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Nationwide internet-delivered computer-assisted cognitive-behavioral therapy (iCBT) for psychiatric disorders

Submission date
21/08/2019

Recruitment status
No longer recruiting

Registration date
26/08/2019

Overall study status
Completed

Last Edited
28/07/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Depression and anxiety disorders are very common and cause serious sufferings and disability for patients, as well as substantial costs for society. Medications and psychotherapy are first-line treatments for most of these disorders, but psychotherapy is costly and its availability is poor in many countries and regions. Therefore, psychologists and psychiatrists have developed semi-automatic therapy programs. The majority of them uses methods of so-called cognitive-behavioral therapy (CBT). In these therapies, patients work with a smart computer program and a therapist follows the progress of treatment and guides and supports the patient. These therapies yield as good results as traditional face to face therapies and can be delivered through the internet (iCBT, where i stays for internet). The iCBTs are less costly, require less trained therapists and are place and time-independent. Typically, the communication between the patient and therapist happen in written in the beginning and end of therapy, as well as in between, as needed. Also, telephone calls can be added if needed. While the efficacy of iCBT in scientific studies is well established, little is known about there effectiveness in the “real world” of usual clinical practice.

The only available Finnish language iCBT for depression and anxiety disorders is developed and nationwide provided by the Department of Psychiatry of the Helsinki University Hospital (HUS). The aim of this study is to evaluate the effectiveness of this Finnish language iCBT (HUS-iCBT) in usual clinical practice.

Who can participate?
All physicians in Finland are authorized to refer their patients to HUS-iCBT if they suffer from ICD-10 defined depressive or anxiety disorder, have a reasonable command of Finnish language, have an access to internet, do not have a known diagnosis of a psychotic or serious neurological or substance abuse disorders that could hinder the therapy. All adult (≥18 y.o.) patients enrolled into HUS-iCBT programs are invited to participate in this study.

What does the study involve?
The participants receive HUS-iCBT as usual. Change in their symptom severity and Health-

Related Quality of Life are measured prospectively from baseline to end-point (or to premature discontinuation).

What are the possible benefits and risks of participating?
All study patients will have the same usual HUS-iCBT as those who do not participate in the study. Since iCBT does not contain known risks, we therefore do not expect any risks from the study.

Where is the study run from?
Department of Psychiatry, Helsinki University Hospital, Finland

When is the study starting and how long is it expected to run for?
September 2015 to December 2019

Who is funding the study?
1. Government of Finland
2. Hospital Region of Helsinki and Uusimaa

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
TYH2019104

Study information

Scientific Title
Guided internet-delivered computer-assisted cognitive-behavioral therapy for psychiatric disorders - a nationwide naturalistic prospective effectiveness study.

Study objectives
HUS-iCBT (a low resource-consuming, low-threshold iCBT program developed and nationwide provided by the Department of Psychiatry of Helsinki University Hospital, HUS) is as effective as earlier programs as assessed in regular clinical practice

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/06/2014, Naisten, lasten ja psykiatrian eettinen toimikunta (Ethics Committee for Pediatrics, Gynecology/Obstetrics, and Psychiatry of the Hospital Region of Helsinki and Uusimaa (Keskuskirjaamo (Central Registry Office), P.O. Box 200, 00029 HUS, Finland; +358 9 4711; keskuskirjaamo@hus.fi.), ref: n\a

Study design
Open-label prospective naturalistic effectiveness single-center trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Depressive disorders, General Anxiety Disorder, Panic Disorder, Social Anxiety Disorder, Obsessive-Compulsive Disorder

Interventions
All physicians registered in Finland are authorized to refer their patients with a number of ICD-10 verified psychiatric disorders (mostly depressive and anxiety disorders) to municipality-purchased, internet-therapist supported HUS-iCBT. The time-schedule of the programs is flexible. Concomitant treatments are allowed.

All consented patients are enrolled in a pertinent diagnosis-specific iCBT program.

The treatment is Cognitive-Behavioral Therapy provided via the internet. A patient works with a highly structured, smart program. An internet-therapist supervises the progress and supports the patient. Therapy lasts from three to five (sometimes, six) months and consists of 7 to 12 steps (sessions). Homework is assigned between the sessions. The therapist and the patient interact in written (may be supplemented with telephone calls) in a safe, protected environment of the HUS-iCBT system. Therapist-patient contact happens in the beginning, in the middle and in the end of therapy or, if needed, more often. Currently available HUS-iCBT programs: Depressive Disorders, Panic disorder, Generalized Anxiety Disorder, Obsessive-Compulsive Disorder, Social Anxiety Disorder and Sleep Disorders; Bulimia Nervosa program is available soon.

Intervention Type
Behavioural

Primary outcome(s)
Primary outcomes are a disorder-specific symptom measure scale.
For each specific disorder, we measure one or two pertinent symptom scales as primary measures: Beck's Depression Inventory (BDI) for Depressive Disorders, Panic Disorder Severity Scale (PDSS-SR) for Panic disorder, Generalized Anxiety Disorder 7-item Scale (GAD-7) and Penn State Worry Questionnaire (PSWQ) for Generalized Anxiety Disorder, Obsessive-Compulsive Inventory, short version (OCI-R) for Obsessive-Compulsive Disorder, Social Phobia Inventory, Finnish version (SPIN-FIN) for Social Anxiety Disorder and Sleep Disorders, and Eating Disorder Examination Questionnaire (EDE-Q), the Eating Disorder Examination-Self-Report Questionnaire Version (EDE-Q) for Bulimia Nervosa. The scales are applied at baseline, mid-treatment and endpoint with the exception of GAD-7 which is applied as each session. All measures are filled in by patients online.

Key secondary outcome(s))
1. Overall Anxiety Severity and Impairment Scale (OASIS) assessed at baseline and mid-treatment
2. Health-Related Quality of Life scale 15D at baseline, end-point and three months follow-up

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. Diagnosis of a psychiatric disorder being explored
2. Aged 18 years or more
3. Reasonable command of Finnish language
4. Access to the internet
5. Provided informed consent
6. Referral to the HUS-iCBT by the patient's treating physician

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria

1. Reported or observed suicidal intentions
2. Current alcohol misuse as judged by referring physician
3. Known diagnosis of schizophrenia or other psychotic disorder, bipolar disorder or serious personality disorder
4. Neurologic or neuropsychiatric disorder that adversely affects the patient's cognitive performance

Date of first enrolment
15/09/2015

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
Finland

Study participating centre
Department of Psychiatry, Helsinki University Hospital
Stenbäckinkatu 9
PO Box 100
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FI-00029 HUS

Sponsor information

Organisation
Hospital District of Helsinki and Uusimaa

ROR
https://ror.org/020cpqb94

Funder(s)

Funder type
Government

Funder Name
Government of Finland

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	substudy results	23/07/2020	28/07/2020	Yes	No