D*Phase psychotherapy study: efficacy of short-term psychodynamic therapy versus cognitive-behavioral therapy for major depression

A randomized clinical trial adressing predictors, moderators and initial treatment non-response

Gepubliceerd: 26-08-2016 Laatst bijgewerkt: 15-05-2024

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

Samenvatting

ID

NL-OMON26978

Bron
Nationaal Trial Register

Verkorte titel
D*Phase psychotherapy study

Aandoening

major depressive disorder

Ondersteuning

Primaire sponsor: Dimence
Overige ondersteuning: Dimence

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Severity of depressive symptoms, measured through a self-report questionnaire (IDS-SR; Inventory of Depressive Symptomatology - Self Report)

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Depression has important consequences, for the individual patients' wellbeing and for society also economically. Luckily, for patients suffering from depression different evidence-based treatment options are available. Not only medication, but also different kinds of psychotherapy have been studied and found to decrease depressive symptoms, to a large extent. Short-term Psychodynamic Supportive Psychotherapy (SPSP) as a relatively new form of psychotherapeutic treatment, has been studied less but is a promising alternative to other available evidence-based psychotherapeutic treatment methods. In order for SPSP to be considered as a treatment for depression of first choice according to the Dutch guidelines for the treatment of depression, however one more well-conducted RCT is needed to prove once more its non-inferiority to another psychotherapeutic treatment options of first-choice. Despite the evidence for the effectiveness of these different kinds of psychotherapy for depression however, research also shows that a large part of patients does not, or does not fully recover from treatment. Beforehand, we cannot predict who will benefit from treatment, and who will benefit from which kind of treatment. If this were possible, we would be able to specifically assign patients to a certain kind of psychotherapy, which would be one possible step towards maximizing treatment effects. Another step towards maximizing treatment effects would be knowing exactly what to do if a particular form of psychotherapy doesn't have the desired effect. According to the Dutch guidelines for the treatment of depression, for patients that still prefer psychotherapeutic treatment to medication after an initial non-response, the advice is to switch to another kind of psychotherapy. However, there is no scientific evidence underlying this advice. According to recent literature, it would be even better to transfer the patient to another psychotherapist. But more research is needed, to discover which switching strategy is most effective. With respect to the option of switching therapists, not enough is known about the influence of the working alliance between the patient and the therapist and we specifically don't know at what point in time and treatment

the quality of the therapeutic relationship can predict treatment effect. Knowing this is the key to answering the question if changes could be made earlier in case of inadequate match between the patient and a particular therapist, so an optimal decrease in depressive symptoms can be accomplished by maybe switching therapist.

Objectives are:

1. To prove that Short-term Psychodynamic Supportive Psychotherapy (SPSP) is in fact non-inferior to Cognitive Behavioural Therapy (CBT) in the treatment of Major Depression.

2. To identify prognostic and prescriptive variables that can predict the effect of psychotherapy for Major Depression and specifically for CBT versus SPSP.

3. Increasing knowledge about the influence of the therapeutic relation on treatment effect.

4. Gaining knowledge about an effective policy (change of therapist and/or change of treatment method) in psychotherapeutic treatment in the case of initial non-response.

We are also interested in whose ratings (therapist's or patient's), if significant, are the best predictors of treatment effect, what characteristics of the therapist influence the working alliance and, lastly, the influence of protocol adherence and allegiance on treatment effect.

Our hypotheses are as following:

1. We expect Short Psychodynamic Supportive Psychotherapy (SPSP) to be non-inferior to Cognitive Behavioural Therapy (CBT) in the treatment of Major Depression.

2. We expect to identify the same prognostic and prescriptive variables that are found in earlier research.

3. We expect a positive influence of a better working relationship on treatment effect.

4. We expect a moderate effect of change of therapist and an additive small effect of changing the treatment method, in case of a switch in the case of initial non-response.

Study design: We will conduct a randomized non-inferiority study. The first part of the study is aimed at proving that SPSP is not inferior to CBT, a well-researched and proven effective treatment for Major Depression. In the second part of the study, the goal is to assess which switching strategy is most effective in treatment of non-responders to an evidence-based form of psychotherapeutic treatment, who nevertheless prefer to continue psychotherapeutic treatment.
These subjects will be randomly assigned to one of three conditions: a) continuing the same

treatment with another therapist,
b) following a different treatment with another therapist and c) no changes in treatment or therapist.

Power-analysis for continuous outcomes indicated that to prove non-inferiority of SPSP compared to CBT, for the first part of the study 268 patients in total are needed to provide 80% power to demonstrate that the lower limit of the one-sided 95% confidence interval (CI) will be above the non-inferiority limit of -5 on the IDS-SR (1-β= 80%, SD = 16.42). Taking into account the observed dropout rate of around 15% over the first 100 included patients, we aim to include 308 patients to perform the per-protocol analysis. Alteration of the sample size has been approved by the METC on july 23h, 2019.

By conducting post-hoc analyses we will also try to gain more evidence for the prescriptive and prognostic qualities of variables that were found to predict treatment results in earlier studies. Another post-hoc analysis is aimed at finding out what influence working alliance and characteristics of the therapist have on treatment effect, in different phases of psychotherapeutic treatment.

Study population: Participants will be recruited from among those patients who seek treatment at Dimence, an institution for specialized mental healthcare located in the east of the Netherlands. The research population will consist of adults between 18 and 65 years old. Most will be Dutch, but also people with another ethnic background will be included.

Intervention: During the 8 week period of the first part of the study, subjects will be offered 16 treatment sessions of SPSP or CBT. In the second part of the study, the patients who did not respond after the first 8 week period of psychotherapeutic treatment (as defined bij less than 50% reduction compared to the initial score on the primary outcome measure), will then again receive the same number of treatment sessions, during another 8 week period. One third of the patients will continue treatment and stay with the same therapist, as during part 1 of the study. One third will continue the same treatment but will switch therapist, for the second part of the study. One third will switch to another therapist and the other form of psychotherapeutic treatment investigated in the study.

Main study parameters/endpoints: The primary parameter is severity of depressive symptoms, measured through a self-report questionnaire.
Secondarily, we are interested in wellbeing and self-reported disabilities and functional impairment. Both will also be measured through self-report questionnaires.

Doel van het onderzoek

1. We expect Short-Term Psychodynamic Psychotherapy (SPSP) to be non-inferior to Cognitive Behavioural Therapy (CBT) in the treatment of Major Depression.

2. We expect to identify the same prognostic and prescriptive variables that are found in earlier research.

3. We expect a positive influence of a better working relationship on treatment effect.

4. We expect a moderate effect of change of therapist and an additive small effect of changing the treatment method, in case of a switch in the case of initial non-response.

Onderzoeksopzet

Participants fill in questionnaires before the initial treatment phase of 16 sessions psychotherapy within 8 weeks. During this phase, assessments will take place in weeks 2 and 4. Posttreatment assessment for this phase, which also serves as baseline measurement for phase 2, will take place in week 8. For patients who will receive a second treatment phase, assessments will follow in week 9, 10, 12 and 16. Patients who do not receive treatment in this phase fill in questionnaires in week 12 and 16.

Onderzoeksproduct en/of interventie

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One third will continue the same treatment but will switch therapist, for the second part of the study. One third will switch to another therapist and the other form of psychotherapeutic treatment investigated in the study.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Subjects have to suffer from a moderate to severe Major Depressive Disorder according to the MINI (Mini International Neuropsychiatric Interview), which has to be the primary DSM-IV-diagnosis.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- insufficient competency in the Dutch language

- Psychotic sympoms

- Substance dependency (except nicotine)

- Not being able to commit to treatment requirements (eg. following treatment sessions, twice weekly)

- Severe risk of suicide

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	02-09-2016
Aantal proefpersonen:	308
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	26-08-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47741
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5753
NTR-old	NTR6019
CCMO	NL56047.099.16
OMON	NL-OMON47741

Resultaten