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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

Submission date
22/10/2014

Recruitment status
No longer recruiting

Registration date
22/10/2014

Overall study status
Completed

Last Edited
21/05/2024

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
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Contact information

Type(s)
Scientific

Contact name
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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: Cannotgive 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?
Results article	accelerometry results	01/06/2020	17/12/2020	Yes	No
Results article	Qualitative focus group results of staff attitudes to cardiac rehabilitation for stroke survivors	15/05/2024	21/05/2024	Yes	No