The clinical and cost-effectiveness of mindfulness training in the improvement of physical health in patients with medically unexplained symptoms in primary care

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The objective of this research is to examine the (cost-)effectiveness of mindfulness training in patients with persistent medically unexplained symptoms in primary care.

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

Summary

ID

NL-OMON33324

Source
ToetsingOnline

Brief title
Mindful Body Trial

Condition

- Other condition

Synonym
medically unexplaind symptoms, unexplaind physical symptoms

Health condition

onverklaarde lichamelijke klachten

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: ZonMW;AGIKO financiering

Intervention

Keyword: medically unexplained symptoms, mindfulness, primary care, randomised controlled trial

Outcome measures

Primary outcome

Our primary outcome measure is the perceived physical health status in the past week. This is measured by the EQ-5D, a validated questionnaire for measurement of the quality of physical health and quality of life.

Secondary outcome

Secondary outcome measures are: psychological symptoms (Patient Health Questionnaire, PHQ-15 ad PHQ-9), quality of life (SF-36), physical health as measured by the SF-36 Physical Component Summary (PCS), health anxiety (Illness Attitude Scale), mindfulness skills (Five Facet Mindfulness Questionnaire, FFMQ), rumminative response style (RRS), medical consumption (Cost Diary for medical consumption) and coping (Orientation to life questionnaire).

Study description

Background summary

Medically unexplainded complaints are very common. Especially the patients with persistent medically unexplained symptoms have high levels of functional impairment and a relatively low quality of life. For the general practitioner

these patients take a lot of time and energy. Cognitive behavioral therapy is one of the most effective therapies within the field of medically unexplained symptoms. Mindfulness based approaches are a new development within the field of cognitive behavioral therapy. Mindfulness training is a group skills-training in which patients learn to become more aware of their thoughts, feelings and bodily sensations and to relate to them in a nonjudgmental way. Mindfulness training has been developed as a stress reduction training. Research has shown that after two months of training the participants are able to relax more easily, demonstrate a decrease of psychological and physical symptoms and can better cope with chronic pain. Therefore, we expect mindfulness training to be effective in patients with medically unexplained symptoms.

Study objective

The objective of this research is to examine the (cost-)effectiveness of mindfulness training in patients with persistent medically unexplained symptoms in primary care.

Study design

A randomized controlled clinical trial with patients with medically unexplainde symotoms in primary care. Patients who accept to take part in the study will be randomized to intervention (mindfulness training) or control condition (usual care). Patients will be followed up for one year. Patients in the control group condition will be offered mindfulness training one year after the start of the trial. This research is a collaboration between the department of general practice and the department of psychiatry at the UMCN St Radboud Nijmegen.

Intervention

The intervention, mindfulness training, consists of 8 weekly sessions of 2,5 hours duration in which patients take part in meditation, yoga and cognitive therapy exercises. The aim is to pay attention to the present moment and accept bodily sensations, emotions and thoughts rather than to try to get rid of them. Participants share their experiences with the group members and the trainer.

Study burden and risks

Patients randomised to the mindfulness training will be invited in the 8-week course and will be expected to practive at home on a daily basis.

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 medically unexplaind symptoms for at least 6 months
Patients who frequently visit the general practitioner, belonging to top 10% of frequent attenders
Patienst have visited the general practitioner at least once in the past 3 months

Exclusion criteria

Patients younger than 18 and older than 70 years
Patients with insufficient understanding of the Dutch language
Patients with severe psychiatric problems (major depression, psychosis)
Patients with mental retardation

Patients with severe psychical disease

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-12-2009
Enrollment:	100
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	05-10-2009
Application type:	First submission
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

ID: 26867
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL27551.091.09
OMON	NL-OMON26867