Ultra-high resolution imaging of the subcortex in major depressive disorder

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A unique and cutting-edge 7T imaging study to unravel subregional perturbations in structure and functional connectivity of deep-lying subcortical systems relevant to MDD pathophysiology.

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

Summary

ID

NL-OMON45813

Source ToetsingOnline

Brief title Deep-lying brain regions and depressive symptoms (URIS-MDD)

Condition

• Mood disorders and disturbances NEC

Synonym clinical depression, major depression

Research involving Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum Source(s) of monetary or material Support: Alliance Grant van Amsterdam Neuroscience

Intervention

Keyword: Depression, Subcortex, Ultra-High Resolution MRI

Outcome measures

Primary outcome

- MRI data on structural/functional properties of deep-lying subcortical brain

regions

- Clinical phenotypes of depression

- (Epi)Genetic data on relevant neurotransmitter systems

Secondary outcome

na

Study description

Background summary

Despite notable advances in recent years, neuropathological mechanisms underlying Major Depressive Disorder (MDD) are still poorly comprehended and this has lagged treatment development significantly. Whereas key subcortical regions and their major subnuclei are theorized in animal and theoretical models of affective psychopathology, commonly available neuroimaging techniques lack the resolution to accurately probe the structural, functional, and connectional integrity of these territories. This tends to preclude a fine-grained, modular understanding of key subcortical brain systems in MDD, and greatly limit translational and clinical utility of findings on the topic. It is anticipated though that the use of ultra-high resolution MRI protocols (*7 Tesla (7T)) will tackle these challenges, and allow for mesoscopic level of detail to formulate more plausible neurobiological models of MDD. Despite its undeniable merits, however, studies employing ultra-high resolution imaging in MDD are largely lacking, owing to the technical and financial resources needed to acquire and operate high field MRI machines.

Study objective

A unique and cutting-edge 7T imaging study to unravel subregional perturbations in structure and functional connectivity of deep-lying subcortical systems relevant to MDD pathophysiology.

Study design

cross-sectional, observational study comparing cases with controles

Study burden and risks

No specific risks are associated to participating in this observational MRI study. The MRI scan employs magnetic field strengths and no from of hazardous radiation is involved. Risk and discomfort associated to the blood draw (venipuncture) may possibly be some slight pain and potential haemorrhage. There is also the possibility of unexpected findings that may not be directly relevant to the study but nonetheless carry significance for the participant's physical and/or mental health. In such cases, the general practitioner of the participant is informed and urged to inform the patient about the finding and take further action. No other significant risks or disadvantages are anticipated.

Contacts

Public Vrije Universiteit Medisch Centrum

Oldenaller 1 Amsterdam 1081 HJ NL **Scientific** Vrije Universiteit Medisch Centrum

Oldenaller 1 Amsterdam 1081 HJ NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

Inclusion criteria patient sample;a) Primary diagnosis of major depression according to DSM-V criteria ;Inclusion criteria healthy control sample;b) No lifetime diagnosis of/treatment for depression or other psychopathology

c) Normal/subclinical scores on dimensional measures of psychopathology

Exclusion criteria

- a) Psychoses, mania, Tourette*s syndrome, obsessive-compulsive disorder
- b) Major internal or neurologic disorder
- c) Traumatic head injury
- d) Current substance abuse or dependence requiring treatment
- e) Evidence of acute suicidal risk requiring intervention
- f) MRI contradictions such as metal implants en claustrophobia
- g) Left-handedness
- h) Pregnancy
- i) Insufficient knowledge of Dutch language

Study design

Design

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

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Primary purpose:

Basic science

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	18-06-2019
Enrollment:	50
Туре:	Actual

Ethics review

Approved WMO	
Date:	21-12-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC

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 CCMO **ID** NL66885.029.18