An exploratory study to biotype adult patients with unipolar depression using digital technologies

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Primary Objectives* To characterize patients with unipolar depression in terms of social, physical, biometric activity, and neurophysiological and -psychological data outcomes using digital technologies * Evaluating the feasibility and subjective...

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

Summary

ID

NL-OMON48415

Source
ToetsingOnline

Brief title
Digital biotyping of patients with unipolar depression

Condition

- Mood disorders and disturbances NEC

Synonym
Unipolar depression; Depression

Research involving
Human

Sponsors and support

Primary sponsor: Centre for Human Drug Research
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Biotyping, Unipolar depression

Outcome measures

Primary outcome

Primary endpoint

* Patients and healthy controls will be characterized using the following data,

as collected by digital technologies:

o Social activity

- Voice activation (probability of human voices in proximity)

- Phone (length of call, last 3 digits of phone number, number known/unknown)

- SMS (amount of characters, last 3 digits of phone number, number

known/unknown)

- App usage (categories of apps, start time, running in background/foreground)

- Light sensor (lm)

o Physical activity

- Acceleration

- Gyroscope

- Magnetic field

- Step count

- Google Places

- Relative location

o Neurocart:

- Saccadic eye movements:

* Saccadic reaction time (second),

* Saccadic peak velocity (degrees/second), and

* Saccadic inaccuracy (%);

- Smooth pursuit eye movements:

* Percentage of time the eyes of the subjects are in smooth pursuit of the

target (%);

- N-back

* Number correct words * number incorrect words / total number of words

- Pupillometry

* Pupil size (mm)

- Body sway:

* Antero-posterior sway (mm);

- Adaptive tracking:

* Average performance (%);

- Visual Analog Scales (VAS) according to Bond and Lader:

* Mood (mm),

* Alertness (mm), and

* Calmness (mm)

- Visual Analog Scales (VAS) according to Bowdle:

* Internal (mm)

* External (mm)

o Biometric data collected using the Withings Health platform:

- Withings Steel HR smartwatch

* Sleep pattern

* Heart rate data

* Physical activity (steps, walking distance)

- Withings Body+ scale

* Weight

* Body composition

- Withings Blood Pressure Monitor

* Systolic blood pressure

* Diastolic blood pressure

* User experience and subjective burden of the smartphone-based technologies

will be assessed with a questionnaire.

Secondary outcome

Secondary endpoints

* Questionnaires assessing subjective mood, anxiety and stress symptoms:

o Structured Interview for the Hamilton Rating Scale for Depression (SIGH-D)

o Positive Affect and Negative Affect Schedule (PANAS)

o Depression Anxiety Stress Scales (DASS)

o Columbia Suicide Severity Rating Scale (C-SSRS)

Exploratory endpoints

Discriminating features in voice recordings as recorded by the REMOS active

voice recording module.

Study description

Background summary

The pharmacological treatment of unipolar mood disorders with currently available antidepressant drugs is characterized by (partial) ineffectiveness. A

significant proportion of patients with major depressive disorder (MDD) are considered treatment resistant since they fail to recover despite (sequential) treatment with therapeutic doses of monoamine modulating drugs and various augmentation strategies with lithium and/or second generation antipsychotic drugs. Treatment resistance is even more prevalent in more chronic forms of the illness such as dysthymia or persistent depressive disorder. At the same time, patients who do achieve symptomatic relief often experience burdensome adverse effects related to antidepressant drugs or residual mood symptoms. Taken together, the development of more effective antidepressant drugs with favourable side-effect profiles is needed.

Study objective

Primary Objectives
* To characterize patients with unipolar depression in terms of social, physical, biometric activity, and neurophysiological and -psychological data outcomes using digital technologies
* Evaluating the feasibility and subjective burden of remote monitoring in patients with unipolar depression using smartphone-based technologies.
Secondary Objective
* To correlate social, physical, biometric activity, and neurophysiological and -psychological data outcomes, and *gold standard* psychometric questionnaires in patients with unipolar depression.
Exploratory Objective
* To characterize the mood of patients with unipolar depression in terms of audio features as recorded by the active audio recording module in the REMOS application.

Study design

The study will be a cross-sectional, non-interventional study with two subject groups for a duration of 3 weeks:
* Subject group 1: patients with unipolar depression according to the Diagnostic and Statistical Manual of Mental Disorders (DSM), 4th or 5th edition (n=30)
* Subject group 2: healthy, age and sex-matched controls (n=30)

Study burden and risks

There is no benefit expected for subjects participating in this study and no or minimal risk (blood withdrawals) is anticipated. Patients will be carefully evaluated to assess whether it would be desirable and safe for them for participate. The evaluation will be based on the severity of depressive symptoms and the presence of suicidality, previous psychiatric history and information provided by their attending psychiatrist, general practitioner or

clinical psychologist.

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

Patients:
1. Written informed consent must be obtained before any assessment is performed.
2. Males and females, age 18 to 65 years (inclusive).
3. Body mass index (BMI) between 18 and 32 kg/m2.
4. Primary diagnosis of moderate to severe major depressive disorder (MDD) without psychotic features or persistent depressive disorder (PDD)/dysthymia according to the DSM-IV or DSM-5, as diagnosed by the attending general practitioner, psychiatrist or clinical psychologist and confirmed with the Mini International Neuropsychiatric Interview (MINI) version 7.0.

5. Total MADRS-SIGMA total score of >22 at Screening.
6. Meeting one of the following conditions;
o no treatment with mono-aminergic antidepressant drugs (SSRI, SNRI, mirtazapine, TCA, MAO-I) and/or lithium for at least 2 weeks (6 weeks for fluoxetine) before Screening; or
o treatment with mono-aminergic antidepressant drugs (SSRI, SNRI, mirtazapine, TCA, MAO-I), with or without lithium, at a stable dose for at least 4 weeks prior to Screening (6 weeks for fluoxetine)
7. Must read and speak Dutch as a first or second language.
8. Able to comply with the study procedures, prohibitions and restrictions (drug and alcohol use) as specified in the protocol.
9. Android-based smartphone with Android version 5.0 or higher.;Healthy volunteers:
1. Written informed consent must be obtained before any assessment is performed.
2. Male or female subjects, 18 to 65 years (inclusive).
3. Body mass index (BMI) between 18 and 32 kg/m2.
4. Must read and speak Dutch as a first or second language.
5. Able to comply with the study procedures, prohibitions and restrictions (drug and alcohol use) as specified in the protocol.
6. Android-based smartphone with Android version 5.0 or higher.

Exclusion criteria

Patients:
1. Current or previously diagnosed psychotic disorder, bipolar disorder, mental retardation, cluster B personality disorder (i.e. borderline, antisocial, narcissistic or histrionic personality disorders).
2. Clinically significant suicidality within the past 6 months as demonstrated with the C-SSRS or as judged by the investigator.
3. Use of sedative medication started within 2 weeks before Visit 1 and/or daily use of benzodiazepines with a dose equivalent of more than 10 mg Diazepam.
4. Foreseeable alterations in the dose of mono-aminergic antidepressant drugs (SSRI, SNRI, mirtazapine, TCA, MAO-I) and lithium during the course of the study.
5. Positive alcohol breath test or urine test for drugs of abuse at Screening (positive urine test for benzodiazepines is allowed) or a current diagnosis of substance use disorder (including alcohol but excluding nicotine), or previous substance use disorder (including alcohol but excluding nicotine) within the past 12 months according to DSM-IV or DSM-5.
6. Evidence of any active or chronic disease or condition that could interfere with the conduct of the study.
7. Positive urine *-human chorionic gonadotropin (*-hCG) pregnancy test at Screening in women of childbearing potential.
8. Wearing a pacemaker or other internal medical device (e.g. Vagus nerve stimulation (VNS), Deep Brain Stimulation (DBS)).
9. Current enrollment in another study.;Healthy volunteers:
1. Current or previous clinically relevant history or family history of psychiatric disorders, neurological disorders or neurosurgery.
2. Positive alcohol breath test or urine test for drugs of abuse at Screening or a current

diagnosis of substance use disorder (including alcohol but excluding nicotine) or previous substance use disorder (including alcohol but excluding nicotine) within the past 12 months according to DSM-IV or DSM-5.
3. Evidence of any active or chronic disease or condition that could interfere with the conduct of the study.
4. Clinically significant abnormalities, as judged by the investigator, in laboratory test results (including hepatic and renal panels, complete blood count, chemistry panel and urinalysis). In the case of uncertain or questionable results, tests performed during Screening may be repeated before inclusion to confirm eligibility or judged to be clinically irrelevant for healthy subjects.
5. Use of any medications (prescription or over-the-counter [OTC]), within 14 days of Visit 1, or less than 5 half-lives (whichever is longer). An exception is paracetamol (up to 2 g/day). Other exceptions will only be made if the rationale is clearly documented by the investigator.
6. Positive urine *-human chorionic gonadotropin (*-hCG) pregnancy test at Screening in women of childbearing potential.
7. Wearing a pacemaker or other internal medical device (e.g. Vagus nerve stimulation (VNS), Deep Brain Stimulation (DBS)).
8. Current enrollment in another study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-01-2019
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	05-12-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	01-02-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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: 23849
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL67989.056.18