Cognitive control training (CCT) as an add-on intervention in elderly depressed patients

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What is the cost-effectiveness of a cognitive control training (CCT) as an add-on intervention in elderly depressed patients (EDP)?

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

Summary

ID

NL-OMON55524

Source
ToetsingOnline

Brief title
CCT in EDP

Condition

- Mood disorders and disturbances NEC

Synonym
depression, mood disorder

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Cognitive control, Depression, Elderly, Training

Outcome measures

Primary outcome

Investigate whether the training could change patients* depressive symptoms

into a positive direction.

Secondary outcome

Rumination (state en trait)

Working memory

Cognitive functioning

Cognitive coping strategy

Emotional executive functioning and inhibition

Cost-effectiveness

Budget-impact analysis

Implementation study

Study description

Background summary

Major Depressive Disorder (MDD) is a severe, highly prevalent (20% lifetime prevalence in the Netherlands) and often chronically recurrent psychiatric illness. Approximately one in every 50 community-dwelling adults aged 65 years or older meet the criteria for MDD in the past year (Kessler et al., 2010). They suffer from perturbations in their affect, weight, sleep patterns, ability to concentrate, and/or suffer from feelings of worthlessness. Unfortunately, geriatric depressed patients seem less responsive to standard treatment protocols and demonstrate a higher rate of chronicity than younger patients (Netherlands Study of Depression in Old age, NESDO). The high recurrence rate of depression suggests that current treatments are not able to modify

vulnerability mechanisms that trigger relapse. A major risk factor for depression is impaired cognitive control (De Raedt & Koster, 2010). Therefore, researchers started to use cognitive control training (CCT) as an add-on intervention for depression. Results of this research line are encouraging, as cognitive control training seems to reduce depressive symptoms by targeting a crucial risk factor for the relapse of depression. Importantly, the training of cognitive control has proven to be especially effective in elderly depressed patients (EDP), specifically long-term (Brunoni et al., 2014).
In the proposed project, we aim to implement a promising cognitive control training that is based on (1) an individual computerized assessment, and (2) that trains specific cognitive impairments which are known to be critical for the depressive symptomatology and the recurrence of the disorder. The training will be administered in EDP who continue receiving treatment as usual.

Study objective

What is the cost-effectiveness of a cognitive control training (CCT) as an add-on intervention in elderly depressed patients (EDP)?

Study design

A randomized controlled trial with two arms, in patients receiving treatment as usual (TAU).

Study burden and risks

The burden is approximately 7 hours of filling out questionnaires and doing computer tasks. Since it concernes a computerized add-on intervention that patients can perform from their own homes, the expected effort is low. There are no know risks associated with filling out the questionnaires or doing the computer tasks.

Contacts

Public
Radboud Universiteit Nijmegen

Montessorilaan 3
Nijmegen 6500 HE
NL
Scientific
Radboud Universiteit Nijmegen

Montessorilaan 3

Nijmegen 6500 HE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Eligible patients are 60 years or older with MDD who attend old-age psychiatry outpatient care
of GGNet or ProPersona as secondary treatment centers, and the outpatient clinic for the elderly of the Department of Psychiatry of the Radboudumc. All patients receive standard treatment for the primary diagnosis of MDD according to the multidisciplinary Dutch guideline for depression (addendum elderly).

Exclusion criteria

Psychotic symptoms or diagnoses, (hypo)mania, bipolar disorder, primary diagnosis of substance abuse or dependence or alcohol abuse or dependence, as well as severe neurocognitive disorders, severe visual disabilities that interfere with the computer task, acute suicidal risk will
serve as exclusion criteria.

Study design

Design

Study phase: 4

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-05-2019
Enrollment:	104
Type:	Actual

Ethics review

Approved WMO Date:	07-03-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-02-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-04-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL67671.091.18