Optimising treatment dosage for depression and comorbid personality disorders

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22507

Source
Nationaal Trial Register

Brief title
PsyDos

Health condition

Depression
Personality disorder

Sponsors and support

Primary sponsor: NPI/Arkin
Source(s) of monetary or material Support: NPI/Arkin

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Personality parameters (SCID-II, SIPP, YSQ, SMI, DPI), Treatment condition: ST or SPSP), cost evaluation from a societal perspective (Tic-P, EQ-5D, happiness item).

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

- 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)

Contacts

Public
NPI-Arkin

A.M. Kool
Domselaerstraat 12

Amsterdam 1093 MB
The Netherlands
020-5904700
Scientific
NPI-Arkin

A.M. Kool
Domselaerstraat 12

Amsterdam 1093 MB
The Netherlands
020-5904700

Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

- 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.

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2016
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-07-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50650
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results