

COVID-19 Impacts Mental Health Outcomes and Ability/Desire to Participate in Research Among Current Research Participants

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Objective: This study aimed to examine the impact of coronavirus disease 2019 (COVID-19) on current research participants' mental health outcomes, ability to adhere to behavioral intervention recommendations, and desire to participate in research.

Methods: A quantitative/qualitative cross-sectional survey was used among adults currently enrolled in health-related research ($N=250$; 85% women; >50% currently enrolled in behavioral weight loss intervention).

Results: COVID-19 was perceived as a severe threat by most (62.3%). Related to COVID-19, 29.6% of participants reported moderate/severe symptoms of anxiety/depression, and 68.4% reported moderate/severe posttraumatic stress disorder (PTSD) symptomatology, with women more likely to demonstrate moderate/severe anxiety/depression ($P=0.047$) and PTSD symptomatology ($P=0.028$) relative to men. Those with moderate/severe levels of anxiety/depression ($P=0.0154$) and distress ($P=0.0330$) were more likely to report a decreased desire to participate in research. Among those in behavioral interventions, individuals perceiving COVID-19 as a moderate/severe threat or experiencing moderate/severe depression or PTSD symptomatology were 4 to 19 times more likely to report that COVID-19 affected their ability to adhere to behavioral recommendations. Qualitative analysis identified four themes describing COVID-19's impact on research experiences: transition, remote intervention delivery, ability to adhere to program goals, and research participation interest.

Conclusions: These data suggest that participants engaged in health-related research perceive COVID-19 as a significant threat, affecting mental health, desire to participate in research, and ability to adhere to intervention recommendations.

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Introduction

Coronavirus disease 2019 (COVID-19) (1) is a rapidly evolving infectious disease. Since its identification in November 2019, COVID-19 has resulted in >4.7 million infections and more than 317,000 deaths worldwide. As of May 18, 2020, there have been >90,000 confirmed deaths in the United States alone. Because of rapid spread, schools and nonessential

Study Importance

What is already known?

- ▶ Global or local emergencies can all lead to psychological and physical health changes because of the perceived threat and insecurity they pose.
- ▶ COVID-19 has affected research activities, particularly those involving in-person interactions, as academic institutions have shut down most research activities for patient safety. We do not know how COVID-19 has affected participants of research studies.

What does this study add?

- ▶ We found that current research participants' perceptions of COVID-19 indicate a significant threat that has significantly affected their mental health and desire to participate in research.
- ▶ Among those enrolled in behavioral intervention trials, individuals perceiving COVID-19 to be a moderate/severe threat or those experiencing moderate/severe anxiety/depression or PTSD symptomatology are 4 to 19 times more likely to report that COVID-19 had impacted their ability to adhere to behavioral recommendations in their intervention.

How might these results change the direction of research?

- ▶ Participant data and study findings during the COVID-19 pandemic, particularly from behavioral interventions, should be interpreted with caution.

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businesses have closed, international travel has halted, and millions of individuals around the world are on “stay-at-home” orders.

COVID-19 has also affected research activities, particularly those involving in-person interactions, as academic institutions have shut down research activities for patient safety. Given that behavioral research often occurs within clinical care and regular in-person interactions, a particular challenge facing the research sector is the necessity to either stop health-related research or identify a way to move to remote delivery while COVID-19 remains a threat. Importantly, these necessitated changes may negatively impact participant desire and ability to engage in research and to adhere to research-related recommendations, particularly among those enrolled in behavioral interventions.

Research participation may also be influenced by adverse mental and behavioral health outcomes that accompany a global health emergency such as COVID-19. Global or local emergencies, including economic recession (2), terrorism (3), natural disasters (4), and pandemics (5,6), can all lead to psychological and physical health changes because of the perceived threat and insecurity they pose, including anxiety/depression (5,7) and posttraumatic stress disorder (PTSD) symptoms (6,8). Thus, experiencing COVID-19-related stress, anxiety, and trauma has the potential to impact research participants’ mental health outcomes and ability or desire to continue participation in health-related research studies.

The purpose of this study was to examine the extent to which the COVID-19 pandemic has affected the lives of current research participants in terms of mental health outcomes, ability to adhere to behavioral intervention recommendations, and desire to participate in future research. We hypothesized that COVID-19 has negatively impacted the mental health of research participants and their ability and desire to engage and participate in research studies.

Methods

Participants

We recruited individuals currently enrolled in behavioral interventions or health-related research studies via ResearchMatch (<https://www.researchmatch.org/>). Additionally, word-of-mouth techniques were used, for which study team members notified colleagues currently conducting behavioral interventions or health-related research studies and requested study information be shared with research participants if allowed by their respective Institutional Review Boards. Any individuals actively enrolled in a health-related research study were eligible to participate. Ethical approval for the study protocol was obtained through the University of Florida Institutional Review Board, and consent was provided by all participants.

Survey instrument

This survey included modifications and additions to a previous survey utilized to characterize Ebola experiences and effects on mental health in Sierra Leone in 2015 (5). Survey questions included sociodemographic characteristics; perceived threat of COVID-19; current status of research enrollment; and the COVID-19 impact on participation, investigation of anxiety/depression and PTSD symptomatology, and experiences during the COVID-19 pandemic (online Supporting Information Appendix S1). The survey was open from April 1 to April 12, 2020, providing survey data during weeks 14 and 15 of 2020.

Demographics

Sociodemographic characteristics included age, gender, race/ethnicity, height, weight, insurance type, and socioeconomic status (via highest education level and total household income). Participants were also asked to report any current underlying conditions suspected to increase severity of COVID-19 (1).

Perceived COVID-19 threat

Perceived COVID-19 threat was assessed using four potential levels of risk: personal, city, community, and household. Each item was measured using a four-point Likert scale (0=strongly agree to 4=strongly disagree), with a possible score of 0-12. Total perceived threat scores were categorized (mild=0-5, moderate=6-8, and severe=9-12) (5).

Anxiety/depression

Anxiety/depression was assessed using the Patient Health Questionnaire-4, a reliable measure of anxiety/depressive symptoms reported in the past 2 weeks (9). The Patient Health Questionnaire-4 uses a four-point Likert scale (0=not at all to 3=nearly every day), with a possible score of 0-12. Higher scores indicate higher levels of anxiety/depression. Total anxiety/depression scores were categorized (normal/mild=0-5, moderate=6-8, and severe=9-12) (10).

PTSD

PTSD symptoms were assessed using the validated Impact of Event Scale-6 (IES-6) (11). The Impact of Event Scale-6 uses six items to measure self-reported PTSD symptoms that have occurred in the past week. Each item is reported using a five-point Likert scale (0=not at all to 4=extremely), with a total score of 0-24. PTSD scores were also categorized (normal/mild=0-7, moderate=8-11, and severe distress=12-24) (12).

Research participation

Research participation questions included type of research (behavioral intervention or other health-related), delivery modality (if applicable, e.g., group-based, individual-based, self-guided intervention), and current intervention stage (if applicable, i.e., early, middle, late). Participant responses for perceived impact on current and future research participation were measured using a five-point Likert Scale (1=not at all to 5=extremely). Questions to assess perceived impact on research participation included dichotomous assessment of the COVID-19 pandemic on desire to participate in research, transition to telehealth, and the COVID-19 impact on adherence to behavioral recommendations provided in behavioral interventions.

Qualitative assessment

One question qualitatively assessed how COVID-19 has influenced participants’ research experience and gave the opportunity to provide a free-form response.

Quantitative statistical analysis

χ^2 and Fisher exact tests were used to compare frequency distributions of baseline characteristics by research type (behavioral intervention vs. other health-related research). Total scores of perceived threat, anxiety/depression, and distress were not normally distributed and were

evaluated using nonparametric Mann-Whitney *U* and Kruskal-Wallis tests. The impact of COVID-19 on desire and ability to participate in research was examined by selected subgroups: age, gender, race/ethnicity, presence of any underlying condition, telehealth transition, intervention delivery type, and intervention stage. Multivariable logistic regressions were used to examine associations between adverse mental health symptoms and components of research participation with desire to participate in research and ability to adhere to behavioral recommendations (dichotomized as had impact or not). Models were adjusted for age, gender, race/ethnicity, household income, and education. Model fit was assessed with the Hosmer-Lemeshow test. Data management and univariate analyses were conducted using SPSS software version 26 (IBM Corp., Armonk, New York). We used SAS software version 9.4 (SAS Institute, Cary, North Carolina) to perform bivariate and multivariable analyses. Two-tailed $P < 0.05$ was considered statistically significant.

Qualitative analysis

A grounded theory approach was used to analyze qualitative data (13). Two members of the research team read participant responses to the open-ended question to develop and collapse codes into categories and themes, using constant comparative analysis methods. These two coders discussed discrepancies in coding to reach consensus. Thematic saturation was reached, and initial codes were collapsed into 13 categories representing 4 themes: transition, impact of remote intervention delivery, pandemic impact on ability to adhere to program goals, and interest in research participation.

Quantitative Results

Sample characteristics

Participants ($N = 250$) were individuals currently engaged in health-related research (median age = 45; 85% women; 74.3% non-Hispanic White). Table 1 includes overall demographics stratified by research type. The majority of participants ($n = 147$; 58.8%) were engaged in a behavioral intervention, whereas the rest ($n = 103$) were engaged in other health-related research. Behavioral health interventions spanned weight loss, mental health, eating disorders, smoking cessation, sleep, physical activity, and others. Sociodemographic characteristics were similar between those participating in behavioral health interventions and those participating in other health-related research. However, most participants in a behavioral health intervention (76%) reported transitioning to remote format, whereas only 19.2% of those participating in other health-related research transitioned to remote format ($P < 0.001$).

Perceived threat, anxiety/depression, and distress of COVID-19

Table 2 shows distributions and total scores of perceived threat of COVID-19 and symptom severity of anxiety/depression and distress related to COVID-19. Overall, a considerable proportion of participants (62.3%) perceived COVID-19 as a severe threat. More than 29% of participants reported moderate/severe symptoms of anxiety/depression related to COVID-19, and 36.8% reported severe symptoms of PTSD-related distress. Young adults (ages 18-34) and elderly (ages ≥ 65) participants reported more severe distress than participants aged 45-64 ($P = 0.04$). Compared with men, women reported more severe levels of anxiety/depression ($P = 0.048$) and distress

($P = 0.03$). Participants who did not report any underlying conditions were more likely to report moderate symptoms of anxiety/depression relative to those who had an underlying condition ($P = 0.03$). No significant differences in adverse mental health symptoms by race/ethnicity, household income, education, and health insurance were observed.

COVID-19 impact

Table 3 presents distributions of perceived risk of COVID-19 and desire to participate in research. The majority of participants reported they were a little/moderately hesitant to attend in-person study visits (41.7%) or quite a bit/extremely hesitant (25.2%). However, the majority of participants did not report research participation as an additional risk (57.2%) or that COVID-19 negatively affected desire to participate in research (62.2%). Among behavioral health intervention participants, >68% reported that their ability to adhere to behavioral recommendations was affected by COVID-19. Behavioral health intervention participants that transitioned to telehealth delivery reported greater hesitancy to attend in-person study sessions than participants in similar studies that had not transitioned; however, they were less likely to report that participating in research would put them more at risk for COVID-19. We did not observe significant differences across individual characteristics (age, gender, race/ethnicity, underlying condition) in items of COVID-19 negatively affecting desire to participate in research (Supporting Information Table S1).

Associations of intervention components and mental health factors with COVID-19

Those with moderate (as compared with mild) anxiety/depression were significantly more likely to report a decreased desire to participate in research (Table 4). Compared with participants in individual or group-based interventions, participants in self-guided programs were significantly more likely to report that COVID-19 had affected their ability to adhere to behavioral intervention recommendations. Individuals who reported perceiving COVID-19 to be a moderate/severe threat were nearly 7 to 10 times more likely, respectively, to report that COVID-19 had significantly impacted their ability to adhere to behavioral recommendations (moderate odds ratio [OR]: 6.83, severe OR: 9.62). Individuals who reported moderate/severe depression were 7 to 12 times more likely to report that COVID-19 had significantly impacted their ability to adhere to behavioral recommendations (moderate OR: 12.63, severe OR: 7.01). Individuals who reported moderate/severe distress were 4 to 19 times more likely, respectively, to report that COVID-19 had significantly impacted their ability to adhere to behavioral recommendations (moderate OR: 4.02, severe OR: 19.33).

Qualitative Results

Four themes were identified in the qualitative response assessing how COVID-19 influenced participant research experiences: transition, impact of remote intervention delivery, pandemic impact on ability to adhere to program goals, and interest in research participation.

Transition

While some individuals noted that studies were postponed or stopped, the majority of participants noted that active interventions transitioned

TABLE 1 Sample characteristics overall and by research type

	N (%) ^a			P ^b
	Research type			
	Total	Behavioral intervention	Other health-related research	
Sample no.	250	147 (58.8)	103 (41.2)	
Median age (IQR)	45 (35-55)	46 (36-56)	44 (34-53)	0.4055
Age group, y				
18-34	62 (24.8)	39 (23.1)	23 (28.4)	0.5968
35-44	61 (24.4)	40 (23.7)	21 (25.9)	
45-54	56 (22.4)	38 (22.5)	18 (22.2)	
55-64	48 (19.2)	37 (21.9)	11 (13.6)	
≥ 65	23 (9.2)	15 (8.9)	8 (9.9)	
Gender				
Women	210 (85.0)	140 (83.3)	70 (88.6)	0.2787
Men	37 (15.0)	28 (16.7)	9 (11.4)	
Race/ethnicity				
Non-Hispanic White	179 (74.3)	116 (71.6)	63 (79.7)	0.7102
Non-Hispanic Black	27 (11.2)	21 (13)	6 (7.6)	
Hispanic/LatinX	14 (5.8)	10 (6.2)	4 (5.1)	
Other races	21 (8.8)	15 (9.2)	6 (7.6)	
Education				
High school or less	13 (5.2)	8 (4.7)	5 (6.2)	0.2548
Some college	52 (20.8)	36 (21.3)	16 (19.8)	
College graduate	64 (25.6)	50 (29.6)	14 (17.3)	
Some graduate or professional	30 (12.0)	18 (10.7)	12 (14.8)	
Graduate or professional degree	91 (36.4)	57 (33.7)	34 (42)	
Household income				
< \$25,000	35 (14.2)	24 (14.5)	11 (13.6)	0.6029
\$25,000-\$49,999	35 (14.2)	22 (13.3)	13 (16)	
\$50,000-\$74,999	37 (15.0)	29 (17.5)	8 (9.9)	
\$75,000-\$99,999	46 (18.6)	30 (18.1)	16 (19.8)	
\$100,000+	94 (38.0)	61 (36.7)	33 (40.7)	
Insurance type				
Private	179 (74.0)	122 (73.9)	57 (74)	0.8652
Federally funded	24 (9.9)	15 (9.1)	9 (11.7)	
State funded	30 (12.4)	22 (13.3)	8 (10.4)	
No insurance	9 (3.7)	6 (3.6)	3 (3.9)	
Number of comorbid conditions known to increase risk for severe COVID-19 infection				
0	186 (74.7)	122 (72.2)	64 (79)	0.4224
1	49 (19.4)	35 (20.7)	14 (17.3)	
2+	15 (5.9)	12 (7.1)	3 (3.7)	
Health-related research study transitioned to telecommunication after COVID-19 outbreak				
No	99 (41.3)	40 (24)	59 (80.8)	<0.0001
Yes	141 (58.8)	127 (76)	14 (19.2)	
Type of intervention delivery for those enrolled in behavioral intervention ^c				
Group based		107 (67.3)		
Individual based (met one on one)		32 (20.1)		
Self-guided intervention		20 (12.6)		
Stage of intervention ^c				
Early		48 (29.3)		
Middle		64 (39.0)		
Late		52 (31.7)		

^aSample size not equal to total sample size because of missing data.

^b"Don't know"/"Prefer not to disclose"/missing responses are not presented and are excluded from analysis.

^cIncludes only those who participated in behavioral health research.

COVID-19, coronavirus disease 2019; IQR, interquartile range.

TABLE 3 COVID-19 impact on perceived risk and desire to participate in research by research type, transition to telehealth, type of intervention delivery, and stage of intervention

	N (%) ^a														
	Research type			Transition to telehealth			Type of intervention delivery ^b			Stage of intervention ^b					
	Total sample	Behavioral	Other	P	No	Yes	P	Group	Individual	Self-guided	P	Early	Mid	Late	P
Since COVID-19, hesitant to come in for a study visit or session				0.2144			0.0023				0.1066				0.3082
Not at all	50 (33.1)	39 (31.2)	11 (42.31)		21 (52.5)	29 (26.36)		23 (28.05)	7 (28)	8 (66.67)		13 (32.5)	15 (30.61)	10 (31.25)	
A little/moderately	63 (41.7)	56 (44.8)	7 (26.92)		8 (20)	54 (49.09)		37 (45.12)	12 (48)	3 (25)		14 (35)	22 (44.9)	18 (56.25)	
Quite a bit/extremely	38 (25.2)	30 (24)	8 (30.77)		11 (27.5)	27 (24.55)		22 (26.83)	6 (24)	1 (8.33)		13 (32.5)	12 (24.49)	4 (12.5)	
Participating in research increases risk for COVID-19				0.0635			0.0008				0.3575				0.7889
Not at all	139 (57.2)	105 (62.13)	34 (45.95)		42 (43.3)	94 (67.14)		71 (66.36)	15 (46.88)	13 (65.0)		33 (68.75)	40 (62.5)	31 (58.49)	
A little/moderately	81 (33.3)	50 (29.59)	31 (41.89)		45 (46.39)	34 (24.29)		29 (27.1)	13 (40.63)	6 (30.0)		11 (22.92)	20 (31.25)	17 (32.08)	
Quite a bit/extremely	23 (9.5)	14 (8.28)	9 (12.16)		10 (10.31)	12 (8.57)		7 (6.54)	4 (12.5)	1 (5.0)		4 (8.33)	4 (6.25)	5 (9.43)	
COVID-19 negatively affected desire to participate in research				0.6775			0.7408				0.2609				0.746
Not at all	150 (62.2)	102 (61.08)	48 (64.86)		61 (62.89)	86 (61.87)		66 (62.86)	15 (46.88)	14 (70.0)		25 (53.19)	41 (64.06)	32 (62.75)	
A little/moderately	69 (28.6)	48 (28.74)	21 (28.38)		29 (29.9)	39 (28.06)		28 (26.67)	13 (40.63)	6 (30.0)		16 (34.04)	16 ⁿ	15 (29.41)	
Quite a bit/extremely	22 (9.1)	17 (10.18)	5 (6.76)		7 (7.22)	14 (10.07)		11 (10.48)	4 (12.5)	0 (0.0)		6 (12.77)	7 (10.94)	4 (7.84)	
COVID-19 impacted ability to adhere to behavioral recommendations ^b											0.1433				0.9721
Not at all	44 (31.6)	-	-		-	-		24 (26.4)	8 (34.8)	5 (71.4)		10 (25.6)	17 (30.9)	9 (32.1)	
A little/moderately	66 (49.6)	-	-		-	-		47 (51.7)	11 (47.8)	2 (28.6)		21 (53.9)	27 (49.1)	13 (46.4)	
Quite a bit/extremely	25 (18.8)	-	-		-	-		20 (22.0)	4 (17.4)	0 (0.0)		8 (20.5)	11 (20.0)	6 (21.4)	

Bold indicates significant values.

^aSample size not equal to total sample size because of missing data.

^bIncludes only those who participated in behavioral health research that did not transition to telehealth.

COVID-19, coronavirus disease 2019.

TABLE 4 Associations of intervention delivery, stage, and mental health factors with negatively impacted desire to participate in research and ability to adhere to behavioral recommendations due to COVID-19

	Outcome: negatively impacted desire to participate in research			Outcome: impact on ability to adhere to behavioral recommendations		
	OR (95% CI)	P	Adjusted OR (95% CI) ^a	OR (95% CI)	P	Adjusted OR (95% CI) ^a
Transition to telehealth						
No	1.00 [Referent]		1.00 [Referent]			
Yes	1.21 (0.56-2.53)	0.6203	1.10 (0.46-2.66)			
Type of delivery						
Group	1.00 [Referent]		1.00 [Referent]			
Individual based	1.98 (0.89-4.39)	0.0944	1.87 (0.70-5.04)	1.00 [Referent]		1.00 [Referent]
Self-guided	0.75 (0.27-2.12)	0.581	0.88 (0.26-2.99)	0.67 (0.25-1.78)	0.4244	0.42 (0.12-1.52)
Stage of intervention				0.14 (0.03-0.79)	0.0255	0.11 (0.02-0.85)
Early	1.00 [Referent]		1.00 [Referent]	1.00 [Referent]		1.00 [Referent]
Middle	0.66 (0.31-1.42)	0.2914	0.74 (0.31-1.78)	0.77 (0.31-1.93)	0.5786	1.01 (0.35-2.92)
Late	0.68 (0.31-1.52)	0.3459	0.72 (0.28-1.85)	0.73 (0.25-2.12)	0.561	0.73 (0.20-2.64)
Perceived threat						
Normal/mild	1.00 [Referent]		1.00 [Referent]	1.00 [Referent]		1.00 [Referent]
Moderate	1.10 (0.30-4.08)	0.8835	1.49 (0.31-7.19)	2.30 (0.58-9.11)	0.2358	6.83 (1.20-39.06)
Severe	1.92 (0.57-6.50)	0.2966	2.64 (0.59-11.76)	3.60 (0.99-13.08)	0.0517	9.62 (1.88-49.23)
Depression/anxiety						
Normal/mild	1.00 [Referent]		1.00 [Referent]	1.00 [Referent]		1.00 [Referent]
Moderate	2.46 (1.13-5.36)	0.0231	3.02 (1.23-7.39)	9.50 (2.12-42.48)	0.0032	12.63 (2.38-66.90)
Severe	3.13 (1.10-8.86)	0.0319	2.67 (0.77-9.29)	4.75 (1.01-22.29)	0.0483	7.01 (1.09-45.11)
PTSD						
Normal/mild distress	1.00 [Referent]		1.00 [Referent]	1.00 [Referent]		1.00 [Referent]
Moderate distress	1.62 (0.70-3.73)	0.2605	1.66 (0.62-4.41)	2.85 (1.11-7.29)	0.0294	4.02 (1.21-13.37)
Severe distress	2.46 (1.10-5.47)	0.0281	2.92 (1.09-7.82)	9.21 (3.06-27.77)	<0.0001	19.33 (4.41-84.62)

Bold indicates significant values.

^aAdjusted for age, sex, race/ethnicity, family income, and education. COVID-19, coronavirus disease 2019; OR, odds ratio; PTSD, posttraumatic stress disorder.

to remote format. As expected, some participants reported technological difficulties; however, most reported this transition as having minimal impact on participation.

"I have always been interested and active in research; COVID-19 has not majorly increased or decreased my interest in research nor my research experience. I would still be willing to participate in future research experiences. I was impressed that research coordinators were able to quickly adapt to a telecommunication format while still adhering to privacy whereas other businesses or organizations struggled."

"I feel like I am not getting to practice my new skills in social settings and real life. I am afraid that the program will be over, and I won't have had a chance to work through some things with guidance."

"I like online meetups. It's only interfering because others require so much assistance with technology."

Impact of remote intervention delivery

Despite minimal impacts on participation in remote interventions, many participants commented that they missed support and connection previously experienced during in-person visits.

"Just that we moved from physical interaction to just social interaction via Zoom meetings. Makes it a little tougher as human connection in the physical is just as important as the social."

"I dislike participating virtually. The technical aspects are stressful, and the Zoom group meetings are extremely boring. In person I enjoyed meeting people and hearing what they had to say. On a computer screen it is just tedious."

A smaller proportion of participants noted a preference for remote intervention delivery.

"The move to teleconference has actually been better in that the group has bonded through (another) shared experience. We hope to continue when the study changes to one-on-one."

"In fact, I actually prefer doing [the program] remotely. In the future, you guys should try to do as much as you can remotely. It is a big hassle to come over to [location], and I would have more stress if I had to do all my appointments on campus. I hope to continue...doing mainly remote therapy after the outbreak."

Pandemic impact on ability to adhere to program goals

While participation in interventions may have been only minimally impacted, participants noted substantial pandemic effects on ability to adhere to program goals. Participants noted challenges with physical activity because of restrictions and modifications in eating patterns because of staying home. Many participants also mentioned feeling stressed, anxious, fearful, or depressed.

"I have to homeschool 3 children, and I literally forget what I have to do for myself and then sometimes feel that weight loss is really unimportant with how the world is going."

"There are so many restrictions on activities available that I cannot fully engage in my program."

*"My family and I have been super emotional about one of my family members being in critical shape. It's just hard to concentrate on anything else."
"Changing to working from home part of the time makes it more difficult to not snack and emotionally eat when stressed."*

Other participants noted both positive and negative pandemic impact on adherence to program goals ("less distractions but more temptations"), and some even noted beneficial impacts.

"My participation in the research has improved my overall physical health, so I think if I do contract COVID-19, I am in better physical health to fight it than I would have been before the study. I am motivated to continue to gain the health benefits from participating in the program by a desire to increase my ability to potentially fight off the virus. I am concerned that I will receive lessened health care due to my overweight status, should I contract the virus, and be viewed as a patient less worth saving. Because I am in a study that results in weight loss, it is critical that I continue my participation in the hopes of mitigating possible doctor bias in a triage setting or in a one-on-one decision-making setting."

Interest in research participation

While individuals are hesitant to attend in-person visits, some participants expressed increased dedication to research and awareness of more studies to participate in remotely.

"I made sure the research I was participating [in] did not need me to go out of the house, but I wanted to help in research or any study needed for COVID or any other cause as I wanted to contribute in any way I can."

Discussion

This is the first study to examine the effect of COVID-19 on individuals participating in health-related research, including those engaged in behavioral interventions. We examined the influence of COVID-19 on research participants' general mental health, desire to participate in research, and perceived ability to adhere to behavioral intervention recommendations. Results demonstrated that, among individuals currently engaged in health-related research, a majority perceived COVID-19 as a severe threat and reported hesitancy to attend in-person study sessions. Over one in four participants demonstrated moderate/severe symptoms of anxiety/depression related to COVID-19, and one in three reported severe distress in response to COVID-19, with women being more likely to demonstrate anxiety, depression, or PTSD symptomatology related to COVID-19, differing from a previous study in which no sex differences were noted for PTSD and anxiety/depression symptoms following Ebola (5). Participants with moderate/severe levels of anxiety/depression and distress were more likely to report a decreased desire to participate in research. Among those enrolled in behavioral interventions, individuals perceiving COVID-19 to be a moderate/severe threat or those experiencing moderate/severe depression or PTSD symptomatology were 4 to 19 times more likely to report that COVID-19 had impacted their ability to adhere to behavioral recommendations provided in their intervention. These findings suggest that COVID-19 has significantly affected mental health, desire to participate in research, and ability to adhere to recommendations in a behavioral intervention.

Approximately two-thirds of participants perceived the threat posed by COVID-19 as severe, and interestingly, distress related to

COVID-19 was particularly high among young people (aged 18-34) and elderly individuals (aged ≥ 65) relative to those aged 45-64. We posit that distress was elevated in these two age groups for distinct reasons. Distress among older adults may be elevated because of increased risk of serious illness and death from COVID-19 among this age group. Conversely, given the lower risk of severe illness among younger individuals (1), distress among young people may be more related to impacts of COVID-19 stay-at-home orders on everyday life (e.g., loss of income, no childcare). Women reported higher levels of anxiety/depression and distress compared with males, potentially reflecting a disproportionate burden of household responsibility on women (14,15) that has been exacerbated (e.g., homeschooling while continuing to work, domestic care) during stay-at-home orders. Additional research is needed to identify causes of distress and explore gender- and age-related differences.

The majority of participants did not report that their desire to participate in research was affected by COVID-19, perhaps because most research studies at the time of survey had transitioned to remote format. However, those with moderate (compared with mild) anxiety/depression or severe distress were significantly more likely to report a decreased desire to participate in research. Thus, it is possible that individuals with adverse mental health symptomatology because of COVID-19 may be more likely to eventually drop from research participation. For behavioral intervention participants, withdrawal from research participation has the potential to further negatively affect mental health because of loss of support from the interventionist and/or group members. As such, researchers should consider frequently monitoring mental health symptoms and extend extra retention efforts to individuals with elevated anxiety/depression.

The majority of the study sample was engaged in behavioral intervention research, and factors related to perceived ability to adhere to behavioral recommendations during COVID-19 were assessed. Compared with those receiving an individual- or group-based intervention, those participating in a self-guided intervention were significantly more likely to report that COVID-19 had negatively impacted their ability to adhere to behavioral recommendations. Support from interventionists and/or group members for those receiving individual- or group-based interventions may help individuals navigate new challenges in adherence related to stay-at-home orders, while individuals in self-guided programs may have difficulty problem-solving without extra support. Importantly, moderate/severe perceived threat from COVID-19, anxiety/depression, or PTSD symptoms conferred a very large (i.e., 4- to 19-fold) risk for difficulty adhering to behavioral recommendations. PTSD symptomatology was a particularly salient risk factor, as those with severe distress had a 19-fold risk for reporting that COVID-19 had affected their ability to adhere to behavioral recommendations. Increased perceived threat from COVID-19 may lead to greater mental health symptoms, thereby leading to greater struggles with implementing health-related behavior change. Given that a large number of individuals in this study were engaged in an intervention for decreasing behaviors often used for coping with negative emotions (e.g., eating, smoking), increased distress and mental health symptoms may increase the difficulty of decreasing such behaviors (and simultaneously decrease motivation to participate). In fact, many research participants qualitatively noted changes in their health behaviors resulting from the pandemic. Thus, researchers should be cautious when interpreting results from behavioral interventions during this time.

Our qualitative data also indicated that, overall, transitioning to remote format went smoothly, despite technical issues. Most participants reported missing the connection derived from in-person interventions; however, participants also expressed hesitation regarding resuming in-person visits because of infection risk, indicating that researchers should take a conservative stance with resuming in-person visits. Before resuming in-person operations, researchers should also be conscious of underlying health conditions (e.g., obesity, respiratory problems) that may predispose individuals to a more severe course of illness and higher risk for COVID-19.

Study strengths

This study was conducted during weeks 14 and 15 of 2020, corresponding with the weeks in which the US reached the height of the COVID-19 pandemic. This allowed us to conduct measurements during the peaks of COVID-19 and assess mental health factors and perceptions at the height of virus impact. This study sample also allowed us to assess factors that might influence desire and ability to engage in important health behaviors, which can inform strategies to improve health outcomes during this critical time.

Limitations

Although this study assessed self-report of anxiety/depression and additional mental health outcomes specifically resulting from the COVID-19 pandemic, participants may have difficulty separating outcomes that may be resulting from other sources (e.g., mental health outcomes reported may have been preexisting). Participant inclusion criteria were based on self-report of current research participation and did not allow for verification. Classification of mental health outcomes may be subject to further validation using a standardized diagnostic interview (16). Our sample was predominately non-Hispanic White and female, which is generally representative of those who engage in research but limits generalizability of our findings. Lastly, our study was cross-sectional, precluding the ability to analyze temporal relationships.

Conclusion

The majority of participants engaged in health-related research perceive COVID-19 as a severe threat, and this pandemic is negatively affecting various components of mental health, particularly among women. Perceived threat and mental health significantly influenced how individuals viewed research and their desire to participate. Importantly, those reporting moderate/severe symptoms of anxiety/depression and PTSD related to COVID-19 were most likely to report that their ability to adhere to behavioral intervention recommendations were affected, potentially altering outcomes. This has important implications for the generalizability of behavioral intervention data collected during this pandemic. Given the rapidly changing impacts of COVID-19, future research should aim to examine the pandemic's influence on behavioral-health-related research and health-related behaviors over time. **O**

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Supporting information: Additional Supporting Information may be found in the online version of this article.

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