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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23849

Source
Nationaal Trial Register

Brief title
CHDR1837

Health condition

Patients with unipolar depression (Major Depressive Disorder/Persistent Depressive Disorder).

Sponsors and support

Primary sponsor: Centre for Human Drug Research
Source(s) of monetary or material Support: Centre for Human Drug Research

Intervention

Outcome measures

Primary outcome

• Patients and healthy controls will be characterized using the following data, as collected by digital technologies:
• Social activity

o Voice activation (probability of human voices in proximity)
o Phone (length of call, last 3 digits of phone number, number known/unknown)
o SMS (amount of characters, last 3 digits of phone number, number known/unknown)
o App usage (categories of apps, start time, running in background/foreground)
o Light sensor (lm)
• Physical activity
o Acceleration
o Gyroscope
o Magnetic field
o Step count
o Google Places
o Relative location
• Neurocart:
o Saccadic eye movements:
- Saccadic reaction time (second),
- Saccadic peak velocity (degrees/second), and
- Saccadic inaccuracy (%);
o Smooth pursuit eye movements:
- Percentage of time the eyes of the subjects are in smooth pursuit of the target (%);
o N-back
- Number correct words – number incorrect words / total number of words
o Pupillometry
- Pupil size (mm)
o Body sway:
- Antero-posterior sway (mm);
- Adaptive tracking:
- Average performance (%);
o Visual Analog Scales (VAS) according to Bond and Lader:
- Mood (mm),
- Alertness (mm), and
- Calmness (mm)
o Visual Analog Scales (VAS) according to Bowdle:
- Internal (mm)
- External (mm)
• Biometric data collected using the Withings Health platform:
o Withings Steel HR smartwatch
o Sleep pattern
o Heart rate data
o Physical activity (steps, walking distance)
o Withings Body+ scale
- Weight
- Body composition
o 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

• 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)

Study description

Background summary

The study will be a cross-sectional, non-interventional study with two subject groups for a duration of 3 weeks:
o Subject group 1: Dutch patients with unipolar depression according to the Diagnostic and Statistical Manual of Mental Disorders, 4th or 5th edition (DSM-IV or DSM-5) (n=30)
o Subject group 2: Dutch healthy, age (± 6 months) and sex-matched controls (n=30)
30 patients with unipolar depression and 30 healthy controls who own and use an Android based smartphone on a daily basis will be included in this study. Subjects are instructed to download the REMOS application, designed to continuously collect phone sensor data and phone usage data in a non-clinical setting, to wear the Withings Steel HR smartwatch, and to use the Withings Body+ scale and Withings Blood Pressure monitor to collect biometric data for 3 weeks. The study period of 3 weeks was chosen to also include 1 week of “getting used” to the smartphone-based remote monitoring technologies.

Study objective

To characterize patients with unipolar depression in terms of social, physical, biometric activity, and neurophysiological and -psychological data outcomes using digital technologies

Study design

• Screening (up to day -28)
• Visit 1 (day 1)
• Visit 2 (day 8)
• Visit 3 (day 15)
• Visit 4 EOS (day 22)

Intervention

N.A., non-interventional study

Contacts

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Eligibility criteria

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 score of >22 at Screening.
6. Meeting one of the following conditions;
o no treatment with 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 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 antidepressant drugs (SSRI, SNRI, mirtazapine, TCA, MAO-I) or 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 β-human chorionic gonadotropin (β-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 β-human chorionic gonadotropin (β-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 controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-02-2019
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	19-02-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48415
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7532
CCMO	NL67989.056.18
OMON	NL-OMON48415

Study results