Evaluation of a multidisciplinary cognitive behavioural programme for coping with chronic neuropathic pain following spinal cord injury.

No registrations found.

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

Summary

ID

NL-OMON27517

Source
NTR

Brief title
CONECSI (COping with NEuropathiC Spinal cord Injury pain)

Health condition

multidisciplinary
behavioural program
coping
chronic neuropathic pain
spinal cord injury

multidisciplinair
gedragsinterventie
chronische neuropathische pijn
dwarslaesie

Sponsors and support

Primary sponsor: Rehabilitation Centre De Hoogstraat, Utrecht, The Netherlands
Source(s) of monetary or material Support: This study was performed within DALI for

PAIN, a national program that focuses on neuropathic paincare optimalisation. DALI for PAIN is an initiative of Pfizer. This project is supported by an unrestricted grant from Pfizer.

Intervention

Outcome measures

Primary outcome

Pain intensity and pain related disability:

Chronic Pain Grade questionnaire (CPG)
at t1, t2, t3, t4, and t5.

Secondary outcome

Secondary outcome(s):

1. Level of activation and participation: Utrecht Activities List (UAL);

2. Life satisfaction: Life Satisfaction Questionnaire (LiSat-9);

3. Mood: Hospital Anxiety and Depression Scale (HADS);

at t1, t2, t3, t4, and t5.

Psychological variables:
- Pain coping: Coping with Pain Questionnaire (CPV) and
Pain Coping Inventory List (PCI)
- Pain cognitions: Pain Cognition List (PCL-2003)
at t1, t2, t3 (only intervention group) and t5 (only waiting list control group).

Study description

Background summary

Background:

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 in most people. Therefore, psychosocial factors in the maintenance and aggravation of chronic pain following spinal cord injury have been considered.

Objective:

To evaluate a multidisciplinary cognitive behavioural programme for coping with chronic neuropathic pain following spinal cord injury.

Study design:

A multi-centre, randomised intervention study with a waiting list control group. Care as usual will continue, but patients will be requested to held pain medication and other pain treatments constant during the intervention period (3 months). A maximum of 80 persons will be included (four intervention groups of 10 persons and four control groups of 10 persons).

Study population:

Patients visiting the outpatient departments of rehabilitation centre De Hoogstraat (Utrecht), Rijndam (Rotterdam), Het Roessingh (Enschede), and Adelante zorggroep (Hoensbroek) will be invited to participate.

Study parameters:

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. The participants complete a questionnaire on satisfaction with the programme immediately after completion of the programme at 3 months. Measures of primary and secondary outcomes, and pain treatment will be administered at all measurements. Psychological variables will be administered at t1, t2, t3, and t5.

Study objective

A multidisciplinary cognitive behavioural programme for coping with chronic neuropathic pain following spinal cord injury has a positive effect on pain intensity and pain related disability.

Study design

t1 (start intervention)

t2 (end intervention)

t3 (3 months follow-up)

t4 (6 months follow-up)

t5:(9 months follow-up)

Intervention

The multidisciplinary programme, comprising educational, cognitive, and behavioural interventions for coping with chronic neuropathic pain following spinal cord injury, 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 in three sessions. 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;

4. homework.

Contacts

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Eligibility criteria

Inclusion criteria

1. Spinal cord injury;

2. at least 18 years old;

3. at least one year and at most ten years after discharge from first inpatient spinal cord injury rehabilitation;

4. informed consent;

5. main type of pain is neuropathic pain;

6. duration of neuropathic pain is at least six months;

7. pain intensity score at least 40 on the Chronic Pain Grade last week;

Exclusion criteria

1. Spinal cord injury by metastatic tumour;

2. former cognitive behavioural therapy for coping;

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2009
Enrollment:	60
Type:	Actual

Ethics review

Positive opinion Date:	11-12-2008
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	NL1509
NTR-old	NTR1580
Other	08-152/E METC : 007-04 Pfizer/DALI voor PIJN
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
Heutink M, Post MWM, Luthart P, Pfennings LEMA, Dijkstra CA, Lindeman E. A multidisciplinary cognitive behavioural programme for coping with chronic neuropathic pain following spinal cord injury: the protocol of the CONECSI trial. BMC Neurology 2010,10:96

(doi:10.1186/1471-2377-10-96).
Heutink M, Post MWM, Bongers-Janssen HMH, Dijkstra CA, Snoek GJ, Spijkerman DCM, Lindeman E. The CONECSI trial: A randomized controlled trial of a multidisciplinary cognitive behavioral program for coping with chronic neuropathic pain following spinal cord injury. Pain 2012;153(1):120-8.