

# Cognitive group therapy in the treatment of catastrophizing in patients with chronic non-cancer musculoskeletal pain

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The objective of the study is to gain more understanding of the effectivity of cognitive therapy, specifically aimed at the treatment of pain catastrophizing in (chronic) pain.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON30827

### Source

ToetsingOnline

### Brief title

Cognitive grouptherapy for catastrophizing in chronic non-cancer pain

### Condition

- Other condition

### Synonym

chronic musculoskeletal pain

### Health condition

chronische niet-oncologische musculoskeletale pijn

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Academisch Ziekenhuis Maastricht

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Catastrophizing, Chronic pain, Cognitive, Group therapy

## Outcome measures

### Primary outcome

The primary study parameters/outcome measures of the study are the level of pain catastrophizing, fear of pain, the level of disability, and pain intensity after treatment in relation to the baseline.

### Secondary outcome

Not applicable

## Study description

### Background summary

Today, there are numerous studies in which the important role of pain catastrophizing in relation to various pain-related problems such as pain intensity, depression, and disability is demonstrated (for an extensive review see Sullivan et al., 2001). Given this relationship, pain catastrophizing seems an important starting point in the treatment of chronic pain. Pain catastrophizing is about an extremely negative way of thinking about pain and its possible consequences in which threat and fear of pain are important ingredients. Not surprisingly therefore, pain catastrophizing is closely related to fearful cognitions about pain. Given this cognitive nature of pain catastrophizing, it is obvious to use the principles of cognitive therapy in its treatment. In a meta-analysis of rct's of cognitive behavior therapy for chronic pain, Morley et al. (1999) found that treatments based on the principles of cognitive behavior therapy were effective compared to waiting list conditions. Also, there are two studies that showed that patients with chronic low back pain treated with cognitive behavior therapy improved on a number of outcome measures (such as disability, pain intensity, depression and pain behavior). Moreover, this improvement was mediated by a reduction in pain

catastrophizing (Smeets et al., 2006; Spinhoven et al., 2004). Remarkably, the level of pain catastrophizing decreased in various treatment conditions and by using different techniques, even though none of these techniques were specifically targeted at the reduction of catastrophizing (Smeets et al., 2006; Spinhoven et al., 2004).

In this study we want to examine whether a treatment specifically aimed at reducing pain catastrophizing is effective in treating patients with chronic pain who catastrophize highly about their pain. In this respect the study fits with the idea that treatments for chronic pain may be improved by tailoring them to the specific characteristics and needs of the patient (in this case patients who catastrophize highly about their pain).

We hypothesize that, compared to a baseline period, the treatment period will involve a reduction in the level of pain catastrophizing, fear of pain, and level of disability.

## **Study objective**

The objective of the study is to gain more understanding of the effectivity of cognitive therapy, specifically aimed at the treatment of pain catastrophizing in (chronic) pain.

## **Study design**

The study design is a so-called 'replicated single-case experimental design'. It consists of a baseline period lasting two weeks, followed by a treatment period of eight weeks (Onghena & Edgington, 2005).

- Onghena, P., & Edgington, E. S. (2005). Customization of pain treatments: single-case design and analysis. *Clinical Journal of Pain*, 21(1), 56-68; discussion 69-72.

## **Intervention**

The intervention consists of a cognitive grouptherapy of eight weekly sessions of one and a half hour each.

## **Study burden and risks**

Participation holds no specific risks for the participants. The burden for the participants consists of eight 90-minutes sessions of grouptherapy, the completion of 4 questionnaires on 4 different occasions during the study (catastrophizing, fear of pain, disability, and pain), and keeping a diary during the course of the study (63 days). The latter consists of 13 VAS-scales concerning catastrophizing, fear of pain, disability, and pain. The estimated total time load is approximately 22 hours.

## Contacts

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

18 and older, chronic non-cancer musculoskeletal pain, informed consent, a high level of catastrophizing (a PCS score > 31), no more other medical treatment options

### Exclusion criteria

- not able to speak, read and write Dutch
- the presence of an anxiety and/or a mood disorder

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-08-2007

Enrollment: 6

Type: Anticipated

## Ethics review

Approved WMO

Date: 29-10-2007

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

CCMO

### ID

NL17912.068.07