

# The study of mindfulness in cancer patients from a self-regulatory stress-coping perspective

Published: 27-10-2010

Last updated: 04-05-2024

1 To examine the differences in mindfulness between cancer patients and healthy references.2 To examine possible correlates of mindfulness, i.e. factors that may enhance or deplete mindfulness.3 To examine the relationship between mindfulness and...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Miscellaneous and site unspecified neoplasms malignant and unspecified
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON35002

### Source

ToetsingOnline

### Brief title

Mindfulness and quality of life after cancer

### Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

### Synonym

Cancer, neoplasm

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

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

## Intervention

**Keyword:** cancer, mindfulness, quality of Life, self-regulation, stress-coping

## Outcome measures

### Primary outcome

- 1 Mindfulness, measured by the 15-item MAAS and the 39-item FFMQ
- 2 Coping, measured by the 18-item CERQ, the 8-item COPE, the 12-item ICQ and the 25-item SPSI
- 3 Well-being, measured by the 30-item EORTC, the 16-item CES-D and the 20-item PANAS

### Secondary outcome

Not applicable

## Study description

### Background summary

Past empirical research on mindfulness in cancer patients focused on the effectiveness of mindfulness interventions. A recent meta-analysis on the effectiveness of mindfulness-based interventions on cancer patients' psychological well-being found a moderate effect size. These positive effects of the intervention are attributed to learning and developing mindfulness, yet this idea has not been thoroughly empirically tested. As more conceptual studies on mindfulness are generally conducted in college students, very little is known about the adaptive value of mindfulness in cancer patients' adaptation. The present study will focus on this important issue, using an integrated stress-coping self-regulation model as theoretical background. The model postulates that people appraise an event as being positive, neutral or negative, partly depending on the extent to which the event interferes with important personal goals. People also appraise their confidence and coping resources to deal with the event. These appraisals influence people's cognitive and behavioural coping strategies to solve problems, attain goals, and regulate emotions. These coping strategies ultimately affect adaptation to the event and well-being.

## Study objective

- 1 To examine the differences in mindfulness between cancer patients and healthy references.
- 2 To examine possible correlates of mindfulness, i.e. factors that may enhance or deplete mindfulness.
- 3 To examine the relationship between mindfulness and well-being in cancer patients and the underlying mechanisms.

## Study design

Observational, cross-sectional research, data collection by means of one self-report questionnaire.

## Study burden and risks

For all participants the burden exists of once completing a questionnaire.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Cancer patients from the University Medical Center Groningen, in the curative phase of treatment, varying in time since diagnosis and end of active treatment (from two months after finishing radiotherapy up to five years after diagnosis), age 18 years and older.

Healthy references from the same region as cancer patients, matched on gender and age.

### Exclusion criteria

1) not being able to speak Dutch, 2) a serious psychiatric disorder

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	13-04-2011
Enrollment:	500
Type:	Actual

## Ethics review

Approved WMO

Date: 27-10-2010

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

## 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	NL30595.042.09