Pilot of a therapist-guided internet-delivered cognitive behavioral therapy intervention for anxiety and depression (eHealth CF-CBT) in Dutch adults with Cystic Fibrosis

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23818

Source
NTR

Brief title
TBA

Health condition

Cystic Fibrosis

Sponsors and support

Primary sponsor: Dutch Cystic Fibrosis Foundation (NCFS)
Source(s) of monetary or material Support: Dutch Cystic Fibrosis Foundation

Intervention

Outcome measures

Primary outcome

We will calculate frequency and percentages of feasibility and acceptability scores and summarize the themes of our qualitative data. The differences between baseline and post-intervention will be analyzed.

Secondary outcome

n.a.

Study description

Background summary

Rationale: Adults with Cystic Fibrosis (CF) are at increased risk to develop depression and anxiety, with devastating consequences for health outcomes. Given international guidelines recommending routine screening, this project addresses an urgent need for new approaches to prevent and treat depression and anxiety in adults with CF. Drs. Verkleij, Friedman and Georgiopoulos have recently developed “eHealth CF-CBT”, a blended care program for adults with CF based on cognitive behavioural therapy that integrates therapist-guided online self-management modules with in-person sessions. The program is being developed in English and Dutch, with input from Dutch adults with CF and CF healthcare providers, and the Dutch Cystic Fibrosis Foundation.
Objective: The proposed pilot study will test the feasibility and acceptability of the Dutch eHealth CF-CBT program for adults with CF.
Study design: In this uncontrolled single-center pilot study, feasibility and acceptability, will be assessed, measuring pre-post changes in anxiety, depression, perceived stress, and health-related quality of life (HRQoL).
Study population: The intervention is targeted for adults with CF screening in the mild to moderate range on anxiety and/or depression measures. Participants will be recruited from a pool of 124 adult CF patients at AMC. We aim to enroll 10 patients in this study.
Intervention: The 8 modules of the online CF-CBT program are delivered through blended care: face-to-face/videocall contact with the psychologist in combination with online modules. At the intake, after four sessions and at the end, there will be a face-to-face/videocall session. eHealth CF-CBT provides an opportunity to build skills to face current and future challenges in living with CF and increase quality of life. Individual barriers to CF self-management (e.g., negative medication beliefs) are addressed in multiple ways. Each module includes teaching on the session topic, a skill-building exercise, and a homework assignment to apply each skill in-between sessions. Experiential out-of-session exercises (e.g., relaxation practice) are a key component of CBT treatment programs with the goal of consolidating learning. The intervention is built into the online platform Minddistrict, which is an internet-based application enabling individuals to flexibly engage in mental health intervention. Minddistrict is approved as a secure information technology vendor for international use.
Main study parameters/endpoints: We will calculate frequency and percentages of feasibility and acceptability scores and summarize the themes of our qualitative data. The differences between baseline and post-intervention will be analyzed.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: There are no risks associated with the investigational treatment. CBT is already a psychological evidence-based intervention. This study aims to improve emotional well-being and HRQoL with potential longitudinal impact on pulmonary exacerbations, hospitalizations, core health outcomes, and mortality.

Study objective

Study Hypotheses:
We hypothesize that there will be:
1) High ratings of treatment acceptability (treatment satisfaction ratings) from participants
2) A reduction in depression (PHQ-9) and anxiety (GAD-7) symptoms, and perceived stress (PSS) scores from immediate pre- to post-eHealth CF-CBT measurement
3) An improvement in CF-specific HRQoL (CFQ-R) from immediate pre- to post-eHealth CF-CBT measurement.

Study design

Endpoint will be: finishing the 8 sessions of the eHealth CF-CBT program and completing the questionnaires.

Intervention

Behavioural intervention eHealth CF-CBT in Minddistrict:
As described below, the 8 modules of the online CF-CBT program are delivered through blended care: face-to-face/videocall contact with the psychologist in combination with online modules. At the intake, after four sessions and at the end, there will be a face-to-face/videocall session.
CF-CBT provides an opportunity to build skills to face current and future challenges in living with CF and increase quality of life. Individual barriers to CF self-management (e.g., negative medication beliefs) are addressed in multiple ways. Each module includes teaching on the session topic, a skill-building exercise, and a homework assignment to apply each skill in-between sessions. Experiential out-of-session exercises (e.g., relaxation practice) are a key component of CBT treatment programs with the goal of consolidating learning.
Content of sessions is as follows:
1) Overview and Introduction to CBT
2) Relaxation Skills
3) Depression in CF: What Helps?
4) Adaptive Thinking Skills, part 1
5) Adaptive Thinking Skills, part 2
6) Taking Charge of My Health
7) Anxiety in CF: What Helps?
8) Maintaining Positive Changes

Minddistrict (https://www.minddistrict.com/) is an internet-based application enabling individuals to flexibly engage in mental health intervention. Minddistrict is widely used in the

Netherlands, including at Amsterdam UMC location VUmc and AMC, and will be inexpensive to embed in the CF care system. The Minddistrict eHealth format incorporates simple text, interactive text, audio and videos, easily integrating questionnaires, diaries, and clinician monitoring and feedback. Minddistrict is approved as a secure information technology vendor for international use. Participants receive online access for at least half a year after finishing the intervention, and can view and print their work. Interventionists have access to an administrator page allowing them to view patients' progress and give feedback. Following completion, the CF psychologist can enter outcomes and follow up plans into the medical file to ensure continuity of care.

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

Diagnosis of CF, under medical care at Amsterdam UMC-AMC-site. Age: ≥ 18 yrs.; willing/able to give informed consent. Scores on the Generalized Anxiety Disorder Scale (GAD-7) for anxiety and/or Patient Health Questionnaire (PHQ-9) for depression in the mild or moderate range (scores 5-14), without either score above moderate range (>15).

Subjects will not be excluded for the following reasons: CF severity or transplant status, if otherwise able to participate. If subjects are medically hospitalized, they may continue to participate.
-A history of more severe depression or anxiety currently at mild to moderate levels with or without treatment. This is important to best replicate real-world conditions during depression/anxiety screening in CF Centers to ensure broader generalizability of the intervention.

-Participation in concomitant psychosocial treatments (with the exception of formal CBT) or psychopharmacologic treatments at baseline, although these will be tracked and considered in analysis.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
Inability to read, write, and/or follow instructions in Dutch; or no internet access.
Severe psychiatric dysfunction, including acute safety risk to self or others. Subjects reporting suicidality on question 9 on the PHQ-9 will be further assessed. Those reporting suicidal intent will be excluded and referred for urgent/emergent care as indicated.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-03-2021
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	18-03-2021
Application type:	First submission

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
NTR-new	NL9349
Other	METC VUMC : 2020.240

Study results

Summary results
n.a.