# Physical and emotional well-being and cognitive functioning: the PREDICT-MR study

Published: 28-09-2010 Last updated: 04-05-2024

We aim to answer the following research questions:Primary:1) Is a history of major depressive disorder associated with smaller volumes of the hippocampus and is this volume reduction disproportionate to the total brain volume?2) Are depression and...

**Ethical review** Approved WMO

**Status** Recruitment stopped

Health condition type Mood disorders and disturbances NEC

**Study type** Observational invasive

## **Summary**

#### ID

NL-OMON36665

#### Source

**ToetsingOnline** 

## **Brief title**

Well-being and cognitive functioning: the PREDICT-MR study

## **Condition**

- Mood disorders and disturbances NEC
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

#### **Synonym**

Depression, mood disorder. Cognitive impairment

## Research involving

Human

## **Sponsors and support**

**Primary sponsor:** Universitair Medisch Centrum Utrecht **Source(s) of monetary or material Support:** NWO

## Intervention

Keyword: Cognition, Depression, Hippocampus, Small vessel disease

## **Outcome measures**

## **Primary outcome**

Outcome variables for research question 1 are the volume of the hippocampus and

total brain volume on MRI.

Outcome variables for research question 2 are the small vessels on MRI.

## **Secondary outcome**

Hypothalamic-pituitary-adrenal (HPA) axis, antidepressant medication, cognitive functioning.

# **Study description**

#### **Background summary**

Depression and cognitive decline are frequently observed and disabling conditions in later life. Evidence exists that persons with major depressive disorder have structural brain abnormalities. One of these brain structures is the hippocampus. In stress-related disorders, such as depression, the regulation of the stress hormone cortisol may be disturbed, which may lead to increased levels of cortisol and damage to the hippocampus. Another potential mechanism is changes in the small vessels in the brain. If these changes occur in mood-regulating brain regions, this could result in mood disorders and cognitive decline.

## Study objective

We aim to answer the following research questions: Primary:

- 1) Is a history of major depressive disorder associated with smaller volumes of the hippocampus and is this volume reduction disproportionate to the total brain volume?
- 2) Are depression and normal aging associated with cerebral small vessel disease?

## Secondary:

- 1) What is the rol of the HPA-axis in the relation between depression and structural brain changes?
- 2) What is the rol of antidepressant medication in the relation between depression and structural brain changes?
- 3) Are the potentially observed structural brain changes associated with cognitive impairment?

## Study design

Cross-sectional observational study.

## Study burden and risks

The burden will consist of a visit to the UMC Utrecht on a normal weekday, which will take about the whole day. The risks will be nausea or dizziness after the MRI, and a small chance of hematoma resulting from venapunction. These risks will not result in permanent damage, but only in short-term discomfort. In addition, participants will fill in two questionnaires and collect 5 saliva samples.

## **Contacts**

#### **Public**

Universitair Medisch Centrum Utrecht

Postbus 85500 3508 GA Utrecht NL

#### Scientific

Universitair Medisch Centrum Utrecht

Postbus 85500 3508 GA Utrecht NL

# **Trial sites**

## **Listed location countries**

**Netherlands** 

# **Eligibility criteria**

## Age

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

## Inclusion criteria

- 1) All participants who were diagnosed with major depressive disorder in one or more measurements of the PREDICT study (03-177/O).
- 2) Participants without a diagnosis of major depressive disorder on any of the PREDICT measurements.
- 3) All PREDICT participants of 65 years or older.

## **Exclusion criteria**

Contra-indications for MRI scan (metals in the body, claustrophobia, pregnancy). Dementia, psychosis, terminally ill, or physically unable to come to the UMCU as diagnosed by the general practitioner of the participant.

# Study design

## Design

Study type: Observational invasive

Intervention model: Other

Allocation: Non-randomized controlled trial

Masking: Open (masking not used)

Control: Active

Primary purpose: Basic science

## Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-10-2010

Enrollment: 250

Type:	Actua

# **Ethics review**

Approved WMO

Date: 28-09-2010

Application type: First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date: 02-05-2011
Application type: Amendment

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

# **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 NL32748.041.10