

Study Protocol

Study Title:

An investigation into neuropilates on motor function in chronic stroke: a pilot randomised feasibility study

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Study Protocol

Study Aim:

To examine the effects of a 6 week “neuropilates” exercise class compared to a generalised exercise class on gait and functional outcome in chronic stroke patients.

Study Objectives:

1. To conduct a randomised controlled pilot feasibility study to examine the effects on gait and functional outcome in an intervention group participating in a once weekly supervised, 6-week neuropilates exercise class when compared to a control group participating in a once weekly supervised, 6-week generalised exercise class. All participants will also be given a version of their programme to exercise at home.
2. To examine the feasibility of conducting a neuropilates class in this patient cohort
3. To investigate any adverse effects of group neuropilates training in this population.
4. To investigate the need for additional and supportive equipment to enable neuropilates group training in this client group.

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.

Exercise Classes: Physiotherapy Department, St. John’s Hospital, Ballytivnan, Sligo.

Intervention:

Experimental Group:

The intervention group will attend a once-weekly 60-minute neuropilates exercise class for 6 weeks facilitated by the principal investigator (a chartered physiotherapist who is also a pilates instructor). Participants will be asked to participate in exercises in a group setting targeted at improving their posture, core stability, flexibility, abdominal and pelvic strength and balance. These exercises will be pitched at a beginner level focused on the core elements of neuropilates and progressing week on week as appropriate.

The exercise class will include a warm up, cool down and neuropilates exercises in line with the teaching of APPI (the Australian Physiotherapy and Pilates Institute). Exercises may be completed on mats, chairs, gym balls, plinths and in standing, depending upon the ability

level of the participant. Exercises may be modified by the physiotherapist to suit the needs of the participant and supportive equipment may be used as necessary.

It is hoped that there will be two classes running with 7 to 8 participants in each. The classes will be split based on their initial assessment into the higher functionally independent participants and the lower functionally independent participants. Examples of some typical pilates exercises for lower functioning patients would be; seated scapular setting exercises, seated thoracic mobility exercises, seated transversus abdominis activation with leg lifts, knee extension or hip abduction, simple standing balance exercises, supported squats and strengthening exercises with therabands in supported positions. For the more able patients who can get on and off a mat on the floor with ease, exercises may be more challenging, for example, clams, side leg lifts, exercises in “table top” position (supine, with one or both legs off the floor flexed at the knees and hips), exercises in 4 point kneeling, exercises in prone and more challenging standing balance and squatting exercises.

Participants will be given a home exercise programme weekly based on exercises from the class and will be asked to complete these independently at home twice more during the week and to keep a training diary.

Control Group

The control group will attend a once weekly, 60-minute generalized exercise class which will be designed by a chartered physiotherapist to address strength, cardiorespiratory fitness and mobility. Exercises will be more functional and generic than in the pilates classes and will be conducted in a circuit style, including mobility practice, sit to stand practice, cycling with the motomed, and general upper and lower limb strengthening. Warm up and cool downs will also be a feature of this class.

Participants will be also be given a home exercise programme based on exercises completed in the class and will be asked to complete these exercises twice more during the week and to keep a training diary.

Outcome Assessments:

Outcome Measures will be taken before and after the 6-week class / home exercise programme period and at 3 months follow up and will include:

Primary:

Gait analysis: Timed Up & Go Test (G Walk BTS bioengineering)
Motor Assessment Scale for stroke (Carr and Shepherd 1985)

Secondary:

Strength: Oxford grading scale
Spasticity: Modified Ashworth Scale (Bohannon and Smith 1987)
Function: Functional Independence Measure, FIM (Granger et al 1993)
London Handicap Scale (Harwood et al 1994)