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Improving community walking after a stroke, a new approach

Submission date	Recruitment status	[_] Prospectively registered
28/02/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/02/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/06/2021	Circulatory System	

Plain English summary of protocol

Background and study aims
A stroke is a serious condition where the blood supply to a part of the brain is cut off, usually by a blood clot blocking an artery (ischaemic stroke) or a bleed (haemorrhagic stroke). Many stroke victims suffer from long-term complications depending on the area of the brain that is affected, which can affect their ability to move, speak or even their cognitive function (memory loss, difficulty reasoning and confusion). One of the most common complications of a stroke is weakness or paralysis on one side of the body. The leg is often affected by this, making movements such as walking very difficult. Patients therefore often need extensive physiotherapy to help them recover. Community walking after stroke is often affected even if stroke survivors have had good recovery of leg function. This study aims to explore the feasibility and possible effect of dual task treadmill training (walking on the treadmill while completing thinking tasks) to improve community walking ability in stroke survivors.

Who can participate?
Adults who have had a stroke at least six months ago who have difficulty walking.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group are asked to walk for 45 minutes on a treadmill whilst performing distracting tasks (dual task). This involves completing mental processing tasks such as counting backwards or chatting with the trainer. Those in the second group are asked to walk for 45 minutes on a treadmill whilst concentrating on their walking. Both groups take part in 24 sessions spread over a course of 10 weeks. At the start of the study and then after 11 and 22 weeks, participants complete a range of assessments to evaluate their walking performance, community walking, health and wellbeing and dual task walking ability.

What are the possible benefits and risks of participating?
Treadmill walking exercise has been shown to be an effective intervention for improving mobility, health, wellbeing and fitness in people following stroke. Participants in both groups will benefit from participation in treadmill walking. There are no risks in taking part. Exercise training is carried out by trained professionals and heart and blood pressure are monitored before and after training.

Where is the study run from?
1. Clinical Exercise and Rehabilitation Unit, Oxford Brookes University (UK)
2. St Crispin's Leisure Centre (UK)

When is the study starting and how long is it expected to run for?
August 2011 to August 2016

Who is funding the study?
The Stroke Association (UK)

Who is the main contact?
Professor Helen Dawes
hdawes@brookes.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Helen Dawes

ORCID ID
http://orcid.org/0000-0002-2933-5213

Contact details
Movement Science Group
School of Life Sciences
Gipsy Lane
Headington
Oxford
United Kingdom
OX3 0BP
+44 1865 483469
hdawes@brookes.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13923

Study information

Scientific Title

A single blinded randomized controlled trial to explore the efficacy of a 10 week dual task treadmill training in comparison to treadmill training without distraction on walking performance and community walking in chronic stroke survivors

Acronym
Stroke WALK

Study objectives
Dual task treadmill training will improve community walking levels, dual task ability and confidence about community walking more than training treadmill walking without dual tasks.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Oxford C, 19/11/2012, ref: 12/SC/0403

Study design
Pilot randomised trial with an active comparator control group

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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 Research Network; Subtopic: Rehabilitation; Stroke

Interventions
Participants will be into one of two treatment groups using a computer generated randomization list 1:1 into one of both groups with stratification for baseline treadmill speed to balance groups for walking performance.

Intervention group: Participants perform 45 minute treadmill walking whilst performing distracting tasks. This involves performing arious cognitive tasks whilst walking (i.e. counting backwards in steps of 3 or 7, listening to audio fragments, chatting with the trainer about planning daily activities).

Comparison group: Participants perform 45 minute treadmill walking, and are trained to focus on the walking as much as they can without be distracted.

The training sessions will be run over ten weeks, with individuals completing 24 sessions in this period. The sessions will be supported in a Clinical Exercise and Rehabilitation Unit. Individuals will initially walk for as long as they are comfortably able. Both training groups receive a 10 week biweekly training. Each training session lasts for a maximum of 45 min, or when a person is not able to complete the full 45 minutes, as long as they can handle. During the training 30 minutes will be in the aerobic training zone (55%-85% maximum heart rate).

Training is preceded by a baseline assessment to assess walking performance, community walking, health and wellbeing and dual task walking ability. Another assessment is done after 10 weeks of training and a follow-up assessment is performed at 22 weeks (10 week follow-up).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Primary outcomes as of 16/01/2017:
1. Walking performance is measured using the Two minute walk test at baseline, 11, 22 weeks
2. Walking performance in dual task conditions is measured using the Two minute walk test with distraction at 0, 11, 22 weeks
3. Community walking ability and confidence about community walking is measured using Community walking questions at at 0, 11, 22 weeks

Original primary outcome:
Effect of walking whilst performing distracting tasks training

Secondary outcome measures
Added 16/01/2017:
1. Dual task effect on walking distance during two minute walk with distraction is measured by the change in walking distance from single to dual task at baseline, 11, 22 weeks
2. Number of cognitive responses during two minute walk with distraction is measured by cognitive response rate walking at baseline, 11, 22 weeks
3. Physical activity level is measured using the Physical activity scale for elderly at baseline, 11, 22 weeks
4. Physical activity and community walking levels are measured using Step activity monitors, worn for a week at baseline, 11, 22 weeks
5. General health and wellbeing are measured using the SF-36 questionnaire at baseline, 11, 22 weeks
6. Health and wellbeing on the day is measured using the EQ-5D questionnaire at baseline, 11, 22 weeks
7. Community walking levels specified for specific surroundings is measured using the Modified version of the University of Alabama study of Aging Life Space Assessment at baseline, 11, 22 weeks

Overall study start date
01/08/2011

Completion date

31/08/2016

Eligibility

Key inclusion criteria
1. Adults will be selected who are more than 6 months following a first stroke with some walking impairment. Walking impairment will be determined by asking participants, on initial expression of interest to participate, if they have a walking problem (Yes/No) and confirmed by a reduced six minute walk distance (compared to normative data) on testing
2. With an ischaemic infarct
3. Able to perform a simple reciprocal bilateral foot tapping task
4. Walk safely on a treadmill with or without mobility aids and to give informed consent.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
UK Sample Size: 50

Total final enrolment
50

Key exclusion criteria
1. Individuals with a high risk of psychosis
2. Aphasia significantly limiting communication
3. History of previous symptomatic stroke or neurological disease
4. A mental state that precludes safe participation (as stated by GP or referring consultant)
5. Any known contraindication to safe participation in exercise.
6. Individuals will be checked for safe participation in the MRI scanning: claustrophobia, or other conditions precluding safe MRI (e.g., pacemaker or other metal implant). Individuals determined safe and willing to take part will participate in additional scanning.

Date of first enrolment
30/01/2013

Date of final enrolment
30/12/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clinical Exercise and Rehabilitation Unit
Sports Centre
Oxford Brookes University
Headington Campus
Oxford
United Kingdom
OX3 0BP

Study participating centre
St Crispin's Leisure Centre
London Road
Wokingham
United Kingdom
RG40 1SR

Sponsor information

Organisation
Oxford Brookes University (UK)

Sponsor details
Movement Science Group
School of Life Sciences
Gipsy Lane
Headington
Oxford
England
United Kingdom
OX3 0BP

Sponsor type
University/education

Website
http://www.brookes.ac.uk/

ROR
https://ror.org/04v2twj65

Funder(s)

Funder type
Charity

Funder Name
The Stroke Association

Results and Publications

Publication and dissemination plan
Planned publication of the main results and a paper with a very detailed description of training and the clinical lessons learned in peer reviewed journals.

Intention to publish date
31/08/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository of Oxford Brookes University.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2019	21/08/2019	Yes	No
Results article	sub study results	30/05/2021	01/06/2021	Yes	No