

Relapse, cognitive, and daily functioning in recurrently depressed individuals: DELTA study 20-year follow-up

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The objectives of the current study, are to assess in a sample of remitted recurrently depressed patients over a 20-year follow up period: the long-term effects of PCT; the long-term predictive value of cognitive functioning on relapse and daily...

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

Summary

ID

NL-OMON52298

Source

ToetsingOnline

Brief title

DELTA study 20-year follow-up

Condition

- Mood disorders and disturbances NEC

Synonym

Depression, major depressive disorder

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cognitive functioning, Daily functioning, Depression, Relapse

Outcome measures

Primary outcome

The primary study parameter is: time to MDD relapse (main).

Secondary outcome

Secondary study parameters are: number and severity of MDD relapses over 20 years; current cognitive, and daily functioning; 20-year changes in cognitive functioning; affective functioning (emotions); dysfunctional attitudes; health care use; and course of (subclinical) depressive symptoms; cognitive effort (neuropsychological symptom validity).

Study description

Background summary

Major depressive disorder (MDD) is highly prevalent with high relapse rates, especially in patients with recurrent episodes. It is therefore essential to advance knowledge on preventative methods such as Preventative Cognitive Therapy (PCT). Gaining more insight into factors associated with relapse such as cognitive impairment and reduced daily functioning can facilitate optimizing preventative methods. To this date, questions remain regarding long-term effects of PCT, the predictive value of cognitive impairment, long term changes in cognitive functioning, and the nature of the relationship between relapse, cognitive, and daily functioning in patients with recurrent depression.

Study objective

The objectives of the current study, are to assess in a sample of remitted recurrently depressed patients over a 20-year follow up period: the long-term effects of PCT; the long-term predictive value of cognitive functioning on relapse and daily functioning; changes in cognitive functioning; and whether MDD-related variables predict possible change.

Study design

This is a long-term follow-up of a randomized controlled trial (DELTA).

Study burden and risks

For the current follow-up study, participants will be subjected to a clinical interview (65-80 minutes) and neuropsychological testing (80 min.). Participants will also be invited to fill in four questionnaires (35 min.). The total time investment for participants is approximately 180-195 min. There are no risks for the participants. If preferred, participants receive an oral report of their individual assessment outcomes. If applicable, participants will be advised how and where to seek professional help. Contributing to knowledge about aspects of a condition participants experienced themselves, may be rewarding.

Contacts

Public

Academisch Medisch Centrum

Meibergdreef 5
Amsterdam 1105AZ
NL

Scientific

Academisch Medisch Centrum

Meibergdreef 5
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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Adults (18-64 years)

Inclusion criteria

All individuals ($n \leq 187$) who participated in the DELTA study (Bockting et al., 2005) 20 years ago, are eligible for the present follow-up study. There are no additional inclusion criteria to be invited to participate in the present follow-up study.

Exclusion criteria

There are no additional exclusion criteria.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-08-2021

Enrollment: 80

Type: Actual

Ethics review

Approved WMO

Date: 21-01-2021

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO

Date:	21-07-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	04-02-2022
Application type:	Amendment
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	ID
CCMO	NL75326.018.20