

# The mediating role of hope in relation with fear of COVID-19 and mental health: A study on tertiary level students of Rajshahi District

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## Abstract

**Background and Aims:** The novel coronavirus disease (COVID-19) is influential in all parts of people's lives, specifically psychological states due to the fear related to the pandemic. Thus, this study aimed to investigate the mediating role of hope in the connection between the fear of COVID-19 and mental health among tertiary college students of Rajshahi district during the COVID-19 disease.

**Method:** A cross-sectional survey was conducted among tertiary college students a sample of 498 participants (53.4% females and 46.6% males) ranged between ages 19 and 31 ( $M = 22.03 \pm 1.92$ ) and participants filled out the fear of COVID-19 Scale, Trait Hope Scale, and General Health Questionnaire.

**Result:** In the case of correlation analysis, fear of COVID-19 is reversely correlated with mental health, while lower but positive correlations were found with hope. Findings from the process macro v3.5 by Hayes analysis for the study model indicated that hope mediated in the relationship between the fear of COVID-19 and mental health controlling for gender, and socioeconomic status, and the hypothesized model explained approximately 27% of the variance in mental health.

**Conclusion:** Overall, the findings suggest that a high level of mental health is impacted by a low level of fear of COVID-19. Additionally, a low level of fear of COVID-19 contributes to increasing levels of hope, which enhances mental health.

## KEYWORDS

fear of COVID-19, hope, hope agency, hope pathway, mental health

## 1 | INTRODUCTION

The coronavirus is currently the most discussed issue in the world, which has caused widespread outbreaks. The coronavirus has not only claimed the lives of thousands of people worldwide but has also caused many severe psychological problems among people and changed the daily routine of millions of people. And the number of

cases and deaths is increasing day by day.<sup>1</sup> The current outbreak of coronavirus is a very important worldwide health problem and the biggest challenge. This outbreak created feelings of hopelessness, sickness, fear, and death in the minds of people. Fear is the most primary emotion that rises on a person's face. As a result, some physical and mental reactions are seen<sup>2</sup> such as increased heart rate, increased blood pressure, muscle stiffness, and rapid breathing.

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Fear changes cognitive levels like attention in some cases.<sup>3</sup> In some countries, there have committed suicides due to fear of corona.<sup>4,5</sup> In some cases, COVID-19 causes panic and fear.<sup>6</sup> This kind of feeling is created, when a loved one is infecting or dying. Furthermore, fear can arise when a person is unable to afford the necessary health care or is more likely to lose a job or business.<sup>7-10</sup> Other probable causes of fear and panic in humans include measures to prevent the spread of coronavirus, such as self-quarantine, maintaining physical distance, and restricting movement at a public place, which causes fear, sadness, worry, anger, solitariness, frustration, helplessness, loneliness, and nervousness.<sup>6,11-13</sup> Tertiary education refers to postsecondary education obtained at universities (public or private), polytechnics, and teacher training colleges.<sup>14</sup>

## 1.1 | Mental health

According to Asmundson and Taylor,<sup>15</sup> the continuity and severity of the COVID-19 epidemic have created uncertainties among people. During this particular period, other psychological problems, including fear, affect a person's life.<sup>16</sup> High infectivity and mortality rate have also created fear in people's minds.<sup>6</sup> Fear is a negative mental tendency, which is observed due to threats.<sup>17</sup> Like other pandemics, the coronavirus has created not only epidemiological crises but also various psychological crises such as fear, anxiety, depression, anger, insomnia, and trauma.<sup>18-21</sup> Mental strength plays an important role in fighting the coronavirus epidemic.<sup>10</sup> Moderate to extreme levels of depression, anxiety, and stress are present in Bangladeshi people in the COVID-19 pandemic situation, whose levels are 47.2%, 46.0%, and 32.5%, respectively, but no gender difference was found.<sup>22</sup> Khatun et al.<sup>23</sup> revealed that marital status, working hours, and job locations are closely linked to anxiety levels. On the other hand, gender, age, and marital status are related to depression levels. A study on Bangladeshi university students found that mild symptoms of depression, anxiety, and depression were found in 76.1%, 76.1%, and 70.1%, respectively; least moderate symptoms were found in 62.9%, 63.6%, and 58.6%, respectively; least severe symptoms ranged from 35.2%, 40.3%, and 37.6%, respectively, and demonstrated quality symptoms ranged from 19.6%, 26.5%, and 16.5%, respectively.<sup>24</sup> A large portion of respondents reported mental health problems during the COVID-19 pandemic in Bangladesh. The prevalence of loneliness, depression, anxiety, and sleep disturbance was estimated at 71% (mild: 32%, moderate: 29%, severe: 10%), 38% (mild: 24%, moderate: 11%, severe: 3%), 64% (mild: 30%, moderate: 17%, severe: 17%), and 73% (mild: 50%, moderate: 18%, severe: 5%), respectively.<sup>25</sup>

## 1.2 | The mediating role of hope

Hope is an important factor for well-being and it is positively related to mental health and physical health.<sup>26</sup> Demirli et al.<sup>27</sup> revealed that hope is a significant predictor of positive emotions, negative

emotions, satisfaction with life, and so on. Rubin<sup>28</sup> suggested that people with high hopes can handle stressful situations better and evaluate the situation in positive ways and they are confident, energetic, and have the lowest level of depression.<sup>29</sup> Moreover, hope is positively related to increasing positive thoughts, optimism, happiness, physical health, psychological health, resilience, self-esteem, and negatively related to depression.<sup>26,30,31</sup> Based on Synder's hope theory, hope is a cognitive set, human qualities to overcome depression, perceived abilities to drive pathways to expected goals, and reduces the intolerable feeling of future; it is connected by two main elements; one is hope agency and the other is hope pathway.<sup>32</sup> Hope pathway is the perceived ability to create an accessible route to achieve the desired goal,<sup>33</sup> and hope agency is the power to accomplish the goal, the plan to achieve the goal, which helps pathway to achieve the goal and identify the right track.<sup>32,33</sup> Hopelessness is a situation in a person's life that causes depression and loss of hope to survive. In almost all cases, hope is a significant aspect in the act with stress and on the other hand, hopelessness identifies itself as a forecaster of depression and mental health. Moreover, hope is a constructive state of inspiration oriented to the desired goal.<sup>34,35</sup> Various studies have shown that hope is positively related to mental health,<sup>36</sup> adapted with stress,<sup>37</sup> and negatively related to fear. From the above discussion, it can be determined that individuals with high levels of Hope and mental health can easily cope with complex life situations. Hope is the way to reach the goal. In the same way, Hope is an important protective factor of maintaining psychological well-being in case of various mental problems produced by coronavirus. During the coronavirus epidemic, hope helped people adapt to various changes, such as health care, new working environments, social relationships, new law and regulations, and so on. Ahorsu et al.<sup>6,38</sup> This is called hope is includes positive opportunities for the future.<sup>39</sup>

A curvilinear relationship between worry and hope exists in most samples, with larger degrees of fear related to greater hope, up to a threshold point, on the far side that a plateau or decline is observed. The findings additionally recommend that greater proximity to trauma is associated with higher levels of both fear and hope.<sup>40</sup>

In the same way, people think and have hopeful expectations that coronavirus will be extinct from earth one day. However, based on the above discussion, hope plays an important role in sustaining good psychological health and takes a stand against psychological problems in the COVID-19 pandemic.

## 1.3 | Rationale of the study

The majority portions of our population are young generations. In the future, young generations will have to lead the development of our country. It would be impossible to develop our country without the contribution of young generations. Good mental health and hope are needed for life satisfaction and to live a pleasant life. Negative emotions cause various psychological and physical problems, on the other hand, positive emotions help solve various psychological

problems and increase happiness. The mental health and hope of the students are very concerned matter at present perspectives. Researchers found that there is a statistically significant relationship between fear of COVID and mental health and hope.<sup>41</sup> Thus, the results from this study will help to understand the relationship between fear, hope, and mental health, and at the same time, these research results help teachers, health officials, and decision-makers on how to maintain good mental health during the COVID-19 pandemic.

## 1.4 | Present study aimed

This study aimed to examine the mediating role of hope in the relationship between the fear of COVID-19 and mental health among tertiary level students. Researcher tested the mediation analyses by conducting a mediation analysis. In particular, the investigator hypothesize that (a) fear of COVID-19 would be negatively associated with hope and mental health, (b) hope is positively associated with mental health, and (c) hope mediates the relationship between fear of COVID-19 and mental health.

The hypothetical model of the research is presented in Figure 1.

## 2 | METHOD

### 2.1 | Research model

In this study, the correlational research design was used in which the relationships among the variables were examined through mediation analysis Table 1.

### 2.2 | Participants

The sample of this study consisted of 498 individuals, including 266 (53.4%) females and 232 (46.6%) males. Their ages ranged from 19 to 31 ( $M = 22.03$ ,  $SD = 1.92$ ). Additionally, 294 (59%) of the participants were found to live in a rural area and 204 (41%) in an urban area.

### 2.3 | Data collection tools

- *The Fear of COVID-19 Scale (FCV-19S)*: The fear of COVID-19 was measured by the Bengali version of the FCV-19S scale<sup>6</sup>; which was adapted by Sakib et al.<sup>42</sup> The FCV-19s is a five-point Likert-type unidimensional scale with seven items (ranging from 1: *Strongly disagree* to 5: *Strongly agree*) and its score range is 7–35. The total score of the scale is obtained by adding all items and the higher score of this scale is the higher levels of COVID-19 fear. Bangla adaptation of the scale confirmed acceptable psychometric properties.<sup>42</sup> Sakib et al.<sup>42</sup> reported that Bangla form of the FCV-19S has acceptable reliability (Cronbach's  $\alpha$ : 0.871, corrected item-

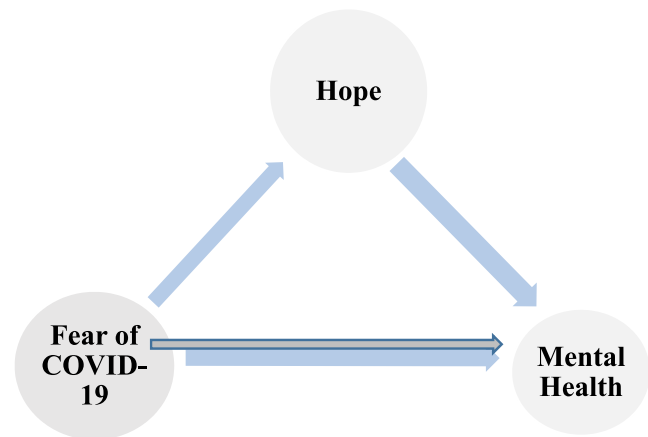


FIGURE 1 The hypothesized structural model

TABLE 1 Participant demographics ( $N = 498$ )

Variable	<i>n</i>	%
Gender		
Male	232	46.6
Female	266	53.4
Education level		
Hon's	413	82.9
Masters	77	15.5
MPhil	8	1.6
Family type		
Nuclear	388	77.9
Joint	110	22.1
Residence		
Rural	294	59.0
Urban	204	41.0
Socioeconomic class		
Lower class	71	14.3
Middle class	426	85.5
Upper class	1	0.2

total correlations: 0.72–0.80) and validity (confirmatory factor analysis [CFA]: comparative fit index [CFI] = 0.946, TLI = 0.947, RMSEA = 0.071, Root Mean Square Error of Approximation [WRMSR] = 0.889). The fit of the data for Rasch model was acceptable: log-likelihood  $\chi^2 = 116, 264,6277$ ,  $df = 116, 964$ ,  $p = 0.9261$ , and root mean square standard error = 0.7228.

- *Trait Hope Scale*: The Bengali version of the Trait Hope Scale was adapted by Joarder and Khan,<sup>43</sup> cited by Sorcar,<sup>44</sup> which was originally developed by Snyder et al.<sup>32</sup> The parallel form reliability coefficient was 0.91 ( $\alpha = 0.01$ ) and test–retest reliability was found 0.84 ( $\alpha = 0.01$ ). The scale has 12 items, which are divided into two

subscales. The scale consists of 12 items and a two-factor structure. The total Trait Hope Scale score range varies from 8 to 64. The higher Hope Scale scores indicating higher levels of hope. Each item is answered using an 8-point Likert type scale ranging from 1 = *definitely false* to 8 = *definitely true*. When administering the scale, it is called The Future Scale. Adding items 2, 9, 10, and 12 gives the total score in the Agency subscale and the subscale ranges from 4 to 32 and here the higher score indicates higher Agency. Adding items 1, 4, 6, and 8 gives the total score in the Pathway subscale and the subscale ranges from 4 to 32 and here the higher score indicates higher Pathway. And total hope scores range from 8 to 64 and here also higher score indicates that higher hope. The items of 3, 5, 7, and 11 are fillers and they are not considered at the time of scoring.

- **General Health Questionnaire (GHQ-12):** The Bengali version of GHQ-12, adapted by Sorcar and Rahman,<sup>45</sup> cited by Nahar et al.<sup>46</sup>; Roshni et al.<sup>47</sup> was used to measure the mental health of the participant. GHQ-12, originally developed by Goldberg.<sup>48</sup> While translating into Bengali, Sorcar and Rahman<sup>45</sup> adopted the scoring system and he scored 0, 1, 2, and 3 for the positive items and reverse score for negative items. It is a scale of 12 items where, 1 = *not at all*, 2 = *somewhat*, 3 = *to a considerable extent*, and 4 = *to a great extent*. The probable score on this scale is 0–36. High scores are an indicator of good mental health.

## 2.4 | Procedure

Self-report measures were used in data collection. Data are collected using online social media like Facebook between November 20 to December 10, 2020. Students from different educational intuitions were contacted by the Facebook group, Facebook pages, Facebook messenger groups, and were requested to participate in the research. The first page of Google Forms provided the participants with information about the goals and objectives of the study. They were further assured that the information they provided would be kept confidential and would only be used for research purposes. All students voluntarily took part in the research. It took approximately 20 min to fill the questionnaire.

## 2.5 | Data collection and analysis

In the data analysis, to determine whether the data have a normal distribution, the measurements of central tendency, minimum, maximum, kurtosis, and skewness values are taken into consideration. Table 2 indicates that the values of skewness and kurtosis are between +1 and -1 and do not violate the normal distribution. Pearson correlation has been used to look at the interrelationships among variables, especially fear of COVID-19, hope, and mental health. The PROCESS Macro Ver. 3.5 have been used for multiple mediation analysis (model 4.<sup>49</sup>); previous research has shown that some demographic variables have an effect on hope, for example,

**TABLE 2** Descriptive statistics

	Min	Max	M	SD	Skew	Kurt	N
Gender	1	2	-	-	-	-	498
SES	1	3	-	-	-	-	498
COVID-19 fear	7	35	22.65	5.562	-0.390	-0.053	498
Mental health	1	36	20.97	6.911	-0.325	-0.361	498
Hope (total)	22	64	50.87	8.137	-0.743	0.404	498

Note: Hope (total), sum scores of hope agency and hope pathways subscale.

Abbreviation: SES, socioeconomic status.

**TABLE 3** Correlations between study variables

	Gender	SES	COVID-19	Hope (total)	MH
Gender	1				
SES	0.244 <sup>a</sup>	1			
COVID-19	0.177 <sup>a</sup>	0.039	1		
Hope (total)	-0.026	0.041	0.096 <sup>b</sup>	1	
Mental health	-0.147 <sup>b</sup>	-0.014	-0.198 <sup>a</sup>	0.466 <sup>a</sup>	1

Note: Hope (total), sum scores of hope agency and hope pathways subscale.

Abbreviations: MH, mental health; SES, socioeconomic status.

<sup>a</sup>Correlation is significant at the 0.05 level (two tailed).

<sup>b</sup>Correlation is significant at the 0.01 level (two tailed).

gender<sup>50</sup> and socioeconomic status,<sup>39</sup> which are controlled in the model. Before conducting the analyses, 104 participants were excluded from the data set, which was not tertiary level students and further analyses were conducted with 498 observations after removing 9 cases for outliers. Mahalanobis distance values have been calculated to identify the outliers.

## 3 | RESULTS

### 3.1 | Descriptive statistics

The descriptive statistical data is presented in Table 2, where the values of skewness are between -0.325 and -0.743 and values of kurtosis between -0.361 and 0.404, which indicate normal distribution.

### 3.2 | Correlation analysis

Pearson's correlation values are presented in Table 3. Fear of COVID-19 was negatively correlated with mental health ( $r = -0.198$ ,  $p < 0.01$ ) but positively correlated with hope ( $r = 0.096$ ,  $p < 0.05$ ). On other hand, a positive and significant correlation between hope and mental health was ( $r = 0.446$ ,  $p < 0.01$ ).

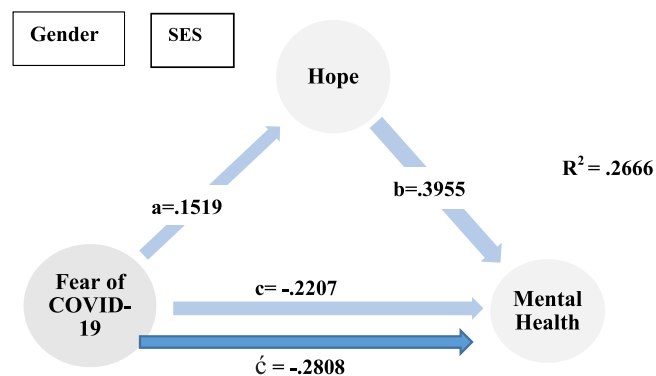
### 3.3 | Mediation analyses

The findings of the tested model of the mediation of hope in the association between fear of COVID-19 and mental health are presented in Table 3.

PROCESS macros are used for regression (mediation) analysis, which works through International Business Machines (IBM) SPSS version 26 (Statistical Package for Social Science) software. 5000 bootstrap method and 95% confidence intervals (CI) have been used for mediation analysis between fear of COVID-19 and mental health. In this model, fear uses as an independent variable, mental health as a dependent variable, and hope as a mediator, as well as controlling gender and socioeconomic status as a demographic variable. First, fear of COVID-19 was entered as an independent variable (X), mental health as an outcome variable (Y), and hope agency and pathway as mediator variables.

According to Hayes<sup>51</sup> "If there is no zero between the upper and lower limits, the researcher can claim, the indirect effect is not zero" (p. 412). In other words, when the CI for an indirect effect does not contain zero, a statistically significant mediation outcome is inferred. Hayes<sup>51</sup> also argues that bootstrapping, a resampling technique that creates a sampling distribution of indirect effects, is the most powerful and valid test of mediation. Here Bootstrapping investigations were examined by using Mediation Model 4 through PROCESS Macro 3.5 and IBM SPSS 26.0.<sup>49</sup>

As illustrated in Figure 2 and Table 4, the total effect of fear of COVID-19 on mental health is statistically significant ( $B = -0.2207$ ,



**FIGURE 2** The mediating role of hope in the relationship between fear of COVID-19 and mental health

**TABLE 4** Mediation analysis

	Model pathway	Coefficient	SE	t	p Value	LL 95% CI	UL 95% CI
a path	Fear of COVID-19 to hope	0.1519	0.0664	2.39*	0.0226	0.0214	0.2824
b path	Hope to mental health	0.3955	0.0330	11.99***	0.0000	0.3307	0.4603
c path	Fear of COVID-19 to mental health	-0.2207	0.0553	-3.99***	0.0001	-0.3293	-0.1121
c-hat path	Fear of COVID-19 to mental health	-0.2808	0.0489	-5.74***	0.0000	-0.3770	-0.1846

Abbreviations: CI, confidence interval; LL, lower limit; UL, upper limit.

\* $p < 0.05$ ; \*\*\* $p < 0.001$ .

$SE = 0.0553$ ,  $t(3494) = -3.9924$ ,  $p < 0.001$ ) (step 1 and c path). The direct effect of fear of COVID-19 on hope is statistically significant ( $B = 0.1519$ ,  $SE = 0.0664$ ,  $t(3494) = 2.39$ ,  $p < 0.05$ ) (step 2 and a path) and the direct effect of hope on mental health ( $B = 0.3955$ ,  $SE = 0.0330$ ,  $t(3494) = 11.99$ ,  $p < 0.001$ ) (step 3 and b path). When fear of COVID-19 (predictor) and hope (mediator) were entered into the model (step 4 and c-hat path), the significant relationship between fear of COVID-19 and mental health decreased but significant ( $c-hat = -0.2808$ ,  $SE = 0.0489$ ,  $t(4493) = -5.7369$ ,  $p < 0.001$ ). These outcomes accept the mediational hypothesis. The model is significant  $F(4, 493) = 35.98$ ,  $p < 0.001$  and explained approximately 27% ( $R^2 = 0.2666$ ) of the variance in mental health.

### 3.4 | Indirect effect of fear of COVID-19 on mental health through hope

The comparison of direct and specific indirect effects of fear of COVID-19 on mental health through Hope. The results are presented in Table 5.

The indirect effect was verified by 5000 bootstrap samples. The results are presented in Table 5. The results point out that the indirect effect (the variance between the total effects and direct effects/ $c-c-hat$ ) of fear of COVID-19 through hope on mental health is statistically significant (point estimate = 0.0601% and 95% BCa CI (0.0094, 0.1104).

## 4 | DISCUSSION

Fear is an issue in life that has negative consequences, affecting positive and negative emotions, especially mental health. Hope performs as a preventative factor in psychological problems and increases happiness.<sup>52,53</sup> In this sequence, hope will prevent the fear of the damage that arises by the COVID-19 as a protector. Thus, based on this mechanism, the mediating role of hope has been explored in this study. The present research reports three main outcomes: (a) fear of COVID-19 is negatively connected with mental health but positively associated with hope; (b) hope is positively associated with mental health; and (c) hope mediates the relationship between fear of COVID-19 and mental health.

Regarding the first hypothesis of the study, the hypothesis was partially supported. In the case of the relationship between fear of COVID-19 and mental health, such results are compatible with the

**TABLE 5** The comparison of direct and indirect effect of fear of COVID-19 on mental health through hope

	Product of coefficients		t	p Value	Bootstrapping 95% BCa confidence interval	
	Point estimate	SE			Lower	Upper
Total effect	-0.2207	0.0553	-3.99	0.0001***	-0.3293	-0.1121
Direct effect	-0.2808	0.0489	-5.74	0.0000***	-0.3770	-0.1846
Indirect effect	0.0601	0.0254	-	-	0.0094	0.1104

Note: N = 498, k = 5. Control variables: gender, socioeconomic status, BCa: bias corrected and accelerated 5000 bootstrapping samples.

\*\*\*p < 0.001.

after-mentioned study. Some studies described that fear regarding COVID-19 raises the risk to enhance mental health problems together with depression.<sup>54-56</sup> During the coronavirus epidemic, symptoms related to fear, anxiety, and depression were developed.<sup>6,57,58</sup> Thus, the results in the current study are fitting with the findings of the previous study. But, fear of COVID-19 is lower but positively associated ( $r = 0.096$ ,  $p < 0.05$ ) with hope, which is not consistent with the findings of the previous study. Although the majority of studies reported a negative association between fear of COVID-19 and hope,<sup>10</sup> the present study found that hope is correlated lower but positively with fear of COVID-19. Concerning the second hypothesis of the study, in the case of the relationship between mental health and hope, authors found negative relationship. Regarding the third hypothesis of the study, the results of the study showed that hope mediated the relationship between fear of COVID-19 and mental health (Tables 4 and 5). In the case of the second and third hypotheses, to the best of our knowledge, this was the first study attempting to investigate the role of hope as a mediator in the relationship between fear of COVID-19 and mental health. Contrary to our hypothesis, hope was connected with the fear of COVID-19 positively and found to mediate this relation. In our study, fear of COVID-19 was shown to be a significant predictor of mental health, and lower levels of fear of COVID-19 were connected with a higher level of mental health. According to Karataş and Tagay<sup>59</sup> the higher the level of hope, the higher the level of resilience. The person who has high hopes finds meaning in life; can cope well under complex life situations and is more resilient. Therefore, based on the findings, Hope will help increase mental health by reducing the fear of COVID-19. Although there are immense fear and challenge to the COVID-19 virus, there are still signs of hope and support. There are hints that the COVID-19 vaccine has been discovered in various sources. Although the prevalence of corona is increasing day by day worldwide, there is still growing hope among people in the expectation of getting vaccinated. The spirit of global affection for each other around the world, living together, and standing together, gives us hope. From the point of view of positive psychology, hope is such a psychological strength; which fights against mental illness, increases mental strength, and protects psychological health. Even in positive psychology intervention programs hope is used to decline fear and enhance happiness.

In conclusion, the present study has studied the mediating role of hope in the relation between fear of COVID-19 and mental health.

The results verified that there is an association between fear of COVID-19 and mental health. In this study, high corona fear was related to lower mental health. It is further found here that hope mediates between fear of COVID-19 and mental health.

#### 4.1 | Limitations

There are some limitations to current research. First, the data is collected using an online platform through Google Forms. Second, information providers have provided information voluntarily. Third, it is a self-fulfilling prophecy, so it is not impossible to be biased in answering.

The investigator recommend that research be conducted using other methods and designs in the future. While only two variables have been controlled in this study, other variables may be controlled in the future. The present study is conducted in light of Bangladeshi culture, so it can be conducted in light of other cultures.

#### 4.2 | Future research

This study highlights the necessity for mental state assessment and correct management of those problems throughout the COVID-19 pandemic and future analysis among health care professionals to explore their actual mental health standing during this pandemic situation.

#### AUTHOR CONTRIBUTIONS

**Pramath C. Sarker:** Conceptualization; data curation; formal analysis; investigation; methodology; resources; software; supervision; validation; visualization; writing – original draft; writing – review and editing. **Daichi Sugawara:** Conceptualization; formal analysis; investigation; methodology; resources; software; supervision; validation; visualization; writing – review and editing. **Md. Fazle Rabbi Nishad:** Conceptualization; formal analysis; investigation; methodology; resources; software; validation; visualization; writing – review and editing.

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## CONFLICT OF INTEREST

The authors declare no conflict of interest.

## DATA AVAILABILITY STATEMENT

The data analyzed for this paper are available from the author upon reasonable request meeting institutional guidelines.

## ETHICS STATEMENT

Informed consent was obtained from the participants for this study. The researchers strongly declare that all procedures were accomplished in studies concerning human participants in accordance with national and Institutional ethical standards and with the Helsinki declaration. The Researchers are fully committed to research ethics.

## TRANSPARENCY STATEMENT

The lead author Md. Fazle Rabbi Nishad affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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