# interpretation Bias Modification (IBM) in patients with Major Depressive Disorder

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The hypothesis is not public yet, because of the quality of the study.

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON27494

**Bron**
NTR

**Aandoening**

Major Depressive Disorder (MDD)

### Ondersteuning

**Primaire sponsor:** Pro Persona, Trimbos Institute
**Overige ondersteuning:** ZonMw

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

For testing the main hypothesis, that IBM is able to reduce depressive symptom levels, the Beck’s Depression Inventory II (BDI) will be used.

# Toelichting onderzoek

### Achtergrond van het onderzoek

The summary is not public yet, because of the quality of the study.

### Doel van het onderzoek

The hypothesis is not public yet, because of the quality of the study.

### Onderzoeksopzet

Primary outcome measure

-BDI (baseline, 2 weeks, 1 month, 6 months, 12 months)

Secondary outcome measures

-AST (baseline, 2 weeks, 1 month)

-PIT (baseline, 1 month, 6 months)

-IDS-SR (baseline, 1 months, 6 months, 12 months)

-STAI (baseline, 1 month, 6 months)

-SUIS (baseline, 1 month, 6 months)

-DAS (baseline, 1 month, 6 months)

-EQ (baseline, 1 month)

-TIC-P (baseline, 1 month, 6 months, 12 months)

-EQ-5D (baseline, 1 month, 6 months, 12 months)

-MINI (baseline, 12 months)

-Patient satisfaction questionnaire (1 month, 6 months)

-Patient satisfaction interview (12 months)

-Demographic items (baseline, 1 month)

**Onderzoeksproduct en/of interventie**

Interpretation Bias Modification (IBM)

Patients will be offered IBM when just starting their treatment (maximum of 4 sessions) or when waitlisted for treatment, accompanied or followed by further indicated care. IBM entails 10 20-minute computer training sessions over the course of 4 weeks: 7 daily sessions during in week 1, followed by weekly sessions during the following 3 weeks. The first session will be completed at Pro Persona. All other sessions will be completed via the internet at home.

Both groups will receive a mixture of auditory and picture-word training sessions.

Not all of the information about the intervention is public yet, because of the quality of the study.

# Contactpersonen

## Publiek

Pro Persona Research
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Nijmegen 6534 AM
The Netherlands
-

## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-A diagnosis of major depressive disorder, first or recurrent according to the DSM- IV-TR (APA; American Psychiatric Association, 2000), as assessed with the MINI
-18-65 years old
-Provides informed consent

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-Any psychotic disorder (current or previous)

-Current mania or hypomania or a history of bipolar disorder

-Cognitive disabilities (IQ < 80)

-Visual disabilities that interfere with a computer task

-Acute suicidal risk

-No sufficient command of Dutch language to participate in the study

-Lack of sufficient experience with the use of computers (based on subjective estimation of the patient)

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Enkelblind |
| Controle: | Placebo |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 01-06-2017 |
| Aantal proefpersonen: | 198 |
| Type: | Verwachte startdatum |

### Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 19-07-2016 |
| Soort: | Eerste indiening |

# Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47198
Bron: ToetsingOnline
Titel:

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

| Register | ID |
|---|---|
| NTR-new | NL5786 |
| NTR-old | NTR5949 |
| CCMO | NL55683.091.15 |
| OMON | NL-OMON47198 |

# Resultaten