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A rehabilitation programme for individuals who have suffered a stroke

Submission date	Recruitment status	[_] Prospectively registered
14/01/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/01/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/02/2017	Circulatory System	

Plain English summary of protocol
Background and study aims
Physiotherapy-led rehabilitation support is beneficial for people who have had a stroke. However, people require a longer duration of rehabilitation than is provided by an NHS hospital. This study will consider a specialist physiotherapy-led exercise program for people in the community who have had a stroke. The aim of this study is to find out if a specialist physiotherapy-led exercise program for people who have had a stroke is beneficial for their physical and psychological well-being.

Who can participate?
People living in the Birmingham area who have had a stroke.

What does the study involve?
An independent physiotherapist will allocate the participants to either a specialist-supported exercise program or to a control group. The exercise group will be supported by physiotherapy students who will guide them through an exercise program devised by a specialist neurological physiotherapist. The individuals in the control group will not receive any treatment. However, once the study is completed the individuals in the control group will be offered the chance to participate in the same exercise program.

What are the possible benefits and risks of participating?
Participants will likely benefit in many ways from improved psychological and physical well-being. The risks are considered to be minimal.

Where is the study run from?
We hope to recruit around 70 people who have had a stroke from the Birmingham and Solihull boroughs. This will provisionally be from the Stroke Association Centres in Birmingham.

When is the study starting and how long is it expected to run for?
The study will begin in January 2014 and is expected to run for a year.

Who is funding the study?
The charity Action After Stroke, UK.

Who is the main contact?
Dr A Soundy

Contact information

Type(s)
Scientific

Contact name
Dr Andrew Soundy

Contact details
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Additional identifiers

Protocol serial number
2.0

Study information

Scientific Title
The psychosocial Benefits of an Innovative Community-university Rehabilitation programme for Individuals who have suffered a Stroke: a controlled trial

Acronym
BICRIS

Study objectives
The specialist supported rehabilitation setting will provide greater improvements in an individual s self-efficacy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Birmingham Ethics Committee, 02/12/2013, ref.: ERN_13-1091

Primary study design
Interventional

Study design
Quasi-experimental controlled trial

Study type(s)

Treatment

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

Interventions
An independent physiotherapist provides study details and assigns individuals to groups. This study is non-randomised due to resource limitations and access.

Control group: no treatment

Experimental group: the experimental group will take place within the University of Birmingham, in accordance with our earlier work (Soundy et al., 2013) and supported by the charity Action After Stroke. This gives individuals with a stroke access to a private hall space, a private fitness suite and when they are ready transitions them to the Inclusive Fitness Facility (IFI) Gym at the University of Birmingham (see http://www.efds.co.uk/inclusive_fitness/ifi_gyms). This gym has been used in our previous research for individuals with neurological disorders (Meek et al., 2012; Elsworth et al., 2011).

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Stroke self-efficacy (Jones et al., 2008), questionnaire measured by a blind assessor at two time points (at baseline and at 11 and 22 weeks).

Key secondary outcome(s)
1. Social identification measure (Postmes et al., 2013).
2. A 7-item falls efficacy questionnaire (Kempen et al., 2007)
3. 10-meter walk and reach and grasp

Outcomes will be measured by a blind assessor at two time points (at baseline and at 11 and 22 weeks).

Completion date
15/01/2015

Eligibility

Key inclusion criteria
Participants:
Seventy two (36 in each group) individuals from the community that have been diagnosed as having a stroke will be included. Individuals will be selected from a sample within the Birmingham area including South Birmingham and Solihull borough. Individuals will be referred to the study by different charities including the Stroke Association, Different Strokes Charity, conductive education or referred by another related charitable organisation and local stroke support groups. We will not recruit from NHS sources.
Inclusion Criteria

1. Individuals must have been diagnosed with a stroke (DOH, 2010).
2. Either gender, age range 18-100 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Key exclusion criteria
1. Individuals who are experiencing acute mental health symptoms or that are medically unstable will also be excluded
2. Individuals who are currently involved in a physical activity, behavioural or nutritional research trial
3. Individuals who are currently undertaking exercise within a group or within the community on more than one day a week.

Date of first enrolment
15/01/2014

Date of final enrolment
15/01/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
School of Sport, Exercise and Rehabilaition Sciences
The Old Gym
University of Birmingham
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Charity

Funder Name
Action After Stroke (UK)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Andrew Soundy A.A.Soundy@bham.ac.uk

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	results	01/01/2016		Yes	No