

# Mirror therapy for the lower extremity after stroke

<b>Submission date</b> 22/10/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 20/01/2016	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 20/01/2020	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## 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). A large proportion of 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 paralysis (hemiplegia) or weakness (hemiparesis) on one side of the body. This can make movements such as walking very difficult and so patients need extensive physiotherapy to help them recover. Mirror therapy (MT) is a technique that uses the movements of the stronger limb to “trick” the brain into thinking that the weaker part of the body is moving. The therapy uses a mirror, placed at the midline of the patient, to hide the defective limb and reflect the movement of the unaffected limb. This causes the brain to attribute the movement of the reflection to the defective limb, giving the impression that both limbs are functioning normally. Previous studies have shown this technique to be very effective at improving arm and hand function, however little is known about the use of mirror therapy for the recovery of leg function and walking. The aim of this study is to find out whether using MT is an effective way to help stroke patients to improve the range of movement in the affected leg and to help them recover their walking ability.

### Who can participate?

Adults stroke patients with normal vision, who have been admitted to the rehabilitation programme at Toronto Rehabilitation Institute.

### What does the study involve?

Participants are randomly allocated to one of two groups who receive ten to fifteen 30-minute physiotherapy sessions. Those in the first group take part in mirror therapy training sessions throughout their time in the rehabilitation ward. In the sessions, participants are asked to perform bending and stretching exercises of the hip, knee and ankle with a mirror placed along their midline. The affected leg is positioned behind a curtain so that only the movements of the unaffected leg are seen in the mirror. The participants are asked to watch the movements of the unaffected leg in the mirror while trying to complete the exercises with both legs. Those in the second group are positioned in the same way and perform the same bending and stretching

movements. For these participants, the mirror is replaced with a non-reflective board so they cannot see the movements of their unaffected leg in a mirror. For both groups of participants, before and after the physiotherapy sessions, the degree to which their movement is affected is measured.

What are the possible benefits and risks of participating?

Participants may benefit from improved control of leg movement, as well as an improved gait (way of walking). Risks of taking part are small, however some participants may find the training sessions tiring or painful (lower back pain or muscle soreness).

Where is the study run from?

Toronto Rehabilitation Institute (Canada)

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

October 2014 to December 2016

Who is funding the study?

Physiotherapy Foundation of Canada (Canada)

Who is the main contact?

1. Mr Anthony Aqui (Public)

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2. Dr Kara Patterson (Scientific)

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## Contact information

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## **Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

14-7482

## **Study information**

### **Scientific Title**

Mirror, mirror, in therapy, whose leg moves with the most dexterity? A pilot study of a lower extremity, multi-joint mirror therapy intervention after stroke

### **Study objectives**

The overall goal of the proposed project is to examine the feasibility of a multi-joint, lower extremity, mirror therapy intervention for the improvement of lower extremity motor impairment, spatiotemporal gait parameters and EMG activity gait profiles in individuals with stroke.

The hypotheses related to the main objective of the proposed study are:

1. Improvements in Chedoke-McMaster Stroke Assessment (CMSA) foot and leg scores will be greater in the MT intervention group than the control group after the intervention and at follow-up
2. Improvements in spatiotemporal gait parameters will be greater in the MT intervention group than the control group after the intervention and at follow-up
3. Improvements in lower extremity EMG amplitude and timing, with respect to the gait cycle, will approximate expected normal values and will be greater in the MT intervention group than the control group after the intervention and at follow-up

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

The University Health Network Research Ethics Board, 17/10/2014, ref: 14-7482-DE

### **Study design**

Randomized controlled pilot study

### **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

## **Health condition(s) or problem(s) studied**

Stroke

## **Interventions**

Participants are randomly allocated to one of two groups:

Mirror Therapy intervention group: Participants will be positioned in long-sitting on a plinth with back support and a mirror at the participant's midline. Participants will then perform repeated bilateral hip and knee flexion-extension and ankle dorsiflexion movements and/or repeated bilateral hip adduction and abduction movements. The affected limb will be placed behind a curtain to block the participant's view of that limb. The unaffected limb will be positioned outside the curtain such that the movements are reflected in the mirror. The entire apparatus will be positioned to create the illusion of the affected limb moving as the unaffected limb would. Participants will be instructed to observe the reflection of their unaffected limb while performing the bilateral LE exercise.

Control intervention group: Participants will be positioned in the same manner as described for the MT intervention group. Participants will also perform the same repeated bilateral hip and knee flexion-extension and ankle dorsiflexion movements. The MT apparatus will also be used, however the mirror will be replaced with a non-reflective board.

All participants will attend 10-15 training sessions. The exact amount will vary depending on the individuals' length of stay in rehabilitation. A goal of 30 minutes for the duration of each intervention session will be set but the actual duration will be guided by patient tolerance.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

1. Degree of motor impairment is measured using the Chedoke McMaster Stroke Assessment before and after the participant completes the mirror therapy sessions
2. Over-ground gait performance is measured using spatiotemporal gait parameters before and after the participant completes the mirror therapy sessions. Parameters of interest are gait velocity and temporal gait symmetry. Gait symmetry will be calculated using a ratio of left and right limb values for swing time as outlined in previous work.
3. EMG gait profile is measured by recording EMG activity bilaterally from the tibialis anterior, medial gastrocnemius, vastus lateralis and biceps femoris before and after the participant completes the mirror therapy sessions. Footfall events are recorded using insole foot switches.

## **Secondary outcome measures**

1. Standing balance is measured using the Berg Balance Scale before and after the participant completes the mirror therapy sessions
2. Motor coordination is measured before and after the participant completes the mirror therapy sessions using the finger to nose test and the heel to shin test. These tests are video recorded with a digital camera to later analyse for performance and quality of movement
3. Electrodermal activity is measured during the first and last mirror therapy session completed by the participant
4. Electroencephalogram activity (EEG) and EMG activity coherence is measured during the first and last mirror therapy session completed by the participant

**Overall study start date**

17/10/2014

**Completion date**

31/12/2016

**Reason abandoned (if study stopped)**

Participant recruitment issue

## Eligibility

**Key inclusion criteria**

1. First time occurrence of stroke
2. Normal or corrected to normal vision
3. Chedoke McMaster Stroke Assessment (CMSA) leg and foot score of 2 or greater
4. Passive ankle dorsiflexion to neutral, passive knee flexion to 60 degrees and passive hip flexion to 100 degrees
5. Have been admitted to the stroke rehabilitation program at the Toronto Rehabilitation Institute

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

20

**Key exclusion criteria**

1. Visual neglect or inadequate vision that would impede the viewing of the mirror's surface
2. Bilateral stroke or bilateral sensorimotor impairments
3. Inability to comprehend and/or follow multiple step instructions

**Date of first enrolment**

01/11/2015

**Date of final enrolment**

30/11/2016

## **Locations**

**Countries of recruitment**

Canada

**Study participating centre**

**Toronto Rehabilitation Institute (University Health Centre)**

550 University Avenue

Toronto

Canada

M5G 2A2

## **Sponsor information**

**Organisation**

Toronto Rehabilitation Institute

**Sponsor details**

550 University Avenue

Toronto

Canada

M5G 2A2

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.torontorehabfoundation.com/>

**ROR**

<https://ror.org/00mxe0976>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Physiotherapy Foundation of Canada

**Alternative Name(s)**

Fondation de physiothérapie du Canada, PFC

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

Canada

## **Results and Publications**

**Publication and dissemination plan**

Planned publication of a study protocol and the results of the study in peer-reviewed journals. Study findings will also be presented at a national or international conference.

**Intention to publish date**

31/12/2017

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Available on request