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Treadmill training in sub-acute stroke

Submission date	Recruitment status	[ ] Prospectively registered
22/03/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/04/2017	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/09/2017	Nervous System Diseases	

Plain English summary of protocol

Background and study aims
A stroke occurs when the blood supply to the brain is cut off. This can cause long term problems with mobility due to the injury to the brain. A major problem for people who have had a stroke is learning to walk again. Physiotherapy is a type of rehabilitation that helps restore movement and function to patients. Physiotherapists help stroke patients to walk using different types of exercises. Sometimes different equipment, such as using a treadmill, can be used to help patients to walk again. This study looks at the feasibility of using a treadmill and the outcomes of relearning how to walk for people who had had a stroke within the last three months. The main aims of this study is to see if a study like this is feasible, to see how to provide treadmill training for stroke patients, see if using a treadmill can help improve mobility when compared to standard physiotherapy patients and to create a larger study in the future.

Who can participate?
Adults over the age of 18 who have had a stroke.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the standard physiotherapy treatment and gait (walking) training. Those in the second group receive the standard physiotherapy treatment three times a week over eight weeks. They also receive at least two gait training sessions that use a treadmill. After the eight weeks, participants continue with their standard physiotherapy treatments without using a treadmill. Participants are assessed before the treatment, right after the treatment and in a six month follow up to assess their mobility.

What are the possible benefits and risks of participating?
Participants may benefit from improving their mobility, independence and quality of life. There are minimal risks with participating, such as falling during physiotherapy; however participants are given support by physiotherapists to prevent this.
Where is the study run from?
This study is run by Queen Margaret University Edinburgh and takes place in Astley Ainslie Hospital (UK), St Johns Hospital (UK), the Royal Victoria Hospital (UK) and the Liberton Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2005 to December 2008

Who is funding the study?
Chest Heart and Stroke Scotland (UK)

Who is the main contact?
Dr Gillian Baer

Contact information

Type(s)
Scientific

Contact name
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Physiotherapy
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Additional identifiers

Protocol serial number
R06/A99

Study information

Scientific Title
Treadmill Training for people with Sub-Acute Stroke: A phase II randomised controlled trial

Acronym
STATT

Study objectives
The aim of this pilot study is to evaluate the effects and feasibility of using treadmill training in people with stroke, within the first 3 months after stroke.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Scotland A Multi-Centre Research Ethics Committee, 16/10/2006, 06/MRE00/82

Study design
Exploratory phase II single-blind feasibility multi-site randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Sub-acute Stroke

Interventions
Participants are randomly allocated to either the intervention group or the control group. Randomisation is done after participants undergo baseline measurements using a computer generated minimisation method. Minimisation takes into account the side of the body that the stroke occurred on and whether the participants are ambulant without physical assistance (using the Functional Ambulation category 4-6) or the participants are non-ambulant or ambulant only with physical assistance (Functional Ambulation category 1-3).

Intervention Group (TT): This intervention occurs over eight weeks (or fewer if the participant is discharged from the unit before the eight weeks). Participants in this group receive at least three treatment sessions per week comprising of normal physiotherapy and gait training. At least two gait training sessions include the treadmill. The actual time on the treadmill is determined by the treating physiotherapist. All the time on the treadmill is recorded. After eight weeks, participants in this group reverted back to normal physiotherapy with no further access to the treadmill.

Control group (CON): This intervention occurs over eight weeks (or fewer if the participant is discharged from the unit before the eight weeks). Participant in this group receive at least three treatment sessions per week comprising of normal physiotherapy and gait training. Gait training has no access to a treadmill. The time for the normal physiotherapy is determined clinically.

Participants are assessed for their mobility at baseline, at the end of the interventions (eight weeks) and at a six month follow up. As this is a feasibility phase II randomised controlled trial, data from a battery of secondary outcome measures are collected.

Intervention Type
Other

Primary outcome(s)
Mobility is measured using the Rivermead Mobility Index at baseline, eight weeks and six months.

Key secondary outcome(s))
1. Mobility and balance is measured using the Timed Up and Go (TUG) at baseline, eight weeks and six months
2. Gait speed is measured using a 10 metre walk (10mwt), at baseline, eight weeks and six months
3. Walking endurance is measured using a six minute walk test (6minwt) at baseline, eight weeks and six months
4. Confidence in walking is measured using a vertical 10cm Visual Analogue Scale (VAS), patient

interviews and following a standardised operating procedure at baseline, eight weeks and six months
5. Motor impairments and everyday motor function is measured using the Motor Assessment Scale (MAS) at baseline, eight weeks and six months
6. Dependence in Activities of Daily Living is measured using Barthel Index at baseline, eight weeks and six months
7. Self reported recovery and quality of life is measured using the Stroke Impact Scale v3.0 at baseline, eight weeks and six months

Completion date
19/12/2008

Eligibility

Key inclusion criteria
1. Aged over 18
2. Had a stroke as defined by WHO 1988
3. One minute standing balance (with or without support, this was required to allow donning a safety harness if supported treadmill training was required)
4. Medically stable
5. Within three months of stroke onset
6. Able to understand and follow verbal instructions; and
7. Able to give informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Co-existing non-stroke related neurological impairments
2. Co-morbidities precluding gait training (e.g. amputee)
3. Non-ambulant prior to stroke
4. Body weight greater than 138kg (Weight limit of equipment)
5. Unsafe to use treadmill
6. Unable to follow simple commands

Date of first enrolment
04/05/2007

Date of final enrolment
20/06/2008

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Astley Ainslie Hospital
Physiotherapy
33 Grange Loan
Edinburgh
United Kingdom
EH9 2HL

Study participating centre
St Johns Hospital
Physiotherapy
Howden Road West
Howden
Livingston
United Kingdom
EH54 6PP

Study participating centre
The Royal Victoria Hospital
Physiotherapy
13 Craigleith Road
Edinburgh
United Kingdom
EH4 2DN

Study participating centre
Liberton Hosptial
Physiotherapy
113 Lasswade Road
Edinburgh
United Kingdom
EH16 6UB

Sponsor information

Organisation
Queen Margaret University

ROR
https://ror.org/002g3cb31

Funder(s)

Funder type
Charity

Funder Name
Chest Heart and Stroke Scotland

Alternative Name(s)
Chest Heart & Stroke Scotland, CHSScotland, CHSS

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

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 Dr Gillian Baer (Principal Investigator) gbaer@qmu.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2018		Yes	No
Participant information sheet	version V3	01/11/2007	21/04/2017	No	Yes

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