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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

Registration date
12/12/2014

Overall study status
Completed

Last Edited
01/09/2022

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
njc36@le.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mrs Nicola Clague-Baker

Contact details
Physiotherapy Department
Maurice Shock Building
University of Leicester
Leicester
United Kingdom

LE1 7RH
0116 252 3305
njc36@le.ac.uk

Additional identifiers

Protocol serial number
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

Study type(s)
Quality of life

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(s)
Cardiovascular fitness

Key secondary outcome(s))
N/A

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Study participating centre
University of Leicester
Physiotherapy Department
Maurice Shock Building
Leicester
United Kingdom
LE1 7RH

Sponsor information

Organisation
UHL NHS Trust

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Charity

Funder Name
The Stroke Association (UK)

Funder Name
/08

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes