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# Mirror therapy in children with hemiplegia

**Submission date**
12/02/2013

**Recruitment status**
No longer recruiting

**Registration date**
04/03/2013

**Overall study status**
Completed

**Last Edited**
06/04/2016

**Condition category**
Nervous System Diseases

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

## Plain English summary of protocol

Background and study aims
Spastic hemiplegia, a neuromuscular condition of spasticity that results in the muscles on one side of the body being in a constant state of contraction, in childhood is a disabling motor condition [affecting mobility] occurring during prenatal, perinatal or infant brain development or acquired cerebral damage during later childhood. It is one of the most frequent motor disorders of childhood with a prevalence estimated at 1 in 1000 children. Upper limb difficulties often predominate, affecting function and skill and grace in physical movement especially of hands, limiting motor independence in activities of daily life (such as using cutlery, dressing or grooming). Mirror therapy (MT) is a new approach aiming to improve upper limb motor function in hemiplegia. In MT patients train by looking into a mirror placed along their midline and hiding their defective limb. The observed reflection of the normally functioning limb superimposes itself on the defective one, thus generating the visual illusion of a limb that functions normally. Hemiparesis [weakness on one side of the body] following adult stroke was confirmed to be improved by mirror therapy in four recent clinical trials. MT is easy to apply, inexpensive, non invasive and as such may be considered an interesting additional treatment to the rehabilitation of children with hemiplegia. The aim of this study is to determine the efficacy of MT in children with hemiplegia and provide further evidence regarding this approach, by conducting a study in 100 children with hemiplegia.

Who can participate?
Children and teenagers with hemiplegia aged 7 to 16 years old.

What does the study involve?
The 100 participants will be randomly assigned to one of two groups (MT versus sham). All of the children will undergo 15 minutes of daily home-based upper limb training for 5 weeks, half of the children using the mirror and the other half without. They will be assessed for hand strength and function before training, after the 5 weeks of training and finally 5 weeks after having ceased the programme.

What are the possible benefits and risks of participating?
Our participants will possibly improve their paretic hand strength and function with the daily motor training routine. The limited duration (15 minutes) and type of exercises that were selected for the study (against absent to low resistance) render strain or overuse injuries very unlikely. None of the devices that are used present any inherent risk (unbreakable mirror).

Should any participant present unusual symptoms during training (e.g. pain) the training would be withheld and the participant examined at short notice by the study medical team.

Where is the study run from?
The study is run from Lausanne University Hospital (CHUV) in collaboration with Bern University Hospital, Switzerland.

When is the study starting and how long is it expected to run for?
Recruitment started in January 2013. Participants will be enrolled on the study for a period of 18 months.

Who is funding the study?
Swiss National Science Foundation and the Pierre Mercier Foundation for Science [Fondation Pierre Mercier pour la Science].

Who is the main contact?
Dr Christopher Newman
Christopher.Newman@chuv.ch

# Contact information

### Type(s)
Scientific

### Contact name
Dr Christopher Newman

### Contact details
Paediatric Neurorehabilitation Unit
Hôpital Nestlé - CHUV
Av. Pierre Decker 5
Lausanne
Switzerland
1011
-
Christopher.Newman@chuv.ch

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
SNF141167

# Study information

## Scientific Title
Mirror therapy in children with hemiplegia: a prospective randomized single-blinded trial

## Study objectives
Mirror therapy improves hand function and strength of the paretic arm in children with hemiplegia more than bimanual training without a mirror.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Cantonal Commission (VD) ethics of research on human beings [Commission cantonale (VD) d'éthique de la recherche sur l'être humain], 13/08/2012, ref: protocol 211/2012

## Study design
Prospective randomized single-blinded (assessor blinded) multicentre trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## 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
Spastic hemiplegia

## Interventions
Both groups will take part in a home-based 5-week motor training programme, 5 days per week. Participants will accomplish a standardised daily routine of 15 minutes of symmetrical bimanual activities, including fine motor tasks (e.g. finger tapping or thumb-forefinger pinch) and muscle strengthening of both hands and forearms (e.g. repeated sub-maximal strength grasp) using silicone putty whose density will be adapted to their individual abilities. All participants will take part in an initial training session with the research therapist at the beginning of the study (day 0), where they will be instructed in detail on how to perform the same standardized and systematic sequence of activities. They will be instructed to focus their visual attention on the side of the paretic hand during the training. The first group (mirror group) will perform this training using a mirror box which will be placed at a 70 to 80° angle to the child hiding the paretic limb, therefore providing the mirror feedback (illusion) of a normally functioning affected hand. The second group (sham group) will perform the same bimanual training without a mirror, under direct visual control of both hands.

### Intervention Type
Behavioural

### Primary outcome measure
1. Maximal hand strength:
Palmar grasp strength and thumb-forefinger pinch strength will be measured with specific dynamometers (respectively a 30 ppsi pneumatic dynamometer, Baseline®, USA and a 30 lbs mechanical pinch gauge, Baseline®, USA). Patients will be instructed to perform a maximal effort for each of these tasks that will be repeated three times at 30 second intervals. The maximal value will be retained for analysis. Two series of strength measurements will be performed, with and without a mirror box, in a random order to determine the immediate effect of mirror feedback on strength generation.
2. Melbourne assessment of unilateral upper limb function:
The Melbourne Assessment measures quality of unilateral upper limb movement in children with neurological conditions, aged 5-15 years. The assessment is designed to be a simple, easy to administer test that provides information about levels of ability/disability.

### Secondary outcome measures
1. ABILHAND-Kids:
This is a measure of manual ability in daily life and explores a representative inventory of 21 manual activities. The score is built on parents perception of their childs performance.
2. Sensory testing:
This will include two-point discrimination and proprioception testing with vision occluded. For two-point discrimination we will use a two-point aesthesiometer (Baseline®, USA) which contains a mobile pair of prongs that can be fixed from 1 to 130 mm apart. Moving two-point discrimination will be measured on the volar surfaces of the distal phalanxes of the thumb, forefinger and little finger, of the hand and the forearm according to the protocol in order to determine the smallest distance between two points that the subject identifies without an error. Proprioception at the level of the metacarpophalangeal joints of the thumb, forefinger and little finger will be measured, the number of correct responses out of five being scored (correct identification of flexion vs extension).

### Overall study start date
07/01/2013

### Completion date
30/06/2014

## Eligibility

### Key inclusion criteria
1. Age 7 to 16 years old, either sex
2. Hemiplegia diagnosed by a paediatric neurologist or paediatric rehabilitation specialist

### Participant type(s)
Patient

### Age group
Child

**Lower age limit**
7 Years

**Upper age limit**
16 Years

**Sex**
Both

**Target number of participants**
100

**Key exclusion criteria**
1. Mental age below 7 years
2. Behavioural comorbidities, especially untreated Attention deficit hyperactivity disorder (ADHD)
3. Moderate to severe visual defects, including hemianopsia
4. Focal spasticity treatment to the upper limb during the four months preceding inclusion (botulinum toxin, surgery)

**Date of first enrolment**
07/01/2013

**Date of final enrolment**
30/06/2014

# Locations

**Countries of recruitment**
Switzerland

**Study participating centre**
**Hôpital Nestlé - CHUV**
Lausanne
Switzerland
1011

# Sponsor information

**Organisation**
Lausanne University Hospital (Switzerland)

**Sponsor details**
Département médico-chirurgical de Pédiatrie
Centre Hospitalier Universitaire Vaudois

Rue du Bugnon 46
Lausanne
Switzerland
1011
-
dmcp@chuv.ch

**Sponsor type**
Hospital/treatment centre

**Website**
http://www.chuv.ch/pediatrie

**ROR**
https://ror.org/05a353079

# Funder(s)

**Funder type**
Government

**Funder Name**
Swiss National Science Foundation (Switzerland) ref: subsidy n°32003B_141167/1

**Alternative Name(s)**
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, SNF, SNSF, FNS

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Trusts, charities, foundations (both public and private)

**Location**
Switzerland

**Funder Name**
Pierre Mercier Foundation for Science (Fondation Pierre Mercier pour la Science) (Switzerland)

# Results and Publications

## Publication and dissemination plan
Not provided at time of registration

## Intention to publish date

## 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 | 01/09/2016 | | Yes | No |