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Learning not to fall: perturbation training to promote safe independent mobility post-stroke

Submission date
25/03/2014

Recruitment status
No longer recruiting

Registration date
03/04/2014

Overall study status
Completed

Last Edited
20/08/2018

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Remaining active after a stroke is essential to recovery, a good quality of life and reduced risk of another stroke in the future. However, individuals who have had a stroke also have an increased risk of falling. Physical exercise can prevent falls in older adults, but no exercise program has effectively reduced this risk among individuals who have had a stroke. In order to keep from falling down, individuals must have rapid and sophisticated reactions that are often greatly impaired after a stroke. This study will explore a new way of re-training those rapid reactions. The aim is to assess whether the new approach will prevent falls and how it will increase confidence (reduce fear of falling), participation in daily activities, balance and mobility.

Who can participate?
People who have had a stroke.

What does the study involve?
Participants will be randomly allocated one of two training groups: the perturbation training group or the traditional balance training group. The perturbation training group will repeatedly experience instability and lose balance during training; they will be trained to execute appropriate reactions to avoid falling. The traditional balance training group will complete balance exercises without any induced instability.

What are the possible benefits and risks of participating?
One group might do better than the other group. Participants in this study will get the same or better standard of care than those who do not participate in the study. Participants will be asked to travel to the research centre for testing or to exercise 18 times over a one-year period and they might find this a burden. Participants who require a family member to assist with transport may also find that this is an inconvenience for the family member. Participants might find the exercises or balance tests challenging or tiring. To minimize the risk of physical harm, we do not allow people with certain medical conditions to participate in this study. The exercise program will be supervised by a trained physiotherapist who will monitor participants for any adverse reactions. Participants will have regular rest breaks and can request additional breaks. Participants can stop the testing at any time if they are too tired to continue or are uncomfortable. During the exercises and balance tests, there is a risk that participants will not

be able to regain balance on their own and will start to fall. Participants will wear a safety harness to prevent them from falling to the floor. The researchers will help participants regain their balance. There is a very small chance participants will have an injury (such as a sprain or a bruise), even if they are caught by the safety harness. However, we have done these types of tests and exercises with hundreds of people with stroke without any injuries.

Where is the study run from?
Toronto Rehabilitation Institute (Canada)

When is the study starting and how long is it expected to run for?
April 2014 to March 2017

Who is funding the study?
Toronto Rehabilitation Institute (Canada)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MOP-133577

Study information

Scientific Title
Learning not to fall: perturbation training to promote safe independent mobility post-stroke - a multi-centre single-blind randomized controlled trial

Study objectives
The primary objective of this study is to determine if a novel perturbation-based training program focused on improving reactive stepping in individuals with chronic stroke will reduce the risk of falls in the community. The secondary objectives are to determine the effect of perturbation training on: balance confidence and activity restriction; functional balance and mobility; and reactive balance control.

Primary hypothesis falls
We hypothesize that individuals with stroke who complete perturbation training will be less likely to experience a fall up to 12 months following completion of the program, compared to individuals who complete a traditional balance training program (control group). We hypothesize this reduction in fall rates will occur despite increased physical activity following training (see secondary hypotheses).

Secondary hypotheses balance, mobility, confidence and activity
We hypothesize that, compared to individuals in the control group, individuals with stroke who complete the perturbation training program will show:
1. Reduced fear of falling
2. Increased participation in daily activities in the year following completion of the program
3. Greater gains in functional balance and mobility

Additionally we will explore changes in control of reactive stepping that occur with training, and retention of these changes up to 12 months following cessation of the training program. This analysis will identify features of reactive balance control that improve and features that are resistant to training to help to further develop the training program.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University Health Network Rehabilitation Medicine and Science Research Ethics Board, 26/03/2014, ref: 14-7428
2. Sunnybrook Health Sciences Centre Research Ethics Board, 15/05/2014, ref: 134-2014

Study design
Multi-centre single-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Falls among people with stroke

Interventions
Participants will be randomized to one of two training groups: perturbation training (experimental group) or 'traditional balance training (control group). Interventions will be administered on a 1:1 basis (i.e., one physiotherapist per participant) by a trained and licensed physiotherapist. Interventions will follow a general guide but will be tailored to the individual participants ability. Participants will complete two one-hour training sessions per week for 6 weeks. Additionally, participants will be asked to return for two one-hour booster training sessions 3 months and 9 months following the initial training period.

Perturbation training (experimental group)
Participants will initially complete an assessment of reactive balance control to identify participant-specific impairments in the control reactive stepping. The individualized training program will then be designed to target participants specific impairments. A variety of tasks will be included to induce external or internal postural perturbations. External perturbations will be caused by forces outside the participants control (e.g., a push or pull from the physiotherapist). Internal perturbations are caused when the participant fails to control the centre of mass-base of support relationship during voluntary movement; agility tasks, such as kicking a soccer ball, can be used to induce internal perturbations. Previous studies employing manual perturbations and agility tasks have found positive training effects on reactive balance control and falls. Each session will include a 5-10 minute warm-up, voluntary (agility) tasks that may induce internal perturbations, voluntary tasks combined with up to 60 external perturbations, and a 5-10 minute cool-down. The task difficulty will be set such that participants will fail to recover balance 50% of the time; 'failure is defined as use of an upper extremity response, use of external assistance (i.e., from the overhead harness or physiotherapist), or taking more than two steps to regain stability. The progression in voluntary tasks occurs on a continuum from stable to mobile, and from predictable to unpredictable. Additionally, progression occurs by increasing the magnitude of the external perturbation, or imposing sensory or environmental challenges.

Traditional balance training (control group)
The control group will complete a traditional balance training program without intentionally experiencing postural perturbations. Previous research found no effect of such traditional balance training on falls post-stroke; we expect that the control participants will not be at a reduced risk of falls as a result of completing this program. Participants assigned to the control group will complete the Keep Moving with Stroke program (http://www.tbrhsc.net /clinical_partners/regional_stroke_program/video_resources/community_based_exercise.asp). This is an exercise program for individuals living in the community following stroke developed by a group of physiotherapists, in cooperation with the Ontario Stroke System and the Ontario Ministry of Healths Active 2010 initiative based on balance and mobility interventions evaluated in clinical trials. Each session includes a 5-10 minute warm-up followed by 40 minutes of mobility and balance-related activities, and a 5-10 minute cool-down with stretching.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Number of falls experienced in daily life for up to 12 months following the intervention

Secondary outcome measures
1. Fear of falling will be measured with the Activity-specific Balance Confidence scale at four time points: 1) prior to the start of the exercise program; 2) immediately at the end of the exercise program; 3) 6 months after the end of the exercise program; and 4) 12 months after the end of the exercise program.
2. Participation in daily activities will be measured immediately before the start of the exercise program, and every 2 months following completion of the exercise program until the end of the 12-month falls monitoring period, using the Physical Activity Scale for Individuals with Physical Disabilities, and the Subjective Index of Physical and Social Outcome
3. Functional balance and mobility will be measured with the Berg balance scale, the mini-Balance Evaluation Systems Test, and the Timed-up and Go at four time points: 1) prior to the start of the exercise program; 2) immediately at the end of the exercise program; 3) 6 months after the end of the exercise program; and 4) 12 months after the end of the exercise program.

Overall study start date
01/04/2014

Completion date
31/03/2017

Eligibility

Key inclusion criteria
Current participant inclusion criteria (as of 14/02/2018):
1. Community-dwelling individuals with chronic stroke (>6 months post-stroke)
2. Can stand independently without upper limb support for >30 seconds
3. Can tolerate at least 10 postural perturbations while wearing a safety harness

Previous participant inclusion criteria:
1. Community-dwelling individuals with chronic stroke (>6 months post-stroke)
2. 50 years old or older
3. Can stand independently without upper limb support for >30 seconds
4. Can tolerate at least 10 postural perturbations while wearing a safety harness

Participant type(s)
Patient

Age group
Other

Sex

Both

Target number of participants
92

Key exclusion criteria
1. >2.1 m tall and/or weighing >150 kg (limits of the safety harness system)
2. Other neurological condition that could affect balance control (e.g., Parkinsons disease)
3. Lower extremity amputation
4. Cognitive, language or communication impairments affecting understanding instructions
5. Recent (last 6 months) significant illness, injury or surgery
6. Severe osteoporosis, defined by diagnosis of osteoporosis with fracture
7. Poorly controlled diabetes or hypertension
8. Contraindications to physical exercise, as identified using the Physical Activity Readiness Questionnaire
9. Currently attending in- or out-patient physiotherapy or other exercise targeting balance and mobility
10. Received perturbation training at Toronto Rehab <1 year previously

Date of first enrolment
24/04/2014

Date of final enrolment
29/09/2016

Locations

Countries of recruitment
Canada

Study participating centre
Toronto Rehabilitation Institute
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
http://www.uhn.ca/TorontoRehab

ROR
https://ror.org/00mxe0976

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research (Canada) (MOP-133577)

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal 1 year after study termination.

Intention to publish date
01/08/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to privacy legislation and institutional research ethics restrictions.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		26/03/2018	26/03/2018	No	No
Results article	results	17/08/2018		Yes	No