Think different. A study into the feasibility and the effectiveness of an online Cognitive Bias Modification training on an app for adolescents with an obsessive compulsive disorder (OCD)

Published: 14-10-2016
Last updated: 17-04-2024

This study concerns research into the applicability and effectiveness of CBM-I training through an app on the mobile phone. The research is done in adolescents (12-18 years) treated at the Bascule clinic for OCD. The training will take place during...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON43502

Source
ToetsingOnline

Brief title
Cognitive Bias Modification training on an app for adolescents with OCD

Condition

- Anxiety disorders and symptoms

Synonym
Obsessive 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

Intervention

Keyword: app, cognitive interpretation bias, Obsessive compulsive disorder, online training

Outcome measures

Primary outcome

The primary outcome of the study is severity of compulsion symptoms, measured

by the CY-BOCS, a semi-structured interview conducted with child and parents

and an individualized daily measure of the severity of the complaints

(VASschaal). To measure the applicability of the training on the app an

evaluation inventory will be used at the end of the training.

Secondary outcome

There are no secondary outcome of the study

Study description

Background summary

The present study is a continuation of our recently conducted pilot study into the effectiveness of CBM-I training for children and adolescents with a obsessive compulsive disorder (OCD), METC number: NL 35351.018.11 and on the still ongoing study into the effect of CBM-I training as pre-therapy on the effectiveness of Cognitive Behaviour Therapy (CBT) METC nummer: NL 44055.018.13. .

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 accidents, disasters or sickness. Examples of compulsions are washing hands too often and too long, checking rituals that take hours, repeatedly asking for reassurance about 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. So there is a need for improving the therapy.

According to cognitive models (Salkovskis et al.) (fast) negative interpretations play a crucial role in Obsessive Compulsive Disorder (OCD). Recently, methods have been developed to change these fast, initial interpretations with the aid of a computer training (Mathews & Mackintosh, 2000); Cognitive Bias Modification- Interpretation training (CBM-I). Promising effects of this training have been found in adults both with anxiety symptoms (see eg Salemink et al., 2009) and with OCD (Clerkin & Teachman, 2011). In a pilotstudy we examined this training in adolescents with OCD and found evidence for a positive effect of CBM-I at different clinical outcomes (CY-BOCS obsessions severity score, and score on scale for internalizing problems) (Salemink, Wolters, & de Haan, 2015. The preliminary results of the ongoing study

This indicates an added value of the CBM-I training above the 'treatment as usual' (CBT). The evaluation of the training, however, shows that, although the training is perceived as useful, a major drawback is that the training at the moment can only be done on a computer or PC. This possibly affects the frequency and duration, of the training and will thus have a negative influence on the effectiveness. It is expected that the application of CBM-I on a mobile phone through an app better fits into the lifestyle of adolescents and consequently will be better used.

Study objective

This study concerns research into the applicability and effectiveness of CBM-I training through an app on the mobile phone. The research is done in adolescents (12-18 years) treated at the Bascule clinic for OCD. The training

will take place during the regular treatment (CBT possibly with medication). When the CBM-I training through an app appeals to the adolescents and leads to a better treatment effect, this implies a positive contribution to the treatment.

Study design

The study has a Multiple Baseline Single Case Experimental Design, with two baseline periods to investigate the effect and the appreciation (apllicability) of the CBM-I training (12 sessions in two weeks). There are two phases: baseline phase and training phase. The Baseline phase consists of two 'conditions': 10 days and 14 days baseline. Patients will be randomly allocated to one of the two baseline conditions. Measurements are carried out at the start of the baseline, at the beginning of the training phase (= end of the baseline phase) and at the end of the training phase. During the baseline and the training phase there is a daily severity measurement, through a Visual Analogue Scale. .
Training takes place during the usual treatment with CBT and possibly medication.

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 on the patient is as follows:
Pre test: 1 hour
- A semi-structured interview into the severity of OC symptoms (CYBOCS), with patient by the assessor
- An interview to determine the dimensions of OCD (DOCS).
- Establishement of the patient's individualized VASschaal taken

Mid- test: 15 minutes
- CY-BOCS

Post test: 30 min
- CY-BOCS
- a questionnaire to evaluate the evaluation

3,5 or 4 weeks (depending on the duration of the Baseline-phase) daily measurement: VASschaal: 2 minutes a day (total 48 or 56 minutes)

Training
- 12 sessions CBM-I of from about 15 minutes in 2 weeks: 180 minutes

In total, the load is 5-6 hours in three and half to four weeks.
Risks

The measurements and the intervention have no risks.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 5
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 5
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

diagnosis obsessive compulsive disorder
age between 12- 18 years
informed consent
CY-BOCSscore>15
in patient treatment for OCD

Exclusion criteria

psychosis
severe depression
IQ < 80
drugs- or alcohol problems

Study design

Design

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

Recruitment

NL
Recruitment status: Will not start
Enrollment: 8

Type:	Anticipated

Ethics review

Approved WMO Date:	14-10-2016
Application type:	First submission
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	NL55696.018.16