

Mindfulness based cognitive therapy in treatment of chronic pelvic pain

Published: 02-04-2024

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Does mindfulness based cognitive therapy in addition to treatment as usual (TAU) improve QoL compared to TAU alone in patients with CPP based on a hypertonic pelvic floor ?

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

Summary

ID

NL-OMON56706

Source

ToetsingOnline

Brief title

Mindfulness in chronic pelvic pain

Condition

- Peripheral neuropathies

Synonym

chronic pelvic pain, overactive pelvic floor

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

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

Intervention

Keyword: Chronic pelvic pain, Cognitive, Mindfulness

Outcome measures

Primary outcome

EQ 5D scores to measure QoL

Secondary outcome

NRS scores to measure the level of pain.

PCS scores to measure the sensation of pain.

HADS to measure depression and anxiety.

MAPLe measurements to measure the pelvic floor tension.

Study description

Background summary

Chronic pain has a great impact, including on daily functioning. This can be accompanied by feelings of uncertainty, sadness, anxiety and gloom.

Mindfulness is about being present in the moment. It is about becoming aware of thoughts and feelings in an accepting and neutral way. In this way, space can be created to deal with pain symptoms differently, for instance by making choices that allow you to take better care of yourself.

During the mindfulness training, you practise focusing your attention, for instance through a sitting meditation or body scan. This teaches you to become aware of thoughts, feelings and physical sensations, and then learn to distance yourself from them. This can help break through negative thoughts.

Mindfulness training was originally developed to teach people to cope better with pain and physical symptoms. Scientific research has shown that mindfulness training is effective in reducing and learning to cope better with pain.

Study objective

Does mindfulness based cognitive therapy in addition to treatment as usual (TAU) improve QoL compared to TAU alone in patients with CPP based on a hypertonic pelvic floor ?

Study design

Pilot study in the form of a randomized controlled trial

Intervention

The intervention group receives mindfulness based cognitive therapy in addition to treatment as usual (TAU).

The control group receives treatment as usual (TAU) alone.

Study burden and risks

The burden for subjects in this study consists of extra visits to Radboudumc to receive mindfulness based therapy. There are no risks associated with this therapy. All additional operations are part of regular care for similar (pain) conditions.

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

Female patients with chronic pelvic pain caused by a hypertonic pelvic floor

Exclusion criteria

Patients < 18 years of age
Incapacitated subjects

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	04-02-2024
Enrollment:	16
Type:	Anticipated

Ethics review

Approved WMO	
Date:	02-04-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	18-04-2024

Application type: Amendment
Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL86058.091.24