Mindful Body Trial: Mindfulness training for medically unexplained symptoms.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26867

Source
Nationaal Trial Register

Brief title
MBT

Health condition

medically unexplained symptoms, somatoform disorders, undifferentiated somatoform disorder, functional syndrome, somatisation, randomized controlled trial, mindfulness training, frequent attenders.
onverklaarde lichamelijke klachten, ongedifferentieerde somatoforme stoornis, somatoforme stoornissen, somatisatie, gerandomiseerd gecontroleerd onderzoek, mindfulnesstraining, frequente huisartsbezoeker

Sponsors and support

Primary sponsor: UMC St Radboud Nijmegen
Source(s) of monetary or material Support: ZonMW project number 92003532

Intervention

Outcome measures

Primary outcome

Perceived physical health, measured by the visual analogue scale of the EQ-5D and the SF-36 (physical component summary).

Secondary outcome

1. Psychological and physical symptoms (patient health questionnaire, PHQ);

2. Quality of life (SF-36 and EQ-5D);

3. Health anxiety (Whitely Index);

4. Mindfulness skills (Five facet mindfulness questionnaire, FFMQ);

5. Rumination (Rumminative response style, RRS);

6. Medical consumption (Cost Diary for medical consumption);

7. Work limitations (work limitation questionnaire, WLQ);

8. Relationship with GP (difficult doctor patient relationship-9, DDPRQ-9);

9. Sense of coherence (SoC-13).

Study description

Background summary

The Mindful Body Trial is a randomized controlled trial in which the effects of mindfulness training on patients with medically unexplained symptoms are measured. We are interested in the effects on the perceived physical health and the cost-effectiveness of mindfulness compared to patients who receive usual care. Patients are recruited in general practices in the Netherlands.

Study objective

Mindfulness training is effective for patients with medically unexplained symptoms. The perceived physical health improves. The training is cost effective in terms of improved quality of life versus the medical costs.

Study design

All primary and secondary measures are measured at baseline, 3 months after baseline and 12 months after baseline. The medical consumption and the participation in work are measured every month.

The relation with the GP is measured at baseline and after one year.

Intervention

Intervention:

Mindfulness training (mindfulness based cognitive therapy), consists of 8 weekly sessions of 2,5 hours duration in which patients take part in meditation, yoga and cognitive therapy exercises. Homework takes about 45 minutes per day. Patients share their experience with the group members and the trainer.

Control:

Care as usual during follow up, no participation in mindfulness training. After follow up (1 year) patients in the control condition are offered mindfulness training.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with medically unexplaind symptoms for at least 6 months;

2. Patients who frequently visit the general practitioner, belonging to top 10% of frequent attenders.

Exclusion criteria

1. Patients younger than 18 and older than 70 years;

2. Patients with insufficient understanding of the Dutch language;

3. Patient with a physical disease that fully accounts for the physical symptoms;

4. Patient with unexplained physical symptoms, but without effects on the quality of life;

5. Patients with psychosis or bipolar disorder in the medical history;

6. Patients with mental retardation;

7. Patients with severe psychical disease;

8. Patients who have already had mindfulness training.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-12-2009
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-02-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 33324
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2105
NTR-old	NTR2222
CCMO	NL27551.091.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON33324

Study results

Summary results
N/A