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

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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:	Actual

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