Does mindfulness heighten emotional resilience against depression? A study of gene-person-environment interactions.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23910

Source
NTR

Brief title
MindMaastricht

Health condition

1. Depression;

2. relapse;

3. positive emotions;

4. reward experience;

5. rumination;

6. mindfulness;

7. gene-environment interaction;

8. resilience.

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: NWO, Universiteit Maastricht

Intervention

Outcome measures

Primary outcome

The increase in reward experience in daily life, whereby reward experience is conceptualised as the effect of small daily life positive events on positive mood state. The Experience Sampling Method (ESM) will be used to assess reward experience before and after the intervention. ESM is a structured diary, momentary assessment technique to study subjects in their daily life. Since ESM measurements are performed 10 times a day for 6 days, there will be a maximum of 60 measurements within each subject concerning effects of positive events on positive mood state in the flow of daily life.

Secondary outcome

1. Association between increase in reward experience and decrease in (i) depressive symptoms and (ii) risk of relapse;

2. Association between individual variation in reward experience (and increase in reward experience) and genetic variation in polymorphisms related to the brain reward system.

Study description

Background summary

Rationale: The experience of positive emotions reduces daily life stress-sensitivity, an endophenotype for depression, but also attenuates the expression of genetic risk for depression. This research proposal, therefore, will focus on the changeability (plasticity) of the ability to experience positive emotions in response to daily life events (natural rewards), as a first step towards novel (preventive) interventions in depression

Objective:

1. Can the ability to experience reward in daily life be experimentally modified?;

2. How does experimental modification of reward impact on depressive symptomatology and can individual variation be traced to genetic variation.

Study design: An intervention study is used in which subjects are randomized to treatment as usual (TAU) or TAU + mindfulness-based cognitive therapy. Experience Sampling Method (ESM) is a structured diary, momentary assessment technique to study subjects in their daily life. Before and after the intervention subjects undergo a six-day period of ESM assessment. Subjects will be globally informed, but remain blind as to how ESM measures relate to testing the hypothesis.

Study population: A sample of 120 depression-remitted adult subjects with residual symptomatology (Ham-17>7) recruited from the community mental health centre in Maastricht (CMHC).

Intervention: The experimental group receives 8 weeks of mindfulness training by an experienced trainer in addition to their normal treatment, if any. Sessions are weekly (2,5 hours a session) and subjects receive daily homework exercises. The control group continues their normal treatment, if any.

Main study parameters/endpoints: The increase in reward experience in daily life, whereby reward experience is conceptualised as the effect of small daily life positive events on positive mood state. Since ESM measurements are performed 10 times a day for 6 days, there will be a maximum of 60 measurements within each subject concerning effects of positive events on positive mood state in the flow of daily life.

Study objective

1. Mindfulness training can be used to modify the ability to experience positive emotions from everyday life situations assessed with ESM (reward experience);

2. Experimentally induced increases in reward experience in daily life will reduce depressive symptoms in patients with residual symptomatology and will lead to reduced risk for future relapse;

3. Polymorphisms of genes related to the brain reward system are associated with reward experience in daily life and its modifiability.

Study design

1. Premeasure: 6 days ESM;

2. postmeasure: after 8 weeks of mindfulness training/time control: 6 days ESM;

3. follow-ups are planned, but were not yet submitted to ethical committee:

4. Follow-up at 6 months;

5. Follow-up at 12 months.

Intervention

Mindfulness-based cognitive therapy vs. non-active control group. The experimental group receives 8 weeks of mindfulness training by an experienced trainer in addition to their normal treatment, if any. Sessions are weekly (2,5 hours a session) and subjects receive daily homework exercises. The control group continues their normal treatment, if any.

Contacts

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Eligibility criteria

Inclusion criteria

1. At least one depressive episode in past;

2. Hamilton Depression Scale >7.

Exclusion criteria

1. Current depressive episode;

2. Conditions that make working in a group impossible. (MBCT is given in a group of approximately 15 people).

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2008
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-10-2007
Application type:	First submission

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
NTR-new	NL1051
NTR-old	NTR1084
Other	NWO : 916 76 147
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A