Cognitive behavioral therapy versus a combination of pain neurophysiology education and cognitive behavioral therapy in patients with chornic musculoskeletal pain

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Our research question is: *What is the additional value of pain neurophysiology education when it precedes cognitive behavioral therapy on the physical and psychological functioning of patients with chronic musculoskeletal pain?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON44990

Source
ToetsingOnline

Brief title
Chronic pain education

Condition

- Other condition

Synonym
chronic pain

Health condition

chronische pijn

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Neuro Orthopaedic institute;Adelaide;Australia en Theia;Achmea

Intervention

Keyword: Chronic pain, Cognitive behavioral therapy, Pain neurophysiology education, Quality of life

Outcome measures

Primary outcome

The primary outcomes are the differences in pain intensity, pain coping, and

pain cognitions between patients that received both PNE and CBT and patients

that only received CBT.

Secondary outcome

Secondary measures are psychological complaints, quality of life, functional

status, kinesiophobia, health care use and dropout rates.

Study description

Background summary

Chronic pain is a common and disabling disorder. Epidemiologic data have shown that chronic pain is a burden for the individual patient as well as for society. Cognitive behavioral therapy (CBT) has proven its positive effects on chronic pain, although the effect sizes are small and the adherence of patients to CBT is restricted. Furthermore, CBT is often not in concordance with the more biomedical view of patients on the cause of their pain. Pain neurophysiology education (PNE) is a relatively new, promising educational intervention for patients with chronic pain focusing on cognitive and behavioral factors. PNE bridges the gap between the view of the patient on pain and that of his physician by changing maladaptive pain cognitions (e.g. *pain

equals harm*). Our hypothesis is that PNE might make chronic pain patients more receptive to cognitive behavioral interventions.

Study objective

Our research question is: *What is the additional value of pain neurophysiology education when it precedes cognitive behavioral therapy on the physical and psychological functioning of patients with chronic musculoskeletal pain?

Study design

Randomized controlled trial

Intervention

All participants (n = 90) will receive 10 weekly group sessions of cognitive behavioral therapy of 2 hours each. Some of the patients (n = 30) will also participate in a pain neurophysiology education program of 3 individual sessions of 45 minutes each preceding CBT.

Study burden and risks

All participants will visit the hospital ten times for two-hour CBT sessions. Additionally, all participants will fill-out 8 questionnaires at three different time-points. Some of the participants (n = 30) will visit the hospital an extra three times for 45 minutes education sessions. These participants will also fill-out an extra questionnaire at three different time-points. All participants have chance to benefit from the intervention, since CBT is proven to have positive effects on chronic pain. It is hypothesized that the participants that will also participate in the education sessions will benefit even more. As far as known, there are risks associated to both CBT and PNE.

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) Chronic musculoskeletal pain
2) Ability to speak, read and write Dutch
3) a at least above average score on 2 subscales of the Four-Dimensional Symptom Questionnaire (4DSQ, Terluin 1996; Terluin et al. 2006), which was confirmed by means of an anamnestic interview with a psychologist and/or a score of 8 or higher on one of the subscales Hospital Anxiety and Depression Scales (HADS, Spinhoven et al. 1997).
4) Age >18

Exclusion criteria

1) Migraine,
2) Limited health literacy (as measured by the SBSQ (Chew et al. 2008; Fransen et al. 2011))
3) Currently being treated by a psychologist

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):	28-01-2016
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	10-12-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-12-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL52800.078.15