Frequency and change mechanisms of psychotherapy among depressed patients: a multicenter randomized trial.

Published: 16-10-2014
Last updated: 21-04-2024

The effectiveness of psychotherapy can be improved by increasing the frequency of sessions at the beginning of therapy. In addition, understanding processes that account for therapeutic change might enable us to optimize treatments.

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

Summary

ID

NL-OMON44191

Source
ToetsingOnline

Brief title
Frequency and change mechanisms of psychotherapy among depressed patients.

Condition

- Mood disorders and disturbances NEC

Synonym
depression, melancholy

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: change mechanisms, depression, intensity, psychotherapy

Outcome measures

Primary outcome

Depression (BDI-II) and quality of life (EQ-5D (5L)) will be the main outcome measures over the course of two years. Besides the completion of a clinical interview at baseline, patients will complete monthly assessments during the first six months of the study. There will be follow-up assessments 9, 12 and 24 months after start of treatment. For the patients who are willing to participate, blood samples will be collected during baseline and end of treatment.

Secondary outcome

The following secondary study parameters will be involved in the study:

Therapeutic alliance (Working Alliance Inventory), cognitive skills (Competencies of Cognitive Therapy Scale/Performance of CT Strategies), interpersonal skills, recall (patients recall of the last session rated by the therapist), motivation for therapy (Autonomous and Controlled Motivation for Treatment Questionnaire), compliance (amount of no-show and rated by patient and therapist), emotion regulation (Action Control Scale), executive functioning (n-back task), automatic thoughts (Cognition Checklist), behavioral activation (Behavioral Activation for Depression Scale) and biological factors (brain-derived neurotrophic factor (BDNF), DNA methylation

of CpG islands adjacent to promoters I and IV) and oxytocin.

Study description

Background summary

Recently, a strong association was found between the number of psychotherapy sessions per week and treatment outcome. However, there is no clarity about the optimal session frequency neither about the change mechanisms in the effects of psychotherapy. Finding an effect for session frequency will lead to higher therapy efficacy and lower the economic burden for depression while understanding the processes that account for therapeutic change might make us better able to optimize treatments.

Study objective

The effectiveness of psychotherapy can be improved by increasing the frequency of sessions at the beginning of therapy. In addition, understanding processes that account for therapeutic change might enable us to optimize treatments.

Study design

Multicenter randomized trial with four parallel groups (n=230) : a) twice-weekly sessions at the start of CT, b) twice-weekly sessions at the start of IPT, c) once-weekly sessions at the start of CT, d) once-weekly sessions at the start of IPT. Randomization (patient level) will be pre-stratified according to severity (high severity = BDI score =>30; low severity = BDI score <=29).

Intervention

Twice-weekly sessions of cognitive therapy or interpersonal therapy at the start of therapy, up to 20 sessions in total. Standard intervention to be compared to: once-weekly sessions of cognitive therapy or interpersonal therapy at the start of therapy, up to 20 sessions in total.

Study burden and risks

Patients will be invited to a clinical screening interview. Other measurements will be administered online, which guarantees maximum flexibility for the participant. Participation to the venipuncture will be an optional part of the study. Though the burden includes a time investment of the patient, no risks are associated with participation in the study.

Contacts

Public
Vrije Universiteit

van der Boechorststraat 1
Amsterdam 1081 BT
NL
Scientific
Vrije Universiteit

van der Boechorststraat 1
Amsterdam 1081 BT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

a. DSM diagnosis of major depression
b. Eligible patients who are on antidepressants and who are willing to discontinue their medications during treatment, prior to participation, will be eligible to participate in the study. Patients already on antidepressants who wish to continue medication are also eligible, but only if their medication use is stable for at least three months before start of treatment

Exclusion criteria

a. severe mental illness (e.g. schizophrenia)
b. high risk for suicide
c. drug and/or alcohol dependence

d. a primary diagnosis other than MDD
e. a cluster A or B personality disorder diagnosis
f. prior psychotherapy in the previous year
g. no access to internet facilities

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2014
Enrollment:	230
Type:	Anticipated

Ethics review

Approved WMO Date:	16-10-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-12-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-06-2016

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

No registrations found.

In other registers

Register	ID
CCMO	NL49657.029.14