Exercise therapy and cognitive behavioural therapy in Postpoliomyelitis Syndrome: effects on fatigue, activities and quality of life.

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Primary Objective: (1) To study the efficacy of exercise therapy and CBT for reducing fatigue and improving activities and HRQoL in patients with PPS. Secondary Objectives: (2) To identify generic and disease-specific determinants of effects.(3) To...

Ethical review	-
Status	Recruitment stopped
Health condition type	Neuromuscular disorders
Study type	Interventional

Summary

ID

NL-OMON35382

Source
ToetsingOnline

Brief title
FACTS-2-PPS

Condition

- Neuromuscular disorders

Synonym
Postpoliomyelitis Syndrome, PPS

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Prinses Beatrix Fonds

Intervention

Keyword: cognitive therapy, exercise therapy, fatigue, Postpoliomyelitis Syndrome (PPS)

Outcome measures

Primary outcome

At baseline, completion of the intervention and at 3- and 6-months follow-up, fatigue (Checklist Individual Strength, domain fatigue), limitations in activities (Sickness Impact Profile, domains: mobility range, mobility control, social behaviour), HRQoL (SF-36), and secondary outcome measures will be assessed.

Secondary outcome

Secundary outcome measures are pain, psychological well being, cardiorespiratory fitness, neuromuscular capacity, physical activity level in daily life, participation, functional capacity, self efficacy, illness cognitions, coping and resource use.

Study description

Background summary

Postpoliomyelitis Syndrome (PPS) is a complex of neuromuscular symptoms that appears in many survivors of paralytic polio, usually 15 years or more after the acute illness. Subjects with PPS often complain of severe fatigue and deterioration in functional abilities. The pathogenesis of PPS is probably multifactorial. Since PPS is not considered curable, rehabilitation management is the mainstay of treatment. To preserve functioning at the highest achievable level, two distinctly different therapeutic interventions can be executed: exercise therapy or cognitive behavioural therapy (CBT). However, evidence to support either approach is still insufficient and understanding of the underlying mechanisms of the approaches is unclear. We hypothesize that

exercise therapy and CBT are both effective in reducing fatigue, improving activities and quality of life of patients with PPS compared to usual care. There is need for rigorous, appropriately controlled assessment of the efficacy of these interventions for PPS patients.

Study objective

Primary Objective:
(1) To study the efficacy of exercise therapy and CBT for reducing fatigue and improving activities and HRQoL in patients with PPS.

Secondary Objectives:
(2) To identify generic and disease-specific determinants of effects.
(3) To evaluate the cost-effectiveness of each intervention compared to usual care.
(4) To obtain insight into patients* expectations of and experiences with both interventions.

Study design

A multi-centre, single-blinded, randomized controlled trial

Intervention

The 81 patients will be randomized to one of three groups i.e. (1) exercise therapy + usual care, (2) CBT + usual care, (3) usual care.

Study burden and risks

All patients will be asked to visit the AMC at 4 times and the VU at 3 times over the study period of 10 months to participate in a physical examination. The duration of these examinations will be approximately 2 hours. Additionally, patients will be asked to wear a small ankle-worn accelerometer for 7 consecutive days at the 4 different time measurements, and all patients receive questionnaires to fill out at home. The duration for completing the questionnaires is approximately 1,5 to 2 hours. At baseline patients will receive cost diaries which they will send back every month during the 10 months. There are no costs related to the interventions for the patients. Possible medical risks related to the physical examonations are considered minimal and a physician will be present during the examinations. All participating centres are well experienced in providing exercise therapy in patients with different neuromuscular diseases. Therefore, the occurrence of medical events is considered minimal. No risks are associated with CBT. Considering the positive effects of both CBT as well as the exercise therapy known from preliminary research it can be concluded that the benefits outweigh

the burden en minimal risk associated with this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

(1) diagnosis of PPS according to the criteria of March and Dimes i.e.
a. A confirmed history of paralytic poliomyelitis characterized by an acute illness with fever and a usually asymmetrically distributed, flaccid paresis of a varying number of muscle groups. Evidence of motor neuron loss on neurological examination with signs of residual weakness, atrophy, loss of tendon reflexes and intact sensation.
b. A period of partial or complete functional recovery after acute paralytic poliomyelitis, followed by an interval (usually 15 years or more) of stable neurologic function.
c. Gradual or sudden onset of progressive and persistent new muscle weakness or abnormal muscle fatigability (decreased endurance), with or without generalized fatigue, muscle

atrophy, or muscle and joint pain. Symptoms persist for at least a year.
d. No other medical diagnosis to explain the symptoms (anemia and thyroid dysfunction as a cause of fatigue will be ruled out by blood test).
(2) suffering from severe perceived fatigue (CIS-fatigue >< = 35)
(3) age between 18 and 70 years
(4) a life-expectancy longer than one year
(5) consultation (not necessarily the first consultation) of a neurologist or physical medicine and rehabilitation specialist in the previous 5 years
(6) walking-ability at least indoors with or without a walking aid
(7) ability to cycle on a bicycle ergometer against a load of at least 25 Watt.

Exclusion criteria

(1) cognitive impairment
(2) insufficient mastery of the Dutch language
(3) pregnancy
(4) use of psychotropic drugs (except simple sleeping medication) or other psychiatric treatment.
(5) use of medication causing fatigue
(6) disabling co-morbidity interfering with the intervention programs or influencing outcome parameters (including cardiopulmonary disease like chest pain, arrhythmia, pacemaker, cardiac surgery, severe dyspnoea d*effort or emphysema, epileptic seizures, poorly regulated diabetes mellitus).
(7) respiratory insufficiency

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-05-2009

Enrollment:	81
Type:	Actual

Ethics review

Not available

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	1371
CCMO	NL23702.018.08