Preventive Cognitive Therapy with Neurocognitive Remediation Therapy for partially remitted depressed patients

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To investigate the added effectiveness of Preventive Cognitive Therapy (PCT) with oNCRT as compared to PCT on depressive symptomatology over a one-year period in 115 partially remitted depressed patients. We hypothesize that oNCRT is able to augment...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON55338

Source
ToetsingOnline

Brief title
HERSTEL-study

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: Hersenstichting

Intervention

Keyword: Major depressive disorder, Neurocognitive remediation Therapy, Partial remission, Preventive Cognitive Therapy

Outcome measures

Primary outcome

Main study parameter will be assessed monthly during a one-year period after

baseline assessment using the Inventory of Depressive Symptomatology (IDS-SR).

Secondary outcome

The secondary objectives are to investigate the effectiveness of PCT plus

oNCRT, compared to PCT only, in patients partially remitted from depression on:

Neuropsychological functioning (Verbal learning: immediate and delayed memory

recall; Mental flexibility (inhibition and set-shifting ability); Verbal

working memory; Planning)

Positive and negative affect, dysfunctional attitudes, and stress

Time to MDD relapse within a year from baseline

Disability

Health-related quality of life

Health care and associated costs and costs from productivity loss

Study description

Background summary

Neurocognitive remediation therapy (NCRT) is a transdiagnostic intervention that is widely applied to reduce cognitive dysfunction in various disorders, such as acquired brain injury, stroke, schizophrenia, multiple sclerosis, and attention-deficit/hyperactivity disorder. Cognitive deficits are likewise present in many depressed patients, as well as in partially remitted patients.

These cognitive deficits are linked to worse psychiatric and functional outcomes (i.e. relapse, chronicity), and reduced quality of life. Current evidence-based interventions for partially remitted depressed patients include (continuation of) psychotherapy and pharmacology. In the case of remitted or recovered patients, relapse prevention interventions are found to be effective, however, do not protect all patients against relapse. Therefore, adding an online NCRT (oNCRT) to psychotherapy may reduce depressive symptoms further and improve quality of life. The present study may provide a new effective neuropsychological intervention to reduce the huge burden of depression in terms of improvement of symptoms, cognitive functioning, and quality of life as assessed by patient reported outcome measures.

Study objective

To investigate the added effectiveness of Preventive Cognitive Therapy (PCT) with oNCRT as compared to PCT on depressive symptomatology over a one-year period in 115 partially remitted depressed patients. We hypothesize that oNCRT is able to augment the effects of regular Preventive Cognitive Therapy (PCT) in partially remitted depressed patients. Primary objective is the course of depressive symptoms over a one-year period. Secondary objectives are neuropsychological function, affect, time to relapse, disability, health-related quality of life and health care costs.

Study design

This is a national pragmatic randomized controlled multicentre study (1:1). Prior to the RCT, a small non-randomized pilot study will be conducted with PCT and oNCRT only.

Intervention

All patients will receive weekly sessions of PCT during 8-weeks. PCT consists of 8 weekly sessions of 60 minutes each, provided by trained and licensed health care and clinical psychologists. The PCT will be offered online through one of the trial sites. The oNCRT is targeted at the following deficits relevant to depression: Attention, verbal working memory, shifting, and planning. It consists of 3 weekly online sessions of 45-50 minutes each during the 8 weeks. The oNCRT will be delivered at home, online, at the persons* home computer.

Study burden and risks

This dual approach including the oNCRT to improve cognitive functioning combined with PCT to further reduce residual depressive symptomatology, improve cognitive functioning and daily functioning, and prevent recurrence, will provide the patients with more tools to stay well longer. The oNCRT is added to

PCT in order to improve cognitive functioning. A potential benefit of participating in this study might be the superiority of the intervention compared to treatment as usual with respect to the health outcome. There will be some burden of participating in this study, which includes a structured psychiatric interview (+/- 60min) and neuropsychological assessment at baseline (+/- 60min) and two times during study participation, and questionnaires at baseline and monthly up to one year after baseline (+/- 20min). There are no risks associated with PCT or oNCRT.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Does not meet the criteria of a current MDD episode according to the DSM-5, as assessed with the SCID-5-S;

Is at least 8 weeks MDD diagnosis-free (with a maximum of 2 years);
Has a HAM-D score of >=8 and <=15;
Is aged 18 or older;
Speaks Dutch or English.

Exclusion criteria

- Current (hypo)mania or a history of bipolar illness;
- Any psychotic disorder;
- Alcohol or drug misuse;
- Primary Anxiety disorder diagnosis;
- Electroconvulsive therapy in the previous 12 months;
- Neurological disorder;
- Disabling sensory and/or motor deficit.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-01-2021
Enrollment:	115
Type:	Actual

Ethics review

Approved WMO

Date:	13-10-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-04-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-04-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-05-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-10-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-11-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22498
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL74547.018.20
OMON	NL-OMON22498