Psychological, cognitive and neural factors associated with distinct profiles of mood change following the dissolution of a romantic relationship

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We investigate: (1) whether young women can be grouped according to distinct trajectories of depressive symptom change, measured with the Major Depression Inventory (MDI), over a period of 8 months following the breakup of a romantic relationship; (…

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

Summary

ID

NL-OMON48640

Source
ToetsingOnline

Brief title
Romantic relationship breakup and mood changes

Condition

- Mood disorders and disturbances NEC

Synonym
emotional state, mood

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: donatie particulier

Intervention

Keyword: breakup, depression, heartbreak, mood

Outcome measures

Primary outcome

The primary study parameters are listed for each of our six objectives. (1) MDI scores, measured every two weeks (2) cognitive control ability, measured three times during the study (3) neural processing of reward and punishment during the Monetary Incentive Delay (MID) task in the fMRI scanner (4) brain activity and FC during resting-state fMRI scanning, (5) rumination scores and resting-state FC data (6) resting-state fMRI data collected both before and after the task-based fMRI scanning session.

Secondary outcome

Secondary outcomes of objective 2 will be trait rumination and degree of neuroticism. The secondary outcome of objective 3 will be behavioral performance during the MID task.

Study description

Background summary

Upsetting life-events are known to be risk factors for the development of depressive symptoms. Possibly, individual differences in coping with upsetting events can (partly) explain individual differences in vulnerability for developing depressive symptoms. Mediating aspects previously suggested comprise personality factors including rumination and neuroticism, cognitive control and reward-related processes, as well as aberrant brain functional connectivity (FC), specifically in the default mode network (DMN) and task-control related networks. In this study, we will use subjects with a recent romantic

relationship breakup as an experimental human model. Studying people who have just experienced the breakup of a relationship will allow us to investigate mood disturbances, and associated brain alterations, in individuals without a psychiatric disorder. This way, we can provide new insights into factors that play a role in dealing with upsetting events and vulnerability factors for the development of depressive symptoms.

Study objective

We investigate: (1) whether young women can be grouped according to distinct trajectories of depressive symptom change, measured with the Major Depression Inventory (MDI), over a period of 8 months following the breakup of a romantic relationship; (2) effects of trait rumination and neuroticism on cognitive control abilities among the different trajectory groups; (3) whether processing of reward and punishment can be seen as a marker of the different trajectory groups; (4) to what extent patterns of brain activity can be used to distinguish group trajectory membership; (5) differences in rumination-related brain activity patterns across trajectory groups and to what extent these differences can be explained by rumination trait, rumination state or both; (6) the impact and/or confound of task-related effects on the participants` baseline resting-state.

Study design

We will follow subjects with a recent relationship breakup for a period of 30 weeks and assess symptoms of depression over time. Subjects come three times to our laboratory to fill in questionnaires and perform cognitive tasks. The last visit includes an fMRI scanning session. In between the three visits, subjects will complete a brief online questionnaire concerning depressive symptoms every two weeks.

Study burden and risks

Subjects will fill in questionnaires and perform cognitive tasks during three visits in this study. In addition, subjects will receive an invitation to a brief online questionnaire every two weeks. During the last visit, subjects will also undergo MRI scanning. During the fMRI session, subjects perform the MID task and undergo scanning while resting. Time inside the fMRI scanner will be approximately 50 minutes. The study will not entail more than minimal risk to the subjects. Concerning the fMRI scanner, subjects will be exposed to a field strength of 3 Tesla and to the noise of the scanner. Thus far, there is no evidence to suggest that exposing humans to a magnetic field of this strength has any negative influence on health. With regard to the noise, earplugs will be provided. The study is not intended to benefit the subjects directly. However, the data collected during this study will enhance our understanding of coping with upsetting events and vulnerability factors for the

development of depressive symptoms. Subjects involved in the study will receive a compensation of ¤75 at the end of the last visit. Subjects who decide to withdraw from the study will receive financial compensation on a pro rata basis. Compensation for questionnaire administration and cognitive task performance will be ¤9 per hour. Compensation for MRI scanning will be ¤20. Furthermore, an additional compensation for travel expenses will be made available, if necessary.

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

Age between 18 and 35 years
Caucasian ethnicity
Heterosexual

Right-handed
Dutch as a native language
Dissolution of a romantic relationship in the preceding two months at the time of giving written informed consent
Relationship duration (prior to breakup) of at least six months

Exclusion criteria

Presence of a neurological disorder (such as epilepsy)
Presence of a psychiatric disorder
Vision problems that cannot be corrected
(suspected) Pregnancy
Claustrophobia
MR incompatible implants or objects in the body
Tattoos containing pigments that form a safety risk
The refusal to be informed of structural abnormalities that could be detected during the experiment

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2018
Enrollment:	130
Type:	Actual

Ethics review

Approved WMO

Date:	08-10-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	14-12-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-07-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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: 25623
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL66208.042.18
Other	NTR candidate number: 29251
OMON	NL-OMON25623