




Psychological interventions during COVID pandemic: Telehealth for individuals with cystic fibrosis and caregivers

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Abstract

Introduction: Coronavirus disease 2019 (COVID-19) emerged in China, leading to worldwide morbidity and mortality, including depression and anxiety. As the pandemic spread throughout Italy, mental health concerns increased for people with cystic fibrosis (pwCF), who are at greater risk. The aim was to pilot a Telehealth Psychological Support Intervention for pwCF and caregivers to reduce stress, depression, and anxiety during the lockdown in Italy in March 2020.

Methods: This intervention utilized cognitive behavioral skills (e.g., cognitive reframing). Participants included 16 pwCF and 14 parents, who completed four individual telehealth sessions with a psychologist. Stress ratings, Patient Health Questionnaire and General Anxiety Disorder, PHQ-8 and GAD-7, were completed, in addition to Feasibility and Satisfaction ratings.

Results: Ratings of stress significantly decreased from pre- to post-testing for pwCF (paired $t(14) = -4.06, p < .01$) and parents (paired $t = -5.2, p < .001$). A large percentage of both groups scored in the clinical range for depression and anxiety at baseline (pwCF: depression/anxiety = 71%; parents: depression = 57%; anxiety = 79%); a large proportion (20%–40%) reported moderate to severe symptomatology. Significant reductions in depression for pwCF were found (pre: $M = 8.0$ to post: $M = 4.7$; paired $t(14) = 2.8, p < .05$) but not anxiety (pre: $M = 6.9$ to post: $M = 5.6, t(14) = 1.2, p = \text{NS}$ —non-significant). Parental depression decreased for parents (pre: $M = 6.4$ to post: $M = 5.1, t(14) = -2.5, p < .05$), but not anxiety (pre: $M = 8.1$ to post: $M = 7.9, t(14) = -0.2, p = \text{NS}$). Feasibility and Satisfaction were positive.

Conclusion: This telehealth intervention yielded reductions in stress and depression for participants. Anxiety did not significantly decrease, possibly because COVID was ongoing. This feasible, satisfactory intervention was effective for improving mental health.

KEYWORDS

anxiety, cognitive behavioral therapy, COVID-19 lockdown, depression, telehealth intervention

1 | INTRODUCTION

In December 2019, a novel coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (i.e., coronavirus disease 2019 [COVID-19]), spread in Hubei, China. The virus caused a variety of symptoms, ranging from asymptomatic/mild symptoms to serious impairments and death.¹ The spread of COVID-19 has led to significant morbidity and mortality worldwide,² causing high levels of stress, fear, and anxiety about this extremely contagious, rapidly spreading virus.³ Anxiety was related to fears of being infected, infecting others, and concerns about its associated comorbidities and high mortality rate. Loss of normal routines, reduction of activities, and a severe economic recession contributed to increasing stress and worsening mental health. A previous systematic review on large-scale disasters revealed increased depression, anxiety, posttraumatic stress disorder (PTSD), substance misuse, and domestic violence.⁴ The severe acute respiratory syndrome (SARS) epidemic was also associated with increased psychological distress in patients and clinicians.⁵

The first study in China on the impact of COVID-19 found elevated depression and anxiety in a sample of 1210 individuals: 17% reported moderate–severe depression and 29% moderate–severe anxiety.⁶ A study in Hong Kong screened 500 adults using well-validated screening tools (i.e., Patient Health Questionnaire and General Anxiety Disorder—PHQ-9 and GAD-7), reporting high levels of depression (19%) and anxiety (14%). Further, 25% of the sample reported a *worsening* of mental health due to the pandemic.⁷ Adolescents in China also reported high levels of depression (43.7%) and anxiety (37.4%) using PHQ-9 and GAD-7.⁸ Similar elevations in psychological distress have been documented across the world.^{9–11}

As the pandemic spread throughout Italy and Europe, new mental health concerns were raised by people with cystic fibrosis (pwCF) and parent caregivers, who are already at increased risk for depression and anxiety.^{12–14} Before the pandemic, numerous studies have indicated that psychological symptoms in pwCF are associated with worse adherence, more frequent hospitalizations, and earlier mortality.^{15,16} In response to this pandemic, several studies have been conducted to evaluate its impact on pwCF and caregivers.^{14,17,18} Havermans et al.¹⁷ reported on 80 adults with cystic fibrosis (CF), 66 adults who had received a lung transplant, and 73 parent caregivers. This was a survey study in which the authors asked these three groups to rank order their psychological concerns. The top-ranked concerns for adults with CF were “afraid of being infected by the virus” and “extra alert for dangerous situations,” and “I cannot adhere to my usual routines.” These same top three concerns were also endorsed by parents. Thus, anxiety and fear were the predominant psychological issues for both. Although both groups reported disruption in their daily routines, they also reported spending more time on nebulized treatments and airway clearance. Increased stress, negative thoughts, and trouble sleeping were also reported by both pwCF and parents.¹⁷

In a study of adolescents with CF and their mothers,¹⁸ anxiety was measured using the State-Trait Anxiety Inventory. Mothers of children with CF reported higher trait anxiety than age-matched controls. In contrast, healthy children and their parents reported

higher state anxiety than the group with CF, unless the child was colonized with *Pseudomonas* infection. In that case, their state anxiety was also quite elevated.

As Italy became a COVID-19 “hot spot,” concerns about the psychological functioning of pwCF increased. In a large study in Italy, an online questionnaire, the COVID-19 Peritraumatic Distress Index, was completed in an adapted form by 712 pwCF and 3560 respondents from the general population.¹⁹ Psychological distress in the mild to moderate range affected similar proportions of both samples; 40.2% of pwCF and 43.9% of the general population. Severe distress was endorsed by 5.3% of pwCF and 6.2% of the controls. Thus, although a majority of respondents were reporting substantial psychological distress, there were no differences by health status.

To address these concerns, psychologists on the CF Team at Bambino Gesù Children's Hospital developed and piloted a Telehealth Psychological Support Intervention. It targeted adolescents/young adults with CF and caregivers, providing them with cognitive-behavioral strategies to cope with the stress and emotional challenges of the lockdown in March. The lockdown was highly restrictive: schools and universities were closed, people were told to work from home, and individuals could go out only for essential tasks (e.g., supermarket, pharmacy). Access to routine healthcare also changed for pwCF and many were afraid of coming to the CF Center; in-person appointments were reserved for those with serious health problems. The purpose of this study was to evaluate the effectiveness of a cognitive-behavioral telehealth intervention to reduce symptoms of stress, depression, and anxiety in pwCF and parents during the lockdown. This 4-session telehealth intervention was delivered via the internet and was aimed at reducing psychological symptomatology. Feasibility and Satisfaction were assessed.

2 | METHODS

2.1 | Procedure

This study was a within-subject, pre–post design. Because we initiated the study during an emergency situation, 1 week after the complete lockdown in Italy, the Ethics Committee was not meeting frequently. A summary of the project and consent forms were sent to the Ethics Committee at Bambino Gesù Children's Hospital, and they notified us of their approval. It involved pwCF, ages 12–36 years, and caregivers of pwCF younger than 18. Enrollment criteria included diagnosis of CF, ages 12 and older, and parents of children with CF. Exclusion criteria were mainly related to age, having a stable internet connection, and familiarity with using the internet. Participants completed measures electronically; medical data were extracted from charts.

The Telehealth Psychological Support Intervention was carried out during the COVID-19 lockdown from March through May 2020. A letter inviting participation was sent by the CF Patients/Parents Association 1 week after lockdown.

The Parent Association has an office located in the hospital and has a page of its own on Facebook and Instagram, which provided immediate communication with pwCF and caregivers during this pandemic

lockdown. Participation in the intervention was also shared through social media (e.g., Facebook, Instagram). A dedicated phone line accepted requests for participation. Participants completed four “zoom” sessions using online video platforms, 30–40 min each, conducted by a clinical psychologist on the CF Team. Participants were asked to find a quiet, private place using headphones and microphones.

Written, informed consent was obtained by sending the consent form via email or “whatsapp” and getting the signature. All individuals provided a stress rating (10-point Likert scale) at the beginning of each session and completed the PHQ-8 and GAD-7 measures at the pre- and post-assessment. For the stress ratings, the psychologist asked the participant for their rating and it was recorded in an excel file. PHQ-8 and GAD-7 were completed online using a link that was emailed to them. Once they completed the questionnaires, they were automatically sent to the Principal Investigator. Feasibility and Satisfaction were rated 1 week after the last session using an email link.

2.1.1 | Analytic plan

This was a within-subject, cohort design, using each participant as his/her own control. Analyses of the major endpoints were conducted on each individual's score from pre to post on the measured variables (i.e., stress ratings, depression, anxiety).

2.2 | Measures

2.2.1 | Demographic and medical characteristics

Participants completed a demographic form (e.g., age, gender, education); measures of physical health status were collected via chart review: (a) FEV₁% predicted, (b) body mass index (BMI), (c) pancreatic insufficiency, and (d) CF-related diabetes. Health outcome data that is collected at each clinic visit, such as FEV₁ and BMI were extracted from electronic medical records from the last clinic visit. Typically, before the pandemic, these visits occurred every 2–3 months.

2.2.2 | Perceived stress ratings

At the beginning of each session, a stress rating was elicited, asking participants to evaluate their perceived level of stress on an ad hoc, 10-point Likert scale, ranging from 1 (*not stressed at all*) to 10 (*extremely stressed*).

2.2.3 | PHQ-8 (Patient Health Questionnaire-8 item)

The PHQ-9²⁰ is a brief, self-administered measure of depressive symptoms, with nine items that fit the diagnostic criteria for Major Depressive Disorder. It is free, available in all major world languages

and recommended by international guidelines.^{15,21} It has extensive reliability (Cronbach's $\alpha = .86-.89$) and validity.²² The minimal important difference (MID) score of 5 points, in either direction, has been established as a clinically meaningful change.²³ This is a screening instrument and thus, does not represent a clinical diagnosis. However, strong correlations have been found between scores on the PHQ-9/8 and diagnoses. PHQ-8 was used because sessions were remotely, the country was in a heightened state of alert, and asking about suicidal ideation (Item #9: thoughts that you would be better off dead, or of hurting yourself) was not clinically appropriate. This is recommended when you are not able to provide immediate assistance to someone who endorses this question. The recall period is 2 weeks, using a 4-point frequency scale. Severity of depressive symptoms was categorized as “no symptoms” (0–4), “mild symptoms” (5–9), “moderate symptoms” (10–14) and “severe symptoms” (≥ 15) range.²⁴ The Italian version was used (<http://www.phqscreeners.com/>).

2.2.4 | GAD-7 (Generalized Anxiety Disorder-7 item)

The GAD-7 is a brief, 7-item self-report measure of anxiety, rated on a 4-point Likert scale.²⁵ This is a screening instrument and does not represent a clinical diagnosis. However, strong correlations have been found between scores on the GAD-7 and diagnosed anxiety. It has extensive reliability and validity (Cronbach's $\alpha = .92$). The total score was categorized into “no symptoms” (0–4), “mild” (5–9), “moderate” (10–14), and “severe” (≥ 15) range. The MID score of 4 points, in either direction, has been established as a clinically meaningful change.²⁶ The Italian version of this instrument was used.

2.2.5 | Feasibility and Satisfaction

Feasibility of participation (1 “*not at all practical*” to 4 “*very practical*”) and Satisfaction with the intervention (1 to 4 from “*not at all*” to “*very satisfied*”) were assessed using ad hoc scales, 1 week after the last session. Two feasibility questions were asked (*How practical/easy was it to participate in the program? Do you think the program should continue?*) and two items were rated for satisfaction (*Did you find it helpful to participate in this program? How satisfied were you with this program?*).

2.3 | Telehealth psychological support intervention

This intervention utilized evidence-based Cognitive Behavioral Therapy (CBT) skills for depression and anxiety (Figure 1) which have been published in numerous references.^{27–31} The 4-session intervention focused on self-care (e.g., relaxation training, daily CF treatments), coping skills (e.g., cognitive reframing), exercises to improve mood, and individual, emotional challenges (e.g., extreme fear of the virus). In Session 1, individuals were asked to describe their stressful

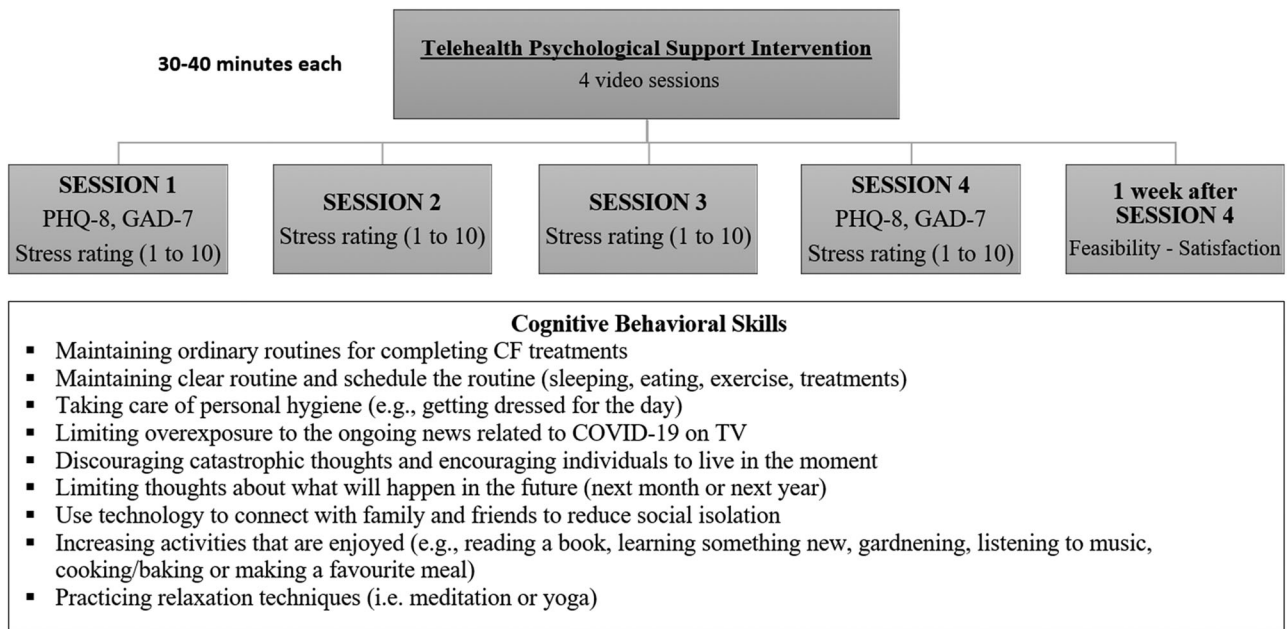


FIGURE 1 Telehealth Psychological Support Intervention. CF, Cystic Fibrosis; COVID-19, coronavirus disease 2019; GAD-7, General Anxiety Disorder-7 item; PHQ-8, Patient Health Questionnaire-8 item

experiences with the pandemic and consider coping strategies that had been useful, identify their own resilience skills (e.g., call a friend for support), and protective factors (e.g., family support, reducing time watching the news).

Initially, there was tremendous fear about the pandemic, and pwCF and caregivers were engaging in a lot of catastrophic thinking (e.g., this virus can kill me). In all sessions, therapists encouraged a focus on the present moment and emphasized how well-prepared they were to deal with COVID-19, given their CF experience with infection control. A toolkit of cognitive-behavioral skills was built and used flexibly in all sessions to promote psychological and physical health (Figure 1). CBT skills included: cognitive reframing (facilitating positive thoughts), relaxation training, increasing positive emotions, and getting physical exercise. One exercise, "catching joy,"³² asked them to identify three moments of joy each day and record them in WhatsApp; these joyful moments were discussed in the next session. The importance of maintaining normal routines was reinforced, which included getting up and dressed, performing CF treatments, getting good sleep, and identifying activities that increased positive mood (e.g., cooking a favorite dish, listening to music).

During each session, individuals were asked to describe a recent stressful experience with COVID-19 and the effects of the lockdown. Next, they were asked about coping with this stressor and discussed new strategies they could use. Time was also spent identifying the "upsides" of the lockdown (i.e., reframing), having more time for CF treatments, watching movies as a family, and for parents, spending more time with their children. In general, increasing positive emotions and adaptive thinking were fostered to counter negative thoughts, and self-efficacy and resilience were encouraged.

3 | RESULTS

3.1 | Baseline demographic, medical, and psychological data

3.1.1 | Demographic information

Sixteen adolescents/young adults (9 female, 7 male), ages 12–36 years and 14 parents, ages 26–49 years (13 mothers, 1 father) agreed to participate (Table 1). All participants completed the measures (100%). A majority of pwCF were in middle school. Most parents were unemployed (46%), some worked from home, and some were furloughed.

3.1.2 | Clinical and psychological characteristics

Average lung function (FEV₁%) was 67%, average BMI was 22, and 81% were pancreatic insufficient (Table 2). At baseline, average stress ratings were fairly high: 7.1 for pwCF and 7.8 for parents out of 10 points (Table 3). A large percentage of participants in both groups scored in the clinically elevated range on the screening measures (scores ≥ 5) prior to the intervention. The mean score on the PHQ-8 was 8.0 for pwCF and 6.4 for parents, respectively. The mean score on the GAD-7 was 6.9 for pwCF and 8.1 for parents, respectively. Among patients, 71% scored in the elevated range on both depression and anxiety, with most in the mild–moderate range. Among parents, 57% scored in the elevated range of depression, with most reporting mild–moderate severity, and 79% scored in the elevated range for anxiety, with 45% scoring in the moderate–severe range (Table 3).

TABLE 1 Participant characteristics

	PwCF	Parents
Sample size, <i>n</i>	16	14
Female, <i>n</i>	9	13
Male, <i>n</i>	7	1
Age, mean (SD)	22.5 (6.9)	37 (6.3)
Years of education, mean (SD)	12 (4)	15 (3.0)
Marital status		
- Single, <i>n</i> (%)	14 (87)	3 (21)
- Married, <i>n</i> (%)	2 (13)	11 (79)
- Divorced, <i>n</i> (%)	0 (0)	0 (0)
Level of education		
- Middle School, <i>n</i> (%)	7 (44)	1 (7)
- High School, <i>n</i> (%)	6 (37)	7 (50)
- University, <i>n</i> (%)	3 (19)	6 (43)
Employment status		
- Unemployed, <i>n</i> (%)	4 (25)	6 (46)
- Employed/Education, <i>n</i> (%)	9 (56)	1 (8)
- Working from home during lockdown, <i>n</i> (%)	1 (6)	2 (15)
- Job suspended during lockdown, <i>n</i> (%)	2 (13)	4 (31)

Abbreviations: *n*, number; PwCF, people with cystic fibrosis; SD, standard deviation.

3.2 | Intervention results: People with CF

Analyses of these within-subject changes demonstrated statistically significant reductions in stress for pwCF: 7.1 at the pretest to 4.9 at the posttest (paired *t* test, $t(15) = 4.1$, $p < .01$). The effect size, using Cohen's *d*, was 1.02, which indicated a large effect. Significant reductions in depression were also found; from 8.0 at the pretest to 4.7 at the posttest (paired *t* test, $t(15) = 2.8$, $p < .05$); Cohen's *d* effect size was 0.69 indicating that it ranges from a medium to large effect. Symptoms of anxiety decreased, 6.9 at pretest to 5.6 at posttest, but were not statistically significant (paired *t* test, $t(15) = 1.2$, $p = \text{NS}$ —non-significant; Figure 2).

TABLE 2 Clinical parameters

	PwCF
FEV ₁ , mean % predicted (SD)	67 (28)
BMI (kg/m ²) (SD)	22 (3.2)
Pancreatic insufficiency, <i>n</i> (%)	13 (81)
Diabetes, <i>n</i> (%)	1 (6)

Abbreviations: BMI, body mass index; FEV₁% predicted, percentage of forced expiratory volume in 1 sec; *n*, number; PwCF, people with cystic fibrosis; SD, standard deviation.

3.2.1 | Categorical changes in symptoms of depression

Next, categorical changes from pre- to post-testing were analyzed. At baseline, 25% ($n = 4$) of pwCF had no symptoms of depression, 31.2% ($n = 5$) were mild, 37.5% ($n = 5$) moderate, and 6.3% ($n = 1$) severe (Table 3). Overall, most pwCF remained stable from pre- to post-testing (56.2%; $n = 9$), 37.5% ($n = 6$) of pwCF reported *decreases* in depression and 1 individual (6.3%; $n = 1$) reported worse symptoms. Specifically, six pwCF improved, one worsened, and nine remained stable. For those in the mild range ($n = 5$), all remained mild. The largest changes were observed in three pwCF who were moderate at pre and dropped into the *no symptoms* category, followed by two pwCF who were moderate but dropped into the *mild* category. The person who worsened reported no symptoms at pre-testing but had a *1-point increase* at post-testing in that mild range.

3.2.2 | Categorical changes in symptoms of anxiety

Categorical changes were also analyzed for anxiety. At baseline, 25% of pwCF had no symptoms ($n = 4$), 56.2% were mild ($n = 9$), 12.5% moderate ($n = 2$), and 6.3% severe ($n = 1$) (Table 3). Overall, most pwCF remained stable ($n = 11$; 68.7%), 25% ($n = 4$) reported *decreases* in anxiety and one person (6.3%) reported no symptoms at pre-testing, but reported mild symptoms at post-testing. For those who were mild at pretesting ($n = 9$), all remained mild. Although stability or improvements were observed in most pwCF, changes in anxiety were less substantial.

We utilized the MID (PHQ-9 = 5 points; GAD-7 = 4 points) in the next analysis to examine the percentage of pwCF who made clinically significant improvements. More than one-third of the sample (37%; $n = 6$) reported a clinically meaningful change in depression and 17% ($n = 3$) reported meaningful changes in anxiety.

3.3 | Intervention results: Parent caregivers

Similar results emerged for parents. Statistically significant decreases were found in stress ratings, 7.8 at the pre-test to 5.7 at post-testing (paired *t* test, $t(13) = 5.2$, $p < .001$). The effect size, using Cohen's *d* was 1.34, indicating a large effect. Significant reductions were also found for depression, 6.4 at pretest to 5.1 at posttest (paired *t* test, $t(13) = -2.5$, $p < .05$); Cohen's *d* effect size was 0.65, indicating an effect size between medium and large. In contrast, symptoms of anxiety decreased from 8.1 to 7.9 but were not statistically significant (paired *t* test, $t(13) = -0.2$, $p = \text{NS}$; Figure 2).

3.3.1 | Categorical changes in symptoms of depression

Next, categorical changes in scores from pre- to post-testing were analyzed. At baseline, 42.8% of caregivers ($n = 6$) had no symptoms of

TABLE 3 Stress, depression, and anxiety: Scores pre–post intervention

	PwCF-Pre	PwCF-Post	Parents-Pre	Parents-Post
Stress Rating Scale, mean (SD)	7.1 (1.8)	4.9 (1.8)	7.8 (2.6)	5.7 (1.9)
PHQ-8, mean (SD)	8 (4.3)	4.7 (3.2)	6.4 (3.8)	5.1 (3.6)
- No symptoms, <i>n</i> (%)	4 (25)	7 (43.7)	6 (42.8)	5 (35.7)
- Mild, <i>n</i> (%)	5 (31.2)	8 (50)	4 (28.6)	7 (50)
- Moderate, <i>n</i> (%)	6 (37.5)	1 (6.3)	4 (28.6)	2 (14.3)
- Severe, <i>n</i> (%)	1 (6.3)	0 (0)	0 (0)	0 (0)
GAD-7, mean (SD)	6.9 (4.4)	5.6 (2.9)	8.1 (5.4)	7.9 (2.7)
- No symptoms, <i>n</i> (%)	4 (25)	4 (25)	3 (21.4)	3 (21.4)
- Mild, <i>n</i> (%)	9 (56.2)	11 (68.7)	5 (35.7)	7 (50)
- Moderate, <i>n</i> (%)	2 (12.5)	1 (6.3)	4 (28.6)	4 (28.6)
- Severe, <i>n</i> (%)	1 (6.3)	0 (0)	2 (14.3)	0 (0)

Abbreviations: GAD-7, Generalized Anxiety Disorder 7-item; *n*, number; PHQ-8, Patient Health Questionnaire-8 item; PwCF, people with cystic fibrosis; SD, standard deviation.

depression, 28.6% (*n* = 4) were mild, 28.6% (*n* = 4) moderate, and no parents reported severe symptoms (Table 3). Overall, most caregivers remained stable from pre to post (64.3%; *n* = 9), however, 21.4% (*n* = 3) of parents reported *decreases* in depression and 2 reported worse symptoms (14.3%). The largest changes were observed in three caregivers who reported moderate symptoms at pre and dropped into the mild category at post. In addition, three parents (21.4%) who were mild remained mild. For the two parents who

worsened, one moved from mild to moderate and one reported no symptoms at pre and mild symptoms at the post-testing.

3.3.2 | Categorical changes in symptoms of anxiety

Categorical changes were also analyzed for anxiety. At baseline, 21.4% (*n* = 3) of caregivers reported no symptoms of anxiety, 35.7%

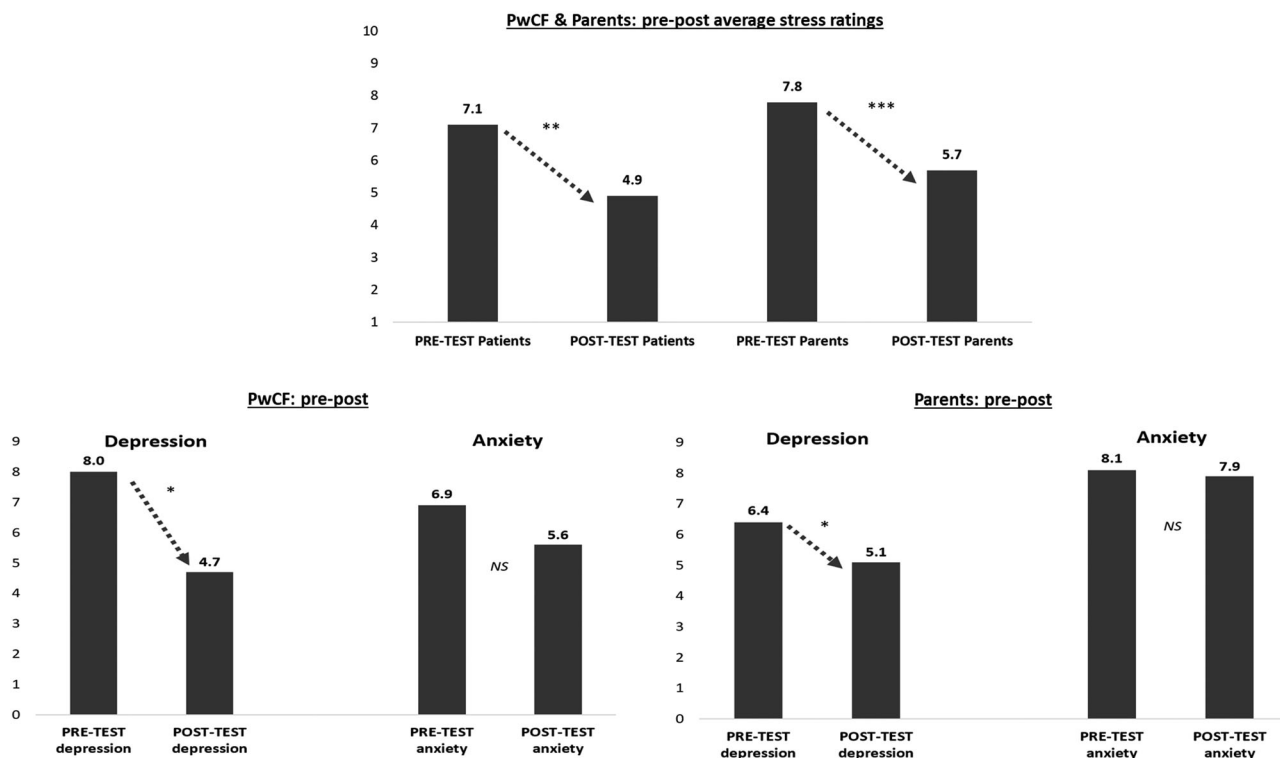


FIGURE 2 Pre-post Telehealth Psychological Support Intervention. Notes: Data are presented as paired *t* tests. **p* < .05; ***p* < .01; ****p* < .001. NS, non-significant; PwCF, people with cystic fibrosis

($n = 5$) reported mild symptoms, 28.6% ($n = 4$) were moderate, and 14.3% ($n = 2$) reported severe symptoms (Table 3). Most parents remained stable ($n = 7$; 50%), however, 28.6% ($n = 4$) reported decreases in anxiety and three parents (21.4%) reported worsening of anxiety at the post-testing. Six (42.9%) parents were stable; three remained mild (21.4%) and three moderate (21.4%). Two parents made dramatic improvements, reporting severe symptoms at pre and mild symptoms at post-testing (14.3%).

The next analysis examined the percentage of parents who made a clinically significant improvement. One parent reported a clinically meaningful improvement in depressive symptoms and two parents reported clinically meaningful improvements in anxiety.

3.4 | Feasibility and Satisfaction

Ratings of feasibility and satisfaction were rated on a 4-point scale by both pwCF and parents, reporting generally high ratings. Average feasibility across patients and parents was 3.3 for the question: "How practical/easy was it to participate in the program?" and 3.2 for the question: "Do you think the program should continue?" Satisfaction was 2.9 for the question: "Did you find it helpful for you to participate in this program?" and 2.8 for the question: "How satisfied were you with this program?" Overall, these results suggested that the intervention was both feasible and helpful.

4 | DISCUSSION

At the beginning of the COVID-19 crisis in Italy, rates of depression and anxiety were highly elevated in pwCF (71%) and parents (57% depression, 79% anxiety), with a large proportion scoring in the moderate to severe range. Ratings of stress were also highly elevated during this crisis. Importantly, these rates of psychological symptomatology were much higher during the COVID-19 lockdown, than those obtained during routine CF care before COVID-19.^{12,33,34} Routine screening in the CF Center was suspended during the lockdown and screening resumed in the middle of May (lockdown ended May 4). Twice the number of pwCF scored in the elevated range at the baseline assessment in this study compared to screening rates obtained on the entire CF Center before the COVID lockdown.¹²

Overall, the results of this Telehealth Psychological Support Intervention demonstrated positive effects, significantly reducing symptoms of stress and depression for both pwCF and caregivers. Despite a small sample, the effect sizes for the statistically significant results were in the medium to large range. Decreases in ratings of stress and symptoms of depression and anxiety were substantial. For pwCF, 38% reported decreases in depression and 25% in anxiety, leading to a change in severity; for parents 21.4% and 28.6% reported less depression and anxiety, respectively. Two parents made a dramatic improvement, reporting severe symptoms at pre and mild symptoms at post, thus, improving by two categories of severity. This intervention may also have served to prevent a worsening of psychological symptoms. Although substantial decreases

in symptomatology were observed, the majority of pwCF and caregivers remained stable within a particular category, with few showing a pattern of increased symptoms.

In considering how many participants achieved a clinically meaningful change in symptomatology, 17%–37% of pwCF and 7%–13% of parents, respectively. Although the overall results of this telehealth intervention were positive, decreases in anxiety did not meet the statistical threshold for significance for either pwCF or parents. Several possible reasons may account for this. First, COVID-19 is a novel coronavirus and there was no information about how this new virus might affect pwCF. Given that CF is a very serious, underlying pulmonary condition, there was considerable fear that pwCF would be more negatively affected than others, and the CF healthcare community did not know if pwCF were uniquely vulnerable. Second, during and after the intervention, people were still living with this crisis every day. Triggers for anxiety were ubiquitous (e.g., news, mortality rates) and the extreme social isolation in Italy may have also raised levels of anxiety. Finally, many people lost their jobs because all services and businesses were closed, and children and adolescents were not able to go to school. The pandemic caused a major economic recession in Italy, as in other parts of the world, and this might have limited reductions in anxiety.

The psychological support intervention was very brief, only four sessions, but was effective. It utilized basic skills derived from CBT, including relaxation training, cognitive reframing, exercises to increase positive emotions (e.g., music), good sleep hygiene, and physical exercises for home. It was delivered via telehealth with a clinical psychologist, which enabled pwCF and parents to access the intervention easily and efficiently. There were no technical difficulties because it utilized simple technology (video call) and if necessary, could be conducted by phone.

4.1 | Limitations and conclusions

This study had several limitations. First, there was no control group to compare to those in active treatment. Thus, we could not account for the effects of time and attention or possible regression to the mean. To attribute these positive results to the effect of this CBT intervention will require a randomized, controlled trial or a waitlist control group design.

A second limitation was a potential bias in the recruitment of participants. Although invitation letters were sent to all families at the CF Center, pwCF who enrolled in this study tended to have lower lung function than the CF Center generally, and two pwCF were being evaluated for the lung transplant list.

Third, this intervention was not as comprehensive or structured as a traditional CBT treatment because it was shorter (four sessions; usually 8–10) and was not guided by a manual. Instead, it was individualized to the concerns participants' raised about their own needs.

Finally, this intervention was limited by a small sample size. Although we obtained statistically significant decreases in both stress and depression, with medium to large effect sizes, this study was underpowered. This might have accounted for the lack of statistical

significance in anxiety scores, which decreased but did not meet standard, $p < .05$ criteria.

Our study results indicated that this telehealth intervention was effective in reducing stress and symptoms of depression in both pwCF and caregivers, and was rated by participants as feasible and satisfactory. This intervention will require further evaluation with a larger sample to establish its efficacy. In addition, this brief intervention is not a substitute for a comprehensive CBT program or ongoing psychological support from a mental health expert on the CF Team. A future randomized, controlled trial of this intervention is being planned to test its efficacy.

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AUTHOR CONTRIBUTIONS

Sonia Graziano: Conceptualization (lead); data curation (lead); methodology (lead); project administration (lead); resources (lead); validation (lead); visualization (lead); writing—original draft (lead); writing—review and editing (lead). **Francesca Boldrini:** Conceptualization (supporting); methodology (supporting); writing—original draft (supporting). **Dario Righelli:** Formal analysis (lead); software (lead); writing—original draft (supporting). **Francesco Milo:** Conceptualization (supporting); methodology (supporting); writing—original draft (supporting). **Vincenzina Lucidi:** Project administration (supporting); resources (supporting); supervision (supporting); writing—original draft (supporting). **Alexandra Quittner:** Conceptualization (supporting); methodology (supporting); writing—original draft (lead); writing—review and editing (lead). **Paola Tabarini:** Conceptualization (supporting); methodology (supporting); writing—review and editing (lead).

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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