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The effect of exercise on brain blood flow and metabolism in stroke survivors

Submission date 10/05/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/08/2011	**Overall study status** Completed	
Last Edited 11/08/2016	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Recent information has suggested that exercise may help people who have suffered from a stroke. Exercise may help to control the levels of glucose in the body and to improve blood flow in different areas of the brain. This may decrease the likelihood of having another stroke by improving the quality of your blood vessels and by decreasing the formation of fatty substances called plaques. Exercise has also been shown to improve functions such as walking and balance. This study will test the effect of exercise on the control of glucose in the body, blood flow in the brain and limb function. Understanding the relationship between exercise, glucose control, blood flow in the brain and limb function is important as it may reduce the risk of further stroke and may improve day to day functions such as walking and balance.

Who can participate?
Men and women aged 50 years or older, who have had a stroke at least six months ago who are able to walk independently with or without a stick for six minutes

What does the study involve?
The study will investigate older adults following stroke caused either by a blockage or bleeding in the brain. Participants will be asked to complete a number of tests like magnetic resonance imaging (MRI), blood tests and functional tests. Participants will then be randomly allocated to either an exercise group where they will complete balance, strengthening and agility exercises three times a week for nineteen weeks, or to a stretching group where they will undertake a home stretching programme for the same period of time. Initial tests will be repeated at the end of the intervention to assess if there has been any change.

What are the possible benefits and risks of participating?
Being more physically active may be beneficial to your glucose control, blood flow in the brain and your limb function and if you continue exercising after the study, this may help in preventing other complications such as heart disease and diabetes. You will have supervised exercise sessions (like a personal trainer) which will teach you about your body, show you how to exercise correctly and help you become more physically fit. Risks include the following. Giving up time to participate has to be considered. There may be a small chance of pulling a muscle during the exercise intervention, but every precaution will be taken to avoid any harm. All the staff involved

in the exercise intervention have experience working with people affected by stroke. The participants will have their body composition measured in a device called the Bod Pod. In order to do this accurately participants will be asked to wear their swimwear. Every effort will be made to avoid embarrassment and maintain dignity during this procedure.

Where is the study run from?
The Campus for Ageing and Vitality at Newcastle University (UK)

When is the study starting and how long is it expected to run for?
January 2011 to February 2012

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
1. Dr Michael Trenell (m.i.trenell@ncl.ac.uk)
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
SFV1

Study information

Scientific Title
The effect of a fitness and mobility exercise programme on glucose control and blood flow in the brain in older adults with chronic stroke

Study objectives

An exercise an mobility programme improves brain blood flow and glucose control in older adults with chronic stroke.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. County Durham and Tees Valley Research and Ethics Committee, 04/01/2010
2. Newcastle upon Tyne Hospitals Trust, 06/04/2010, ref: 09/H0908176

Primary study design
Interventional

Study design
Single-centre single-blinded randomised controlled study

Study type(s)
Treatment

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

Interventions
1. A fitness and mobility exercise programme based upon the intervention protocol devised by Pang and colleagues (Pang et al., 2005b)
2. The exercise intervention lasts 19 weeks and participants will be asked to attend three times a week for one hour on Mondays, Wednesdays and Fridays at 2pm
3. The exercise programme combines elements of fitness, mobility and balance and has been shown to be an effective and feasible intervention for delivery to stroke survivors in the community (Marigold et al., 2005; Pang et al., 2005a; Eng JJ et al., 2003)
4. Previous studies have established very high levels of compliance with the programme, alongside post intervention improvements in fitness levels, paretic femoral bone mineral density and strength (Marigold DS et al., 2005; Pang et al., 2005b; Eng JJ et al., 2003)
5. Participants will wear a Polar heart rate monitor to assess if they are exercising within the set heart rate ranges required by the exercise protocol
6. The polar heart rate monitors will also be used to capture data on energy expenditure, mean heart rate, minimum heart rate and maximum heart rate during each session
7. The intervention will be run by a physiotherapist and fitness instructor with experience in stroke rehabilitation, cardiac rehabilitation and elderly fitness
8. There will be a minimum of 1 instructor to five participants

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Glucose control (frequently sampled oral glucose tolerance test)
2. Cerebral blood flow via magnetic resonance imaging (MRI)

Key secondary outcome(s)
1. Cardiorespiratory fitness
2. Body composition
3. Stroke impairment
4. Cognition
5. Endurance speed and balance
6. Physical activity
7. Quality of life

Completion date
03/02/2012

Eligibility

Key inclusion criteria
1. Over 50 years old
2. Diagnosed with a stroke by a stroke physician through computer tomography or magnetic resonance imaging and clinical characteristics at least six months previously
3. Participants are all able to walk for six minutes independently allowing for rests with or without a stick
4. Lives at home
5. Completed all conventional physiotherapy offered by the National Health Service (NHS)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. The absolute and relative contraindications to exercise testing as stated by the American Heart Association (Fletcher et al., 2001)
2. Other neurological or medical conditions in addition to stroke which would prevent individuals from participating
3. A diagnosis of diabetes, the presence of pain on walking (>5 on a visual analogue scale of pain)
4. Untreated major depression
5. Cognitive or speech problems limiting understanding of the study (participants were excluded if their Mini Mental Scale Examination (MMSE) was under 25 and if they were unable to follow two stage commands) (Folstein et al. 1975)

Date of first enrolment
01/01/2011

Date of final enrolment

03/02/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
MoveLab
Newcastle upon Tyne
United Kingdom
NE2 4HH

Sponsor information

Organisation
Royal Victoria Infirmary, Newcastle (UK)

ROR
https://ror.org/01p19k166

Funder(s)

Funder type
Government

Funder Name
Medical Research Council (ref: G0802536)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United Kingdom

Funder Name
National Institute of Health Research, Biomedical Research Centre for Ageing & Age Related Disease

Results and Publications

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	results	01/08/2015		Yes	No
Results article	results	01/04/2016		Yes	No