Self-Care Mental Health App Intervention for Post–Intensive Care Syndrome–Family: A Randomized Pilot Study

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Background Post–intensive care syndrome–family (PICS-F) is a constellation of adverse psychological symptoms experienced by family members of critically ill patients during and after acute illness. Cognitive behavioral therapy delivered using smartphone technology is a novel approach for PICS-F symptom self-management.
Objective To determine the efficacy of smartphone delivery of cognitive behavioral therapy in reducing the prevalence and severity of PICS-F symptoms in family members of critically ill patients.
Methods The study had a randomized controlled longitudinal design with control and intervention groups composed of family members of patients admitted to 2 adult intensive care units. The intervention consisted of a mental health app loaded on participants' personal smartphones. The study time points were upon enrollment (within 5 days of intensive care unit admission; time 1), 30 days after enrollment (time 2), and 60 days after enrollment (time 3). Study measures included demographic data, PICS-F symptoms, mental health self-efficacy, health-related quality of life, and app use.
Results The study sample consisted of 60 predominantly White (72%) and female (78%) family members (30 intervention, 30 control). Anxiety and depression symptom severity decreased significantly over time in the intervention group but not in the control group. Family members logged in to the app a mean of 11.4 times (range, 1-53 times) and spent a mean of 50.16 minutes (range, 1.87-245.92 minutes) using the app.
Conclusions Delivery of cognitive behavioral therapy to family members of critically ill patients via a smartphone app shows some efficacy in reducing PICS-F symptoms.
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Post–intensive care syndrome–family (PICS-F) is a constellation of adverse psychological symptoms experienced by family members of critically ill patients during and after the acute illness.[1] These symptoms include anxiety, depression, posttraumatic stress, and complicated grief. More than one-third of family members experience clinically significant symptoms within the first 6 months of the intensive care unit (ICU) admission, and some symptoms may last years after the illness.[2-8]

PICS-F has been identified as a research priority by the Society of Critical Care Medicine, the leading critical care organization in the United States, and various multidisciplinary critical care organizations have acknowledged the detrimental effects of critical illness on patients' families and the need for holistic family-based care.[9,10] Interventions that have been developed to prevent or reduce PICS-F symptoms have shown mixed results, with varying approaches, time commitments, and degrees of resource use.[11-15]

Cognitive behavioral therapy (CBT) is a widely researched and empirically supported nonpharmacological treatment used for a growing number of psychological conditions.[16] This therapeutic modality emphasizes strategies for identifying unhelpful or maladaptive thoughts, emotions, and behaviors and substituting active and constructive coping mechanisms to manage psychological distress. Cognitive behavioral therapy has shown effectiveness in the treatment of generalized anxiety, depression, posttraumatic stress disorder (PTSD), substance abuse, and eating disorders.[17] It has been successfully delivered using mobile technologies, both with and without direct clinician supervision, and this delivery mode has been shown to be efficacious, cost-effective, and well accepted by individuals.[18-25] Successful self-management of anxiety and depression using a CBT-based mental health app appears to be mediated by improvements in mental health self-efficacy.[26] The feasibility of delivering CBT via a smartphone mental health app to family members of critically ill patients has been previously reported, although the efficacy of this delivery method is untested.[27]

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The hypotheses of this pilot study were as follows: (1) PICS-F symptom severity (anxiety, depression, posttraumatic stress) will be lower and will decrease significantly over time in family members using the self-care mental health app compared with the control group; (2) health-related quality of life (HRQOL) and mental health self-efficacy will be higher in family members using the mental health app than in family members in the control group; and (3) the prevalence of clinically significant PICS-F symptoms will be lower in the intervention group than in the control group.

> Mental health apps promote the self-management of anxiety, stress, and depression.

Methods

Design, Setting, and Sample

For this randomized controlled pilot study, we used a prospective longitudinal design with block randomization to ensure equal group sizes. The study sample consisted of family members of patients receiving care in 2 adult ICUs at a tertiary care hospital. A family member was defined as the person who would be most involved in the patient's treatment and care decisions. Patients were eligible for the study if they had been treated in the ICU for more than 3 days and were receiving mechanical ventilation, lacked cognitive capacity, had an identified family decision maker, and were aged 18 years or older. Family members were eligible if they were aged 18 years or older, self-identified as the family decision maker of the ICU patient, and were able to read and speak English. We obtained institutional review board approval for the study from Summa Health System, where data were collected.

Instruments

Demographic Form. For family members, we recorded demographic data, history of treatment for psychiatric disorders, whether they were currently taking medications for treatment of a psychiatric disorder, history of previous ICU decision-making

experience, and whether they had durable power of attorney for the patient. For patients, we recorded demographic data, primary diagnosis on admission to the ICU, baseline medical comorbidity, severity of illness, length of ICU stay, and the presence of a living will.

Hospital Anxiety and Depression Scale. We assessed symptoms of anxiety and depression using the 14-item Hospital Anxiety and Depression Scale (HADS) instrument.[28] The scale has 7 items that form an anxiety subscale (HADS-A) and 7 items that form a depression subscale (HADS-D). Each of the 2 subscales can have scores ranging from 0 to 21, with higher scores indicating higher levels of anxiety or depression symptoms. A cutoff score of 11 or greater is consistent with moderate-to-severe symptoms of anxiety or depression.

Data were collected on enrollment and 30 and 60 days later.

Posttraumatic Stress Disorder Checklist for the Diagnostic and Statistical Manual of Mental Disorders *(Fifth Edition)*. We assessed symptoms of posttraumatic stress using the 20-item Posttraumatic Stress Disorder (PTSD) Checklist for the *Diagnostic and Statistical Manual of Mental Disorders* (Fifth Edition) (PCL-5) instrument.[29] A total symptom severity score (0-80) can be obtained by summing all of the items, with higher scores indicating greater severity of PTSD symptoms. A cutoff of 31 to 33 is recommended as indicative of a provisional diagnosis of PTSD. For this study, we used a cutoff of 31 or greater.

Medical Outcomes Study 12-Item Short-Form General Health Survey. This survey (abbreviated as SF-12) is a self-report scale measuring HRQOL.[30,31] Each item on the scale is scored using a Likert scale. Raw scores are transformed to a scale from 0 (worst) to 100 (best). The scale provides a summary score for physical and mental quality of life, with higher scores representing a more positive quality of life.

Mental Health Self-Efficacy Scale. This scale (abbreviated MHSES) is a 6-item scale measuring mental health self-efficacy.[26] Each item is measured on a 10-point Likert scale ranging from 1 (not at all confident) to 10 (totally confident). Items are summed for a total score ranging from 6 to 60, with higher scores indicating higher levels of mental health self-efficacy.

Mental Health App

Use of the App. Use of the app was measured by calculating the total number of times the participant logged in to the app throughout the course of the study and the total time in minutes spent using the app.

Satisfaction With the App. We used a single 5-point Likert scale (1 = very dissatisfied; 5 = very satisfied) to assess the participants' overall satisfaction with the app. Additionally, we elicited open-ended feedback about the app and its utility from family members during and after the ICU experience.

Selection of the App. Our selection of the mental health app was based on several criteria: (1) app uses principles of CBT to deliver strategies for managing stress, anxiety, and depression; (2) app is available in the Android and iOS (Apple Inc) operating systems; and (3) app is publicly available with a free version to allow continued use after the current study. On the basis of these criteria, we chose the Sanvello app by Sanvello Health.[32] The Sanvello app includes a suite of clinically proven tools for the self-management of stress, anxiety, and depression.

Intervention

Upon enrollment in the study, family members randomly assigned to the intervention group were guided through the process of downloading and installing the Sanvello app on their smartphone. Study participants received an introductory training session to review basic components of the Sanvello app. Study participants were instructed to start their use of the app with the first "guided path" module, called *Feeling Better*. Each module (*Feeling Better, Taking Control, Building Confidence,* and *Mindfulness*) contains 6 to 9 lessons. Each lesson takes approximately 15 minutes to complete. Participants were instructed to complete 1 lesson each day until they finished all of the lessons in the module, and then proceed to the next module. Following this plan, users of the app were expected to complete all of the "guided path" modules before the end of the study. Participants received weekly reminders by text encouraging them to use the mental health app.

Procedure

This longitudinal study had 3 data collection points: upon enrollment in the study (within 5 days of the ICU admission; time 1), 30 days after study enrollment (time 2), and 60 days after study enrollment (time 3). Demographic data were obtained from the patient, family member, and medical record upon enrollment. Anxiety, depression, and PTSD symptoms were measured at each time point in the study using the HADS-A, HADS-D, and PCL-5 instruments, respectively. HRQOL and mental health self-efficacy were measured using the SF-12 and MHSES,

respectively, upon enrollment (time 1) and 60 days after enrollment (time 3). Data on app use and family member satisfaction with the app were collected at time 3. Study participants were offered a $30 gift card at enrollment (time 1) and at the 30-day follow-up (time 2) and a $50 gift card at the 60-day follow-up (time 3) for a possible total of $110 per participant.

Data Analysis and Statistical Plan

We used descriptive statistics to assess frequencies and variability of data. Nominal and ordinal variables were described by use of absolute numbers and proportions. Interval and ratio variables were described by use of means and SDs. Changes in variables over time were assessed using dependent-sample *t* tests and repeated-measures analysis of variance. Differences between groups were examined with an independent-sample *t* test and χ^2 analysis. The significance level was set at 2-tailed $P \leq .05$. Data were analyzed using IBM SPSS Statistics, version 25 (IBM Corp).

Results

A total of 86 family members met eligibility criteria and were approached to participate in the study. Twenty-six family members declined to participate, leaving 60 family members (30 in the control group and 30 in the intervention group) making up the study sample (Figure 1). Attrition rates were low, although participants in both groups declined to answer some questions on the various PICS-F symptom surveys. The demographic characteristics of the ICU patients and their family members are summarized in Tables 1 and 2, respectively. Patients (70%) and family members (72%) were predominantly White, and most of the family members were female (78%). The mean (SD) length of ICU stay for patients in the study was 14.92 (8.65) days, and the mean (SD) length of mechanical ventilation was 11.78 (8.24) days. Fifteen percent of the ICU patients died during the course of the study. There were no significant differences in demographic characteristics between control and intervention groups for patients or family members.

Feasibility and Use of the App

Smartphone ownership was nearly ubiquitous among family members of ICU patients, with only a handful of individuals excluded from the study owing to lack of a smartphone. Participants logged on to the mental health app a mean of 11.4 times (range, 1-53 times) during the course of the 2-month study. Approximately one-third (n = 9, 30%) of the intervention group logged on to the app 12 or more times. During the 2 months of use, participants spent a mean of 50.16 minutes with the app (range, 1.87-245.92 minutes), with a mean time per session of 5.47 minutes (range, 1.10-17.83 minutes). The

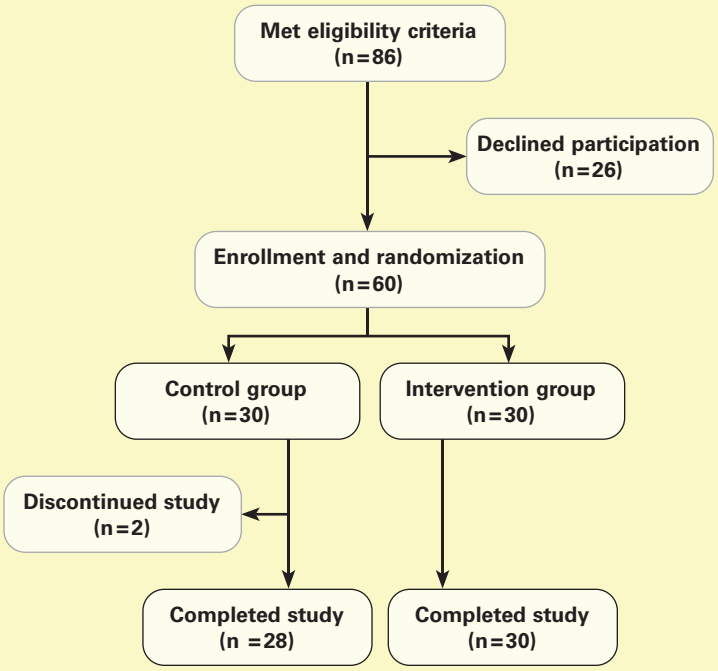

Figure 1 Flowchart of selection of participants in the study.

Table 1
Characteristics of patients in the study

Characteristic	Control group (n=30)	Intervention group (n=30)
Age, mean (SD), y	58.50 (16.01)	55.37 (13.43)
Sex, No. (%)		
Female	13 (43)	14 (47)
Male	17 (57)	16 (53)
Ethnicity, No. (%)		
African American	11 (37)	6 (20)
White	18 (60)	24 (80)
Other	1 (3)	0 (0)
Primary diagnosis, No. (%)		
Cardiovascular	4 (13)	3 (10)
Neurologic	6 (20)	2 (7)
Gastrointestinal	3 (10)	2 (7)
Genitourinary	1 (3)	0 (0)
Respiratory	6 (20)	9 (30)
Trauma	2 (7)	3 (10)
Infectious disease	8 (27)	11 (37)
Charlson Comorbidity Index, mean (SD)	4.30 (3.50)	3.73 (2.39)
SAPS2 score, mean (SD)	44.13 (14.76)	42.52 (12.79)
Living will, No. (%)	10 (33)	8 (27)

Abbreviation: SAPS2, Simplified Acute Physiology Score II.

Table 2
Characteristics of family members in the study

Characteristic	Control group (n=30)	Intervention group (n=30)
Age, mean (SD), y	48.37 (12.00)	44.40 (13.92)
Sex, No. (%)		
Female	23 (77)	24 (80)
Male	7 (23)	6 (20)
Ethnicity, No. (%)		
African American	9 (30)	4 (13)
White	18 (60)	25 (83)
Other	3 (10)	1 (3)
Relationship to patient, No. (%)		
Spouse	9 (30)	7 (23)
Child	12 (40)	11 (37)
Parent	4 (13)	4 (13)
Sibling	3 (10)	4 (13)
Other	2 (7)	4 (13)
Previous history of anxiety, depression, PTSD, No. (%)	10 (33)	14 (47)
Currently taking medications, No. (%)	7 (23)	8 (27)
Previous decision-making experience, No. (%)	17 (57)	13 (43)
Durable power of attorney, No. (%)	13 (43)	9 (30)

Abbreviation: PTSD, posttraumatic stress disorder.

Table 3
Family members' symptoms, HRQOL, and MHSES scores at various times

Scale	Score, mean (SD)		
	At enrollment	30 Days after enrollment	60 Days after enrollment[a]
HADS-A			
Control group	11.79 (4.59)	10.14 (4.13)	9.81 (4.35)
Intervention group	11.03 (6.03)	9.47 (5.39)	8.67 (5.79)[b]
HADS-D			
Control group	8.50 (4.34)	9.52 (4.26)	8.48 (4.85)
Intervention group	7.39 (5.21)	8.97 (5.96)	6.86 (5.64)[c]
PTSD			
Control group	26.43 (19.27)	32.26 (18.12)	26.08 (15.16)[d]
Intervention group	22.86 (14.81)	33.62 (19.86)	25.40 (17.52)[e]
HRQOL physical health			
Control group	52.38 (9.14)		49.58 (9.93)[f]
Intervention group	51.26 (12.64)		48.70 (10.69)
HRQOL mental health			
Control group	39.31 (12.70)		36.33 (13.04)
Intervention group	42.74 (14.53)		38.97 (15.35)
MHSES			
Control group	39.77 (12.70)		39.85 (14.45)
Intervention group	42.27 (12.64)		37.20 (15.33)[g]

Abbreviations: HADS-A, Hospital Anxiety and Depression Scale, anxiety subscale; HADS-D, Hospital Anxiety and Depression Scale, depression subscale; HRQOL, health-related quality of life; MHSES, Mental Health Self-Efficacy Scale; PTSD, posttraumatic stress disorder.
[a] All noted differences are within-group differences. *P* values are from repeated measures analysis of variance post-hoc analysis.
[b] Decrease from enrollment ($P=.05$).
[c] Decrease from 30 days after enrollment ($P=.004$).
[d] Decrease from 30 days after enrollment ($P=.05$).
[e] Decrease from 30 days after enrollment ($P<.001$).
[f] Decrease from enrollment ($P=.02$).
[g] Decrease from enrollment ($P=.01$).

participants' mean rating of their satisfaction with the mental health app, as scored on a single 5-point Likert question (1 = very dissatisfied; 5 = very satisfied), was 4.19 (median, 4; range, 3-5). Although open-ended comments on the app were few, they were generally positive or neutral.

PICS-F Symptoms, HRQOL, and MHSES Score

The outcome measures at each study time point are summarized in Table 3. Anxiety symptoms were highest in both treatment groups at time 1 and decreased over the course of the study, with the intervention group demonstrating a significant decrease from time 1 to time 3 ($F_{2,58}=4.73$, $P=.01$). Depression scores increased from time 1 to time 2 in both groups and significantly decreased from time 2 to time 3 in the intervention group ($F_{2,54}=3.06$, $P=.05$). There was no significant change in anxiety or depression scores over time in the control group. PTSD symptom scores increased from time 1 to time 2 in both groups and significantly decreased from time 2 to time 3 in both groups (control: $F_{2,44}=3.78$, $P=.03$; intervention: $F_{2,54}=14.27$, $P<.001$). Physical HRQOL decreased from time 1 to time 3 in the control group ($F_{1,26}=6.06$, $P=.02$). No statistically significant change over time was noted in the intervention group for physical HRQOL or in either group for mental HRQOL (mental health). Mental health self-efficacy did not change statistically significantly with time in the control group, whereas it decreased significantly in the intervention group between time 1 and time 3 ($F_{1,29}=7.37$, $P=.01$). There were no statistically significant differences between the intervention and control groups for any outcome variable at any time point. The numbers of patients exhibiting clinically significant symptoms of anxiety, depression, or PTSD at each time point are summarized in Figure 2. Although the number and proportion of patients at time 3 with clinically significant symptoms of anxiety, depression, and PTSD tended to be lower in the intervention group than in the control group, the differences were not statistically significant.

Discussion

This pilot study involved a novel approach to addressing symptoms of PICS-F in family members of critically ill patients. Various strategies have been studied to support family members during and after critical illness, including improved communication, ICU diaries, family ICU navigators, proactive palliative care and ethics consultation, and post-ICU clinics.[11-14] Relatively few interventions aimed specifically at PICS-F symptoms have been described in the

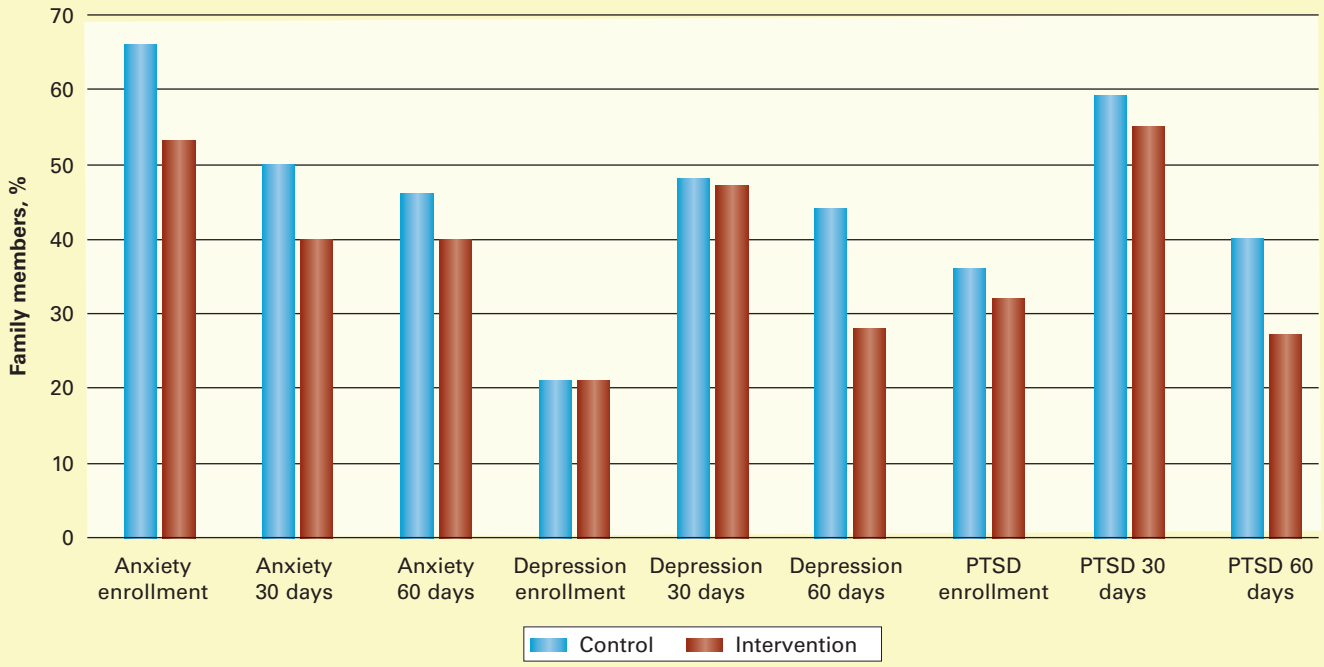

Figure 2 Family members with clinically significant symptoms of post–intensive care syndrome–family (PICS-F) at various times. Symptoms were considered clinically significant for anxiety when the score on the anxiety subscale of the Hospital Anxiety and Depression Scale (HADS) was ≥11, depression when the score on the depression subscale of the HADS was ≥11), and posttraumatic stress disorder (PTSD) when the PTSD Checklist for the *Diagnostic and Statistical Manual of Mental Disorders* (Fifth Edition) (PCL-5) score was ≥31. For anxiety at 60 days, $\chi^2_1 = 0.2$, $P = .64$; for depression at 60 days, $\chi^2_1 = 1.7$, $P = .19$; and for PTSD at 60 days: $\chi^2_1 = 1.1$, $P = .29$.

literature, and the reported results have been mixed.[33,34] A systematic literature review by Zante and colleagues[33] indicated substantial variability in interventional approach, intervention timing, study sample composition, and time frame for the measurement of PICS-F symptoms, making comparisons difficult. Proactive family conferences with a physician and nurse were found to reduce the prevalence of anxiety, depression, and PTSD symptoms. Other interventions were not found to improve PICS-F symptoms, with some actually associated with an increased prevalence and severity of PTSD symptoms. Delivery of CBT through the use of a smartphone app is a way to directly address PICS-F symptoms early in the patient's ICU stay while limiting the resources needed to implement and sustain the intervention.

Our results indicated a prevalence and severity of PICS-F symptoms in line with the findings of other studies.[2-4,8] Although there were no significant differences between the 2 study groups in symptom severity at any study time point, the severity of anxiety, depression, and PTSD symptoms decreased significantly with time in the intervention group, whereas only PTSD symptoms decreased significantly with time in the control group. Additionally, the number of study participants with clinically significant PICS-F symptoms at time 3 was lower for anxiety, depression, and PTSD in the intervention group than in the control group, although the difference was not statistically significant. Anxiety levels were highest at time 1, suggesting a substantial acute anxiety component of PICS-F, as reported by other authors.[8,27,35,36] Depression symptoms increased in severity from time 1 to time 2 in both groups and remained elevated in the control group, corroborating previous reports and suggesting that depression is a more inelastic and persistent component of the syndrome.[8] PTSD symptom severity increased from time 1 to time 2 and decreased from time 2 to time 3. As with depression, PTSD symptoms' prevalence and severity tend to increase over time and remain generally stable, with some researchers describing the persistence of depression and PTSD symptoms up to 4 years after the ICU illness.[6,37] Although the overall differences between groups for individual symptoms were small, our collective findings suggest some efficacy for the app intervention in ameliorating PICS-F symptoms.

> Participants' mean rating of their satisfaction with the mental health app was 4.19 out of 5.

We observed a decrease in physical HRQOL in the control group, with no significant change in physical HRQOL in the intervention group or in mental HRQOL in either group. Although the

literature is scant, previous reports have indicated a decrease in mental HRQOL or no change over time.[8,38] Intuitively, a decrease in mental HRQOL would presumably occur in the presence of significant PICS-F symptoms. A decrease in physical HRQOL might be reported as a physical manifestation of decreased mental HRQOL. The explanation for decreased physical HRQOL without a decrease in mental HRQOL observed in the control group of our study remains elusive. Also puzzling is the decrease in MHSES score in the intervention group. Previous studies have indicated an increase in MHSES score over time associated with smartphone delivery of mental health interventions.[26,27] One possible explanation for our findings is that study participants in the intervention group overestimated their mental health self-efficacy at time 1, which was revealed by subsequent app use.

App engagement was highly variable in our study. Only one-third of the intervention group used the app regularly throughout the course of the study, with many participants logging in to the app only once or a few times. In our previous feasibility study, we provided the app preloaded on a study smartphone.[27] Most users found carrying a second phone to be cumbersome. However, providing the app on participants' own smartphones and offering more prescriptive instructions for its use in this study did not seem to improve engagement. Additionally, we sent push notifications weekly to promote use of the app. Bidargaddi and colleagues[39] reported that sending tailored push notifications increased the likelihood of mobile health app use within 24 hours by 3.9%, with the likelihood varying by day of the week and time of day the notification was sent. The authors found that notifications sent on Saturdays near midday resulted in the highest likelihood of app use. A clinical review of mental health app engagement identified several barriers to engagement, including concerns about privacy and trustworthiness, lack of design with the end user in mind, and lack of helpfulness in emergencies.[40] In a systematic review of health app uptake and engagement, Szinay et al[41] identified 26 factors relating to capability, opportunity, and motivation that may influence app use. Some authors have argued that traditional measures of app engagement (number of downloads, number of times logged in, time spent with the app) may not be appropriate for accurately assessing the utility of mental health apps.[42] They suggest that comprehensive app engagement should be corroborative, involving multiple data points, as well as outcome oriented, process based, and expert driven.

Use of a mental health app decreased the severity of PICS-F symptoms over time.

Limitations

The generalizability of our findings is limited because of the small sample size of this pilot study. Similarly, our study was not adequately powered to detect small differences over time and between groups. Our sample may have been biased owing to significant refusal rates. The study began shortly after the COVID-19 pandemic resulted in decreased family visitation, limiting face-to-face enrollment of family members of ICU patients. This situation may have also biased our sample, although the exact effect is difficult to assess. The study used self-report instruments and cutoff scores to measure PICS symptom severity and involved provisional diagnoses of the respective disorders. The self-report instruments do not replace diagnosis of anxiety, depression, or PTSD by a trained clinician. Complicated grief is also a component of PICS-F and may be a confounding variable that we did not measure in this study. The app chosen for the intervention uses proven CBT principles and has demonstrated efficacy in other treatment samples. However, the app was not designed specifically for family members of critically ill patients and may not offer resources uniquely tailored to their needs.

Conclusion

In this pilot study of a smartphone mental health app intervention for PICS-F, we found a significant decrease over time in the severity of anxiety, depression, and PTSD symptoms in the treatment group compared with the control group. Additionally, the number and proportion of individuals with clinically significant symptoms tended to be lower in the treatment group at the end of the 8-week study period. More research is needed on the trajectory of PICS-F symptoms over a longer period of time, the measurement of complicated grief as a component of PICS-F, ways of increasing engagement with the app, and ways of tailoring app content for family members of ICU patients. Delivery of CBT via a smartphone mental health app is a novel approach to PICS-F that has the potential to reduce the adverse psychological symptoms often experienced by the family members of critically ill patients.

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CE 1.0 Hour Category A

Notice to CE enrollees:

This article has been designated for CE contact hour(s). The evaluation demonstrates your knowledge of the following objectives:

1. Describe the component symptoms and significance of post–intensive care syndrome–family.
2. Identify the known risk factors for post–intensive care syndrome–family.
3. Analyze the advantages and disadvantages of using a self-care app for addressing post–intensive care syndrome–family.

To complete the evaluation for CE contact hour(s) for activity A2362, visit https://aacnjournals.org/ajcconline/ce-articles. No CE fee for AACN members. See CE activity page for expiration date.