Mindfulness Based Cognitive Therapy for subjective fatigue in patients with multiple sclerosis: a prospective cohort study on effectiveness and feasibility.

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The purpose of the present study is the evaluation of the effectiveness of MBCT in MS patients. Based on previous research we hypothesize that after the MBCT intervention period, MS patients will have significantly less symptoms of fatigue than…

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

Summary

ID

NL-OMON37684

Source
ToetsingOnline

Brief title
Mind-MS-study

Condition

- Demyelinating disorders

Synonym
MS, Multiple sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Orbis Medisch Centrum

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

Intervention

Keyword: Fatigue, MBCT, MS

Outcome measures

Primary outcome

Fatigue will be measured with the fatigue severity subscale of the Checklist Individual Strenght-20 (CIS-20).This subscale consists of 8 items, each scored on a 7-point Likert scale with scores ranging from 8 to 56. A score of 35 or higher on the subscale indicates severe fatigue.

Secondary outcome

Symptoms of anxiety and depression will be measured with the Hospital Anxiety and Depression Scale (HADS). The HADS is specially designed to screen anxiety and depression in physically ill patients and does not include somatic symptoms. Both subscales consist of 7 items, with scores ranging from 0-21. Separate scores of 8 or higher or joint scores of 12 or higher are interpreted as high scores, indicating more intensity of anxiety or depression.

Catastrophizing about fatigue will be measured with the Fatigue Catastrophizing Scale (FCS), which is an adapted version of the Pain Catastrophizing Scale (PCS). The PCS is a 13-item questionnaire that measures the frequency of catastrophizing thoughts reported by patients about the pain they experience. Psychometric properties of the PCS appeared adequate (Van Damme, 2000; Crombez, 1998). Bol et al. (2010) adapted the PCS by replacing the word *pain* by the word *fatigue* in all items. Scoring alternatives range from *strongly disagree* to *strongly agree*. Three MS-related items were added by Bol et al.

(2010) (*When I am tired, this is a signal there is something wrong in my brain*, *When I am tired, this is a warning for physical decline*, *When I am tired, this is a sign that my MS is getting worse*). The FCS consists of 16 items, with scores ranging from 0-64 and with higher scores indicating higher intensity

Sleeping problems will be measured with the subscale sleep of the Dutch version of the Symptom Checklist-90 (SCL-90, Arrindell & Ettema, 1986), a frequently used questionnaire for several psychological complaints. The subscale consists of three items, with scores ranging from 3 to 15. Higher scores indicate lower quality of sleep.

As a measure of perceived life satisfaction, we will use the Life Satisfaction questionnaire (LiSat-9). It consists of one question about satisfaction with life as a whole and eight questions about satisfaction within the following life domains; self-care ability, leisure time, vocational situation, financial situation, sexual life, partnership relations, family life and contacts with friends. Each question is rated on a 6 point Likert scale. The total LiSat-9 score is the average of all item scores and has a 1-6 range. Mean score of 1*4 constitutes dissatisfaction with life and a score of 5- 6 indicates satisfaction with life.

Coping style will be measured with the Coping Inventory of Stressful situations (CISS). This self-report inventory (48 items, using 5-point Likert scales) measures three main coping strategies: task focused coping (dealing with the problem at hand); emotion focused coping (concentrating on the resultant emotions, e.g., becoming angry or upset); and avoidance coping (trying to avoid

the problem). Avoidance coping can be divided further into two types: an 8-item distraction subscale; and a 5-item social diversion subscale.

The level of mindfulness will be measured with the short version of the Five Facet Mindfulness Inventory (FFMQ-SF). The FFMQ-SF is a 24-item questionnaire that measures five facets of mindfulness; observing, describing, acting with awareness, nonjudging, and nonreactivity. Total facet scores of the FFMQ-SF were highly correlated with the original long version. Items are scored on a 5-point Likert-type scale. Facet scores are computed by summing the scores on the individual items. Facet scores range from 8 to 40 (except for the nonreactivity facet, which ranges from 7 to 35), with higher scores indicating more mindfulness.

Cognitive complaints will be assessed by the Cognitive Failure Questionnaire (CFQ). This questionnaire consists of 25 items on general daily cognitive mistakes, including failures in memory, attention, action and perception with the total score ranging from 25 to 125. Scores are considered high when between 44 en 54.

Study description

Background summary

Multiple sclerosis (MS) is a chronic inflammatory demyelinating disease of the central nervous system and the most common neurological disorder affecting young adults.Up to 90% of patients with MS complain of fatigue. This fatigue can severely affect the ability to perform activities of daily life and is a major reason for unemployment. Therefore, fatigue in MS patients is related to disability and poor quality of life. Although fatigue is one of the most common and disabling symptoms in MS patients, its pathogenesis is still poorly understood and evidence-based treatment options are limited. Depression might

be an important perpetuating factor in MS-related fatigue and depression and fatigue contribute independently to the patient*s quality of life. Anxiety, either with or without depression, occurs in 25% of MS patients. Anxiety co-morbid with depression, is associated with increased thoughts of self harm, more somatic complaints and greater social dysfunction, and thereby adding to the morbidity associated with MS.
Although there is some evidence for underlying pathophysiological mechanisms in MS-related fatigue, including inflammation, demyelinisation, axonal loss and neuroendocrine dysregulation, these variables appear to explain only a relatively small part of the variance of both MS-related fatigue and its disability. There is growing evidence that cognitive behavioural factors such as catastrophising thoughts about MS and fatigue, influence MS related fatigue and its disability. Cognitive behavioural therapy (CBT) has been proven to be effective for reducing fatigue in several somatic populations. Van Kessel et al. (2008) investigated the effect of CBT for fatigue in MS-patients, where it proved to be clinically effective. More specifically, the change in the negative representation of fatigue plays a crucial role in the reduction of fatigue in MS after CBT.
More recent, there has arisen a new generation of CBT, including mindfulness components. Kabat-Zinn, the founder of mindfulness training, defines mindfulness as *paying attention, on purpose, in the present moment, and nonjudgmentally*. One of the concepts of mindfulness is the assumption that people often function in an automatic pilot mode, which makes them unaware of their potentially maladaptive coping strategies. The aim of mindfulness training is to learn skills that enhance the ability to raise awareness of present experiences. Being aware of their present experience allows people to choose for more helpful coping behavior.
Kabat-Zinn*s Mindfulness-Based Stress Reduction (MBSR) training has been proven effective in several somatic populations for reducing both physical and emotional symptoms. Until now, only one randomized clinical trial on mindfulness approaches has been conducted in MS patients, in which MBSR was compared with care as usual. After six months, the MBSR intervention group reported significantly less symptoms of fatigue and depression compared to the control group. Furthermore, the quality of life of MS patients was significantly improved after the intervention in contrast to the control group.
The effectiveness of MBSR might be improved by integrating elements of cognitive behavioural therapy. The latter has been done by the introduction of mindfulness-based cognitive therapy. MBCT is a group intervention in which participants are trained to become aware of their emotions, sensations and (negative) automatic thoughts. In contrast to CBT, MBCT does not emphasize changing the content or specific meaning of negative automatic thoughts. Empirical evidence for the effectiveness MBCT has been found in fatigued cancer survivors and chronic pain patients. Little is known about MBCT effect in populations with neurological disorders. The results of a qualitative study in Parkinson's Disease (PD), that is like MS, a neurodegenerative disease in which fatigue, depression and cognitive disorders, are frequent and disabling symptoms, are promising; The MBCT helped PD-patients in coping with their

disease.
Until now, there are no studies we know of, on the effectiveness of MBCT in MS and therefore, the proposed study can be considered as a possible addition to the treatments available.

Study objective

The purpose of the present study is the evaluation of the effectiveness of MBCT in MS patients. Based on previous research we hypothesize that after the MBCT intervention period, MS patients will have significantly less symptoms of fatigue than after the waiting list period. Furthermore, we hypothesize that MBCT has a positive effect on symptoms of anxiety and depression, sleep problems, quality of life and catastrophizing thoughts about fatigue. Next, we will explore the impact of MBCT on the level of mindfulness, cognitive complaints and coping style. Finally, we will evaluate whether patients with cognitive disorders will benefit as much of the MBCT as patients without cognitive disorders.

Study design

The design of the current study is a prospective cohort study with a ten weeks waiting list control period, a ten weeks period of treatment and a three-month follow up.

Intervention

The MBCT protocol we will use is described by Segal et al. (2004) and is a group intervention. We made some adaptations for fatigue, because Segal*s protocol was developed for patients with recurrent depressive episodes. The adaptations we use will be acquired by Van der Lee and Garssen (2010), who used this protocol for fatigued cancer survivors. Where van der Lee and Garssen use information about the relation between cancer and fatigue in the protocol, we will use information about the relation between MS and fatigue. Also the case described in the reader about a patient with cancer, will be changed to a case of a patient with MS. The treatment involves eight weekly meetings of 2,5 hours training during a period of 10 weeks. Meditation exercises, yoga exercises and psycho-education are part of the MBCT training. Patients will be given a workbook with instructions to read at home after each session and compact disks with exercises to do at home. Patients are asked to do the homework and exercises on a daily basis for about 45 minutes 6 days a week. Patients will keep track of their home progress by making entries in a diary.

Study burden and risks

The treatment involves eight weekly meetings of 2,5 hours training during a period of 10 weeks.

Completing all the outcome questionnaires will take about 20-30 minutes. All outcome measurements will be performed at inclusion, at the start of the treatment 10 weeks later, at the end of the treatment and at follow up 3 months after finishing the program.
The primary outcome measure will be administered twice during the waiting list period and once during the treatment period. Completing the primary outcome measure will take about 3-5 minutes.
Neuropsychological tests (see p.7 of the protocol) will be adminsitered once at inclusion, and will take about 20-30 minutes.
Patients are asked to do the homework and exercises on a daily basis for about 45 minutes 6 days a weekduring the treatment period. They will keep track of their home progress by making entries in a diary.
Exercising on a daily basis is necessary to accomplish a therapeutic effect.
There are no risks associated with the treatment. In fact, the training is an existing treatment which, by means of this study, will be applied to a new patient group.

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

Age 18-60 years; clinical definite MS diagnosis according to the Mac Donald classification criteria; severe fatigue symptoms (a score * 35 on the subscale subjective fatigue of the Checklist Individual Strenght-20); motivation for the training and daily practicing at home for 45 minutes; fluent in Dutch.

Exclusion criteria

Primary progressive MS; MS relapse or corticosteroid use within the past 6 weeks; Other neurological disorders than MS; Somatic co-morbidity related with fatigue (e.g. diabetes mellitus, inflammatory bowel disease, chronic fatigue syndrome); a current clinical depressive episode according the DSM-IV criteria; other severe psychiatric disorders (psychosis, social phobia, delirium, dementia, alcohol or substance abuse); previous mindfulness training.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2012
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	04-06-2012
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL39852.096.12