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A home based program for improving balance in acquired brain injury patients

Submission date
12/12/2011

Recruitment status
No longer recruiting

Registration date
16/01/2012

Overall study status
Completed

Last Edited
18/01/2012

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Acquired brain injury (ABI) is damage to the brain caused by trauma or other causes (for example, lack of oxygen or haemorrhage). Patients may have a combinations of physical, communicative, cognitive, behavioural, psychosocial and environmental problems. Rehabilitation is a problem-solving educational process aimed at reducing the disability experienced as a result of disease or injury. The rehabilitation will be personal, social, and physical. Different individuals will need different programs of rehabilitation and they will need different programs of rehabilitation at different stages in their recovery.

Problems of balance are among the most frequent problems treated by physical therapists in patients with ABI. Several studies conclude that the use of programs in which patients have a cognitive or motor task (store a sequence of numbers or manipulate objects) while keeping their balance are more effective. Scientific research recommends rehabilitation for long periods and in everyday situations. The aim of this study is to evaluate the effectiveness of a home-based program, without direct guidance of physiotherapist, in addition to traditional physical therapy.

Who can participate?
Participants were of working age (between 18 and 55 years old) and suffering from ABI. They included patients who were attending an outpatient clinic, one year after suffering an injury.

What does the study involve?
All participants received 50-minute individualized physiotherapy sessions for balance disorders, 3 times a week for 7 weeks.
In addition, the study group carried out a series of individual exercises at home for approximately 30 minutes, 6 times a week for 7 weeks, independently or with the help of a caregiver:
1. Body stability with sensory deprivation (standing with eyes closed, standing on foam)
2. With different supports (tandem standing, on one foot)
3. Body transport (transferring from one chair to another, going from sitting to standing)
4. Balance tasks while simultaneously performing a second motor task (pulling up and retrieving a ball, throwing and catching a ball while holding a tray with glasses)
5. Cognitive tasks, (naming objects and remembering numbers)

There was a booklet containing exercises and individualized information for each patient. Every booklet was revised weekly during the physiotherapy session.

What are the possible benefits and risks of participating?
There were no known risks to participants.

Where is the study run from?
We conducted the study one rehabilitation centre: Presidio Sanitario Ausiliatrice Fondazione Don Gnocchi Onlus, Turin, Italy.

When is study starting and how long is it expected to run for?
Patients were enrolled in the study in May 2011. The training started in October 2011 and ended in December 2011.

Who is funding the study?
Presidium Health "Help" Rehabilitation Centre [Presidio Sanitario Ausiliatrice Fondazione Don Gnocchi Onlus], Italy and the University of Piemonte Orientale, Italy.

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
N/A

Study information

Scientific Title

A dual task home based program for improving balance in acquired brain injury patients: single blind, randomised controlled trial of efficacy

Study objectives
Multi task programs are more effective in balance improvement than single task programs.

Home based programs are effective in improving mobility in people after stroke rehabilitation. Intensive rehabilitation programs improve the speed of functional recovery in acquired brain injury (ABI) patients.

The effect of the current financial and economic recession in Europe and in Italy on national health systems are not compatible with the times and needs of people with disabilities. A dual task home based program without direct therapist supervision, extra traditional physical therapy in day hospital, is effective in balance improvement and postural control in patients with severe acquired brain injury, more than one year after the injury, compared to conventional therapy in day hospital.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Piemonte Orientale, Italy, 20 April 2011

Study design
Interventional randomised single blind single centre controlled 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
Acquired brain injury

Interventions
Participants were randomly assigned to one of two groups: a study group and a control group.

Participants completed a battery of balance, attention and multi task assessments. They created a functional target for the end of the training. Participants received 50 minute individualized training sessions of traditional physiotherapy in rehabilitation centre, three times a week for 7 weeks, for balance disorders in accordance with the rules of good practice.

In addition, the study group performed a battery of individual exercises at home for approximately 30 minutes for 6 days a week for 7 weeks. The exercises were exercices of balance in dual task (cognitive and motor) with sensory deprivation, standing with feet together, monopodal, belt. Balance training session followed Gentile's Taxonomy of Movements task.

For each patient a booklet was prepared containing exercises and individualised information about the environmental changes. Every booklet was been revised weekly during a physiotherapy session in the rehabilitation centre.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
One Leg Stand Test - right and left in single and multi task conditions (where normal= stable for 20 seconds; unable = stable for <2 sec)
This is a simple, predictive and inexpensive marker, which is helpful in screening for low functional level in clinical practice

Secondary outcome measures
1. Balance Evaluation Systems Test (BES Test) (normal=108) to identify the disordered systems undelying balance control
2. Activities-specific Balance Confidence (ABC) scale, to determine self-reported confidence when performing 16 different daily activities. (where 0% no confidence; 100% full confidence)
3. Goal Attainment Scaling (GAS), an individualized criterion referenced measure of change suitable for measuring the impact of an intervention (where -2=much worse; +2 = much better)

These were measured at baseline and at the end of the seven weeks of training, precisely during the week following the conclusion of training.

Overall study start date
03/10/2011

Completion date
10/12/2011

Eligibility

Key inclusion criteria
1. Aged between 18 and 55 years
2. Male and female participants
3. 12 - 18 months with ABI
4. Balance deficits with the "One Leg Stance" test - patients scored less than 10 seconds on this test

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
45 potential candidates to study of which 16 were included, 8 males and 8 females

Key exclusion criteria
1. Previous diagnosis of neurodegenerative diseases and psychiatric disorders
2. Presence of serious heart disease
3. Presence of serious cognitive-behavioral disorders
4. Changes to the treatment of muscle relaxant and antispasmodic drugs during the period of enrollment

Date of first enrolment
03/10/2011

Date of final enrolment
10/12/2011

Locations

Countries of recruitment
Italy

Study participating centre
Via S. Bermado, 9
Fossano
Italy
12045

Sponsor information

Organisation
Don Gnocchi Foundation Health Centre (Italy)

Sponsor details
Presidio Sanitario "Ausiliatrice" - Onlus Don Gnocchi Foundation
Street 42 Peyron
Torino
Italy
12045

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02e3ssq97

Funder(s)

Funder type
University/education

Funder Name
Presidium Health "Help" Rehabilitation Centre [Presidio Sanitario Ausiliatrice Fondazione Don Gnocchi Onlus] (Italy)

Funder Name
University of Piemonte Orientale (Italy)

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