# Optimising treatment dosage for depression and comorbid personality disorders

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1. We expect the ST/SPSP-50 condition to be more effective than ST/SPSP-25 condition on depression outcome and/or characterological symptoms. 2. No differences in outcome are expected between ST en SPSP and we don’t expect the type of treatment to…

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

## Samenvatting

### ID

NL-OMON22507

**Bron**
NTR

**Verkorte titel**
PsyDos

**Aandoening**

Depression
Personality disorder

### Ondersteuning

**Primaire sponsor:** NPI/Arkin
**Overige ondersteuning:** NPI/Arkin

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

Depression severity (BDI-II) and diagnoses (MINI) at end of treatment and at 1 year follow-up

# Toelichting onderzoek

### Achtergrond van het onderzoek

Background: Patients with both depression and personality disorders are difficult to treat patients, accounting for a high psychological and economic burden. Little is known about the optimal treatment dosage for this particular group. Finding the optimal treatment-dosage for these patients and understanding the processes that account for the therapeutic changes can lead to both higher treatment efficacy and lower costs.

Methods/Design: The study is a mono-center double-randomized clinical trial. Patients seeking therapy at a Dutch mental health care institute for personality disorders who meet criteria for depression/dysthymia and personality disorder(s) are randomized over therapy-dosage (25 vs 50 sessions) and type of therapy (schematherapy vs short-term psychodynamic psychotherapy). Randomization on patient level will be pre-stratified according to depression severity. The trial is designed to include 200 patients. The primary clinical outcome measure will be depression severity.
Secondary clinical outcome measures will include measures of personality changes, costs from a societal perspective, type of therapy, process measures and quality of life. All patients are assessed at baseline and at 1, 2, 3, 6 months, at the end of therapy (9-12 months) and at one year follow-up.

Discussion: This trial will compare two psychotherapy dosages (25 vs 50 sessions) in patients with both depression and personality disorders. Finding the optimal treatment-dosage for these patients and understanding the processes that account for the therapeutic changes will lead to both higher treatment efficacy and lower costs.

### Doel van het onderzoek

1. We expect the ST/SPSP-50 condition to be more effective than ST/SPSP-25 condition on depression outcome and/or characterological symptoms.

2. No differences in outcome are expected between ST en SPSP and we don’t expect the type of treatment to have a moderating effect on the relation between therapy-dosage and outcome.

### Onderzoeksopzet

T0=baseline: primary + secondary outcomemeasures

T1=1mth primary outcomemeasures

T2=2mth primary outcomemeasures

T3=3mth primary outcomemeasures

T4=6mth primary + selection of secondary outcomemeasures

T5= END (9-12 mths) primary + secondary outcomemeasures

T6=Follow up (END+12mths): primary + secondary outcomemeasures

**Onderzoeksproduct en/of interventie**

- Schematherapy 25 sessions (control group)

- Schematherapy 50 sessions (experimental condition)

- Short term psychodynamic supportive psychotherapy 25 sessions (control group)

- Short term psychodynamic supportive psychotherapy 50 sessions (experimental condition)

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

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

- Age 18-65 years

- DSM-IV diagnosis of a major depressive episode or dysthymia

- DSM-IV diagnoses of one or more personality disorders (including PD NOS)

- A written informed consent

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

- Non-Dutch speakers/readers

- Psychotic symptoms, bipolar disorder or current extreme substance dependence.

- Immediate intensive treatment or hospitalization is needed, e.g. acute suicidality.

- Pregnancy or other reasons why trial demands can’t be met

- Use of medication that influences mental functioning: antipsychotics, mood stabilizers, benzodiazepines > 30mg oxazepam or equivalent per day.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Factorieel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Enkelblind |
| Controle: | Geneesmiddel |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 01-05-2016 |
| Aantal proefpersonen: | 200 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 20-07-2016 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50650
Bron: ToetsingOnline
Titel:

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

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL4057 |
| NTR-old | NTR5941 |
| CCMO | NL55916.029.15 |
| OMON | NL-OMON50650 |

# Resultaten