Neurological MRI-based biomarkers for treatment navigation in depression

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Identification of MRI-based biomarkers to predict clinical outcome of major depressive disorder in comparison with healthy controls. Outcome is defined by level of depressive and cognitive symptomatology and related comorbidity.

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

Summary

ID

NL-OMON55072

Source
ToetsingOnline

Brief title
Neurotrend

Condition

- Mood disorders and disturbances NEC

Synonym
Major Depressive Disorder, mood disturbance

Research involving
Human

Sponsors and support

Primary sponsor: Technische Universiteit Eindhoven
Source(s) of monetary or material Support: Hobo Heeze. Voor dit project is er een particuliere geldbijdrage van 450 k ¤: 375 k ¤ van Philips en 75 k ¤ van Hobo Heeze, betaald aan de TU/e binnen 30 dagen na aanvang van het project. Dit leidt tot 450 k ¤ * 30% = 135 k ¤ HTSM-gebaseerde projecttoeslag. Een additionele 50 k ¤ op HTSM gebaseerde

PPSprogrammatoeslag, op basis van andere PPS-projecten van de TU/e met de industrie, wordt aan het project besteed. Zie document K6. Consortium agreement Neurotrend studie. ,Philips Research,TKI-toeslag;bijdrage Eindhoven Engine en bijdragen private partijen.

Intervention

Keyword: "Biomarkers", "Longitudinal Study", "Magnetic Resonance Imaging", "Major Depressive Disorder", &bullet

Outcome measures

Primary outcome

- Hamilton Depression Rating Scale (HDRS) scores

- Treatment / medication usage

- MRI metrics (varies per MRI modality, an example is volume per region for a

T1-weighted scan and fractional anisotropy for diffusion-weighted scans).

Secondary outcome

- Scores of psychometric assessments (e.g. STAI-DY1 - anxiety score)

- Scores of cognitive assessments (e.g. average response time for the

eye-tracking task)

Study description

Background summary

Major depressive disorder is a severe neuropsychiatric condition that affects approximately 15% to 18% of people worldwide during their lifetime (Malhi & Mann, 2018). Selection of the optimal treatment is difficult. Usually, a depressive episode is treated first-line with psychotherapy, pharmacotherapy or both in different combinations. When these treatments are ineffective, other treatment options are considered, including more invasive treatments such as electroconvulsive therapy, transcranial magnetic stimulation, or deep brain stimulation. Despite the numerous treatment options, two thirds of MDD patients remain symptomatic after treatment and approximately one third will not achieve remission after finishing four consecutive treatments. (Holtzheimer & Mayberg, 2011; Malhi & Mann, 2018). Several scientific studies indicate that brain

imaging can help in choosing the right treatment for patients with depression (Drysdale et al., 2017; Mayberg, 2003; Mayberg et al., 1999). However, these studies have not taken advantage of the latest development in MRI acquisition techniques (Cohen, Nencka, Lebel, & Wang, 2017; Le Bihan, 2019).

A certain correlation (functional / structural, vascular or a mix of both) is expected between clinical data (obtained from psychometric tests such as the HDRS and psychiatric evaluations) and MRI parameters (functional activity, structural connectivity, anatomical variations, perfusion / diffusion etc.).

Study objective

Identification of MRI-based biomarkers to predict clinical outcome of major depressive disorder in comparison with healthy controls. Outcome is defined by level of depressive and cognitive symptomatology and related comorbidity.

Study design

An independent treating physician will inform a potentially eligible patient and ask whether he/she is interested in voluntary participation in the study. If he/she is interested, the independent treating physician will refer the patient to one of the clinicians from the GGz who is also involved in the Neurotrend study for further steps such as providing the information letter / informed consent and scheduling an intake interview at least one week after receiving all necessary information. Healthy controls will be recruited through public advertisement and via the website www.neurotrend.nl. Pilot subjects will be recruited from the Eindhoven University community and via the website www.neurotrend.nl. Both groups, healthy controls and pilot subjects, will have at least one week to consider and decide on participation.

One week later an intake session will take place in which the inclusion and exclusion criteria will be checked. During this session, patients can also ask questions about the study and the informed consent will be signed if the participant is willing to participate voluntarily in the study. Subsequently at the end of the intake session, a starting (baseline) date will be planned for this participant .

The actual participation starts at baseline. In total, 120 depressed patients and 60 healthy controls will participate in the study. Each participant visits Kempenhaeghe twice, whereby each session, is dedicated to complete questionnaires and cognitive tests, such as memory tasks and eye tracking. In the last hour, the participant will be scanned (MRI). Two weeks before each visit, the participant has to fill in some questionnaires that have been sent to the participant.

Study burden and risks

The participant burden is low and is divided into an intake session and two research sessions. The MRI scan is non-invasive, and subjects can indicate that they want to stop the scan at any time during the scan by squeezing a type of balloon that will lie next to the subject in the case that they feel uncomfortable or for any other reason. Subjects with MRI contraindications (e.g. claustrophobia, pregnancy or implants not suitable for MRI) are already excluded in advance and will therefore not participate in the study at all. Mostly, the subjects will lie still during the scan, except for one affective task in which they will be asked to match different emotional faces for about 5 minutes.The cognitive tests will only consist of memory, reaction speed, attention, and processing speed tasks which in total, do not last more than 30 minutes. The risks of the MRI scanner (CE-marked) are minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Satisfy DSM-5 clinical criteria for MDD (Only acute and subacute duration (0-2 years), for MDD group only)
• Unipolar depression (i.e. no bipolar disorder/mania, for MDD group only)
• Age: 18-65 (m/f)
• Willing and able to provide informed consent and agree that incidental findings are reported

Exclusion criteria

• Concurrent neurological disorders (e.g. epilepsy, stroke, head trauma, etc.)
• Current substance or alcohol abuse
• History of psychosis, bipolar depression, autism spectrum disorder, attention deficit hyperactivity disorder or (mild) intellectual disability
• Contra-indication for MRI: implants, tattoos non-compatible with brain MRI, pregnancy, claustrophobia
• Current or previous treatment with electroconvulsive therapy (ECT), deep-brain stimulation (DBS) or transcranial magnetic stimulation (TMS)
• More than 3 depressive episodes in the past (for MDD group only)
• Has a current episode of MDD or ever had an MDD episode (for healthy control group only)

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:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-07-2021

Enrollment:	180
Type:	Actual

Medical products/devices used

Generic name:	Magnetic Resonance Imaging
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	28-09-2020
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	06-07-2021
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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
CCMO	NL73949.015.20