D*Phase psychotherapy study - Research on counselling for depression What works best for whom* and when?

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1. To prove that Short-Term Psychodynamic Psychotherapy (STPP) is in fact non-inferior to Cognitive Behavioural Therapy (CBT) in the treatment of Major Depression so it can be considered a treatment of first choice in the Dutch Guidelines for…

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

Summary

ID

NL-OMON47741

Source
ToetsingOnline

Brief title
D*Phase Psychotherapy Study - Research on counselling for depression

Condition

- Mood disorders and disturbances NEC

Synonym
major depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: Dimence (Deventer)
Source(s) of monetary or material Support: Dimence

Intervention

Keyword: Cognitive Behavioral Therapy, Depression, Psychodynamic, Psychotherapy, Treatment Effectiveness

Outcome measures

Primary outcome

The primary parameter is severity of depressive symptoms, measured through a

self-report questionnaire.

Secondary outcome

Secondarily, we are interested in wellbeing and self-reported disabilities and

functional impairment. Both will also be measured through self-report

questionnaires.

Study description

Background summary

Depression has important consequences, for patients* wellbeing as well as economically. Treatment has been found effective. Not only medication, but also different kinds of psychotherapy have been studied and found to work to a certain extent, to relieve depressive symptoms. Short-term Psychodynamic Psychotherapy (STSP) has been studied less, but is also promising. In order for STSP to be considered as a first-choice treatment for depression according to the Dutch Guidelines for treatment of depression, one more, well-conducted RCT is needed.
Despite evidence for the effectiveness of different kinds of psychotherapy in the treatment of depression, a major part of patients does not, or not fully recover. 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 psychological treatment doesn*t have the desired effect. According to the Dutch Guidelines for the treatment of depression the advice is to shift to another kind of psychotherapy, but there is no scientific evidence underlying this choice. According to recent literature, it would be even better to

transfer the patient to another psychotherapist.
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 relationship can predict treatment effect. Knowing this is the key to answering the question if changes could be made earlier in treatment (eg. a change of therapist) so an optimal decrease in depressive symptoms can be accomplished.

Study objective

1. To prove that Short-Term Psychodynamic Psychotherapy (STPP) is in fact non-inferior to Cognitive Behavioural Therapy (CBT) in the treatment of Major Depression so it can be considered a treatment of first choice in the Dutch Guidelines for treatment of Depression.
2. To identify prognostic and prescriptive variables that can predict the effect of psychotherapy for Major Depression and specifically for CB versus STPP.
3. Acquiring knowledge about whether, and if so at which moment in time, individual variation in affect and emotions during the first phase of treatment of Major Depression predicts treatment effect and if there is a difference between STPP and CBT.
4. Increasing knowledge about the influence of the therapeutic relation on treatment effect.
5. 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.
Secondary, we are 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.

Study design

We will conduct a randomized non-inferiority study aimed at proving that STPP is not inferior to CBT, a well-researched and proven effective treatment for Major Depression. By conducting post-hoc analyses we will try to gain more evidence for the prescriptive and prognostic qualities of variables that were found to predict treatment results in earlier studies. Subjects that can be considered *non-responders* after the first phase of treatment will be randomly assigned to three groups. For the first group this means continuing treatment with another therapist, the second group will, apart from such a change of therapist, also be offered another form of treatment, and for a third group nothing changes. Another post-hoc analysis is aimed at finding out what influence working alliance and characteristics of the therapist have on treatment effect. An additional group of 30 patients will follow the same design, but will use a specially designed app to measure individual variation

in affect and emotions shortly before, and during the first four weeks of treatment.

Intervention

Subjects will receive 16 treatment sessions of STPP or CBT in the initial phase of treatment, within 8 weeks. In the second phase, the patients who did not respond in the first phase will again receive the same number of treatment sessions.

Study burden and risks

There are no known risks associated with either of the treatment methods. The biggest burden for subjects is filling out the questionnaires to assess the different variables that are needed for answering the primary research questions. For subjects who respond in phase 1, this will take 3 hours; for subjects who receive another 8 weeks of treatment, filling out the questionnaires will take about 3,5 to 4 hours. Patients will get treatment sessions twice a week, which is relatively frequent compared to treatment as usual, but by doing this, we expect treatment effects to set in sooner. Subjects cannot use antidepressant medication, unless the maximal effect has been reached prior to the start of the study. They are asked not to make changes with regard to medication, except when necessary, e.g. in case of crisis or severe side effects. For measuring affect and emotions an Experience Sampling Method will be used in an additional group of 30 patients, who will be asked to answer short questions in an app 10 times a day during 3 days a week for a number of weeks.

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

Patients who seak suffer from a major depressive disorder (moderate to severe severity) and seak treatment on one of the Dimence-sites where the research is conducted.

Exclusion criteria

• problems speaking Dutch
• suffering from psychotic symptoms
• substance dependence (except nicotine)
• acute suicidality that has to be adressed immediately
• persons that are not capable of following the treatment protocol, e.g. lengthy absence
• not willing to sign for informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-09-2016
Enrollment:	308
Type:	Actual

Ethics review

Approved WMO Date:	21-07-2016
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	23-07-2019
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	26-07-2021
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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: 26978
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL56047.099.16
OMON	NL-OMON26978