Frequency and change mechanisms of psychotherapy for depression.

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

Samenvatting

ID

NL-OMON28796

Bron
Nationaal Trial Register

Verkorte titel
FREQMECH

Aandoening

ENGLISH: frequency; psychotherapy; depression; mechanisms

DUTCH: frequentie; psychotherapie; depressie; mechanismen

Ondersteuning

Primaire sponsor: VU Amsterdam
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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. At 24 months, the LIFE interview will be administered to assess the presence of depressive episodes in the previous year. For the patients who are willing to participate, blood samples will be collected during baseline and end of treatment.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

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.

Objective of the study:

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).

Study population:

230 depressed patients with a major depressive disorder (MDD) aged 18-65 years seeking treatment recruited from several Dutch mental health centers.

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.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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.

Doel van het onderzoek

We expect that twice-weekly sessions will be more cost-effective and lead to better treatment outcomes than once-weekly sessions at the start of psychotherapy. Furthermore, learning processes, therapeutic-specific variables and physiological factors are expected to be involved as mechanisms of change in the effects of psychotherapy.

Onderzoeksopzet

T0=baseline; T1-T6= month 1-6; T9= month 9; T12= month 12; T24=month 24

Onderzoeksproduct en/of interventie

Cognitive therapy includes psycho-education (explanation of the treatment rationale and the general procedures in CBT treatment), behavioral activation (motivating the patient to build a day structure and increase activities), cognitive therapy (examining automatic negative thoughts and dysfunctional assumptions) and relapse prevention (identifying and adopting techniques/strategies to prevent depressive symptoms to re-occur).

Interpersonal therapy consists of three phases. The initial phase includes an evaluation of symptoms and interpersonal relations, making a case formulation and the agreement on a treatment plan. During the second phase the patient and therapist focus on working on the

interpersonal problem with the expected result of reducing symptoms. The final phase compromises discussion of ending treatment, reviewing improvement, establishing gains and anticipating future problems.

CT and IPT differ in terms of target (cognitions and behavior vs. interpersonal functioning), approach (directive vs. empathic-reflective) and method (homework assignment vs. no assignments) .

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

a. DSM V diagnosis of major depression (DSM V persistent depressive disorder will be included)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	20-10-2014
Aantal proefpersonen:	230
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	21-10-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4602
NTR-old	NTR4856
Ander register	NL49657.029.14 : METC nr:

Resultaten