Versterken van eigen emotionele veerkracht tijdens behandeling met antidepressiva.

No registrations found.

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

Summary

ID

NL-OMON25509

Source
Nationaal Trial Register

Brief title
REMOD-ID

Health condition

depression (depressie)

Sponsors and support

Primary sponsor: J.J. Van Os, head of department Psychiatry & Neuropsychology, University of Maastricht
Source(s) of monetary or material Support: Zon-Mw

Intervention

Outcome measures

Primary outcome

Main outcomes are pre-post intervention change in:

1. Depressive symptomatology;

2. Daily life emotional experience (in terms on NA
and PA) and person-context interaction;

3. Pre-post intervention
change on the empowerment questionnaire;

4. Health care
comsumption and costs. In addition, long-term outcome will be examined.

Secondary outcome

1. Change in daily life emotional dynamics during the intervention
period will be examined in association with future course of depressive
symptomatology;

2. Can individual differences in both the effect of
feedback on daily life person-context interaction and the predictive
value of these daily life emotional dynamics be traced back to genetic
variation in polymorphisms related to the brain reward system.

Study description

Background summary

Rationale:
Recent evidence indicates that individual daily life
person-context interactions determine vulnerability for depression, and
predict relapse as well as recovery. We hypothesize that momentary
assessment technology (with the Psy-mate) to monitor these daily life
person-context interactions during treatment will enrich passive
antidepressant pharmacotherapy with an active resource-mobilising
psychotherapeutic context, thus enhancing therapeutic efficacy (reducing
symptoms and relapse rate).

Objective:
(1) Does feedback on continuous
monitoring with the Psy-mate during pharmacotherapy result in a better
treatment response (immediate and follow-up reductions of depressive
symptoms, decreased relapse risk)? (2) Do measurements of daily life
person-context interactions improve the prediction of future courses of
depressive symptoms? (3) Can individual differences in (1) the effect of
feedback on daily life person-context interaction and (2) the predictive

value of these person-context interactions be traced back to genetic differences?

Study design:
Randomized clinical trial with three groups
of 40 subjects each (2 experimental groups and 1 control group). The first group receives a 5-day pre- and post Psy-mate assessment and a continuous Psy-mate assessment (3 days of Psy-mate measurements during a 6-weeks period) with weekly feedback (to both patient and therapist) during treatment as usual (TAU). The second group also receives a 5-day pre- and post Psy-mate assessment and a continuous Psy-mate assessment (3 days of Psy-mate measurements during a 6-weeks period) but without feedback during treatment as usual (TAU). The third group receives a 5-day pre- and post Psy-mate assessment but no additional intervention during TAU. This is the control group.

Study population:
A sample of
patients (n=120) with a depressive disorder will be recruited within (i) SEARCH, the research network of mental health institutions within Limburg and South-Brabant, The Netherlands, (ii) general practices and (iii) the general population.

Intervention (if applicable):
The Psy-mate
is a recently developed wearable interactive palmtop suitable for the Experienced Sampling Method (ESM) to study subjects in their daily life. The intervention group receives feedback on Psy-mate measurements of the experience of positive emotions in daily life.

Main study
parameters/endpoints:
The rate of change in reward experience measured
with the Psy-mate, and the change in depression symptomatology measured with the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I) and the Hamilton Depression Rating Scale (HDRS).

Study objective

1. Individualized feedback on the experience of positive emotions in daily life situations (activities, events and social interactions) increases the ability of patients to generate positive emotions. In addition, we hypothesize therefore that the feedback condition combined with antidepressant treatment compared to antidepressant treatment alone is more effective in reducing immediate and follow-up depressive symptomatology and future relapse;

2. Giving individualized feedback on relevant daily life person-context interactions during pharmacotherapy is cost-effective compared to treatment as usual;

3. Measurement of relevant dynamic daily life behaviours significantly contributes to the prediction of the future course of depressive symptomatology;

4. Individual differences in (i) the effect of feedback on daily life person-context interactions and (ii) the predictive value of these person-context interactions can be traced back to genetic differences;

5. Subjects who receive feedback on their experience of positieve emotions in daily life will develop an increase in feelings of empowerment compared to subjects who do not receive feedback.

Study design

Screening:

Hamilton Depression Rating Scale (HAM-17), Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I), personality inventory (NEO-PI), Interview for depression symptomatology (IDS), trauma (Childhood Trauma Questionnaire and Recent life Event Scale), PRODISQ, TiC-P, Euroquol-5D and a saliva sample.

Baseline:
5 days of measurement with the Psy-mate, and after completion of this period: the depression part of the SCID-I, the HAM-17, and the IDS.

Intervention period (week 2 to 8):

1. Intervention group: 3 days/week during a 6 week period of Psy-mate measurements combined with weekly feedback during treatment as usual (TAU);

2. Control group 1: 3 days/week during a 6 week period of Psy-mate measurements without weekly feedback during TAU;

3. Control group 2: no Psy-mate measurements, no feedback during TAU.

At the end of the intervention period, all 3 groups have to complete the depression part of the SCID-I, the HAM-17, the IDS, and the Empowerment questionnaire.

Post intervention measurement:
5 days of measurement with the Psy-mate, and after completion of this period: the depression part of the SCID-I, the HAM-17, and the IDS.

Follow-up measurements:

1. 4 weeks after the intervention period: the depression part of the SCID-I, the HAM-17, and the IDS;

2. 8 weeks after the intervention period: the depression part of the SCID-I, the HAM-17, and the IDS;

3. 12 weeks after the intervention period:the depression part of the SCID-I, the HAM-17, the IDS, TiC-P, PRODISQ, EQ-5D;

4. 24 weeks after the intervention period:the depression part of the SCID-I, the HAM-17, the IDS, TiC-P, PRODISQ, EQ-5D, Interview for Recent Life Events.

Intervention

The Psy-mate is a recently developed wearable interactive palmtop suitable for the Experience Sampling Method (ESM) to study subjects in their daily life. The intervention group receives feedback on Psy-mate measurements of positive affect in their daily life.

Contacts

Public
Universiteit Maastricht
Capaciteitsgroep Psychiatrie en Neuropsychologie, UM/FHML
Locatie Vijverdal, SN-gebouw
Postbus 616

Marieke Wichers
Maastricht 6200 MD
The Netherlands
+31-43 - 36 88 669
Scientific
Universiteit Maastricht
Capaciteitsgroep Psychiatrie en Neuropsychologie, UM/FHML
Locatie Vijverdal, SN-gebouw
Postbus 616

Marieke Wichers
Maastricht 6200 MD
The Netherlands
+31-43 - 36 88 669

Eligibility criteria

Inclusion criteria

1. 18-65 years;

2. DSM IV diagnosis of current major depressive disorder or a past DSM-IV diagnosis of major depression with residual symptoms (HAM-17>7);

3. Use of antidepressants or moodstabilizers;

4. Adequate vision;

5. Sufficient Dutch language skills.

Exclusion criteria

No (hypo) manic or mixed episode within the past month.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2010
Enrollment:	120
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date:	31-08-2009
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	NL1862
NTR-old	NTR1974
Other	METC Unimaas : M09-1935
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A