gene-person-environment interaction in resilience against depression

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

Summary

ID

NL-OMON31494

Source
ToetsingOnline

Brief title
The etiology of resilience against depression

Condition

- Mood disorders and disturbances NEC

Synonym
depression, mood disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: NWO vernieuwingsimpuls - VENI beurs

Intervention

Keyword: depression, experience sampling method, positive emotions, resilience

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.

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

- The association between increase in reward experience and decrease in depressive symptomatology

- The association between individual variation in reward experience (or increase in reward experience) and genetic variation in polymorphisms related to the brain reward system.

- The association between increases in reward experience and decreases in risk of future relapse in depression

Study description

Background summary

Depression research focuses almost exclusively on negative mood, with little attention to positive mood. This calls for remediation because i) positive affect (PA) and negative affect (NA) are not two extremes within a unidimensional construct, but relatively independent; and ii) positive emotions

are likely protective since they broaden the attentional focus, thus facilitating the use of positive factors, or natural rewards, in the flow of daily life.
In a recent twin study using novel momentary assessment methodology, I showed that PA not only reduced the risk of developing negative mood states in response to minor daily life stressors (a trait I identified as an indicator of genetic risk for depression), but also attenuated expression of genetic risk for depression.
PA thus mitigates symptoms of, and expression of genetic risk for, depression.

Study objective

My research proposal, therefore, will focus on the changeability (plasticity) of the ability to experience positive emotions in response to daily events (natural rewards), as a first step towards novel (preventive) interventions. The main question is: can the ability to experience reward in daily life be experimentally modified? Additional questions are: how does experimental modification of reward impact on depressive symptomatology, can individual variation be traced to genetic variation, and how do increases in reward experience relate to risk of future relapse in depression?

Study design

Experience Sampling Method (ESM) is a structured diary, momentary assessment technique to study subjects in their daily life. Subjects are randomised to two groups. At baseline, all subjects will undergo a six-day period of ESM. Then, one group receives mindfulness-based cognitive therapy (MBCT) (8 weekly sessions of two hours including daily homework exercises) by an experienced MBCT therapist, and the other group care as usual, followed by a second six-day ESM assessment. Follow-ups will take place 6 and 12 months after participants ended their MBCT training. Any additional treatment, if applicable, will be kept constant within subjects. Subjects will be globally informed, but remain blind as to how ESM measures relate to testing the hypothesis.

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.

Study burden and risks

The main burden for the subjects is participating in the ESM procedure, where they have to fill in a dairy concerning daily life experiences and mood states at 10 random moments during the day (not during the night) for 6 consecutive

days. These ESM measurements are performed two times: before and after the intervention. The advantage is that the subjects fill in these diaries during their daily lifes and do not need to come to the lab for this.
At five moments they have to come to the lab for short periods:
The screening (110 min)
Briefing ESM first period (15 min)
Baseline depression questionnaires and debriefing ESM (1 hour)
Briefing ESM second period (15 min)
After 8 weeks: depression questionnaires and debriefing ESM (50 minutes)
Participants will have to come to additional follow-up meetings 6 and 12 months after the MBCT training (30 minutes each).
Also at baseline some saliva will be taken from the subjects for DNA measurements.

There are no health risks associated with the research.
There is a personal benefit for subjects in that they are offered a free mindfulness training that is expected to improve their resilience against depression.
There is a scientific benefit in that it leads to greater insight into the biological and psychological factors related to resilience, which will be important for the prevention of depressive disorders in the population.

Contacts

Public
Universiteit Maastricht

Vijverdalseweg 1, concordegebouw, Vijverdal
6200 MD Maastricht
Nederland
Scientific
Universiteit Maastricht

Vijverdalseweg 1, concordegebouw, Vijverdal
6200 MD Maastricht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

i) previous episode of major depressive disorder
ii) residual symptoms: score >7 on the Hamilton Rating Scale for Depression (HAM-D17), for at least two weeks.

Exclusion criteria

i) meeting criteria for current major depressive disorder

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-01-2008
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	26-09-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	03-12-2007
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-02-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL17751.068.07