

# A feasibility study to identify attitudes, determine outcome measures and develop an intervention to inform a definitive trial that will determine the effectiveness of adapted cardiac rehabilitation for subacute stroke patients

<b>Submission date</b> 22/10/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/10/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/05/2024	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

A stroke is a serious condition that occurs when the blood supply to part of the brain is cut off. The aim of this study is to determine the best way to support people who have recently had a stroke to improve their fitness, particularly the health of their heart and lungs (cardiovascular fitness). The information from this study will be used to design a larger study to investigate how effective cardiac rehabilitation is for people post stroke.

### Who can participate?

Patients aged over 18 who have had a stroke

### What does the study involve?

Participants attend a cardiac rehabilitation programme, consisting of a warm up, exercise training and cool down, two times a week for six weeks. Patients', carers' and health professionals' opinions of cardiac rehabilitation and attitudes to exercise following stroke are explored through interviews and focus groups.

### What are the possible benefits and risks of participating?

Not provided at time of registration

### Where is the study run from?

Leicester Royal Infirmary (UK)

### When is the study starting and how long is it expected to run for?

September 2014 to August 2017

Who is funding the study?  
The Stroke Association (UK)

Who is the main contact?  
Nicola Clague-Baker  
njc36@le.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mrs Nicola Clague-Baker

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
17359

## Study information

**Scientific Title**  
A feasibility study to identify attitudes, determine outcome measures and develop an intervention to inform a definitive trial that will determine the effectiveness of adapted cardiac rehabilitation for subacute stroke patients

**Acronym**  
Cardiac Rehab and Stroke

**Study objectives**  
The broad aim of this study is to determine the best way to support people who have recently had a stroke to improve their fitness particularly the health of their heart and lungs (cardiovascular fitness).

More details can be found at: <http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=17359>

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Not provided at time of registration

### **Study design**

Non-randomised; Interventional; Design type: Not specified

### **Primary study design**

Interventional

### **Secondary study design**

Non randomised study

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

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

### **Health condition(s) or problem(s) studied**

Topic: Stroke; Subtopic: Rehabilitation; Disease: In hospital study, Community study

### **Interventions**

Subjects will attend a modified (informed by phase I and II) CR programme and is likely to include a modified warm up, functional exercise training and cool down, two times a week for six weeks.

### **Intervention Type**

Behavioural

### **Primary outcome measure**

Effectiveness of adapted cardiac rehabilitation for subacute stroke patients

### **Secondary outcome measures**

Not provided at time of registration

### **Overall study start date**

19/09/2014

### **Completion date**

31/08/2017

## **Eligibility**

**Key inclusion criteria**

1. They will be aged over 18 years of age.
2. They will have suffered from a stroke or Transient Ischaemic Attack (TIA) resulting in mild to moderate disability (NIHSS < 15). This means that they could have visual problems, facial palsy, movement problems in their arm and leg, uncoordinated movement and sensory problems.
3. They will be in the subacute phase of recovery, that is, at least one week after their stroke or TIA up to four months post stroke or TIA.
4. They will not have receptive communication or cognitive deficits, this means they can fully understand and consent to the trial.
5. They will be able to walk 10 metres, with help of another person or walking aid if necessary.

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 902; UK Sample Size: 90

**Key exclusion criteria**

All Parts: Cannot give informed consent and do not speak English.

Part III (Validity study) and Part IV (Cohort study): Heart disease class III and upwards (NYHA Classification), angina on exercise, Class C or D exercise risk (ACSM), uncontrolled arrhythmias and poorly controlled hypertension.

**Date of first enrolment**

19/09/2014

**Date of final enrolment**

31/08/2017

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

Leicester Royal Infirmary

Leicester

United Kingdom  
LE1 5WW

## Sponsor information

### Organisation

University Hospitals of Leicester NHS Trust (UK)

### Sponsor details

Leicester Royal Infirmary  
Infirmary Square  
Leicester  
England  
United Kingdom  
LE1 5WW

### Sponsor type

Hospital/treatment centre

### ROR

<https://ror.org/02fha3693>

## Funder(s)

### Funder type

Charity

### Funder Name

The Stroke Association (UK); Grant Codes: TSA 2013/08

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	accelerometry results	01/06/2020	17/12/2020	Yes	No
<a href="#">Results article</a>	Qualitative focus group results of staff attitudes to cardiac rehabilitation for stroke survivors	15/05/2024	21/05/2024	Yes	No