Multidisciplinary behavioural program for coping with chronic neuropathic pain following spinal cord injury.

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To evaluate a group treatment program to stimulate effective coping with chronic neuropathic pain following spinal cord injury.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Spinal cord and nerve root disorders
Study type	Interventional

Summary

ID

NL-OMON32405

Source
ToetsingOnline

Brief title
Behavioural program for neuropathic pain following SCI.

Condition

- Spinal cord and nerve root disorders

Synonym
nerve pain, neuropathic pain

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum De Hoogstraat
Source(s) of monetary or material Support: DALI voor PIJN;een initiatief van Pfizer (educational grant),Pfizer

Intervention

Keyword: Cognitive behavioural intervention, Coping, Neuropathic pain, Spinal cord injury

Outcome measures

Primary outcome

Pain severity and impact of pain: Chronic Pain Grade questionnaire.

Secondary outcome

- Level of activation and participation: Utrecht Activities List,

- Life satisfaction: Life Satisfaction Questionnaire, and

- Mood: Hospital Anxiety and Depression Scale.

Demographic (e.g., age and gender), disease and pain characteristics (e.g., type of SCI), pain treatment, and functional independence (Barthel Index) will be registered at the baseline measurement (t1). The participants complete a questionnaire on satisfaction with the program immediately after completion of the program at 3 months.

Psychological variables:

- Pain coping: Coping with Pain Questionnaire and Pain Coping Inventory List, and

- Pain cognitions: Pain Cognition List.

Study description

Background summary

Most persons with spinal cord injury suffer from chronic pain and about one-third of them experience their pain as severe. The effective treatment of pain following spinal cord is difficult. Particularly in regards to neuropathic spinal cord injury pain, there are no treatments that produce satisfactory pain relief. Therefore, psychosocial factors in the maintenance and aggravation of chronic pain following spinal cord injury have been considered. One small-scale Swedish study showed promising effects of a cognitive-behavioural group program.

Study objective

To evaluate a group treatment program to stimulate effective coping with chronic neuropathic pain following spinal cord injury.

Study design

A multi-centre, randomised intervention study with a waiting-list control group in four rehabilitation centres. A total of 80 persons will be included (four intervention groups of 10 persons and four control groups of 10 persons). Measurements will be performed in both groups before starting the program/entering the control group (t1), immediately after completion of the program at 3 months (t2), at 6 (t3), at 9 (t4), and 12 months (t5). The control group will be invited for the program after the follow-up measurement at 6 months (t3) and will be measured with the same protocol, so that the t3, t4 and t5 measurements of the control group are equivalent to the t1, t2 and t3 measurements of the intervention group. Care as usual will continue, but pain medication and other pain treatments will be held constant during the intervention period (3 months).

Intervention

The multidisciplinary program, comprising educational, cognitive, and behavioural interventions in the treatment of coping with chronic neuropathic pain, consists of ten sessions of 3 hours over a 10-week period and a comeback session three weeks later. Each meeting will be supervised by a psychologist and physical therapist assisted by guest speakers and a role model. The intervention is directed at knowledge about chronic neuropathic pain, modifying passive coping, negative illness cognitions and feelings of depression and hopelessness, at relaxation and attention-distraction techniques and at stimulating an active lifestyle. Elements of the intervention are: (1) provision of information, (2) guided group discussions, (3) exercises and sport workshops, and (4) homework.

Study burden and risks

Not applicable.

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) spinal cord injury;
(2) at least 18 years old;
(3) at least one year and at most five years after discharge from first inpatient spinal cord injury rehabilitation;
(4) main type of pain is severe chronic neuropathic pain.

Exclusion criteria

(1) spinal cord injury by a malignant tumor;
(2) former cognitive behavioural therapy for coping with pain after spinal cord injury;
(3) inability to function in a group by major language problems or psychopathology;

(4) insufficient mastery of the Dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-02-2009
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	19-08-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL22866.041.08