The effectiveness of Mindfulness Based Compassionate Living (MBCL) in adults with recurrent depression.

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To investigate the effectiveness of Mindfulness Based Compassionate Living (MBCL) in recurrent depressive patients.

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

Summary

ID

NL-OMON38609

Source
ToetsingOnline

Brief title
Mindfulness Based Compassionate Living (MBCL) in 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: Ministerie van OC&W

Intervention

Keyword: Compassion, Mindfulness, Randomized Controlled Trial, Recurrent depression

Outcome measures

Primary outcome

Primary outcome measure is depression symptoms according to the Beck Depression Inventory (BDI-II).

Secondary outcome

Secondary outcome measures will be: mindfulness skills (Five Facet Mindfulness Questionnaire: Baer et al., 2006), self-compassion (Self-Compassion Scale: Neff, 2003), rumination (Ruminative response scale: Raes et al, 2003) and quality of life (WHO-QCL, World Health Organisation, 2004).

Study description

Background summary

Since a few years, Mindfulness Based Cognitive Therapy has been used as treatment for patients suffering from recurrent depression. Though a number of studies show that MBCT is effective in this population (Baer et al., 2011) and MBCT reduces the chances of relapse/recurrence in recurrent depressive patients (Piet et al., 2011), the chance of a new depression developing after end of treatment is still considerable (53%). Ergo, there is room for improvement. Especially the development of a non-judging or compassionate attitude towards all experience seems to mediate the treatment effect. It is therefore our expectation that a follow-up intervention that focuses specifically on self-compassion could prove very useful in elaborating on the effects of MBCT. The research question of this research is therefore: what is the effect of compassion training in people suffering from recurrent depression who have already done an MBCT training?

Study objective

To investigate the effectiveness of Mindfulness Based Compassionate Living

(MBCL) in recurrent depressive patients.

Study design

A randomized, controlled trial. After a baseline interview, patients will be assigned to either MBCL and Treatment as Usual (TAU) or TAU alone. The control group will receive MBCL after 6 months. The two groups will be followed for another 6 months.

Intervention

Mindfulness Based Compassionate Living, added to TAU.

Study burden and risks

For the patients assigned to either the MBCL condition or the control group, the burden will be to attend the 8-week training programme of the MBCL. The participants are expected to do homework at home every day. They are also asked to be present for a baseline interview (1 hour), followed by 2 follow-up measures consisting of questionnaires for the MBCL condition and 3 follow-up measures for the control group (who receive TAU for 6 months first).

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

Adults (18-65) suffering from recurrent depression (1 or more, acc. to DSM-IV criteria) and who have previously participated in a Mindfulness based Cognitive Therapy training.

Exclusion criteria

1. One or more previous (hypo)manic episodes according to DSM-IV criteria
2. Primary psychotic disorder
3. Clinically relevant neurological conditions or somatic conditions that could be related to the depression
4. Current alcohol and/or drug abuse
5. Use of high dosages of benzodiazepines
6. Recent electro convulsive therapy (less than 3 months ago)
7. No prior experience with MBCT.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2013
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	20-06-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-03-2014
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

No registrations found.

In other registers

Register	ID
CCMO	NL44457.091.13