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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26099

Source
Nationaal Trial Register

Brief title
FACTS-2-PPS

Health condition

Postpoliomyelitis Syndrome, neuromuscular disease, exercise therapy, cognitive behavioral therapy, fatigue, activities of daily living, quality of life.

Sponsors and support

Primary sponsor: Academic Medical Center (AMC), Department of Rehabilitation
Source(s) of monetary or material Support: ZonMw, The Netherlands Organization for Health Research and Development.
Prinses Beatrix Fonds

Intervention

Outcome measures

Primary outcome

Primary outcome measures are:

- QoL (SF-36)

- Limitations in activities (Sickness Impact Profile, domains: mobility range, mobility control, social behaviour)

- Fatigue (Checklist Individual Strength, domain: fatigue)

Secondary outcome

Secondary outcome measures are:

- Pain

- Psychological well-being

- Physical activity level in daily life

- Perceived participation

- Illness cognitions

- Coping

- Perceived control or self-efficacy

- Cost effectiveness

Additional secondary outcome measures for the exercise therapy group:

- Cardiorespiratory fitness

- Neuromuscular capacity

- Functional capacity

Study description

Background summary

Rationale:

Postpoliomyelitis Syndrome (PPS) is a disorder of the nervous system that appears in many survivors of paralytic polio, usually 15 years or more after the original illness. Subjects with PPS often complain of severe fatigue and deterioration in functional abilities.

Since cure is generally lacking, rehabilitation management is the mainstay of treatment.
To preserve functioning at the highest achievable level, two distinctly different therapeutic approaches can be followed:
exercise therapy to maintain functional capacity or a cognitive behavioural approach (CBT) to stimulate an active life-style yet avoiding excessive physical strain. It is hypothesized that exercise thrapy and CBT are both effective in reducing fatigue, improving activities and quality of life of patients with PPS compared to usual care. The improvement by exercise therapy is obtained through enhancement of physical capacity, while effects of CBT are achieved through changes in behaviour, illness cognitions and coping. CBT has been proven effective in chronic fatigue syndrome and post-cancer fatigue. The evidence for CBT in PPS is lacking, pilot results from an uncontrolled study of such a program show an increase in quality of life (QoL). Several studies have shown that exercise can improve muscle strength and cardiorespiratory functioning. However the effects of exercise on activities and QoL are hardly investigated in these studies.
There is need for rigorous, multicenter appropriately controlled assessment of the efficacy of these interventions for PPS patients.

Objective:

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

(2) To identify generic and disease-specific determinants of effects.

(3) To evaluate the cost-effectiveness of both interventions.

Study design:

A randomized controlled trial.
Study population:

A sample of 81 patients with PPS, aged 18-70 years recruited from 4 different university hospitals and rehabilitation centres.

Intervention:
The 81 patients will be randomized to one of three groups i.e. usual care, usual care + 16 weeks exercise therapy, usual care + 12-16 weeks CBT.

Main study parameters:

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

Nature and extent of the burden and risks associated with participation and benefits: Patients will participate in either exercise therapy or CBT and/ or receive usual care. At baseline all patients will receive a physical examination in which disease severity is determined by manual muscle testing. At the four different time measurements all patients are asked to fill out several questionnaires including a cost diary and wear a small ankle-worn accelerometer for 7 consecutive days. Additionally patients from the exercise therapy group will participate in a physical examination including measurements of cardiorespiratory fitness, neuromuscular capacity and functional capacity at the four outcome assessments.

Several studies have shown that moderate intensity aerobic exercise training and strengthening exercise in PPS sorts no adverse effects. Blood samples for creatine kinase concentrations will be taken to control for adverse effects in the exercise therapy group at baseline, 4 weeks, 8 weeks at discharge from the program and at 3 months and 6 months follow up. No risks are associated with CBT.

It is expected that exercise therapy and CBT are both effective in reducing fatigue, improving activities and QoL of patients with PPS.

Study objective

It is hypothesized that exercise therapy and CBT are both effective in reducing fatigue and improving activities and QoL in patients with Postpoliomyelitis Syndrome (PPS) compared to the usual care.

Study design

Data will be collected at baseline, at discharge from the program, at 3 moths follow-up and at 6 months follow-up.

Intervention

Patients fulfilling both inclusion and exclusion criteria will be randomised to one of three groups:

- Experimental group 1 (E1) will receive exercise therapy in a nearby rehabilitation centre during 16 weeks. The exercise therapy consists of a home-based individual aerobic training program and a supervised group training program in a rehabilitation centre.

- Experimental group 2 (E2) will receive CBT in a nearby rehabilitation centre during 12 to 16

weeks depending on the number of modules each patient will need. Sessions are once a week with a duration of 1 hour. Cognitive behavioral therapists will provide the therapy.

- A third group will serve as the control group (C) and will receive usual care only.

Contacts

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Eligibility criteria

Inclusion criteria

1. Diagnosis of PPS according to the criteria of March and Dimes i.e.

a. Prior paralytic poliomyelitis with evidence of motor neuron loss, as confirmed by history of the acute paralytic illness, signs of residual weakness and atrophy of muscles on neurologic examination, and signs of denervation on electromyography (EMG).

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. (Sudden onset may follow a period of inactivity, or trauma or surgery.) Less commonly, symptoms attributed to PPS include new problems with breathing or swallowing.

d. Symptoms persist for at least a year.

e. Exclusion of other neurologic, medical and orthopaedic problems as causes of symptoms.

2. Age between 18 and 70 years

3. A life-expectancy longer than one year

4. Consultation (not necessarily the first consultation) of a neurologist or physical medicine and rehabilitation specialist in the previous 5 years

5. Suffering from severe experienced fatigue (CIS-fatigue >= 35)

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. 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'éffort or emphysema, epileptic seizures, poorly regulated diabetes mellitus).

6. Severe progressive weakness and atrophy

7. Inability to cycle on a bicycle ergometer.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2009
Enrollment:	81
Type:	Actual

Ethics review

Positive opinion

Date:	08-07-2008
Application type:	First submission

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
NTR-new	NL669

Register	ID
NTR-old	NTR1371
Other	: ZonMW 89000003
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A