Treatment effects of a short intensive treatment (8 days) of obsessive compulsive disorder and panic disorder of nonresponders of cognitive behaviour therapy.

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The present study is aimed to study the feasibility and effects of ICBT for outpatient nonresponding CBT patients with PD or OCD.Primary Objective: 1. Is this treatment model effective in terms of reduction in PD or OCD symptoms?Secondary Objective(...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON42267

Source
ToetsingOnline

Brief title
Short Intensive treatment for OCD and PD

Condition

- Anxiety disorders and symptoms

Synonym
obsessive compulsive disorder and panic disorder

Research involving
Human

Sponsors and support

Primary sponsor: ProPersona (Nijmegen)
Source(s) of monetary or material Support: Subsidie aanvraag loopt bij Fonds Psychische Gezondheid (inmiddels toegekend). Voor de jongeren loop een subsidieaanvraag bij MENZIS

Intervention

Keyword: CBT, Intensive, Obessive Compulsive Disorder, Panic Disorder

Outcome measures

Primary outcome

Primary study parameters are:

Adults:

PDSS for PD

The main PD symptoms are assessed with the PDSS: The Panic Disorder Severity

Scale

(Shear, et al., 1992; de Beurs, 2002). The PDSS is a 7 item semi-structured

clinical interview. Symptoms of the last week are rated on a 5-points Likert

scale, ranging from 0-4. The most important aspects of panic disorder (panic

frequency, fear or distress during panic attacks, anticipatory anxiety, phobic

avoidance of situations, phobic avoidance of physical sensations, impairment in

work and social functioning.

The (clinician-administered) PDSS is considered a reliable tool for monitoring

of treatment outcome (Shear, et al., 2001).

The scale can be administered in 10-15 minutes.

Y-BOCS for OCD

The main OCD symptoms are assessed with the Y-BOCS: the Yale-Brown Obsessive-Compulsive Scale (1989). The Y-BOCS is a 10-item semi-structured clinical interview. Symptoms of the last week are rated on a 5-points Likert scale, ranging from 0-4. The (clinician-administered) Y-BOCS is considered a reliable tool for monitoring of treatment outcome and is considered as the gold standard measure of obsessive-compulsive symptoms (Storch et al., 2005).
The scale can be assessed in 15-30 minutes.

Adolescents:

CY-BOCS for OCD

The main OCD symptoms are assessed with the CY-BOCS: the Child Yale-Brown Obsessive-Compulsive Scale (Scahill et al., 1997; de Haan & Wolters, 2007). The CY-BOCS is a 10-item semi-structured clinical interview. Symptoms of the last week are rated on a 5-points Likert scale, ranging from 0-4. The (clinician-administered) CY-BOCS is considered a reliable tool for monitoring of treatment outcome and is considered as the gold standard measure of obsessive-compulsive symptoms (Storch et al., 2005).
The scale can be assessed in 15-30 minutes.

Secondary outcome

Adults:

IDS

Depressive symptoms are assessed with the IDS: Inventory of Depressive

Symptomatology (Rush et al., 2000). The IDS contains 30 items with a 4-point Likert Scale. In the present study the Self Rating version is used. The IDS has good validation (Rush et al., 1996).

The scale can be assessed in 10 minutes.

OQ

The Outcome Questionnaire (OQ-45.2) is a 45-item self-report scale designed for repeated measurement of client functioning through the course of therapy and at termination. The instrument has proven particularly useful in documenting the effect of interventions due to therapy as it has been shown to be sensitive to change in a treated population while remaining stable in a nontreated population (Lambert, Burlingame, et al., 1996).

MINI

The Mini International Neuropsychiatric Interview (MINI; Sheehan et al., 1998; Overbeek et al., 1999) is a short diagnostic structured interview (DSI) developed in France and the United States to explore 17 disorders according to Diagnostic and Statistical Manual (DSM)-III-R diagnostic criteria (Sheehan et al., 1998; Overbeek, 2006) . It is fully structured to allow administration by non-specialized interviewers.MINI is a short diagnostic interview schedule that can be easily incorporated into routine clinical interviews. It has good acceptance by patients (Pinninti et al., 2003). In order to keep it short it focuses on the existence of current disorders. For each disorder, one or two screening questions rule out the diagnosis when answered negatively.

CGI

The Clinical Global Impression Scale (CGI; Guy, 1976) is a 3-item questionnaire designed to assess global severity of illness and change in the clinical condition over time. The CGI consists of three global scales: 1) severity of illness; 2) global improvement; 3) efficacy index. The clinical Global Impression Scale (CGI) is commonly used as a primary outcome measure in studies evaluating the efficacy of treatments for anxiety disorders (Zaider et al., 2003).

EQ-5 D

The EQ-5D (EuroQol, group, 1995) is a generic questionnaire which generates a health profile as well as index scores for health-related quality of life that may be used in cost-utility analysis. König et al (2010) examined validity and responsiveness of the EQ-5D in patients with anxiety disorders.
The EQ-5D questionnaire comprises five questions (items) relating to current problems in the dimensions' mobility', 'self-care', 'usual activities', 'pain/discomfort', and 'anxiety/depression' [2,3,16]. Responses in each dimension are divided into three ordinal levels coded (1) no problems, (2) moderate problems, (3) extreme problems. This part, called the EQ-5D descriptive system, provides a five-dimensional description of health status which can be defined by a five-digit number

Patient evaluations of treatment acceptability

Dutch and adapted version of Havnen et al 2013. This questionnaire includes 14

questions about the patients experiences with the Short Intensive 8-day CBT.

The MINI, PDSS or Y-BOCS, IDS, CGI, OQ, and EQ-5D are part of the ROM (Routine Outcome Monitor) and are on a regular basis assessed in all patients with anxiety disorders in Overwaal, ProPersona.

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Adolescents

BDI

Depressive symptoms are assessed with the Beck Depression Inventory (BDI; Beck, Ward, Mendelson, Mock, Erbaugh, 1961; Dutch version: Schotte, Maes, Cluydts, De Doncker, & Cosyns, 1997). The BDI is a 21-item, self-report inventory for measuring the existence and severity of symptoms of depression as listed in the DSM-IV in adolescents and adults. The internal consistency is high for both psychiatric and non-psychiatric samples (Cronbach*s alpha ranged from .76 to .95 and .73 to .92 respectively). The concurrent validity is high in both psychiatric and nonpsychiatric samples (correlation with clinical ratings: r = .55 to .96, correlation with Hamilton Rating Scale for Depression: r = .61 to .86, correlation with Zung: r = .57 to .86, correlation with MMPI-D: r = .41 to .75; Beck, Steer, & Garbin, 1988). The Dutch version of the BDI also shows good internal consistency (.91).

MINI KID

The Mini International Neuropsychiatric Interview for children and adolescents

(MINI KID; Sheehan et al., 2010;) is a structured clinical diagnostic interview designed to assess the presence of current DSM-IV psychiatric disorders in children and adolescents aged 6 to 17 years. The MINI-KID is organized in diagnostic sections or modules. For each disorder the instrument asks 2 to 4 screening questions; additional symptom questions within each disorder section are asked only if the screen question are positively endorsed. The instrument screens for 24 DMV-IV psychiatric disorders and suicidality and takes approximately a half an hour to administer. Sensitivity was substantial (0.61-1.00) and specificity was substantial to excellent (0.73-1.00). Interrater and test-retest kappas were substantial to almost perfect (0.64-1.00).

KIDSCREEN

The KIDSCREEN (The Kidscreen Group Europe, 2006) questionnaires are a family of instruments developed and normalized for surveying health-related quality of life in children and adolescents ages 8 to 18. The questionnaires were developed simultaneously in 13 European countries with special regard to childhood concepts of health and well-beeing. The Kidscreen is a self-report measure that can be administered in hospitals, medical establishments and schools by professionals in the fields of public health, epidemiology, and medicine. In this effect-study the Kidscreen-52 will be used for the

adolescent. The parents will be asked to fill in the Kidscreen-27. The Kidscreen-52 allows detailed profile information for 10 dimensions of health-related quality of life and requires 15-20 minutes to be filled in. The Kidscreen-27 allows detailed profile information for 5 dimensions of health-related quality of life and requires 10-15 minutes to be filled in. The different versions oft he Kidscreen are all reliable and valide.

Family Accommodation Scale*Parent Report

The Family Accommodation Scale (Calvocoressi et al., 1999) is a 13-item clinician-rated measure that assesses the degree to which family members have accomodated the child*s OCD symptoms during the previous month and the level of distress or impairment that the family members and patient experience as a result of the family accomodating or not accomodating the child. Areas assessed include the provision of reassurance or objects for compulsions, decreased behavioral expectations for the child, modification of family routines, and help avoiding distressing objects, places, or experiences. Items are rated on a 5-point scale. The FAS demonstrated good psychometric properties. The FAS demonstrated excellent interrater reliability and good internal consistency and performed well on assessment of its convergent and discriminant validity.

Patient evaluations of treatment acceptability

Dutch and adapted version of Havnen et al 2013. This questionnaire includes 14 questions about the patients experiences with the Short Intensive 8-day CBT.

In adolescents, the Kidscreen is part of the ROM (Routine Outcome Monitor) and

is on a regular basis assessed in all patients with anxiety disorders in

ProPersona.

Study description

Background summary

According to the Dutch Guidelines for the treatment of Anxiety Disorders (DGA; van Balkom et al, 2013) the first treatment of choice for patients with obsessive-compulsive disorder (OCD) or panic disorder (PD) is Cognitive Behaviour Therapy (CBT) and more specific Exposure and Response Prevention (ERP). The effectiveness of CBT for these disorders has been largely proven (van Balkom et al, 2013). Also, the effectiveness in children and adolescents has been largely proven (Skasphedinsson et al., 2015). However, a rather substantial group of patients (25-35%) does not successfully improve of outpatient CBT. These are the so called nonresponders or nonremitters. These nonresponders (and their families/relatives) are at risk for demotivation, higher health service costs, dropout and longer time to social rehabituation. The DGA provides pharmacotherapeutic guidelines for nonresponders. The question is whether further treatment with pharmacotherapy is the best option for this group of nonresponders. Pharmacotherapy is less cost-effective (Furukawa & Watanabe, 2006) and patients have the tendency to attribute their improvement to medication and not to their own actions. Self efficacy will therefore not improve and tapering of medication will be difficult. Further guidelines for psychotherapeutic treatment are expert based and not evidence based and imply mostly intensifying to clinical inpatient treatment or day treatment. These treatments takes 3-6 months. Scientific evidence for the effectiveness for these programs is scarce. This is also due to the fact that is hardly achievable to do scientific research with nonresponders by randomised controlled trials.

ERP is the most important intervention in the psychotherapeutic interventions for anxiety disorders. ERP has the intention to expose the patient to his most feared situation while he does not perform avoidance of safety behaviours to control his anxiety. This is how the patient will learn that his fearful expectations will not come true and his anxiety levels will drop. Although ERP is very successful, a group of patients will not succeed in performing these exposure exercises by themselves. An explanation can be that they are not consistent and are too fearful to confront their fears. However, the performance of exposure exercises are directly correlated to treatment outcome (Le Beau, Davies, Culver, & Craske, 2013). One of the explanations of

nonresponse is that the nonresponding patient does not succeed in exposure exercises without avoidance of safety behaviour. Therefor, therapist assisted exposure could be more effective than non-assisted exposure (Abramowitz, 1996). Therapy assisted ERP could cause more control over the exercises and the avoidance and safety behaviours and therefor create more pressure. Nonresponding patients can expose themselves finally to their fearful situations and turn into responding patients. The therapist can assist in different patient-specific situations, in different locations and when necessary at home. In this manner, also familiy menbers can learn how to cope with the patients and his compulsive behaviour. This leads immediately to an positive effect on the treatment (Thomson-Hollands, 2015).
Most intensive (day-) clinical treatments have treatments of months and do not focus on ERP. A long intensive treatment of months is not desirable because of the continuity with family life, work and social network, and because of the high costs. And, possibly, it is not necessary when a short intensive treatment has a real focus. The focus should be on the intervention with the most evidence: ERP.
Intensive treatments, with 2-10 treatment days with intensive exposure or flooding, are effective for OCD (e.g. Abramowitz, Foa, & Franklin, 2003; Oldfield et al., 2011) and PD (e.g. Britran, Morisette, Spiegel, & Barlow, 2008; Wambach & Rief, 2012).

To the best of our knowledge, there are two studies in which nonresponding patients with an anxiety disorder who were treated with CBT received an intensive exposure treatment. Van der Heiden and colleagues (2010) treated 8 patients with PD in an open trial (without control group or randomisation) and found high effect sizes and a moderate clinical improvement. Dettore, Pozza, and Coradeschi (2013) also performed an open trial with 48 OCD patients. Effect sizes were high.
In Overwaal, Centre for Anxiety Disorders, we recently developed an intensive treatment program for nonresponding patients with PD and OCD, the ICBT. The present study is aimed to study the feasibility and effeciveness of this intensive treatment.

Study objective

The present study is aimed to study the feasibility and effects of ICBT for outpatient nonresponding CBT patients with PD or OCD.

Primary Objective:
1. Is this treatment model effective in terms of reduction in PD or OCD symptoms?

Secondary Objective(s):
1. What is the effect of the intensive treatment on depressive symptoms?
2. What is the effect of the intensive treatment on quality of life?
3. How is the dropout rate?

4. How do patients experience this intensive exposure treatment?

Study design

The proposed study uses a multiple baseline design. A multiple baseline design is an experimental design that is well suited to explore the effects of treatments for disorders with a small chance for spontaneous recovery, such as PD and OCD. Patients all receive the same intervention but are randomly allocated to different time periods before and after treatment in which they are monitored. By assessing the change in symptoms over time, the causal relation between intervention and outcome can be established. Although a randomised controlled trial (RCT) is perceived as the gold standard to examine the effects of a new treatment, the design has shortcomings as well, mainly in user friendliness and costs. Like an RCT, a multiple baseline design can also demonstrate that the intervention causes change in symptoms and that a change is significant (Hawkins, Sanson-Fisher, Shakeshaft, D*Este, & Green, 2007; Onghena, 2005; Onghena & Edgington, 2005).
Compared to a RCT, a smaller number of participants is needed and the included participants operate as their own controls.

The present study consists of 4 phases.
T0 Screening
T 1 Baseline 2-8 weeks
T2 Active Intervention (6 weeks) : ICBT 2 weeks of 8 days and 4 boostersessions (once per week)
T3 Post treatment 2-8 weeks plus 2 weeks to FU
T4 Follow up after 18 weeks after start baseline (4 weken)

In total, the study takes 22 weeks. During the baseline, post treatment and follow-up, the weekly assessments can be done by telephone.
10 patients with PD and 10 patients with OCD (age 18-65) and 10 patients with OCD (age 15-17) will be included in the present study.

randomisation:
7 different baseline randomisations are possible:
1. 2 weeks baseline before treatment - 8 weeks post treatment (1 PS, 1 OCD)
2. 3 weeks baseline before treatment - 7 weeks post treatment (1 PS, 1 OCD)
3. 4 weeks baseline before treatment - 6 weeks post treatment (2 PS, 2 OCD)
4. 5 weeks baseline before treatment - 5 weeks post treatment (2 PS, 2 OCD)
5. 6 weeks baseline before treatment - 4 weeks post treatment (2 PS, 2 OCD)
6. 7 weeks baseline before treatment - 3 weeks post treatment (1 PS, 1 OCD)
7. 8 weeks baseline before treatment - 2 weeks post treatment (1 PS, 1 OCD)

Intervention

Treatment

All patients receive the same intervention of ICBT with ERP. CBT is the treatment of choice for anxiety disorders (van Balkom et al., 2013). Intensive CBT (2-10 days) has been proven to be effective is several controlled studies for OCD (e.g. Abramowitz, Foa, & Franklin, 2003; Oldfield, et al., 2011) and for PD (e.g. Bitran, Morisette, Spiegel, & Barlow, 2008; Wambach & Relief, 2012). There will be additional family psycho-education sessions, for the adolescent patients.
In the present study, intensive treatment will be delivered in 8 days (in two weeks). Patients start in the morning at the treatment site. After a 90 minute CBT session, in which treatment goals and exercises are discussed, patients go to different places to do exposure exercises. E.g. PD patients perform interoceptive exposure exercises, or go with public transportation, or visit busy marketplaces. OCD patients can go to hospitals, their own home, etcetera to perform exposure exercises.
Treatment days are: Thursday, Friday, Monday, Tuesday, Thursday, Friday, Monday and Tuesday. On Wednesdays and in the weekend days patients should perform exposure exercises on their own and are encouraged to keep practising what they already achieved .
Patients can bring their partner of a close friend in the morning session to give psycho-education and help patients with relapse prevention.
After the 8 days ICBT, patients will receive 4 booster sessions of 90 minutes during 4 weeks and an evaluation session. In the boostersessions, some of the exposure exercises will be repeated and response prevention will be discussed. Also, when necessary, orientation on quality of life (work, day-time activities, goals, and social life) will be discussed (max 4 sessions).

Therapists
Therapist are a fixed team of qualified and experienced CBT therapists or workers of CBT trainees. They all work at TOP GGZ centre for anxiety disorders Overwaal and/or at the child/youth department of the centre for mental health care ProPersona. Overwaal has broad experience and expertise in diagnostic and treatment of PD and OCD. Supervision will be given by dr. M. Kampman, clinical psychologist and CBT therapist of Overwaal.

Treatment Integrity
Treatment integrity will be assessed and promoted by the following interventions:
1) Treatment will be delivered following a treatment manual;
2) Supervisions about treatment
3) Weekly meetings
4) Registrations of sessions, numbers, duration in minutes, content.

Study burden and risks

Patients have to fill in questionnaires, and have a weekly interview (15-30 minutes) during 22 weeks. This is 5-7- hours additional on the questionnaires patients already have to fill in as a general procedure of Routine Outcome

Monitoring.
The benefits are the decrease of anxiety related symptoms.
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Contacts

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ProPersona (Nijmegen)

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with a primary diagnosis (DSM IV) of obsessive-compulsive disorder or panic disorder, who had an adequate cognitive behaviour treatment and did not respond ((C)Y-BOCS score of al least 16 or a PDSS score of at least 11).

Exclusion criteria

- Major depressive disorder and/or suicidality
- Psychotic disorder
- Bipolar disorder
- Comorbid diagnosis Hoarding
- Intellectual disability or severe cognitive function disorders
- Inability to fill in questionary
- Inability to focus on treatment because of other problems
- Inability to reduse in alcohol or drugsuse

Additional for adolescents:
- Severe Comorbid Pervasive Developmental Disorder
- Severe disrupted family functioning
- Other problems or problem area's of first priority

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-05-2015
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	31-12-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-01-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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: 20016
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL49574.072.14
OMON	NL-OMON20016
OMON	NL-OMON29480

Study results

Date completed:	21-09-2020
Actual enrolment:	29