

Mindfulness based stress reduction (MBSR) for patients with lung cancer and their partners: a randomised controlled trial.

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The aim of the current study is to examine the (cost)effectiveness of Mindfulness Based Stress Reduction (MBSR) in comparison with treatment as usual for patients with lung cancer and their partners.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON40058

Source

ToetsingOnline

Brief title

Mindfulness for lung cancer patients.

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym

lung cancer

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Keyword: caretakers, lung cancer, mindfulness, psychological distress

Outcome measures

Primary outcome

The primary outcome measures at the assessments will be:

Hospital Depression and Anxiety Scale (HADS; Bjelland et al., 2002; Spinhoven et al., 1997)

Secondary outcome

Secondary outcome measures will be:

- Penn State Worry Questionnaire (PSWQ; Meyer et al., 1990; Van Rijsoort et al., 1999)
- Five Facets of Mindfulness Questionnaire (FFMQ; Baer et al., 2006)
- Core Quality of Life Questionnaire for Lung Cancer (QLQ-LC13; Bergman et al., 1994)
- Maudsley Marital Questionnaire (MMQ; Arrindell et al., 1983)
- Medical costs

In addition, the partners of the patients will be asked complete:

- Caregiver Reaction Assessment (CRA; Given et al., 1992; Nijboer et al., 1999)

Study description

Background summary

The results of a recent meta-analysis of ten randomized controlled trials and observational studies (Ledesma & Kumano, 2009) suggest that mindfulness may improve cancer patients' psychosocial adjustment to their disease and enhance their coping and well-being. A systematic review of twelve further studies (Shennan et al., 2010) reports significant improvements in anxiety, depression, stress and sexual difficulties. The reviews highlight the need for more randomized controlled trials and a more diverse participant base. They also note the need for exploring the underlying mechanisms of mindfulness and expanding outcomes to include quality of life.

Based on the available evidence, the current study would be the first randomized controlled trial of MBSR for cancer patients in the Netherlands. As most of the earlier studies have been conducted in patients with breast cancer, it is important to examine the effectiveness of this approach in patients with other types of cancer, such as lung cancer. Only one earlier study has involved partners of patients (Birnie et al., 2009), although partners also experience many psychological challenges.

Our primary hypothesis is that in patients with lung cancer MBSR might result in a decrease of psychological distress. Secondary outcome measures will include worry, mindfulness skills, marital satisfaction, quality of life and medical costs. Partners of patients with lung cancer might also report less psychological distress and worry, more mindfulness skills and marital satisfaction and might experience less negative consequences as a caregiver.

Study objective

The aim of the current study is to examine the (cost)effectiveness of Mindfulness Based Stress Reduction (MBSR) in comparison with treatment as usual for patients with lung cancer and their partners.

Study design

The design of the study is a randomised controlled trial, comparing an 8-week MBSR training with a treatment as usual condition.

The difference between groups on the contrast between baseline and follow-up will be assessed with multivariate repeated-measures analyses of covariance with baseline and follow-up scores as dependent variables. To determine whether increases in mindfulness or decreases in worry were responsible for the

changes, subsequent mediation analyses will be conducted (Baron & Kenny, 1986).

Intervention

The MBSR course will consist of 8 sessions of 2,5 hours each and a silent day. The structure of the course will be based on the original program developed by Kabat-Zinn (1990) and his colleagues at the Stress Reduction and Relaxation Clinic, Massachusetts Medical Center. Each MBSR group will consist of about 7 patients and 7 partners. The instructors of the MBSR courses will be qualified health professionals and mindfulness trainers, maintaining a personal meditation practice.

Study burden and risks

N/A

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

- cytologically or histologically proven non-small cell lung cancer and small cell lung cancer
- patients can participate after lung cancer diagnosis, from start of treatment or after treatment

Exclusion criteria

- former MBSR or MBCT course
- current psychological treatment by psychologist or psychiatrist

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):	23-02-2013
Enrollment:	110
Type:	Actual

Ethics review

Approved WMO	
Date:	28-02-2012
Application type:	First submission

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	06-05-2014
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	NL37359.091.11