Cognitive behavioral therapy in patients with small fiber neuropathy

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The main objective is that a cognitive behavioral intervention for patients with SFN will have a positive effect on disability and quality of life.

Ethical review	Approved WMO
Status	Pending
Health condition type	Peripheral neuropathies
Study type	Interventional

Summary

ID

NL-OMON53751

Source
ToetsingOnline

Brief title
CBT in SFN

Condition

- Peripheral neuropathies

Synonym
peripheral neuropathy, Small fiber neuropathy

Research involving
Human

Sponsors and support

Primary sponsor: Adelante Zorggroep
Source(s) of monetary or material Support: Prinses Beatrix Spierfonds

Intervention

Keyword: Cognitive behaviour therapy, Small fiber neuropathy

Outcome measures

Primary outcome

Disability, and health related QOL.

Secondary outcome

The secondary endpoints are pain intensity, mood and pain catastrophizing.

Study description

Background summary

Small fiber neuropathy (SFN) is a condition that is dominated by invalidating neuropathic pain. Pharmacological neuropathic pain treatment is often disappointing, since pain reduction is mostly slight and side effects can be debilitating. Although neuropathic pain is caused by a lesion of the somatosensory system, also psychological factors, such as fear and catastrophizing, appear to play a role in the origin and maintenance of disability in chronic pain. Rehabilitation based on pain education and cognitive behavioral treatment including elements of acceptance and commitment therapy, exposure in vivo or graded activity can be performed to influence these factors. To date no specific rehabilitation programs are available for patients diagnosed with SFN.

Study objective

The main objective is that a cognitive behavioral intervention for patients with SFN will have a positive effect on disability and quality of life.

Study design

Sequential replicated randomized single-case experimental ABCD-design

Intervention

Every patient will receive a personalized treatment containing education and a set of sessions improving physical functioning based on a cognitive behavioral approach. All participants start with an educational session. In addition, a personalized treatment based on a cognitive behavioral approach will follow including one or more of the following elements (depending on a patient*s profile):

1. Exposure in vivo (to change 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). The total length of treatment for all participants will be 8-10 weeks (with two sessions each week)

Study burden and risks

All participants will receive one of the rehabilitation treatments. It is expected that the risks associated with participation in the study are negligible and that the burden will be minimal. The measurements that will be conducted during the study consist of diaries and questionnaires and are not invasive or risky full.
SFN is a chronic neuropathic pain condition, with autonomic dysfunction. Adverse events are rarely seen in patients with small fiber neuropathy. Pain will not be recorded as AE. It is known that patients will experience more pain from practical experience since they are stimulated to increase their activity level during therapy and will be actively engaged with their pain. This temporary increase in pain is not harmful

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

- Age >18 years,
- Main goal/purpose to achieve with rehabilitation therapy,
- Skin-biopsy proven idiopathic SFN, diagnosed at our expertise center at the department of neurology of MUMC+.

Exclusion criteria

- Are not able to provide written informed consent,
- Have an underlying condition of SFN (diabetes, SFN9A/10A/11A mutation, hypothyroidism, renal failure, vitamin B12 deficiency, monoclonal gammopathy of undetermined significance, alcohol abuses, malignancies, chemotherapeutic drugs).
- Have other neurological disease than SFN that may cause pain in the feet and/or damage to the somatosensory nervous system, are excluded.
- have received any form of cognitive behavioral therapy within the last 6 months will be excluded from this study.
- 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):	01-03-2023
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	08-03-2023
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL82372.068.22