Coping and living with chronic pain in persons with spinal cord injury: daily life participation and quality of life.

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To design and test a personalized biopsychosocial rehabilitation treatment that aims to restore daily life functioning and QoL in persons with SCI and chronic pain.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56375

Source
ToetsingOnline

Brief title
Pain in SCI

Condition

- Other condition
- Spinal cord and nerve root disorders

Synonym
Chronic pain, Spinal Cord Injury

Health condition

Chronische pijn

Research involving
Human

Sponsors and support

Primary sponsor: Adelante Zorggroep
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Chronic Pain, Cognitive Behavioral Therapy, Spinal Cord Injuries

Outcome measures

Primary outcome

Disability: Pain Disability Index (PDI). This 7-item questionnaire investigates the magnitude of self-reported disability in different domains, e.g., work, leisure time, activities of daily living (ADL) and sports.

Quality of Live: The EuroQoL EQ-5D is a brief self-reported generic measure of current health that consists of five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression).

Secondary outcome

SCI-related complications (SCI-SCS)

Anxiety and Depression (HADS)

Pain-related fear (PASS-20)

Pain Interference (MPI-SCI)

Acceptance (AAQ-II-P)

Psychological inflexibility (PIPS)

Self-efficacy (UW-SES 6)

Study description

Background summary

Spinal cord injury (SCI) is a highly debilitating condition, accompanied by serious secondary health conditions. Over 65% of persons with SCI also suffers from chronic pain, resulting in additional disability and health care costs. There is no cure for the pain. Due to heterogeneity of SCI, an integrated approach aimed on both individual SCI-related health conditions (biomedical) and coping with chronic pain is needed (psychological). Personalized biopsychosocial rehabilitation programs that help to cope with these problems are needed.

Study objective

To design and test a personalized biopsychosocial rehabilitation treatment that aims to restore daily life functioning and QoL in persons with SCI and chronic pain.

Study design

Single case experimental design (SCED).

Intervention

Every patient will receive a personalized biopsychosocial rehabilitation treatment containing education and a set of sessions improving physical functioning based on cognitive behavioural approach. All participants start with an educational session. In addition, a personalized treatment based on a cognitive behavioural approach will follow including one or more of the following elements (depending on a patient*s profile): 1. Exposure in vivo (to challenge catastrophic (mis)interpretations); 2. Acceptance and commitment therapy (to increase the psychosocial flexibility, and to accept events, but not to change the events); 3. Graded activity (aims to gradually increase the amount of activity with the operant conditioning principle). Total length of treatment for all participants will be 10-12 weeks (with two sessions each week).

Study burden and risks

The acceptance and commitment therapy, exposure in vivo and graded activity therapy will be delivered as add-on to the usual care for persons with SCI. The experience of the research group with several kinds of CBT and pain education as applied in other patient groups ensures no negative impact of the

application of this therapy in this group.

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

Patients with Spinal Cord Injury (SCI) longer than 6 months; Patients with the age of 18 years and older; Patients who suffer from SCI related chronic pain, as classified by the International Spinal Cord Injury Pain (ISCIP) classification; Patients where there is a willingness to address and change biopsychosocial factors that are related to daily life functioning despite the pain

Exclusion criteria

Patients who experience severe pain due to other diseases (e.g., neuropathies, cancer, vascular problems)
Patients who have received a biopsychosocial rehabilitation treatment or any other form of cognitive behavioural therapy within the past 6 months will be excluded from this study.
Patients who have insufficient comprehension of Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2023
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	09-10-2023
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL84636.015.23