

A study to identify what is needed for a larger trial which will aim to determine the effectiveness of adapted cardiac rehabilitation for sub-acute stroke patients

Submission date 09/11/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/12/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/09/2022	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Stroke is a serious, life-threatening medical condition that happens when the blood supply to a part of the brain is cut off, usually due to a blood clot or haemorrhage. Symptoms vary according to how much of the brain is affected and where in the brain the stroke occurs, but includes paralysis, muscle weakness and speech problems. A stroke can also have an impact on the sufferers emotions and can lead to anxiety, depression and personality changes. Here, we want to find out the best way to help people who have recently had a stroke to improve their level of fitness with a particular focus on their cardiovascular fitness (health of heart and lungs).

Research has shown that stroke patients can improve their cardiovascular fitness by doing intensive programmes of activity (cardiac rehabilitation) which has also been shown to reduce their risk of further strokes. There are, however, gaps in the research about what is the best form of cardiovascular training, particularly for stroke patients. Our project aims aim to fill those gaps in the research. Opinions on cardiac rehabilitation and attitudes to exercise will be collected from stroke patients, carers and health professionals. This information will then be used to determine what should be included in a cardiac rehabilitation programme. A study to investigate how beneficial cardiac rehabilitation is for people who have had a stroke will then be developed. Stroke patients, carers and therapists will be invited to take part in interviews and focus groups to discuss issues related to cardiac rehabilitation. Stroke survivors will also be involved in a study to determine the best way to test cardiovascular fitness and participate in cardiac rehabilitation.

Who can participate?

Adults who have had a stroke in the last one to 4 months and able to walk at least 10 metres.

What does the study involve?

The study is made up of four parts.

Part I: Participants are interviewed in their own homes where they discuss attitudes to exercise before and after stroke and attitudes to participating in cardiac rehabilitation.

Part II: Participants are invited to take part in one focus group in their work environment. Attitudes to exercise and cardiac rehabilitation are again discussed.

Part III: Participants are brought into the UHL NHS Trust for up to four hours, where they complete three different measures of cardiovascular fitness; the six minute walk test, the shuttle walk test and the VO2 peak test measured on a static bike.

Part IV: After undergoing an initial assessment, including collecting information on how frequently they fall and their activity level (measured by an accelerometer) participants attend the cardiac rehabilitation programme twice a week for six weeks. At the end of the six weeks they undergo the assessment again. They are also interviewed about their experiences.

What are the possible benefits and risks of participating?

There may be no benefits to taking part. However, it has been shown that people who have a stroke can improve their physical fitness doing various forms of exercise. Taking part in cardiac rehabilitation may improve their physical fitness and may also reduce their risk of subsequent strokes through helping them identify and establish lifestyle changes. They will be able to discuss their exercise and their future healthy lifestyle with a chartered physiotherapist and specialist nurses and psychologists. The results of this trial will also help to establish if a larger trial can be run to compare cardiac rehabilitation to other forms of cardiovascular fitness training. Cardiac fitness tests are regularly used for heart disease and stroke patients without any complications. Cardiac rehabilitation programs are used for people who have heart disease and stroke patients have completed other forms of cardiovascular training without complications.

Where is the study run from?

1. University of Leicester (UK)
2. UHL NHS Trust (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
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Contact information

Type(s)

Scientific

Contact name

Mrs Nicola Clague-Baker

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
151210

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 sub-acute stroke patients

Study objectives

As this is a feasibility study the aim is to explore service user and health professionals' attitudes, determine outcome measures and establish an intervention to inform a definitive trial that will determine the effectiveness of adapted CR for sub-acute stroke patients

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee East Midlands - Northampton, 11/8/2014, ref. 14/EM/1067

Study design

Single site feasibility study using a mixed method design

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Patient information sheets available on request

Health condition(s) or problem(s) studied

Sub-acute stroke patients

Interventions

This feasibility study will be undertaken in 4 parts.

Part I - participant interviews exploring attitudes to exercise and cardiac rehabilitation before and after stroke.

Part II - health professional focus groups discussing cardiac rehabilitation and attitudes to exercise before and after stroke.

Part III - a validity study comparing the assessment of cardiovascular fitness of stroke participants using three different measures; the six minute walk test, the shuttle walk test and the VO2 peak test measured on a static bike

Part VI - participants undergo baseline assessments and then attend cardiac rehabilitation programme twice a week for six weeks. At the end of the six weeks baseline measures are repeated and participants are interviewed about their experiences.

Intervention Type

Mixed

Primary outcome measure

Cardiovascular fitness

Secondary outcome measures

N/A

Overall study start date

01/09/2014

Completion date

31/08/2017

Eligibility**Key inclusion criteria**

Patients:

1. Participants will be sub-acute stroke and TIA patients (one week to four months post stroke)
2. Aged over 18 years
3. Able to speak English
4. Able to walk at least 10 metres and their carers

Healthcare professionals working in the field of stroke care or cardiac rehabilitation

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Part I - 20, Part II - 32 (recruitment 25/09/2014 - 28/02/2015). Part III 40 (recruitment 1/03/2015 - 31/12/2015) Part IV - 30. (recruitment 01/01/2016 - 31/08/2016)

Key exclusion criteria

1. Heart disease class III and upwards (NYHA Classification), angina on exercise,
2. Class C or D exercise risk (ACSM)
3. Uncontrolled arrhythmias and poorly controlled hypertension
4. Significant cardio-respiratory, locomotor or psychiatric problems that limit participation in exercise programmes

Date of first enrolment

25/09/2014

Date of final enrolment

31/08/2016

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

University of Leicester

Physiotherapy Department

Maurice Shock Building

Leicester

United Kingdom

LE1 7RH

Sponsor information**Organisation**

UHL NHS Trust

Sponsor details

Gwendolen Road

Leicester

England

United Kingdom
LE5 4QF

Sponsor type

Hospital/treatment centre

Website

<http://www.leicestershospitals.nhs.uk/>

ROR

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

Funder(s)

Funder type

Charity

Funder Name

The Stroke Association (UK)

Funder Name

/08

Results and Publications

Publication and dissemination plan

Plan to publish Part I and Part II by the end of 2015 and present at the UK Stroke Forum in 2015
Plan to publish Part III and Part IV by end of 2016

Intention to publish date**Individual participant data (IPD) sharing plan**

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2022	01/09/2022	Yes	No
HRA research summary			26/07/2023	No	No