

Pilot study eHealth CF-CBT

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Objective: To investigate the feasibility and acceptability of the online cognitive behavioral therapy program (eHealth CF-CGT), so that the program can be tailored to the needs of the patient

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON49785

Source

ToetsingOnline

Brief title

eHealth CF-CBT

Condition

- Anxiety disorders and symptoms
- Lower respiratory tract disorders (excl obstruction and infection)

Synonym

Cystic Fibrosis

Research involving

Human

Sponsors and support

Primary sponsor: Pediatrische Psychologie

Source(s) of monetary or material Support: Nederlandse Cystic Fibrosis Stichting

Intervention

Keyword: cognitive behavioral therapy, Cystic Fibrosis, online

Outcome measures

Primary outcome

Feasibility and acceptability of the eHealth CF-CBT program

Secondary outcome

n.a.

Study description

Background summary

Background: Adults with Cystic Fibrosis (CF) are at increased risk to develop anxiety and depression.

Recent international guidelines recommend routine screening and treatment for depression and anxiety in individuals with CF.

There is a need to create psychological interventions for adults with CF tailored to their needs, stage of life, and goals. Therefore, as a international collaboration of Vumc and specialistst from the USA, an online blended-care psychological treatment program has been developed for adults with CF who are suffering from anxiety and/or depression.

Research question: Is the eHealth CF-CGT program feasible and acceptable and what improvements can be made?

Study objective

Objective: To investigate the feasibility and acceptability of the online cognitive behavioral therapy program (eHealth CF-CGT), so that the program can be tailored to the needs of the patient

Study design

Method: Ten patients with CF from the AMC who report anxiety and / or depression are invited to participate in the eHealth CF-CBT program and research. Before the start of the program, during the program and at the end they fill in questionnaires.

Intervention

As described below, the 8 modules of the online CF-CBT program are

delivered through blended care: face-to-face 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 session.

- 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

Study burden and risks

Burden: No risks. It takes time for the patient to complete the questionnaires and complete the sessions. The patient is also expected three times at the VUmc for an appointment with the psychologist.

The patient may benefit directly from participating in this study. By following the eHealth CF-CGT program and going through all sessions, his / her complaints of anxiety and / or depression can be reduced. In addition, the patient contributes more information about the functioning of the eHealth CF-CGT program and we can further optimize eHealth CF-CGT for other patients based on this feedback.

Contacts

Public

Selecteer

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Cystic Fibrosis and mild/moderate scores on anxiety (GAD-7) and depression (PHQ-9) scales (scores 5-14)

Exclusion criteria

No written informed consent, inability to read, suicide risk.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	25-03-2021

Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Minddistrict
Registration:	Yes - CE intended use

Ethics review

Approved WMO	
Date:	08-01-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	29-03-2021
Application type:	Amendment
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	NL72957.029.20