Enhanced Cognitive Behavioral Therapy for children and adolescents with Obsessive-Compulsive Disorder

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To examine the feasibility and acceptability, and preliminary efficacy, of a new developed enhanced CBT (eCBT) for pediatric obsessive-compulsive disorder

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

Summary

ID

NL-OMON46606

Source
ToetsingOnline

Brief title
eCBT for pediatric 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: Samarbeidsorganet mellom Helse Midt-Norge RHF; Norwegian University of Science and Technology (NTNU)

Intervention

Keyword: children, Cognitive behavioral treatment, e-health, Obsessive compulsive disorder

Outcome measures

Primary outcome

Treatment feasibility and acceptability

Secondary outcome

Treatment efficacy

Study description

Background summary

Pediatric obsessive compulsive disorder (OCD) is a relatively common, severe, and debilitating condition. Cognitive behavioral therapy (CBT) is the first-line treatment for pediatric OCD. However, treatment for OCD is hampered by several problems. Average improvement rates are limited and there are large individual differences in treatment effect. There are organizational and practical barriers to treatment for OCD. The availability of this treatment is limited because of a shortage of experienced therapists, CBT is often poorly implemented and there are long waiting lists for treatment New technologies offer the opportunity to improve accessibility, user friendliness, and effectiveness of traditional office-based cognitive behavioral therapy (CBT).

Study objective

To examine the feasibility and acceptability, and preliminary efficacy, of a new developed enhanced CBT (eCBT) for pediatric obsessive-compulsive disorder

Study design

Open trial

Intervention

Enhanced Cognitive Behaviour Therapy (eCBT) is traditionally office-based cognitive behavioral therapy, adding real-time, interactive videoconferencing technology and a smart phone application.

The treatment consists of 10 in-office face-to-face sessions and 12 videoconferencing sessions (therapist guided exposure exercises at home) in 14 weeks. The treatment contains psychoeducation about OCD and treatment, administration of symptoms, exposure with response prevention (ERP), supportive cognitive interventions, and relapse prevention. Parents are involved in the treatment.

Study burden and risks

There are very little or even no risks for participants of the present study related to the treatment. Enhanced CBT (eCBT) is a new framework for providing treatment based on well-validated principles of CBT. By employing an integrated and age appropriate technological package, a more intensive and focused application of CBT principles can be executed. Furthermore, integrating new technologies may provide treatment that is more easily accessible, user friendly, and motivating, and may be attractive for youth. Therefore, and given current empirical support for the efficacy of CBT for the treatment of pediatric OCD, research participants are offered the usual, evidence-based treatment, but in a format that may offer more convenience (the main part of the treatment sessions will be at home, via video link, which reduces travelling costs and time, and stigmatizing). The video sessions at home may make the treatment more ecologically valid, and use of the app may enhance motivation.
However, a possible disadvantage of study participation is the completion of some extra questionnaires.
Furthermore, although strict security measures are taken, risks related to technology and security can't be excluded. In addition, we can't exclude the risk of faltering technology and loss of connectivity during the video linking. When this happens, the therapist will try to find a solution together with the patient.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 5
Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 5
Amsterdam 1105AZ

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age 7*17 years (inclusive); a primary DSM-5 diagnosis of obsessive-compulsive disorder, CY-BOCS * 16, family home equipped with broadband connection

Exclusion criteria

A Psychiatric comorbidity that makes participation clinically inappropriate (for example, primary anorexia nervosa), depression with suicidality that requires acute treatment, and psychosis
IQ below 70
Insufficient understanding of the Dutch language
State-of-the-art CBT for OCD in the past 3 months
If on concurrent medication for OCD, being a stable dosage for less than 12 weeks

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	a smartphone application to support participants throughout the treatment
Registration:	No

Ethics review

Approved WMO

Date:	06-03-2018
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	NL64063.018.17