

# The clinical and cost-effectiveness of mindfulness based cognitive therapy (MBCT), optimal medical management (OMM) and its combination in the prevention of relapse in patients with recurrent depression.

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The objective of the present study is to assess the clinical and cost-effectiveness of the combination of Mindfulness Based Cognitive Therapy (MBCT) and Optimal Medical Management (OMM) in terms of reducing the risk of relapse and recurrence in...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Mood disorders and disturbances NEC
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON32669

### Source

ToetsingOnline

### Brief title

Mindfulness, medication and its combination for recurrent depression.

### Condition

- Mood disorders and disturbances NEC

### Synonym

major depressive disorder (recurrent), recurrent depression

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud

**Source(s) of monetary or material Support:** ZonMW Doelmatigheidsonderzoek

## Intervention

**Keyword:** antidepressant medication, mindfulness, randomised controlled trial, recurrent depression

## Outcome measures

### Primary outcome

Primary outcome measure: risk of relapse or recurrence of depression defined by DSM-IV criteria as assessed by the Structured Clinical Interview for DSM-IV (SCID; First et al., 1996) and incremental cost-effectiveness ratio.

### Secondary outcome

Secondary outcome measures: time to, duration and severity of relapse or recurrence as assessed by the Inventory of Depression Symptomatology Self Rated (IDS-SR; Rush et al., 1996), psychiatric comorbidity and quality of life.

## Study description

### Background summary

In comparison with treatment as usual, mindfulness based cognitive therapy (MBCT) has been demonstrated to significantly reduce the relapse rate in patients with three or more previous depressive episodes (Teasdale et al., 2000; Ma & Teasdale, 2004). In a recently completed trial (Kuyken et al., 2007), MBCT and maintenance antidepressant medication appeared to have comparable results in patients with recurrent depression, but relapse rates remained considerable in both conditions.

### Study objective

The objective of the present study is to assess the clinical and cost-effectiveness of the combination of Mindfulness Based Cognitive Therapy (MBCT) and Optimal Medical Management (OMM) in terms of reducing the risk of relapse and recurrence in patients with recurrent depression as compared to either of these treatments alone.

## **Study design**

Multi-center randomised controlled trial (RCT) with three interventions and 15 months post-randomisation follow-up.

## **Intervention**

Combination of mindfulness based cognitive therapy (MBCT) and optimised medical management (OMM), OMM alone and MBCT alone.

## **Study burden and risks**

Patients randomised to the MBCT or combined condition will be invited to participate in the 8-week course and will be expected to practice at home on a daily basis.

## **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

Patients with major depressive disorder with at least three previous depressive episodes.  
Patients have been treated with a therapeutic dose of antidepressant medication over the last 6 months.

Patients are currently either in full or partial remission.

### Exclusion criteria

Bipolar disorder

Any primary psychotic disorder

Clinically relevant neurological or other somatic illness

Current alcohol or drug misuse

Use of high dosage of benzodiazepines (>2 mg lorazepam equivalents daily)

Recent Electro Convulsive Therapy

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

## Recruitment

NL  
Recruitment status: Pending  
Start date (anticipated): 01-01-2009  
Enrollment: 400  
Type: Anticipated

## Ethics review

Approved WMO  
Application type: First submission  
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	NL24401.091.08