Think yourself better: A study into the effectiveness of an online pre-treatment Cognitive Bias Modification training for children with an obsessive compulsive disorder

Published: 04-10-2013
Last updated: 24-04-2024

The present study aims to improve treatment of children and adolescents with OCD by adding a short online CBM-I training to CBT. We use a stepped care model in which CBM-I training is provided as a first step of treatment, followed by CBT. The CBM-I...

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

Summary

ID

NL-OMON38575

Source
ToetsingOnline

Brief title
Cognitive Bias Modification training as pre-treatment for youth with OCD

Condition

- Anxiety disorders and symptoms

Synonym
obsessieve compulsive disorder, OCD

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Fonds Nuts -Ohra

Intervention

Keyword: cognitive interpretation bias, Obsessions, Obsessive compulsive disorder, therapy

Outcome measures

Primary outcome

The primary study parameter is the severity of the obsessions and compulsions

as measured by the CY-BOCS,(semi structured interview for children and

parents).

Secondary outcome

Secundary study parameters are:

- the Interpretation Bias Recognition Task. In the Interpretation Bias

Recognition Task children read relevant, ambiguous stories . Afterwards two

possible interpretations of the scenario appear. The child answers on a 4-point

Likertscale if the interpretation corresponds with the scenario read earlier.

- OBQ-CV (Obsessions beliefs Questionnaire- Child Version). The OBQ-CV is a

questionnaire to measure dysfunctional OCD related interpretations.

- Child Behavior Checklist (CBCL) as measure for general psychopathology

filled in by parents

- Youth Self Report (YSR) as measure for general psychopathology filled in by

the child

- Child Depression Inventory (CDI), to measure depressive complaints

In addition to OCD symptoms, anxiety and mooddisorders (Anxiety Disorder Interview Scheme- Child/parents - ADIS-C/P), symptoms of autism spectrum disorders (VISK), executive functioning (BRIEF, Stroop task, SOPT), high sensitivity (HSK) and possible ticdisorders (Yale Global Tic Severy Scale-YGTSS) are measured prior to the training.

Study description

Background summary

The current study is a continuation of our recently conducted pilotstudy into the effectiveness of CBM-I training for children and adolescents with an obsessive compulsive disorder (OCD), METC number: NL 35351.018.11

A patient with an obsessive compulsive disorder (OCD) suffers from obsessions, compulsions or both. Obsessions are intrusive and distressing thoughts that, unwanted, come back repeatedly and cause fear. Examples are: the thought of an accident that will happen, the thought that the patient or his/her relatives become very sick, or the thought that he or she will cause a disaster. Compulsions are repetitive behaviors to prevent or reduce anxiety or distress, often caused by obsessions, even though the patient knows that the compulsions will not prevent aaccidents, disasters or sickness. Examples of compulsions are washing hands too often and too long, checking rituals that take hours, repeatedly asking for reassurance on trivial subjects and counting during all sorts of behaviors. The compulsions are either excessive or not connected in a realistic way with what they are designed to prevent. OCD in children and adolescents is relatively rare, it affects 1-2% of youth. It is associated with significant impairments in functioning, for example bad or non functioning at school, disturbed family relations, social dysfunction and depressive symptoms (Abramowitz, Whiteside, & Deacon, 2005). Untreated symptoms typically persist. In most adults the disorder started before they turned twenty years of age. Cognitive behavioral therapy (CBT) is the treatment of choice (Geller et al., 2012). With CBT an average of 40-65% decrease in symptoms can be achieved (e.g., de Haan, Hoogduin, Buitelaar, & Keijsers, 1998; O*Kearney, Anstey, Von Sanden, & Hunt, 2010; Turner, 2006). Recently, our research group conducted a randomized controlled trial into the effect of CBT in children with OCD. After 16 sessions of CBT an average decrease of 53% in symptoms was achieved (Wolters et al., in preparation). This implies that half of the symptoms are still

present after CBT. There were large individual differences in treatment effect. In some children the symptoms were nearly or completely gone, while other children had still substantial symptoms.
In case of too little improvement with CBT there are a few options for further treatment: medication, inpatient treatment or proceeding with CBT. Although the addition of medication to CBT could lead to a better treatment effect, it is unknown for which children this is the case (March et al., 2004). Unnecessary prescribing of medication is not without risk: undesirable side effects, relaps when medication is discontinuated, little knowledge into longterm effects. Inpatient treatment is expensive and has far reaching influences on the patients life, while there are no research data about the efficacy. The third possibility is proceeding with CBT. The treatment protocol consists mostly of 12-20 sessions (de Haan & Wolters, 2009; O*Kearney et al., 2010). It is unknown whether with that number of sessions the maximum effect can be reached. Continuing CBT can lead to an increase of the effect (Wolters et al, in preparation). However, longer duration of therapy also leads to higher health costs and longer waiting lists.
In conclusion, there are not enough possibilities to increase the effect of treatment without increasing the costs and possible side-effects.
Recently a new treatment has been developed for anxiety and OCD: Cognitive Bias Modification-Interpretation (CBM-I), a computer training, with minimal therapeutic time needed. In research a positive effect of this training is found on anxiety symptoms (Lothmann, Holmes, Chan, & Lau, 2011; Vassilopoulos, Banerjee, & Prantzalou, 2009; Vassilopoulos, Moberly, & Zisimatou, 2012; Vassilopoulos, Blackwell, Moberly, & Karahaliou, 2012). The first study into adults with OCD showed a reduction in OCD-related dysfunctional cognitions and a reduction the tendency to execute compulsions (Clerkin & Teachman, 2011). The pilot study, recently conducted by our department, into the effectiveness of CBM-I training by adolescents with an obsessive compulsive disorder, showed, despite the small sample size, a trend for a positive effect on clinical measures and on an implicit interpretation bias measure (for more information about the pilot study: paragraph 5.3 of the research protocol). The present application concerns a study into the effectiveness of a short-term CBM-I training as pre-treatment for CBT in children with OCD. The purpose is to influence the information processing beforehand which could make CBT faster and more efficient, thereby lowering the need for medication and inpatient treatment.

Study objective

The present study aims to improve treatment of children and adolescents with OCD by adding a short online CBM-I training to CBT. We use a stepped care model in which CBM-I training is provided as a first step of treatment, followed by CBT. The CBM-I training is compared to a waiting list condition in which no treatment occurs. This waiting list condition is not longer than the usual time a patient has to wait before treatment starts.
If CBM-I turns out to be effective, children could be helped better and

quicker. CBM-I training has important advantages over other treatments: the CBM-I training is short-term, applicable in waitlist time for CBT which provides an earlier start with treatment, and CBM-I is motivating for the patient, inexpensive and easy to implement.
The researchproject consists of two parts.
1. The effect of CBM-I training. Our research question for the first part is: Does CBM-I training lead to a change in dysfunctional interpretations and to a decrease of OCD symptoms?
2. The effect of CBM-I training on further therapy. It is expected that CBM-I has a positive influence on further treatment. Research into the effect of CBT versus waiting list control shows an average effect size of CBT of -10.71 points on the Children Yale-Brown Obsessive Compulsive Scale (CY-BOCS; see below) (O-Kearney et al., 2010). We expect to be able to increase this effect size by adding the CBM-I training to CBT. The research question of the second part of this research is: Does the addition of CBM-I training as pre-treatment for CBT lead to a larger effect of CBT? If this is the case, this means a better quality of life for the children and their families, shorter waiting lists for treatment and saving of costs.

Study design

This study is a multi-centered, randomized controlled trial with two conditions in which the effect of the CBM-I training (4 weeks) is compared to a waiting list (4 weeks) that provides no treatment. The waiting list for treatment is no longer than usual. Before and after the period of training measurements will be done by a researcher. After those 4 weeks both groups start CBT according to protocol, 16 weekly sessions. The effect of this treatment (severity of OCS) will be measured every 4 sessions by the researcher. At the end of CBT another measurement will take place.

Intervention

The Cognitive Bias Modificiation-Interpretation (CBM-I) training (Mathews & Mackintosh, 2000) is used. In this training dysfunctional interpretations are changed by teaching new associations between ambiguous situations and functional interpretations. This happens through repeatedly presenting a series of different short stories (called scenarios) in which such ambiguous situations are described and a functional interpretation is given. To actively involve the patient, he or she has to fill in a word. Only one word is possible in the sentence. An example of a scenario is:

You have to set the table for dinner. You feel the urge to wash your hands thorough before you touch the cutlery and dinner-service. You think this is not necess_ry.

The training is provided on a computer. The patient carries out the training at

home, without help of a therapist. The training consists of 12 practice sessions of 15 minutes each. The sessions are divided over four weeks, with three practice sessions a week.

Study burden and risks

The burden for the patients in the experimental condition consists of filling in the questionnaires (one about 90 minutes, twice about 60 minutes) and attending 12 training sessions at home of 15 minutes each, divided over four weeks.
The burden for the patients in the waiting list condition consists of filling in the questionnaires (one about 90 minutes, twice about 60 minutes). There are no risk associated with participation. All patients will receive the usual (evidence based) treatment for OCD. In the CBM-I training no negative or harmful associations will be trained. The waiting list control condition is no longer than usual.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

diagnosis obsessive compulsive disorder,
age between 8 and 18 years
informed consent
CY-BOCS score > 15

Exclusion criteria

psychosis
severe depression
IQ< 80
drugs- or alcohol problems

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:	Recruitment stopped
Start date (anticipated):	16-10-2013
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO Date:	04-10-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-01-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-02-2014
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	NL44055.018.13