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Enhanced cognitive behavioral therapy for children and adolescents with obsessive compulsive disorder: an open trial

Submission date
18/12/2019

Recruitment status
No longer recruiting

Registration date
31/01/2020

Overall study status
Completed

Last Edited
09/09/2021

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Current plain English summary as of 11/06/2020:
Background and study aims
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 CBT 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 address some of these challenges. The researchers have developed an enhanced cognitive behavioral therapy (eCBT), based on traditional CBT enhanced with real-time, interactive videoconferencing technology and a smartphone application, to offer a more intensive and focused application of CBT principles in a way that may be more user-friendly and appealing to children and adolescents and their families.

The present study entails the development of the eCBT treatment package and, as a first step, aims to examine the feasibility, acceptability, and treatment outcomes for enhanced CBT (eCBT) for pediatric OCD. The study is a single-center open trial to examine the acceptability and feasibility of a newly developed enhanced CBT intervention (eCBT) in children and adolescents with OCD.

In response to the COVID-19 lock down measures, starting on 16 March 2020 eCBT is offered fully online (REMOTeCBT). REMOTeCBT closely parallels eCBT with the main difference that all sessions are delivered via the webcam. Feasibility, acceptability, and treatment outcomes for REMOTeCBT are examined, and will be compared to eCBT and traditional face-to-face CBT (data collected in the NordLOTS study; Torp et al., 2015), using a historical control design.

Who can participate?
Children and adolescents (age 7–17 years) with a primary diagnosis of OCD, referred for outpatient treatment

What does the study involve?
Until 16 March 2020 all participants received eCBT. eCBT consists of the usual, evidence-based treatment (CBT) in an 'enhanced' format, including videoconferencing sessions for guided exposure exercises at home in addition to face-to-face sessions, and an app supporting children and their parents throughout the treatment and monitoring progress. The treatment consists of 10 in-office face-to-face sessions and 12 video teleconferencing sessions (at home) within a period of 14 weeks. eCBT contains psychoeducation, administration of symptoms, exposure with response prevention, cognitive interventions, and relapse prevention. Parents are involved in the treatment.

Starting on 16 March 2020 eCBT is offered fully online (REMOTeCBT).

Assessments are performed pre- and post-treatment and at 3- and 6-months follow-up.

What are the possible benefits and risks of participating?
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 therefore attractive for youth. For these reasons, and given current empirical support for the efficacy of CBT for the treatment of pediatric OCD, participants are offered the usual, evidence-based treatment, but in a format that may offer more convenience (part of the treatment sessions will be at home, which reduces travel costs and time, and stigmatizing). The video sessions at home may make the treatment more ecologically valid and creates the opportunity to intensify therapeutic support during the exposure exercises. Use of the app may enhance motivation and treatment adherence.

There are very few risks for participants related to the treatment. However, although strict security measures are taken, risks related to technology and security can't be excluded. In addition, the researchers 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 to together with the patient. A possible disadvantage of study participation is the completion of extra questionnaires.

Where is the study run from?
NTNU, Regional Centre for Child and Youth Mental Health and Child Welfare (RKBU), located in Trondheim (lead site) and Alesund, Norway

When is the study starting and how long is it expected to run for?
October 2015 to December 2021 (updated 09/12/2020, previously: December 2020)

Who is funding the study?
Samarbeidsorganet mellom Helse Midt-Norge RHF, and the Norwegian University of Science and Technology (NTNU) (Norway)

Who is the main contact?
Norbert Skokauskas
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Previous plain English summary:
Background and study aims
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 CBT 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 address some of these challenges. The researchers have developed an enhanced cognitive behavioral therapy (eCBT), based on traditional CBT enhanced with real-time, interactive videoconferencing technology and a smartphone application, to offer a more intensive and focused application of CBT principles in a way that may be more user-friendly and appealing to children and adolescents and their families. The present study entails the development of the eCBT treatment package and, as a first step, aims to examine the feasibility, acceptability, and preliminary efficacy of enhanced CBT (eCBT) for pediatric OCD. The study is a single-center open trial to examine the acceptability and feasibility of a newly developed enhanced CBT intervention (eCBT) in children and adolescents with OCD.

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Who is the main contact?
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Contact information

Type(s)
Scientific

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Prof Norbert Skokauskas

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Samarbeidsorganet mellom Helse Midt-Norge RHF project nr 90023600

Study information

Scientific Title
Acceptability and feasibility of enhanced cognitive behavioral therapy (eCBT) for children and adolescents with obsessive compulsive disorder: an open trial

Study objectives
Enhanced CBT (eCBT) is an acceptable and feasible intervention for children and adolescents with OCD and their parents.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 11/06/2020:
Approved 18/05/2016, amendment approved 26/05/2020, Regional Committees for Medical and Health Research Ethics (REK nord; UiT Norges arktiske universities, Postboks 6050 Langnes, 9037 Tromsø, Norway; Tel: +47 (0)77 64 61 40; Email: rek-nord@asp.uit.no), ref: 2016/716/REK nord

Previous ethics approval:
Approved 18/05/2016, Regional Committees for Medical and Health Research Ethics (REK nord; UiT Norges arktiske universitet
Postboks 6050 Langnes, 9037 Tromsø, Norway; Tel: +47 (0)77 64 61 40; Email: rek-nord@asp.uit.no), ref: 2016/716/REK nord

Study design
Single-center open trial with quasi-experimental design (historical control)

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Pediatric OCD

Interventions
Current interventions as of 11/06/2020:
Until 16 March 2020, all participants received enhanced cognitive behavioral therapy (eCBT) for pediatric OCD. eCBT consists of the usual, evidence-based treatment (CBT) in an 'enhanced' format, including videoconferencing sessions in addition to face-to-face sessions, and an app supporting patients throughout the treatment and monitoring progress. The treatment consists of 10 in-office face-to-face sessions and 12 video teleconferencing sessions (at home) within a period of 14 weeks. eCBT contains psychoeducation, administration of symptoms, exposure with response prevention, cognitive interventions, and relapse prevention. Parents are involved in the treatment.

In response to the COVID-19 lockdown measures, starting on 16 March 2020, eCBT is offered fully online (REMOTeCBT). REMOTeCBT closely parallels eCBT with the main difference that all sessions are delivered via the webcam.

Treatment outcomes for eCBT and REMOTeCBT will be compared to traditional CBT (data obtained in the Nordic Long-term OCD Treatment Study NordLOTS).

Previous interventions:
All participants receive enhanced cognitive behavioral therapy (eCBT) for pediatric OCD. eCBT consists of the usual, evidence-based treatment (CBT) in an 'enhanced' format, including videoconferencing sessions in addition to face-to-face sessions, and an app supporting patients throughout the treatment and monitoring progress.

The treatment consists of 10 in-office face-to-face sessions and 12 video teleconferencing sessions (at home) within a period of 14 weeks. eCBT contains psychoeducation, administration of symptoms, exposure with response prevention, cognitive interventions, and relapse prevention. Parents are involved in the treatment.

Effectiveness of eCBT will be compared to traditional CBT by comparing results from the present study to data obtained in the Nordic Long-term OCD Treatment Study (NordLOTS) (Torp et al., 2015).

Intervention Type
Behavioural

Primary outcome measure
1. Acceptability assessed using Client Satisfaction Questionnaire (CSQ-8), child and parent version post-treatment
2. Feasibility: preterm treatment drop-out measured post-treatment
3. Effectiveness assessed using the Children's Yale-Brown Obsessive Compulsive Scale (CY-BOCS) administered by a blind rater (blinded for treatment phase) pre- and post-treatment, and at 3 and 6 months follow-up

Secondary outcome measures
Acceptability assessed using:
1. Treatment evaluation questionnaire (child and parent version) composed of the User Experience Questionnaire and (self-developed) treatment-specific questions, measured post-treatment
2. Barriers to Treatment Participation Scale (BTPS). For the aim of the present study the researchers shortened the questionnaire and added a child version. Measured post-treatment.

Effectiveness assessed using:
1. K-SADS-Pl at pre- and post-treatment
2. Child Obsessive-Compulsive Impact Scale (COIS-R): child and parent version at pre- and post-treatment, 3 and 6 months follow-up
3. Family Accommodation Scale for OCD – Self-Rated Version (FAS-SR): parents at pre- and post-treatment, 3 and 6 months follow-up
4. Strengths and Difficulties Questionnaire (SDQ): child and parent version at pre- and post-treatment, 3 and 6 months follow-up
5. Child Behavior Checklist (CBCL): parents at pre- and post-treatment, 6 months follow-up
6. Youth Self-Report Questionnaire (YSR): children 11 years and older at pre- and post-

treatment, 6 months follow-up
7. Screen for Child Anxiety Related Emotional Disorders (SCARED): child and parent version at pre- and post-treatment, 3 and 6 months follow-up
8. Mood and Feelings Questionnaire (MFQ): child and parent version at pre- and post-treatment, 3 and 6 months follow-up
9. KINDL: child and parent version at pre- and post-treatment, 3 and 6 months follow-up
10. Children's Global Assessment Scale (CGAS) at pre- and post-treatment, 3 and 6 months follow-up
11. Clinical Global Impressions-Severity (CGI-S) at pre- and post-treatment, 3 and 6 months follow-up
12. Clinical Global Impressions Improvement (CGI–I) at post-treatment, 3 and 6 months follow-up
13. The Trimbos/iMTA Questionnaire for Costs associated with Psychiatric Illness (TiC-P): parents at pre- and post-treatment, 3 and 6 months follow-up

Overall study start date
01/10/2015

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Age 7–17 years (inclusive)
2. A primary DSM 5 diagnosis of obsessive-compulsive disorder
3. CY-BOCS ≥ 16

Participant type(s)
Patient

Age group
Child

Lower age limit
7 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
70 (eCBT + REMOTeCBT)

Total final enrolment
25

Key exclusion criteria

1. A psychiatric comorbidity that has a higher treatment priority than OCD, and makes participation clinically inappropriate (for example, primary anorexia nervosa, depression with suicidality that requires acute treatment, and psychosis)
2. (Estimated) IQ below 70
3. Insufficient understanding of the Norwegian or English language

Date of first enrolment
04/09/2017

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
Norway

Study participating centre
NTNU, Regional Centre for Child and Youth Mental Health and Child Welfare (RKBU)
Klostergata 46
Trondheim
Norway
7030

Study participating centre
NTNU
Larsgårdsvegen 2
Alesund
Norway
6009

Sponsor information

Organisation
Central Norway Regional Health Authority

Sponsor details
Wessels veg 75
Stjørdal
Trondheim
Norway
7030

+47 (0)74 83 99 00
mn.postmottak@helse-midt.no

Sponsor type
Government

Website
http://www.helse-midt.no/EN/

ROR
https://ror.org/04t838f48

Funder(s)

Funder type
University/education

Funder Name
Norges Teknisk-Naturvitenskapelige Universitet

Alternative Name(s)
Norwegian University of Science and Technology, The Norwegian University for Technology an Sciences, Universidad Noruega de Ciencia y Tecnología, NTNU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Norway

Results and Publications

Publication and dissemination plan
The researchers expect that the study protocol will become available in the summer of 2020 (updated 11/06/2020; previously: upcoming months [March 2020]).
Peer-reviewed publications: scientific papers and presentations reflecting different stages of the project are planned.
Outcomes will also be presented at regional, national and international conferences.
Educational workshops are planned for service providers and service users.
Media activities: local and national TV, radio and print media will be approached to disseminate findings from the project.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository at the Department of Mental Health, RKBU, Norwegian University of Science and Technology, Klostergata 46, 7030, Trondheim, Norway. Data includes demographics and baseline characteristics of the participants, and assessment of symptoms during and following treatment. The information will be entered by the Data Manager. All relevant data will be entered into a separate anonymous password protected and encrypted file, protection of participants' identity will be guaranteed by assigning study-specific unique subject codes. Codes will be used to conceal identities in all external communication. Rechecks or later use of the data will be possible using the anonymized data file. Later use of the data will only be possible with the consent of the participant. Information (raw data) will be kept for 10 years. Informed consent is obtained from all participants before study participation. The study will be conducted according to the principles of the Declaration of Helsinki (version 19th October 2013; WMA, 2013).

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	18/12/2020	19/11/2020	Yes	No
Results article		04/09/2021	09/09/2021	Yes	No