

Effecten van Mindfulness Based Stress Reduction (MBSR) bij mensen met longkanker.

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1. MBSR will reduce symptoms of distress, anxiety and depression 2. MBSR will reduce fatigue, pain and sleep disturbance 3. MBSR will improve coping with cancer

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

Samenvatting

ID

NL-OMON21858

Bron

NTR

Aandoening

Lung cancer - longkanker

distress - distress

anxiety - angst

depression - depressie

Ondersteuning

Primaire sponsor: - Atrium Medisch Centrum

- RINO Zuid

Overige ondersteuning: - Atrium Medisch Centrum

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Symptoms of distress, anxiety and depression. Measured with : Distress Thermometer combined with the Problem List (DT; PL) and the Hospital Anxiety and Depression Scale (HADS).

Toelichting onderzoek

Achtergrond van het onderzoek

Lung cancer is the most lethal and common cancer around the world (Parkin, Bray & Devesa, 2001; Jemal, Siegel, Ward, Hao & Xu, 2009). Patients with lung cancer have more physical complaints and a shorter survival rate compared to other cancer types. The five year survival rate is 16% in Europe (Cooley, 2000; Janssen-Heijnen & Coeberg, 2003). Besides the physical burden, research further shows that patients with lung cancer experience a higher degree of psychological burden or distress compared to other cancer populations (Li & Girgis, 2006; Carlson, Angen, Cullum et al., 2004; Sellick & Edwardson, 2007).

Since psychological complaints such as distress, anxiety and depression were reduced and QoL was improved by MBSR in studies with mixed patient populations and mixed cancer groups, MBSR might have the same positive results in lung cancer patients (Bear, 2003; Smith, Richardson, Hoffman & Pilkington, 2005; Carlson & Garland, 2005; Ott, Norris & Bauer-Wu, 2006; Matchim & Armer, 2007; Ledesma & Kumano, 2009; Shennan, Payne & Fenlon, 2011; Musial, Büssing, Heusser, Choi & Ostermann, 2011).

Considering the evidence for positive effects of MBSR on some of the core physical components of lung cancer, e.g. fatigue, pain and sleep disturbance (Carlson & Garland, 2005; Marchand, 2012), it seems critically important to assess whether patients with lung cancer can also achieve a reduction of their physical and psychological burden.

The current study is a semi-experimental prospective between subjects design. The current study is an expansion of a previous study at the Atrium MC concerning patients with lung cancer. In the previous study participants were followed during chemotherapy and three months after chemotherapy to explore possible changes in distress, anxiety, depression and coping with cancer. In the absence of an intervention, no significant changes in symptoms of distress, anxiety and depression were found. Participants with high levels of distress, anxiety and depression before chemotherapy, continued to have high levels of distress, anxiety and depression three months after chemo. The participants in the previous study will be used as a control group for the current intervention group. All participants will receive standard medical care during the study.

Doel van het onderzoek

1. MBSR will reduce symptoms of distress, anxiety and depression
2. MBSR will reduce fatigue, pain and sleep disturbance
3. MBSR will improve coping with cancer

Onderzoeksopzet

T0: last chemotherapy; EORTC QLQ-C30 and QLQ-LC13; DT; PL; SIPP; HADS; MAC-Scale; FFMQ-SF; Subjective burden questions

T1: after MBSR; EORTC QLQ-C30 and QLQ-LC13; DT; PL; SIPP; HADS; MAC-Scale; FFMQ-SF; Subjective burden questions

T2: 4 wks after MBSR; EORTC QLQ-C30 and QLQ-LC13; DT; PL; SIPP; HADS; MAC-Scale; FFMQ-SF; Subjective burden questions

Onderzoeksproduct en/of interventie

The intervention, MBSR, is based on the original protocol as described by J. Kabat-Zinn (1990). The group consists of minimal five participants and maximum 15 participants. For eight following weeks participants will receive a two and a half hour training and one meditation day. They are asked to exercise at least six times a week for approximately 45 minutes. Participants will receive a workbook with written information concerning the MBSR per session and four CD's containing the home exercises.

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age > 18
- Diagnosis: lung cancer
- ECOG PS max. 2
- Fluent in expression and comprehension of the Dutch language
- motivated to complete the MBSR and daily practice at home.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- ECOG PS > 2

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2014
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	28-11-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4146
NTR-old	NTR4290
Ander register	Atrium Medisch Centrum : METC nummer: 13-N-161
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A