Optimizing treatment dosage for depression and comorbid personality disorders: a randomized clinical trial

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Ethical review	Approved WMO
Status	Completed
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON50650

Source
ToetsingOnline

Brief title
Optimizing treatment dosage for depression and personality disorders

Condition

- Mood disorders and disturbances NEC

Synonym
Depression and personality disorders

Research involving
Human

Sponsors and support

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

Intervention

Keyword: comorbid, depression, dosage, personality

Outcome measures

Primary outcome

Depression severity (BDI-II) will be the main outcome measure. The proportion of patients that achieve reliable and clinically significant improvement at termination and follow-up will we calculated on the outcome measure (BDI-II) for both conditions, using the method by Jacobson and Truax.

Secondary outcome

Secondary outcome measures are personality changes, cost-effectiveness and quality of life. Also process variables will be analysed in order to find change mechanisms in psychotherapy. One of the factor that will be investigated is the working alliance and the level of discourse in SPSP. Moderating factors like the type of therapy will also be analysed.

Study description

Background summary

It is unknown what the optimal treatment-dosage is. For depression a recent meta-analysis showed a strong association between the number of therapy-sessions per week and treatment outcome. Patients with both depression and personality disorder(s) are believed to be difficult to treat patients, accounting for a high psychological and economic burden. 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

In this study we will compare the (cost-) effectiveness on depression of 25-

versus 50-sessions of psychotherapy (SPSP or ST) within one year in patients with depression and comorbid personality disorders. In addition we will examine the personality changes that will be achieved in both dosages and we aim to understand therapeutic processes that account for the differences. Knowing these factors can further improve treatment effectiveness.

Study design

A mono-center randomized clinical trial with four parallel groups: 1) SPSP-25, 2)SPSP-50, 3)ST-25 and 4) ST-50. After six months session-frequency decreases by 50% in all groups, from one session a week to one session every two weeks in the 25-conditions and from two session a week to one a week in the 50-conditions.Randomization on patient level will be pre-stratified according to severity (BDI-score >= 30 is high severity, BDI-score<29 is low severity).

Intervention

In the standard condition once-weekly sessions of SPSP or ST are provided during the first six months, followed by fort-nightly sessions in the last six months. In the experimental condition twice-weekly sessions of SPSP or ST are provided during the first six months, followed by once-weekly sessions during the last six months.

Study burden and risks

Patients will be invited to a clinical screening interview. Part of the other measurements can be done either online or on paper-and-pencil. At the end of treatment, at 1 yeear follow up and at 3 years follow up assessments will take place including a semi-structured interview. A small part of the patients (N=20) will, in addition be asked to take part in a qualitative interview. Although the burden includes a time investment of the patient, no risks are associated with participation in the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age 18-65 years
DSM-IV diagnosis of a major depressive episode or dysthymia and
DSM-IV diagnoses of one or more personality disorders

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, moodstabilizers, benzodiazepines > 30mg oxazepam or equivalent per day.

Study design

Design

Study type: Interventional

Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	20-04-2016
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	09-03-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-11-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-03-2022
Application type:	Amendment
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

ID: 22507
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL55916.029.15