

Mindful Body Trial: Mindfulness training for medically unexplained symptoms.

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26867

Bron

Nationaal Trial Register

Verkorte titel

MBT

Aandoening

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

Ondersteuning

Primaire sponsor: UMC St Radboud Nijmegen

Overige ondersteuning: ZonMW project number 92003532

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with medically unexplained symptoms for at least 6 months;
2. Patients who frequently visit the general practitioner, belonging to top 10% of frequent attenders.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	09-12-2009
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	19-02-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 33324

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A