Euroqol EQ-5D), mood (Hospital Anxiety and Depression Scale), experience of services and resource use (adaptation of the Client Service Receipt Inventory) at 12 and 24 months.

For carers: quality of life (Euroqol EQ-5D), carer stress (Caregiver Strain Index) and experience of services at 12 and 24 months.

### Overall study start date
01/01/2013

### Completion date
31/12/2018

## Eligibility

### Key inclusion criteria
Stroke patients:
1. Aged 18 years and over
2. Confirmed diagnosis of new stroke (first ever or recurrent)
3. Will be discharged from hospital under the care of an early supported discharge team

Stroke carers:
A carer is the main family member or friend, who will provide support after discharge. He/she may not necessarily be co-resident with the patient.

If a stroke patient has no carer or the carer does not wish to participate in the study, the patient may still participate in the study.

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants

UK Sample Size: 510

### Total final enrolment
573

### Key exclusion criteria
Stroke patients unable to participate in a rehabilitation programme which focuses upon extended activities of daily living.

### Date of first enrolment
01/01/2013

### Date of final enrolment
31/05/2015

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Institute for Ageing and Health**
Newcastle Upon Tyne
United Kingdom
NE2 4AE

## Sponsor information

### Organisation
Northumbria Healthcare NHS Foundation Trust (UK)

### Sponsor details
North Tyneside General Hospital
Rake Lane
North Shields
England
United Kingdom
NE29 8NH

### Sponsor type
Hospital/treatment centre

### Website

http://www.northumbria.nhs.uk/

**ROR**
https://ror.org/01gfeyd95

# Funder(s)

**Funder type**
Government

**Funder Name**
NIHR Health Technology Assessment Programme - HTA (UK)

# Results and Publications

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

**Intention to publish date**
31/10/2019

**Individual participant data (IPD) sharing plan**
The data sharing plans for the current study are unknown and will be made available at a later date.

**IPD sharing plan summary**
Data sharing statement to be made available at a later date

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 05/05/2015 | | Yes | No |
| Results article | results | 01/12/2019 | 23/10/2019 | Yes | No |
| Results article | results | 01/05/2020 | 01/06/2020 | Yes | No |