Study Protocol

Study Title:

To investigate the potential effectiveness of mirror-aided cross-education using the innovative 'Mirror Strengthening Device' compared to mirror therapy alone in post-stroke upper limb recovery: A pilot randomised feasibility study.

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Study Protocol

To investigate the potential effectiveness of mirror-aided cross-education using the innovative 'Mirror Strengthening Device' compared to mirror therapy alone in post-stroke upper limb recovery: A pilot randomised feasibility study.

Study Objectives:

1. To conduct a randomised controlled pilot feasibility study to examine the effects of mirror-aided cross-education using a specially designed Mirror Strengthening Device in post stroke upper limb recovery.
2. To examine the feasibility of mirror-aided cross-education using a specially designed Mirror Strengthening Device in this patient cohort
3. To investigate any adverse effects of mirror-aided cross-education using a specially designed Mirror Strengthening Device in this population.

Study Design:

The Design is an assessor blinded, randomised control pilot feasibility trial. The independent assessor, who is blinded to the treatment assignment, will perform all the assessments. After baseline measurements are obtained, the patients will be randomly assigned to the intervention or control group using computer generated block random numbers where gender and function will be considered. A statistician who will be blinded to the research protocol and not otherwise involved in the trial will conduct the random number programme.

Setting:

Assessments: Exercise Physiology Lab, IT Sligo.
Intervention: Participants own home.

Intervention:

Both groups will perform a 5 minute warm up, 5 minute cool down and main set of exercises consisting of up to 4 sets of 5 repetitions of 5 dynamic shoulder exercises.
They will be instructed to perform the concentric and eccentric phases of the contraction at 3 seconds and 4 seconds, respectively, rest for 2 sec between contraction and rest between sets.
The full set should take approximately 30mins.
Participants will be asked to complete the intervention 5 days a week for 4 weeks.

<u>Experimental Group:</u>
The experimental group will be performing the repetitions with a set resistance on the Mirror Strengthening Device

<u>Control Group:</u>
The control group will be performing the repetitions with no resistance on the Mirror Strengthening Device.

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Positioning:
Participants will be seated in a chair in front of their own kitchen table. The elbow is flexed at 90 degrees and kept in close to the trunk not resting on anything. Palm of hand is facing the exercise device and holding a pulley. The untrained limb will be positioned in a similar position to the training limb supported on the table behind the exercise device with the shoulder slightly flexed forward to allow this positioning.

Participants will view the mirror reflection of their less- affected limb in the mirror which is positioned lateral to the mid-sagittal plane of the more - affected limb before any strength training commences.
The participant will be asked to look at the reflected image of their less-affected limb in the mirror as they train. They will then complete the prescribed HEP.

Rests:
Participants will be informed that breaks can be taken during the training session for reasons of tiredness or fatigue if required.

Training Diary:
All participants will be provided with a training diary. They will be asked to completed this before and after each training session.

Adverse Effects:
All participants will be asked to record any changes before and after each training session in the HEP record book and to contact Principal Researcher with any adverse effects.

Outcome Assessments:

Outcome Measures will be taken before and after the 4-week home exercise programme and at 3 months follow up and will include:

Primary:
Isokinetic Strength: (Biodex System 4 Pro with advantage software)
Grip Strength: (Hand held dynamometer)

Secondary:
Fugl-Meyer Upper Extremities Test
Stroke Impact Scale
Modified Ashworth Scale (MAS) for spasticity).

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