

Psychological Interventions during COVID Pandemic: Telehealth for Individuals with CF and Caregivers

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Abstract

Introduction: COVID-19 emerged in China leading to worldwide morbidity and mortality, including depression and anxiety. As the pandemic spread throughout Italy and Europe, mental health concerns emerged for people with cystic fibrosis (pwCF), who are at increased risk. This led to development of a Telehealth Psychological Support Intervention to help adolescents/young adults with CF and caregivers cope with the stress and emotional challenges of the lockdown which began in Italy in March 2020. **Methods:** This intervention utilized cognitive behavioral skills (e.g., relaxation training, cognitive reframing). Participants included 16 adolescents/adults and 14 parents, who completed 4 individual video sessions with a psychologist. Stress ratings, PHQ-8 and GAD-7 were completed electronically. Feasibility and Satisfaction were rated. **Results:** Ratings of stress significantly decreased from pre to post-testing for both pwCF (paired $t=-4.06$ (14), $p<.01$) and parents (paired $t=-5.2$, $p<.001$). Most participants reported clinically elevated depression and anxiety at the pre-test, with statistically significant reductions in depression for pwCF (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, $p=NS$). Reductions in depression were found for parents (pre: $M=6.4$ to post: $M=5.1$, (14) $t=-2.5$, $p<.05$) but not anxiety (pre: $M=8.1$ to post: $M=7.9$, t (14)=0.2, $p=ns$). Positive ratings of Feasibility and Satisfaction were documented. **Conclusion:** This brief telehealth intervention yielded significant reductions in stress and depression for participants. Anxiety was not reduced, possibly because COVID was ongoing. This intervention was effective for improving mental health and was highly feasible and satisfactory.

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1. INTRODUCTION

In December 2019, a novel coronavirus, SARS-CoV-2 (i.e., 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 its associated comorbidities and high mortality rate. Loss of normal routines (e.g., attending work, school), reduction of activities (e.g., restaurants), and a severe economic recession contributed to increasing stress and worsening mental health (e.g., depression, anxiety). A previous systematic review on large-scale disasters revealed increased depression, anxiety, PTSD, substance misuse, domestic violence [4]. The 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 large 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., PHQ-9, 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, with rates of depression and anxiety ranging from 7-20% and 10-19%, respectively [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 [12,13, 14]. Psychological symptoms in pwCF have been associated with worse adherence, more frequent hospitalizations, and earlier mortality [15,16]. Havermans et al. (2020) characterized pwCF as at-risk for psychological symptomatology, reporting feelings of sadness, helplessness and difficulties adhering to prescribed treatments. Increased stress, negative thoughts, and trouble sleeping were also reported, combined with a sense of fear and worry. Parents of children with CF reported high levels of anxiety and disturbances in sleep [17,18].

As Italy became a COVID “hot spot,” concerns about the psychological functioning of pwCF and caregivers increased. To address these concerns, psychologists on the CF team at Bambino Gesù Children’s Hospital developed 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 internet and was aimed at reducing psychological symptomatology and improving disease management. Feasibility and satisfaction were assessed.

2. METHODS

2.1 Procedure

This study was a within-subject, pre-post design, notified to the Bambino Gesù Children’s Hospital Ethical Committee. 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. 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 one week after 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 4 “zoom” sessions using online video platforms, 30-40 minutes each, conducted by a clinical psychologist on the CF Team. Participants were asked to find a quiet, private place, using headphones and microphone.

Written, informed consent was obtained. 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. Feasibility and Satisfaction were rated one week after the last session.

2.2 Measures

a) Demographic and medical characteristics

Participants completed a demographic form (e.g., age, gender, education); measures of physical health status were collected: (a) FEV₁ % predicted, (b) Body Mass Index (BMI), (c) pancreatic insufficiency, and (d) CF-related diabetes.

b) 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*).

c) PHQ-8 (Patient Health Questionnaire-8 item)

The PHQ-9 [19] is a brief, self-administered measure of depressive symptoms, with 9 items that fit the diagnostic criteria for Major Depressive Disorder. It is free, available in all major world languages and recommended by international guidelines [15,20]. It has extensive reliability (Cronbach's alpha=0.86–0.89) and validity [21]. PHQ-8 was used because sessions were remote and asking about suicidal ideation was not appropriate. The recall period is two weeks, using a 4-point frequency scale. Severity of depressive symptoms was categorized as “*no symptom s*” (0-4), “*mild symptoms*”(5-9), “*moderate symptoms*” (10-14) and “*severe symptoms*” ([?]15) range [22]. The Italian version was used (<http://www.phqscreeners.com/>).

d) GAD-7 (Generalized Anxiety Disorder)

The *GAD-7* is a brief, 7-item self-report measure of anxiety, rated on a 4-point Likert scale [23]. It has extensive reliability and validity (Cronbach's alpha 0.92). The total score was categorized into “*no symptom s*” (0-4), “*mild*” (5-9), “*moderate*” (10-14) and “*severe*” ([?]15) range. The Italian version was used.

e) 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 an *ad hoc* scales, one 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 [24-25] for depression and anxiety (Figure 1). The 4-session intervention focused on self-care (e.g., relaxation training), 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 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. Therapists encouraged a focus on the present moment and emphasized how well-prepared they were to deal with COVID, given their CF experience with infection control. A toolkit of cognitive behavioral skills was built and used flexibly 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” [26], asked them to identify 3 moments of joy each day and record them in WhatsApp; these joyful moments were discussed in the next session. 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 the 1st session, individuals were asked to describe a recent stressful experience with COVID and 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.

4. RESULTS

4.1 Baseline demographic, medical, and psychological data

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

Clinical and Psychological Characteristics . Average lung function ($FEV_1\%$) 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 $>$ of 5) *prior* to the intervention. Mean score on the PHQ-8 was 8.0 for pwCF and 6.4 for parents, respectively. 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).

4.2 Intervention Results: People with CF . Results demonstrated statistically significant reductions in stress for pwCF: 7.1 at the pre-test to 4.9 at the post-test (paired t -test, $t(15) = 4.1, p < .01$). Significant reductions in depression were also found; from 8.0 at the pre-test to 4.7 at the post-test (paired t -test, $t(15) = 2.8, p < .05$). Symptoms of anxiety also decreased, 6.9 at pre to 5.6 at post-test, but was not statistically significant (paired t -test, $t(15) = 1.2, p = NS$; Figure 2).

Changes in symptoms of depression . Next, categorical changes from pre to post-testing were analyzed. At baseline, 25% of pwCF had no symptoms of depression, 31% were mild, 37.5% moderate and 6.3% severe (Table 3). Overall, most pwCF remained stable from pre to post-testing (56%), 37.5% of pwCF reported *decreases* in depression and 1 individual reported worse symptoms (6%). Specifically, 6 pwCF improved, 1 person with CF worsened, and 9 remained stable (Table 3). For those in the mild range ($n = 5$), all remained mild. The most dramatic changes were observed in 3 pwCF who were moderate at pre and dropped into the *no symptoms* category, followed by 2 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 mild range.

Changes in symptoms of anxiety . Categorical changes were also analyzed for anxiety. At baseline, 25% of pwCF had no symptoms, 56.2% were mild, 12.5% moderate, and 6.3% severe (Table 3). Overall, most pwCF remained stable ($n = 11$; 79%), 25% ($n = 4$) reported *decreases* anxiety and 1 person (6.3%) reported no symptoms at pretesting, 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 dramatic.

Given that the minimal clinically important difference score for these measures is 5 points, the next analysis examined the percentage of pwCF who made clinically significant improvements. More than one-third of the sample (37%; $n = 6$) reported a clinically meaningful improvement in depression and 17% ($n = 3$) reported meaningful changes in anxiety.

4.3 Intervention Results: Parents 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, $t(13) = 5.2, p < .001$). Significant reductions were also found for depression, 6.4 at pre to 5.1 at post-test (paired t -test, $t(13) = -2.5, p < .05$), In contrast, symptoms of anxiety decreased from 8.1 to 7.9, but were not statistically significant (paired t -test, $t(13) = -0.2, p = NS$; Figure 2).

Changes in symptoms of depression . Next, categorical changes in scores from pre to post-testing were analyzed. At baseline, 42.8% of caregivers had no symptoms of depression, 28.6% were mild, 28.6% moderate, and no parents reported severe symptoms (Table 3). Overall, most caregivers remained stable from pre to post (64.2%), however, 21.4% ($n = 3$) of parents reported *decreases* in depression and 2 reported worse symptoms (14.3%). The most dramatic changes were observed in 3 caregivers who reported moderate symptoms at pre and dropped into the mild category at post. In addition, 3 parents (21.4%) who were mild remained mild.

For the two parents who worsened, 1 moved from mild to moderate and 1 reported no symptoms at pre and mild symptoms at the post-testing.

Changes in symptoms of anxiety . Categorical changes were also analyzed for anxiety. At baseline, 21.4% of caregivers reported no symptoms of anxiety, 35.7% reported mild symptoms, 28.6% were moderate and 14.3% reported severe symptoms (Table 3). Most parents remained stable ($n = 7$; 50%), however, 28.6% ($n = 4$) reported *decreases* in anxiety and 3 parents (21.4%) reported worsening of anxiety at the post-testing. Six parents were stable; 3 remained mild and 3 moderate. 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 (7%) reported a clinically meaningful improvement in depressive symptoms and two parents reported clinically meaningful improvements in anxiety (13%).

4.4 Feasibility and Satisfaction

Ratings of feasibility and satisfaction were rated on 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.

5. 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 lockdown, than those obtained during routine CF care prior to COVID [12,27-28]. Twice the number of pwCF scored in the elevated range at baseline assessment in this study than prior published data [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. 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 highly 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 4 sessions, but was highly 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 (videocall) and if necessary, could be conducted by phone.

Limitations & 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 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 (4 sessions; usually 8 to 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, 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.

Results showed that this intervention was effective, feasible and satisfactory. However, it is not a substitute for a comprehensive intervention 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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Declaration of Competing Interest

None.

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Figure 1. Telehealth Psychological Support Intervention

Abbreviation: *CBT* = Cognitive Behavioral Therapy

Figure 2. Pre-Post Telehealth Psychological Support Intervention

Abbreviation: *PwCF* = people with cystic fibrosis

Notes: Data are presented as paired t-tests. Abbreviations: * = $p < .05$; ** = $p < .01$; *** = $p < .001$; *NS* = non-significant.

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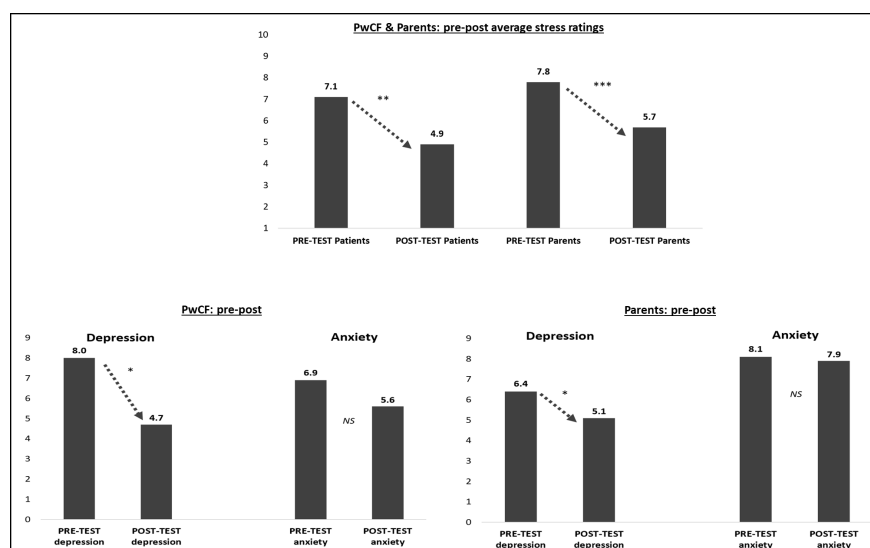
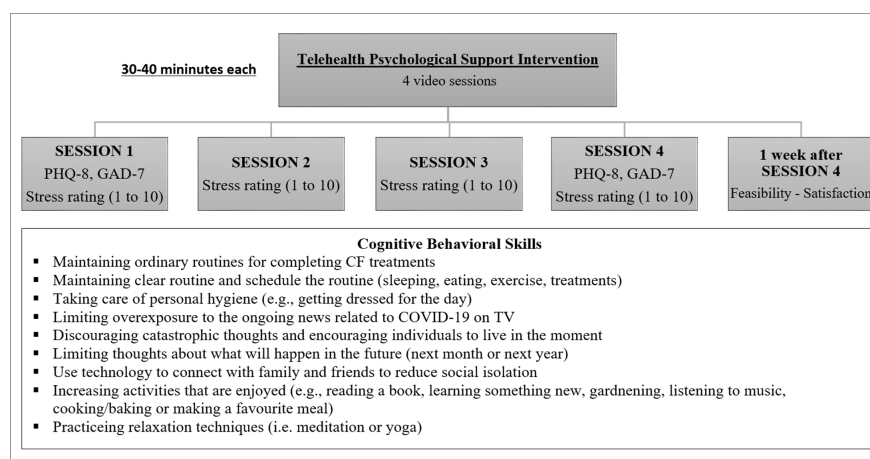
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