The effectiveness of mindfulness based cognitive therapy (MBCT) in adults with chronic, therapy resistant depression in a mental healthcare setting?

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The aim of this study is to examine whether MBCT is also effective in patients with chronic, treatment-resistant depression in a mental healthcare setting.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON37200

Source
ToetsingOnline

Brief title
Mindfulness based cognitive therapy for chronic depression.

Condition

- Mood disorders and disturbances NEC

Synonym
chronic depression, major depressive disorder (chronic)

Research involving
Human

Sponsors and support

Primary sponsor: Pro Persona (lokaties Nijmegen, Arnhem, Ede en Tiel)
Source(s) of monetary or material Support: Fonds Psychische Gezondheid

Intervention

Keyword: Chronic depression, Mindfulness, Randomised controlled trial

Outcome measures

Primary outcome

The primary outcome measure will consist of a reduction in depressive symptoms according to the Inventory of Depression symptomatology (IDS-SR, Rush, Gullion, Base et al, 1996).

Secondary outcome

Secondary outcomes will include: rumination (Ruminative Response Scale and Rumination on Sadness Scale (Raes et al, 2003), mindfulness skills (Five Facet Mindfulness Questionnaire, Baer et al, 2006), self-compassion (Self Compassion Scale; Neff, 2003) and quality of life (QOL WHO, World health Organization, 2004) and general health (EQ-5D; Dolan et al, 1997).

Study description

Background summary

Depression is a major public health problem with high prevalence and burden of disease. A large number of patients
not improve with currently available psychopharmacological and psychological treatments. Mindfulness based cognitive therapy
(MBCT) has proven to be effective in preventing relapse in patients with recurrent depression.

Earlier, uncontrolled study showed that MBCT can also be effective in patients who are currently depressed (Kenny et al, 2007). In a small randomized trial of MBCT in 28 depressed patients with chronic and recurrent course of disease, also demonstrated a 50% reduction in depressive complaints (Barnhofer et al, 2009). Seven of the 10 depressed participants in the MBCT group did afterwards no longer meet the diagnostic criteria. A recent randomized trial conducted by us of more than 200 patients with recurrent depression also showed that MBCT is

as effective in people who are currently depressed as those who are in remission (of Aalderen et al, 2011). The effect size of MBCT in reducing depression was large (Cohen's d = 0.53) and independent of the degree of depressive symptoms at the start of the treatment.

The effectiveness of MBCT in people with recurrent depression who are currently depressed creates interesting possibilities to investigate the effectiveness of MBCT in people with chronic, treatment-resistant depression. MBCT has so far only included in the guideline for those with three or more previous depressions and is not offered to our target group. In addition to specific effects on cognition and mood MBCT can also potentially contribute to the feeling of empowerment among people with chronic depression while the manner of offering (group training) meets the need for support and contact with fellow sufferers. Not only can MBCT in patients with chronic, treatment-resistant depression result in a reduction of complaints, but also in a reduction of the related care and therefore costs.

Study objective

The aim of this study is to examine whether MBCT is also effective in patients with chronic, treatment-resistant depression in a mental healthcare setting.

Study design

The study design will be a randomized clinical trial with a crossover design. Patients will be randomized after a baseline interview about MBCT added to the regular treatment and regular treatment as usual. The control condition wil receive MBCT after three moniths. The two groups will be followed for six months.

Intervention

Mindfulness based cognitive therapy (MBCT) compared with treatment as usual.

Study burden and risks

For the patients randomized into either the MBCT condition or treatment as usual condition, the burden will consist of participation in the 8-week course. In addition, the participants are expected to do exercises at home daily.Furthermore, all patients get a baseline interview (about one hour) and three follow-up visits with several measurements (about one hour). The control condition will have four follow-up visits as they start with care as susal of three months.

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

Patients with a major depressive disorder (according to DSM-IV) with a duration of one year or longer. Patients have responded insufficiently (IDS >21, moderate depression) to a therapeutic dose of antidepressant medication and a psychotherapy protocol (cognitive behavioral therapy or interpersonal psychotherapy).

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:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-01-2013
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	12-10-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-03-2014
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

ID: 27713
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL41357.091.12
OMON	NL-OMON27713