Self-Management of Altered environmental Reactivity Training SCANning.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24727

Source
NTR

Brief title
SMARTSCAN

Health condition

Young people in the earliest phase of expression of psychopathology

Sponsors and support

Primary sponsor: Sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Academisch Ziekenhuis Maastricht
Stichting de Weijerhorst

Intervention

Outcome measures

Primary outcome

Neuroimaging effects:

The primary outcome measure in the intervention study is the pre/post intervention change of fMRI BOLD signal in the regions of interest involved in aversive learning, in reward learning and in anticipation of reward.

The primary outcome measure in the observational study is the pre/post follow-up period change of fMRI BOLD signal in the regions of interest involved in aversive learning, in reward learning and in anticipation of reward.

Secondary outcome

Secondary outcomes:

1. Reward experience;

2. Stress reactivity and salience reactivity as measured with ESM;

3. Cross-sectional associations between fMRI and ESM and psychopathology.

Ancillary outcomes:

Changes in depression, psychosis and fear psychopathology scores.

Study description

Background summary

Rationale:

Young people form over 25% of the world population, and it is during this phase of life that mental disorders form the largest cause of “years lost because of disability”. Self-management interventions for young people in the earliest phase of expression of psychopathology are urgently required, but remain underdeveloped.

Objective:

By relating valid learning fMRI phenotypes to the earliest expression of psychopathology and response to non-pharmacological self-management training, the project will contribute to the new innovative field of practical neuroimaging in the earliest stages of psychopathology. Neuroimaging may provide us with neural correlates indexing vulnerability for mental disorder, some of which will be detectable already at the preclinical stages in the general

population. There is an urgent requirement for novel research approaches helping to operationalize the earliest expression of dysfunction, and elucidate targets for novel self-management approaches, which is what the current project sets out to do. This knowledge is essential for understanding the neural basis and early self-management of mental disorders across the age range.

Study design:

Two complementary randomized controlled trials (RCT's) in two samples of individuals with sub-diagnostic high levels of psychopathology and a parallel observational study in a sample of individuals with no/low levels of psychopathology.

Study population:

Two samples of adolescents / young adults aged 16-25 years with sub-diagnostic, subclinical stage 1b levels of depression and or psychosis (MADRS≥10 and/or CAPE≥12, and GAF<70, following the guidelines of McGorry et al [1] corresponding with approximately 15% of the general population) (n=132), fear (n=66), as well as a comparison group with no/low level of psychopathology (n=50) based on the rating-scores of psychopathology using questionnaires will be studied.

Intervention:

A novel real-life self-management intervention, targeting core vulnerabilities underlying mental disorders using experience sampling methodology (ESM) with versus without feedback will combine (1) "detachment and acceptance" exercises to reduce emotional reactivity to stress and (2) "behavioral activation" to increase motivated behavior.

1. Anxiety Trial: Exposure therapy in the clinical condition of phobia. The control condition consists of relaxation training;

2. Psychosis & Depression Trial: The verum condition consists of a 4 session ACT-training, during 6 weeks of ESM assessments with signals at random time-points to fill out questionnaires, followed by detachment and acceptance exercises, as person-tailored and interactive feedback based on their ESM. The control condition consists of 4 sessions with a group discussion on actualities..

Main study parameters/endpoints:

Primary outcomes: Neuroimaging effects, i.e. structural neuroimaging parameters, and functional neuroimaging BOLD signaling in brain regions of interest involved in aversive learning, in reward learning and in anticipation of reward.

Secondary outcomes: Reward experience, stress reactivity and salience reactivity as measured with ESM, and cross-sectional associations between fMRI and ESM and psychopathology.

Ancillary outcomes: Changes in depression, psychosis and fear psychopathology scores.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Participants will receive an interview and psychometric questionnaires for dimensional assessment of psychopathology. Baseline assessment will include a semi-structured interview for eligibility (MINI, 45 mins),[2] as well as a standard neuropsychological screening (Geestkracht-protocol, 90 mins) Participants will additionally receive a pre-and post intervention PANSS+MADRS interview (45 minutes). Furthermore, participants will be asked to fill in a questionnaire booklet (fill-in time 45mins) covering several domains of psychological, social and physical (dis)functioning. Furthermore, participants will be asked to participate in pre- and post fMRI neuroimaging sessions (ca. 60 minutes, containing neuropsychological tests assessing fear learning, reward learning and anticipation of reward). Furthermore, participants will be asked to let us draw six bloodsamples pre- and post-intervention for epigenetic analyses. Venapuncture is optionally and has no consequences on participating in the intervention. After inclusion in the trial all subjects will assess using PsyMate® over a period of 21 days, their own feelings and symptoms in the context of real life and provide information regarding these contexts (social context, activities they are involved in, location), as well as appraisals of the environment. After baseline, participants will be allocated to either the verum or control-condition. High-fear participants will be allocated to either therapy (i.e. exposure in vivo and modelling with a total duration of 4–5 hours supervised by an experienced psychiatrist and cognitive behavioural therapist in small groups (3-5 persons) or to the comparison condition consisting of relaxation therapy.

Participants with subdiagnostic, subclinical stage 1b levels of depression and / or psychosis will all receive a short 4 training session Acceptance and Detachment training (ACT) as described and tested by Bach & Hayes, to learn them ACT exercises.[3] Participants in the experimental arm will continue to do PsyMate® assessments over a period of 6 weeks for 3 days a week including ACT-exercises. During the first 3 weeks of PsyMate® training, participants will also receive feedback on how daily life activities, events and social situations relate to momentary affective responses. Feedback will be given weekly, after each 3-day assessment period (thus 6 feedback moments). The feedback will be given verbally, written and graphically in clear pie charts and bar graphs, according to a standardized protocol. Participants allocated to the control arm will follow the 6 week PsyMate® assessment without the training exercises. After the intervention all participants will do the same psychometrical test battery again, a final 21-day PsyMate® assessment, and a fMRI neuroimaging session,

using the same neuropsychological tasks assessing fear learning, reward learning and reward anticipation.

The total burden of time required for participants with no or low psychopathology will therefore be 9 hours. The number of visits to the research site will be 11 times in total.

The total burden of time required in participating therefore in the high-fear participants is: 14 hours. The number of visits to the research site will be 12 times in total.

For the subsample with subclinical depression / subclinical psychosis, the total time investment required for participation in the study is: 18 hours. The number of visits to the research site will be 13 times in total.

The burden of PsyMate assessments is: filling in a short questionnaire (fill-in time 1 à 2 min) at 10 random beeps during the day.

The benefit of this new training intervention, extending the psychotherapy beyond the clinical setting targeting real-world and real-time person-environment interactions may prove to be a powerful intervention for patients in mental disorder. ESM-based interventions are based on providing the individual with targeted feedback from patterns of reactivity in daily life, enabling the individual to identify and remedy dysfunctional patterns of reactivity in response to environmental challenges. In our laboratory, several ESM-based psychotherapies incorporating techniques from ACT and Mindfulness are being developed and several randomized controlled trials with ESM-based psychotherapies are currently being developed. In addition, the current project would lay the ground for evaluation of how changes induced by ESM-based therapies and training are mediated by changes in fMRI phenotypes of neural learning and salience measures (possibly providing a basis for novel pharmacological interventions), as well as of experimental psychology tasks of these (possibly providing the basis for novel psychological therapies).

The project will therefore contribute to the elucidation of alterations in brain function that are predictive of psychopathology and thus may contribute to the knowledge base required for the development of novel treatment and preventive strategies. On the individual level, participants will learn on dealing with their complaints, and possibly reduce their risk of developing more severe complaints. Participants receive a maximum of 100,- euro in vouchers, and will be compensated for any travel expences.

Study objective

Young people form over 25% of the world population, and it is during this phase of life that mental disorders form the largest cause of “years lost because of disability”. Self-management interventions for young people in the earliest phase of expression of psychopathology are urgently required, but remain underdeveloped.

By relating valid learning fMRI phenotypes to the earliest expression of psychopathology and

response to non-pharmacological self-management training, the project will contribute to the new innovative field of practical neuroimaging in the earliest stages of psychopathology. Neuroimaging may provide us with neural correlates indexing vulnerability for mental disorder, some of which will be detectable already at the preclinical stages in the general population. There is an urgent requirement for novel research approaches helping to operationalize the earliest expression of dysfunction, and elucidate targets for novel self-management approaches, which is what the current project sets out to do. This knowledge is essential for understanding the neural basis and early self-management of mental disorders across the age range.

Study design

1. Participants with fobia:

T0 (psychometry + fMRI) --> 21 days preassessment with ESM + 1 day exposure / relatation -> 21 days T1 posttreatment assessment (fMRI + psychometry);

2. Participants with psychosis/depression:

T0 (psychometry + fMRI) --> 21 days preassessment with ESM + 6 weeks ACT / discussion group -> 21 days T1 posttreatment assessment (fMRI + psychometry).

Intervention

1. Psychosis & Depression Trial: The verum condition consists of a 4 session ACT-training, during 6 weeks of ESM assessments with signals at random time-points to fill out questionnaires, followed by detachment and acceptance exercises, as person-tailored and interactive feedback based on their ESM. The control condition consists of 4 sessions with a group discussion on actualities;

2. Anxiety Trial: Exposure therapy in the clinical condition of phobia. The control condition consists of relaxation training.

Contacts

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Eligibility criteria

Inclusion criteria

Two samples of adolescents / young adults aged 16-25 years with sub-diagnostic, subclinical stage 1b levels of depression and or psychosis (MADRS≥10 and/or CAPE≥12, and GAF<70, following the guidelines of McGorry et al [1] corresponding with approximately 15% of the general population) (n=132), fear (n=66), as well as a comparison group with no/low level of psychopathology (n=50) based on the rating-scores of psychopathology using questionnaires will be studied.

Exclusion criteria

Exclusion criterion is receiving a current psychological or psychiatric treatment or significant need for care. Contra-indications for (f)MRI are use of pacemaker, metal implants, pregnancy or a history of claustrophobia. Past recovery from depression, psychosis or anxiety disorder is not an exclusion criterion as this would not impact the outcome measures.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2013
Enrollment:	198
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 43911
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3662
NTR-old	NTR3808
CCMO	NL41929.068.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON43911

Study results

Summary results
N/A