Novel Self-management Techniques for Early Expression of Psychopathology: An Experimental Study Linking Neural and Mental State Reactivity Phenotypes: SMARTSCAN (Self-Management of Altered environmental Reactivity Treatment SCANning)

Published: 13-02-2013
Last updated: 19-03-2025

By relating valid learning fMRI phenotypes to the earliest expression of psychopathology and response to non-pharmacological self-management treatment, the project will contribute to the new innovative field of practical neuroimaging in the earliest...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Adjustment disorders (incl subtypes)
Study type	Interventional

Summary

ID

NL-OMON43911

Source
ToetsingOnline

Brief title
SMARTSCAN

Condition

- Adjustment disorders (incl subtypes)

Synonym
psychosis or fear, stage 1b subdiagnostic levels of depression

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,Stichting De Weijerhorst

Intervention

Keyword: experience sampling methodology, neuroimaging, psychopathology, self-management therapy

Outcome measures

Primary outcome

The neuroimaging effects, i.e. structural neuroimaging, and functional

neuroimaging analyzing BOLD signaling in brain regions of interest involved in

aversive learning, in reward learning and in anticipation of reward learning.

Secondary outcome

Reward experience, stress reactivity and salience reactivity as measured with

Experience sampling methodology.

Ancillary outcomes: changes in depression, psychosis and fear psychopathology

scores.

Study description

Background summary

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.

Study objective

By relating valid learning fMRI phenotypes to the earliest expression of psychopathology and response to non-pharmacological self-management treatment, 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

Three complementary randomized controlled trials (RCT*s) in three samples of individuals with level 1b / sub-diagnostic high levels of psychopathology.

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) *behavioural activation* to increase motivated behaviour.
• Anxiety Trial: exposure therapy in the clinical condition of phobia. The Control condition consists of educational support treatment, or a waiting list control group.
• Psychosis & Depression Trial: The Verum condition consists of a 5 session ACT-training, then 6 weeks for 3 days a week 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 Discussion Groups + ESM without exercises or feedback in addition.

Study burden and risks

Subjects will receive an interview and psychometric questionnaires for dimensional assessment of psychopathology. Baseline assessment will include a semi-structured interview for eligibility (Mini-D, 45 mins). Participants will additionally receive a pre-and post intervention 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, participating patients will be asked to

participate in pre- and post fMRI neuroimaging sessions (ca. 120 minutes, containing neuropsychological tests assessing fear learning, reward learing and anticipation of reward). Furthermore, participating subjects will be asked to let us draw pre- and postintervention four bloodsamples 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 15 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 placebo condition. High-fear subjects will be allocated to either therapy (i.e. exposure in vivo and modelling) lasting 4-5 hours supported by an experienced psychiatrist and cognitive behavioural therapist in small groups (3-5 persons) or to the comparison condition consisting of educational support treatment. High subclinical depression or high subclinical psychosis subjects will all receive a short 5 therapy session Acceptance and Commitment training (ACT) as described and tested by Bach & Hayes, to learn them ACT exercises. 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 6 weeks of PsyMate® treatment, high-symptom subjects 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. Subjects allocated in the control arm will so the 6 week Psymate® assessment without the therapy exercises. After the intervention all subjects will do a shorter psychometrical test battery again, a final 7-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 subjects with no or low psychopathology will therefore be: 15 hours.
The total burden of time required in participating therefore in the high-fear subjects is: 20 hours (excl PsyMate-time).
The total burden of time required in participating therefore in the subclinical depression or subclinical psychosis subjects is: 21 hours excl PsyMate-time.
The benefit of this new therapeutic intervention, extending the psychotherapy beyond the clinical setting targeting real-world and real-time person-environment interactions may prove to be a powerful treatment 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 Acceptance and Commitment Therapy 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 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.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

Vijverdalseweg 1
Maastricht 6226NB
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

Vijverdalseweg 1
Maastricht 6226NB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All subjects for the adolescent/young adult sample will be Dutch speaking and aged 16-25 years.
Inclusion criteria for high-fear subject sample is the presence of a specific phobia, diagnosed prior to the experiment using a structured psychiatric interview (Mini International Neuropsychiatric Interview, MINI).[25]
Inclusion criteria for the stage 1b high-depression and psychosis subject sample are stage 1b psychopathology of depressive and or psychotic symptomatology, which is defined as moderate but subthreshold symptoms of depression using the Montgomery-Asberg Depression Rating Scale (MADRS) with a cut-off score = 10, AND/OR subthreshold symptoms of psychosis using the Community Assessment of Psychic Experiences (CAPE) with a cut-off score = 10, with moderate neurocognitive changes and functional decline to caseness (Global Assessment of Functioning [GAF] < 70).[28] Subjects with a minor depression according to DSM-IV will be included. Depression and psychosis subjects will be included at the inclusion phase as if one sample, because of the expected high co-occurrence of above cut-off scores on the CAPE and MADRS in the same subjects.
Inclusion criteria for the the low-no psychopathology subjects are absence or below threshold severity of symptomatology, which is defined as scores below 7 on the MADRS and below 10 on the CAPE and a STAI score < 44, and GAF > 70, without a psychiatric history.

Exclusion criteria

Contra-indications for (f)MRI are use of pacemaker, metal implants, pregnancy, left-handedness or a history of claustrophobia.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-10-2013
Enrollment:	248
Type:	Actual

Ethics review

Approved WMO Date:	13-02-2013
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	19-05-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-03-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	27-07-2016
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

ID: 24727
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL41929.068.12
Other	NTR-code 14248
OMON	NL-OMON24727

Study results

Date completed:	30-06-2018
Actual enrolment:	199