Athens, 1.11.2025

Unique Protocol ID: RAKITZI CYSTIC FIBROSIS

Official title of the study: The effectiveness and efficacy of an online group cognitive behavioral psychotherapy in patients with cystic fibrosis and caregivers in comparison to control groups by the Hellenic Cystic Fibrosis Association A Randomized Controlled Trial

Brief title: The effectiveness and efficacy of an online cognitive behavioral psychotherapeutic program (RAKITZIHCFA)

NCT: not available

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1. Introduction

Cognitive behavioral psychotherapy presents evidence-based psychotherapy and is one

of the most effective psychotherapies today for all mental health disorders. Many studies are published (Hoffmann et al., 2012).

An online group cognitive behavioral psychotherapy for patients with cystic fibrosis and for caregivers is offered voluntary by Dr. Stavroula Rakitzi to the members of the Hellenic Cystic Fibrosis Association since 2022 until today. The first positive results of this implementation have been published (Rakitzi, 2023; Rakitzi et al., 2025). This program is a recovery-oriented psychotherapy (Rakitzi, 2023; Rakitzi et al., 2025).

This research protocol aims to evaluate the efficacy of this online group cognitive behavioral program for patients with cystic fibrosis and caregivers in comparison with control groups in a randomized controlled trial for the first time in Greece.

2. Material and Methods

2.1. Compliance with ethical standards

Prior to the study's inclusion, the patients will read and sign written informed consent for their involvement in this research project and for the publication of the results. Information that could reveal the patients' identities was left out. The authors adhere to the APA ethical standards and to Helsinki.

The study was approved by the scientific and ethical committee of the Hellenic Cystic Fibrosis Association (896/24/09/2025). The study will be registered in clinicalTrials.gov.

2.2 Sample size calculation

G power (Mayr et al., 2007) was used to calculate the sample size. Following parameters were chosen: t-test mean difference between two independent means (2 groups), Type of power analysis: compute required sample size with a given α, power and effect size.

Tail one, effect size: 0.70 (Rakitzi et al., 2025), α=0.05, power(1-β)=0.80, ratio N2/N1 1. Following results are given: noncentrality parameter δ:2.52, t:1.67, Df:50, sample size Group 1:26, sample size Group 2:26, Total sample size: 52, actual power: 0.80.

2.2. Study design

It is a randomized controlled trial. The online group cognitive behavioral psychotherapy for patients with cystic fibrosis will be compared with a control group and the online group cognitive behavioral psychotherapy for caregivers will be also compared with a control group. The online-group cognitive-behavioral program is offered by Dr. S. Rakitzi in two therapy groups: in patients with cystic fibrosis and afterward in caregivers of patients with cystic fibrosis once a week on the same day in different hours via Zoom. Mrs E. Pavlidi, psychologist of the Hellenic Cystic Fibrosis Association, will offer a supportive group in the two control groups once a week on the same day in different hours via Zoom.

2. 3. Participants

Members of the Hellenic Cystic Fibrosis Association can join this research protocol. The call for interest is posted on the association's website approximately 2 months before the start of therapies. The prerequisites for participation are the following: age 18-65, membership of the association, commitment to participate within the treatment at the time and day indicated and the ability to utilize Zoom with sound and video (inclusion criteria). Up to three absences are permitted for participants. The treatment is terminated for anyone who over this threshold (exclusion criteria).

The online treatment was chosen due to the participation of members from all over Greece and the safety distances for health reasons, which must be kept up by patients with cystic fibrosis.

2. 4. Therapy

Dr. S. Rakitzi will offer to every participant of all 4 groups an individual session, in which the research protocol will be explained, a motivational interview will be conducted and finally a written informed consent for participation will be offered. Afterwards, the psychometric tests will be sent to the participant.

After these motivational interviews and the evaluation of the tests before the therapy, participants will be assigned to the treatment group (patients, caregivers) or the patient and caregiver control group by lottery.

A group online cognitive behavioral psychotherapy for two therapy groups (patients with cystic fibrosis and caregivers) is applied once a week for 13 sessions, and each session lasts 1.5 hours by Dr. S. Rakitzi. It is a combination of cognitive-behavioral interventions which point out to decrease stress, improve mood and strengthen assertiveness, and introduce grief. All these interventions are adjusted to cystic fibrosis. The therapy is focused on recovery.

A group online supportive psychotherapy for two control groups (patients with cystic fibrosis and caregivers) is applied once a week for 13 sessions, and each session lasts 1.5 hours by Mrs E. Pavlidi, psychologist.

2. 5. Measures

All measures will be given by a blind rater, a psychologist (Msc clinical psychology) before, after the therapy and in a follow up after 6 months. The blind rater doesn't know the participants and doesn't know anything about this project.

2. 5. 1. Psychopathology

Psychopathology will be evaluated by the Greek adaptations of the reliable and valid instruments SCL-90-R (Donias et al., 1991) (self-test), and Symptoms Rating Scale for Depression and Anxiety (SRSDA) (Bech, 1993; Fountoulakis et al., 2003) (self-test). Depression will be evaluated also from the Hamilton Depression Scale (HAM-D) (Hamilton, 1960) (the Greek version), (Clinician evaluation).

2. 5. 2. Social skills

Social skills will be evaluated by the valid and reliable (U-Unsicherheitsfragebögen)-test, which is translated in Greek, with following the domains: fear of criticism, fear of contact, assertiveness, difficulty of saying no, guilt and decency (Antoniou et al., 2015; Ulrich et al., 1977) (self-test).

2. 5. 3. Functional outcome

Functional outcome will be evaluated by the Greek adaptation of valid and reliable WHODAS with the following domains: 1: Cognitive Function – (understanding and communication); 2: Mobility – (movement and ease of movement); 3: Self-care – (personal hygiene care, dressing, eating and living independently); 4: Socializing/Social contacts – (interacting with other people); 5: Life activities – (household responsibilities, leisure, work and school); and 6: Participation – (inclusion in community activities, participation in society); and WHODAS total (Koumpouros et al., 2018; WHO, 2001) (self-test).

2. 5. 4. Recovery

Recovery will be evaluated by the Greek adaptation of the valid and reliable RAS-DS with the following domains: RAS-DS total, R1: doing things I value, R2: looking forward, R3: mastering my illness, and R4: connecting and belonging (Hancock et al., 2015, 2018, 2019, 2023; Ramesh et al., 2024) (self-test).

3. Statistical analysis

The SPSS 13 Version will be used for statistical analysis. A general linear model and regression analysis will be conducted. Effect sizes will be also calculated. According to Cohen d=0.2 is a small effect size, d=0.4 is a medium effect size, and d=0.8 a large effect size. Pearson correlation coefficients will be calculated (Bortz & Döring, 2002; Cohen, 1988).

This research protocol will begin at 15. 11. 2025 with motivational interviews and the evaluation of the tests before the therapy. The 4 groups will begin on 17. 1 2026. The research protocol will end on December 2028.

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