# PCT after rTMS for relapse prevention of depression

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This pilot study aims to establish the feasibility of offering PCT live or online to MDD patients in remission due to rTMS by measuring treatment adherence using descriptive data and daily affect. Results will be used to improve patient compliance...

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

## Summary

### ID

NL-OMON56852

**Source**
ToetsingOnline

**Brief title**
rTMS-PCT

### Condition

- Mood disorders and disturbances NEC

**Synonym**
MDD; Depression

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Amsterdam UMC
**Source(s) of monetary or material Support:** ZonMw

## Intervention

**Keyword:** Major depression disorder, Preventive cognitive therapy, repetitive Transcranial Magnetic Stimulation

## Outcome measures

### Primary outcome

Treatment adherence (number of sessions, number of weeks in which treatment is given, outcome rating scale of each PCT session, adherence to homework assignments and possible relapse/duration of remission, personal preference for treatment method for each patient) will be used as primary descriptive outcome measures and gathered using registration of therapists and EPIC. Number of weeks of remission will be monitored using the IDS-SR (Rush et al. 1996) and Hamilton Depression Rating Scale (HDRS) (Hamilton, M. 1980). Both questionnaires are used for registering depressive symptoms and response rates in rTMS (treatment as usual) and will be administered directly after completing PCT, after 3 months and after 6 months.

### Secondary outcome

The secondary outcome parameter of the study is affect fluctuations as measured with daily short-form questionnaires during PCT treatment. Patients fill in their affective state and the mean affect score that is derived from the questionnaires will be used as secondary outcome measures.

# Study description

### Background summary

Since 2018, repetitive Transcranial Magnetic Stimulation (rTMS) is a first line

recommendation in the Netherlands for patients with Major Depressive Disorder (MDD), not responding to at least two treatments. Most studies investigated effectiveness up to 6 weeks after treatment, while relapse happens frequently in a larger time frame and occurs in approx. 60-90 percent of patients with a recurring course. MDD is a severe psychiatric illness with a high societal and individual impact. Especially in our targeted refractory population, recurring depressive episodes are seriously debilitating and suicide is not uncommon. Relapse prevention is therefore of substantial importance, however literature on (maintenance) therapy after successful rTMS treatment is scarce and of low quality. For depression treated with psychotherapy and medication, Preventive Cognitive Therapy (PCT; 8 sessions) is effective in reducing relapse risk. To our knowledge, PCT after rTMS has never been investigated as a maintenance strategy. In a larger randomised controlled trial, we aim to prolong rTMS effects and decrease relapse risks in severely depressed patients by adding Preventive Cognitive Therapy after response to effective rTMS treatment. Prolonging the positive effects of rTMS and preventing these patients from additional relapses will improve quality of life of patients and their relatives and lower health care costs. In order to study the feasibility of additional therapy in this patient population and to sufficiently power a large RCT, we conduct the current study, , in which we compare treatment adherence of 20 patients who benefitted from rTMS who either receive face to face or online PCT treatment. To monitor affective state for our secondary parameter, we use a daily short form questionnaire.

## Study objective

This pilot study aims to establish the feasibility of offering PCT live or online to MDD patients in remission due to rTMS by measuring treatment adherence using descriptive data and daily affect. Results will be used to improve patient compliance in a larger RCT investigating the effects of PCT after rTMS.

## Study design

Randomized controlled trial using 2 arms, a face to face PCT and a video call PCT group will be compared. Patients are allocated to either the face to face or video call PCT using a research randomization tool online (CASTOR), designed for experimental research. Patients and researchers will not be blinded for the conditions, however, questionnaires will be administered by a blinded research assistant only involved for measurements. Data will be analyzed using (repeated) linear mixed models in SPSS. If applicable, corrections will be performed for skew data. We aim to describe results in 2 open access publications, focusing on study design in preparation of an efficiency study and first results and secondly on follow-up data. The outcome of the current pilot study will be used to determine power analyses for a larger cost-effective trial aimed to determine the beneficial effects of providing PCT

after rTMS.

## Intervention

PCT may prolong the effect of rTMS leading to a quick and long term effective treatment method for chronically ill patients with high health care costs. Combining these two forms of evidence based treatment for MDD may lead to lower relapse rates and costs reduction. In this trial, half of the randomized patients will receive PCT online via video call and half will receive PCT F2F to study the feasibility of the add-on treatment for patients receiving rTMS. All patients who receive rTMS treatment are psychotherapeutically treated during rTMS treatment period as stated in the depression guideline. After informed consent, patients are included in the current pilot study when responding to rTMS and reaching at least 50% reduction of symptoms or remission (scores 7 or lower) on the IDS self-report scale (Inventory of Depressive Symptoms). Patients not responding will continue to receive regular psychotherapy and will not be included in the current pilot study. PCT consists of 8 weekly sessions of individual psychotherapy according to the protocol and will be performed by a qualified Health care psychologist. PCT sessions via videocall proved to be feasible in a former study by Brouwer et al. (2020) and our study population may be supraregional due to the fact that rTMS treatment is not widely offered in patient care. A short-form questionnaire (experience sampling methodology) will be used to monitor daily positive and negative affective states during the treatment period. All included patients will fill in questionnaires regarding their depressive symptoms directly after rTMS when reaching (partial) remission, directly after PCT, 3 months after PCT and 6 months after PCT. We will use the Hamilton depression rating scale (HDRS) and the Inventory of Depressive Symptoms (IDS) to record depressive symptoms.

## Study burden and risks

A potential benefit of participating in this study might be the beneficial effects of PCT to prolong the effects of rTMS, although this is not established yet. Beneficial effects are expected for future patients participating in a larger RCT trail, since we gather information on best suited treatment options and aim to lower the future burden of additional treatment for participating patients. There will be some burden of participating in this study, which is caused by filling in a daily short-form questionnaire about affect (5 min each day) and follow-up questionnaires (+/- 60 min each measurement). In addition, preventive cognitive training may not work causing you to potentially relapse in your depression. As a result, there is a moderate risk associated with participating in this study.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)

## Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Patients are responding or in remission directly after rTMS
• Have a IDS self-report scale <=7 or a 50% reduction of complaints
• Are aged 18-65
• Speak Dutch

## Exclusion criteria

Not applicable.

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Other |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Prevention |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-08-2024 |
| Enrollment: | 20 |
| Type: | Actual |

# Ethics review

Approved WMO

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| Date: | 17-06-2024 |
| Application type: | First submission |
| 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 | NL85703.018.23 |