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Factors associated with fears due to COVID-19: A Scleroderma Patient-centered Intervention Network (SPIN) COVID-19 cohort study

Yin Wu a,b, Linda Kwakkenbos c, Richard S. Henry a,b, Marie-Eve Carrier a, Maria Garagone a,d, Sami Harb a,b, Angelica Bourgeault a, Lydia Tao e, Andrea Carboni-Jiménez a,b, Zelalem Negeri a,d, Scott Patten e,f,g, Susan J. Bartlett h,i, Luc Mouthon h,k, John Varga l, Andrea Benedetti d,h,i,m, Brett D. Thombs a,b,d,h,n,o,p,q, for the SPIN Patient Advisors, SPIN Investigators

a Lady Davis Institute for Medical Research, Jewish General Hospital, Montreal, Quebec, Canada
b Department of Psychiatry, McGill University, Montreal, Quebec, Canada
c Department of Clinical Psychology, Behavioural Science Institute, Radboud University, Nijmegen, the Netherlands
d Department of Epidemiology, Biostatistics, and Occupational Health, McGill University, Montreal, Quebec, Canada
e Department of Community Health Sciences, University of Calgary, Calgary, Alberta, Canada
f Hotchkiss Brain Institute, University of Calgary, Calgary, Alberta, Canada
ghk O’Brien Institute for Public Health, University of Calgary, Calgary, Alberta, Canada
i Department of Medicine, McGill University, Montreal, Quebec, Canada
j Research Institute of the McGill University Health Centre, Montreal, Quebec, Canada
k Université Paris Descartes, Assistance Publique-Hôpitaux de Paris, Paris, France
l Northwestern Scleroderma Program. Feinberg School of Medicine, Northwestern University, Chicago, IL, USA
m Respiratory Epidemiology and Clinical Research Unit, McGill University Health Centre, Montreal, Quebec, Canada
n Department of Psychology, McGill University, Montreal, Quebec, Canada
o Department of Epidemiology, Biostatistics, and Occupational Health, McGill University, Montreal, Quebec, Canada
p Brien Institute for Public Health, University of Calgary, Calgary, Alberta, Canada
q Biomedical Ethics Unit, McGill University, Montreal, Quebec, Canada

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ABSTRACT

Introduction: No studies have examined factors associated with fear in any group of people vulnerable during COVID-19 due to pre-existing medical conditions.

Objective: To investigate factors associated with fear of consequences of COVID-19 among people living with a pre-existing medical condition, the autoimmune disease systemic sclerosis (SSc; scleroderma), including country.

Methods: Pre-COVID-19 data from the Scleroderma Patient-centered Intervention Network (SPIN) Cohort were linked to COVID-19 data collected in April 2020. Multivariable linear regression was used to assess factors associated with continuous scores of the 10-item COVID-19 Fears Questionnaire for Chronic Medical Conditions, controlling for pre-COVID-19 anxiety symptoms.

Results: Compared to France (N = 156), COVID-19 Fear scores among participants from the United Kingdom (N = 50) were 0.12 SD (95% CI 0.03 to 0.21) higher; scores for Canada (N = 97) and the United States (N = 128) were higher, but not statistically significant. Greater interference of breathing problems was associated with higher fears due to COVID-19 (Standardized regression coefficient = −0.12, 95% CI 0.01 to 0.23). Participants with higher financial resources adequacy scores had lower COVID-19 Fear scores (Standardized coefficient = −0.18, 95% CI −0.28 to −0.09).

Conclusions: Fears due to COVID-19 were associated with clinical and functional vulnerabilities in this chronically ill population. This suggests that interventions may benefit from addressing specific clinical issues that apply to specific populations. Financial resources, health policies and political influences may also be important.

* Corresponding author at: Jewish General Hospital; 4333 Cote Ste Catherine Road; Montreal, Quebec H3T 1E4, Canada
E-mail address: brett.thombs@mcgill.ca (B.D. Thombs).

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1. Introduction

The SARS-CoV-2 coronavirus disease (COVID-19) pandemic has caused over one million deaths worldwide [1] and led to widespread political, economic, and social disruptions. In addition to fear of being infected or that family or friends will be infected, there has been a steady stream of images and news headlines underlining the fragility of health care systems and raising questions about the ability of health care systems to provide necessary medical care to people infected with COVID-19 [2,3]. There are also fears that social isolation may be long lasting and that post-pandemic recovery of individual and public economic resources may be slow or incomplete [4–7]. Individuals who are vulnerable to COVID-19 due to pre-existing medical conditions likely experience high levels of fear, which could lead to acute and ongoing anxiety [4–7]. Based on a living systematic review on mental health in COVID-19 [8,9], as of September 30, 2020, no studies have reported sociodemographic and COVID-19 factors associated with levels of fear.

People with systemic sclerosis (SSc; scleroderma), a rare, chronic autoimmune disease, are representative of groups with medical conditions that put them at high risk for COVID-19 complications. Many people with SSc have interstitial lung disease, can be frail, and many use immunosuppressant drugs [10,11]. The course of SSc is unpredictable and, even prior to COVID-19, fear was a concern among people with SSc due to fears of unpredictable disease progression, becoming physically disabled, and dependency upon others [12,13]. A recent study of 435 participants from Canada, the United States, the United Kingdom, and France from the ongoing Scleroderma Patient-centered Intervention Network (SPIN) Cohort [11,14,15] who also enrolled in the SPIN COVID-19 Cohort found that mean anxiety symptoms increased substantially during COVID-19 compared to pre-COVID-19 levels, but depressive symptoms changed minimally [16]. The study found that people from the United Kingdom and the United States reported the largest increase in anxiety symptom scores and that people who used mental health services pre-COVID-19 had substantially lower increases in anxiety symptoms than others.

Factors associated with fear have not been investigated in any group of people vulnerable during COVID-19 due to pre-existing medical illness. Our objective was to investigate factors associated with fear of COVID-19, including country, comparing results from Canada, France, the United Kingdom, and the United States, controlling for pre-COVID-19 anxiety symptoms.

2. Methods

This was a longitudinal study that linked pre-COVID-19 data from the SPIN Cohort [11,14,15] to data collected during the baseline assessment of the separate SPIN COVID-19 Cohort between April 9, 2020 and April 27, 2020. Person-level, deterministic linking was used with participant email addresses as the identifier. The protocols for the SPIN COVID-19 Cohort and for the present study are available online (https://osf.io/62vut/).

2.1. Participants and procedure

SPIN Cohort participants must be aged ≥18 years and meet the 2013 American College of Rheumatology/European League Against Rheumatism criteria for SSc [17], verified by a SPIN physician. The SPIN Cohort is a convenience sample [11]. Eligible participants are recruited at 47 SPIN sites [15] in Canada, the United States, the United Kingdom, France, Spain, Mexico, and Australia during regular medical visits. Site personnel submit an online medical form to enrol participants, after which participants receive an email with instructions to activate their SPIN account and complete measures via the Cohort online portal in English, French, or Spanish. Assessments are completed at 3-month intervals. SPIN Cohort participants provide informed consent for cohort participation and for contact about additional SPIN studies.

From April 9 to April 27, 2020, SPIN Cohort participants who complete measures in English or French were invited by email and popups during SPIN Cohort online assessments to enrol into the separate SPIN COVID-19 Cohort, which was developed in English and French only [16]. SPIN Cohort participants included in the present study (1) were from Canada, the United States, the United Kingdom, and France; (2) completed the Patient-Reported Outcomes Measurement Information System (PROMIS) Anxiety 4a v1.0 scale [18,19] in English or French between July 1, 2019 and December 31, 2019, when China reported cases of pneumonia later identified as related to COVID-19 to the World Health Organization [20]; and (3) enrolled in the SPIN COVID-19 Cohort and completed baseline measures. SPIN COVID-19 measures were collected using the Qualtrics online survey package.

The SPIN (#MP-05-2013-150) and SPIN COVID-19 (#2021–2286) Cohorts were approved by the Research Ethics Committee of the Centre intégré universitaire de santé et de services sociaux du Centre-Ouest-de-l’Île-de-Montréal. The SPIN Cohort was also approved by ethics committees of SPIN sites.

2.2. Measures

Physician-reported SPIN Cohort data included sex, age, body mass index, time since SSc diagnosis, SSc disease subtype (limited, diffuse, sine scleroderma), presence of interstitial lung disease, and presence of overlap syndromes (systemic lupus, rheumatoid arthritis, Sjögren’s syndrome, idiopathic inflammatory myopathy, primary biliary cholangitis, autoimmune thyroid disease). Patient-reported data during COVID-19 included immunosuppressant drug use, COVID-19 positive test status, financial resource adequacy (Consumer Financial Protection Bureau (CFPB) Financial Well-Being Scale [21]), and fears due to COVID-19, measured by the COVID-19 Fears Questionnaires for Chronic Medical Conditions [22]. Pre-COVID-19 patient-reported data included race/ethnicity, employment status, health professional visit about mental health in previous 3 months, interference of breathing problems in daily activities (single item, past-week, 0–10 severity), the PROMIS Physical Function 4a v1.0 scale [18,19], and anxiety symptoms, measured by the PROMIS Anxiety 4a v1.0 scale [18,19].

2.2.1. Fears due to COVID-19

The 10-item COVID-19 Fears Questionnaire for Chronic Medical Conditions was used to assess respondents’ fears related to COVID-19 and its consequences [4,22]. Respondents were asked to select the response that reflects how much each statement describes their experience on a typical day in the last week. Items are rated on a 5-point numerical scale ranging from 1 (not at all) to 5 (extremely). The score for the scale is the total of all items, with higher scores reflecting greater fear [22]. Prior to launching the SPIN COVID-19 Cohort, fifteen initial items were generated based on suggestions from 121 people with SSc. A total of 15 items were included in the preliminary version COVID-19 Fears Questionnaire for Chronic Medical Conditions and administered as a part of the SPIN COVID-19 measures [5,22]. Validation of the measure was done using baseline and Wave-2 data of SPIN COVID-19 assessments, which were conducted two weeks later [22]. The final 10-item measure can be scored with a total score reflecting a single dimension as indicated by exploratory factor analysis with baseline data and confirmed by confirmatory factor analysis with Wave-2 data [22].
The final scale had good internal consistency reliability and convergent validity [22]. Item suggestions for the preliminary version were obtained in English and French. Items were developed in English then translated into French using a well-accepted forward-backward translation method [23]. In this study, the Cronbach’s Alpha for the 10-item COVID-19 Anxiety Questionnaire for Chronic Medical Conditions was 0.92, suggested a high internal consistency reliability.

2.2.2. Anxiety symptoms
The PROMIS Anxiety 4a v1.0 scale [18,19] includes 4 items asking participants, in the past 7 days, how often: (1) “I felt fearful”; (2) “I found it hard to focus on anything other than my anxiety”; (3) “My worries overwhelmed me”; and (4) “I felt uneasy”. Items are scored 1–5 with response options “never” to “always”. Higher scores represent more anxiety. Raw scores are converted into T-scores standardized from the general United States population (mean = 50, standard deviation (SD) = 10). PROMIS Anxiety 4a v1.0 has been validated in SSC [24,25].

2.2.3. Adequacy of financial resources
The 5-item abbreviated version of the CFPB Financial Well-Being Scale [21] includes items that assess ability to meet financial obligations, feel financially secure, and make choices that provide enjoyment in life. Items are scored on a 0 (Not at all/ Never) to 4 (Completely/ Always) point scale, and total raw scores (range 0 to 20) are scaled from 0 to 100 with higher values reflecting greater financial well-being. The scale was translated into French and back-translated by members of the SPIN research team [23].

2.2.4. Physical function
The 4-item PROMIS Physical Function 4a v1.0 scale [18,19] assesses functional ability. Items measure capacity to complete day-to-day activities on a Likert scale from 1 (unable to do) to 5 (without any difficulty). The summed score of the four items is converted into T-scores standardized from the general United States population (mean = 50; SD = 10). Higher scores indicate better physical function. PROMIS Physical Function 4a v1.0 has been validated in SSC [24,25].

3. Statistical analyses
Descriptive statistics are presented as mean (standard deviation) for continuous variables and frequencies (percentages) for categorical variables. We evaluated the association of sociodemographic characteristics, medical characteristics, and COVID-19 variables with continuous scores of fears due to COVID-19 via multivariable linear regression (see Appendix Table 1). All variables were selected a priori and were entered simultaneously. Variables that were entered in models include male sex (reference female), age (continuous), non-White race or ethnicity (reference White), education years (continuous), living alone (reference living with others), country (reference France), working part- or full-time (reference not working), time since SSc diagnosis (continuous), diffuse subtype (reference limited or sine scleroderma), interstitial lung disease presence, interference from breathing problems (continuous), overweight or obese (reference normal body mass index or less), overlap syndrome presence, PROMIS Physical Function pre-COVID (continuous), immunosuppressant drug use intake, use of mental health services pre-COVID-19, and financial resource adequacy (continuous). Pre-COVID-19 anxiety symptoms (continuous) were added to the model as a control variable since the fears due to COVID-19 scores were not available before the pandemic and anxiety is highly associated with fear conceptually. For continuous variables, we assessed linearity via restricted cubic splines. Missing data was dealt with using multiple imputation via chained equations with 20 imputations. The main output of the regression analyses were standardized coefficients that indicated how many SDs a dependent variable would change, per standard deviation increase in the predictor variable. Standardized coefficients are estimates from a regression model that have been standardized where the variances of dependent and independent variables are 1 [26].

All analyses were conducted using Stata (Version 13) with 2-sided statistical tests and p < 0.05 significance level.

3.1. Changes from the protocol
Changes included (1) exclusion of participants from Australia because there were only 10 eligible patients; (2) removal of COVID-19 infection by test from the model covariates because only 3 participants reported a positive test result.

3.2. Patient involvement
The SPIN Patient Advisory Team (https://spineclero.com) reviews all SPIN research, including the present study, and advises the SPIN Steering Committee to ensure that SPIN research addresses the needs of people with SSC. Additionally, members of the study-specific SPIN COVID-19 Patient Advisory Team were involved in each stage of the present study, including designing the SPIN COVID-19 Cohort, selecting outcomes for assessment, interpreting results, and providing comments on the present manuscript.

4. Results
4.1. Participants
There were 431 SPIN Cohort participants who completed the PROMIS Anxiety 4a v1.0 scale pre-COVID and who enrolled in the SPIN COVID-19 Cohort and completed the COVID-19 Fears Questionnaire for Chronic Medical Conditions at baseline. Ninety-seven were from Canada (11 centers), 156 from France (11 centers), 50 from the United Kingdom (2 centers), and 128 from the United States (11 centers). Participant characteristics are reported in Table 1. Mean age was 56.9 years, and 88.4% of participants were female. Mean time since SSc diagnosis was 12.1 years, 39.7% had diffuse disease subtype, 35.2% had interstitial lung disease, and 48.5% were using immunosuppressant drugs. Participant characteristics were similar for most variables across countries.

4.2. Multivariable analysis of factors associated with fears due to COVID-19
As shown in Table 2, in the multivariable model, compared to France, continuous scores of fears due to COVID-19 for participants from the United Kingdom were significantly higher; scores for Canada and the United States were also higher but not statistically significant. The adjusted mean difference in fear was 4.36 points (Hedge’s g = 0.49) for scores of fears due to COVID-19 between participants from the United Kingdom and France, 3.38 points (Hedge’s g = 0.35) between Canada and France, and 0.60 points (Hedge’s g = 0.06) between the United States and France. Other variables that were statistically significantly associated with greater fear included greater patient-reported interference of breathing problems in daily activities (Standardized regression coefficient = 0.12, 95% CI 0.01 to 0.23), lower financial resources adequacy ratings (Standardized regression coefficient = 0.18, 95% CI 0.09 to 0.28), and higher pre-COVID-19 anxiety symptom scores (Standardized regression coefficient = 0.23, 95% CI 0.12 to 0.34). The adjusted R-square was 0.22.

5. Discussion
5.1. Main findings
Fears due to COVID-19 among people with SSC, in addition to pre-COVID-19 anxiety, were almost half a standard deviation higher among participants from the United Kingdom compared to those from France, which had the lowest levels, and this was statistically significant.
in multivariable analysis. Scores among Canadian participants were almost one-third of a standard deviation higher, but this was not statistically significant in multivariable analysis. Scores among respondents from the United States were minimally and not statistically significantly higher. Other variables that were associated with greater fear included interference of breathing problems in daily activities and financial resource inadequacy, which was associated at almost the same level as pre-COVID-19 anxiety based on standardized multivariable regression coefficients.

5.2. Findings in context

Our study was the first to explore factors associated with fears due to COVID-19 in a vulnerable population due to a pre-existing medical condition. Findings on fear during COVID-19 in the present study differed from results from a study with the same participant sample that focused on anxiety, more generally, measured with the PROMIS Anxiety 4a v1.0 [16]. In that study, anxiety symptoms were significantly and substantively higher in the United States and United Kingdom (highest in the United States), compared to France with symptoms in Canada only modestly and non-significantly higher. In the present study, fear was
Table 2
Regression analysis of factors associated with the fears due to COVID-19.

| Variable                          | Crude Regression Coefficient (95% Confidence Interval) | Adjusted Regression Coefficient* (95% Confidence Interval) | Regression Coefficient | Standardized Coefficient |
|----------------------------------|--------------------------------------------------------|-------------------------------------------------------------|------------------------|--------------------------|
| Sociodemographic                 |                                                        |                                                             |                        |                          |
| Age in years (continuous)        | -0.02 (-0.10, 0.05)                                    | 0.01 (-0.07, 0.08)                                          | -0.07 (-0.14, -0.01)   | 0.03                      |
| Male sex (reference = female)    | -1.14 (-4.00, 1.72)                                    | -1.50 (-4.22, 1.22)                                         | -1.69 (-4.41, 0.04)    | -0.50                     |
| Education in years (continuous)  | -0.03 (-0.28, 0.21)                                    | 0.14 (-0.09, 0.16)                                          | 0.38                   | 0.10                      |
| Living alone (reference = living with others) | 0.63                                             | 0.54 (0.04, 1.02)                                           | 0.78                   | 0.02                      |
| “Other” Race or ethnicity (reference = White) | 0.92 (-1.51, 3.35)                                  | -0.49 (-2.75, 0.78)                                         | -0.02 (-0.11, 0.07)    | -0.10                     |
| Working part- or full-time (reference = not working) | -2.93 (-4.75, -1.10)                                | -1.75 (-3.51, 0.17)                                         | -0.09 (-0.18, 0.00)    | -0.06                     |
| Country (reference = France)     |                                                        |                                                             |                        |                          |
| Canada                           | 2.94 (0.50, 5.38)                                      | 2.21 (0.30, 4.11)                                           | 0.10 (0.00, 0.20)      | 0.20                      |
| United States                    | 0.77 (-1.48, 3.03)                                    | 1.22 (0.06, 2.31)                                           | 0.06 (0.05, 0.17)      | 0.17                      |
| United Kingdom                   | 4.05 (0.99, 7.12)                                     | 3.75 (0.86, 6.64)                                           | 0.12 (0.03, 0.21)      | 0.21                      |
| Medical characteristics          |                                                        |                                                             |                        |                          |
| Body mass index (reference = underweight or normal) |                                                        |                                                             |                        |                          |
| Overweight                       | -0.01 (-2.18, 2.16)                                   | 0.37 (-1.66, 2.41)                                          | 0.02 (-0.09, 0.13)     | 0.10                      |
| Obese                            | 2.90 (0.34, 5.46)                                    | 0.69 (-1.75, 3.12)                                          | 0.03 (-0.08, 0.14)     | 0.10                      |
| Time since diagnosis of SSc (continuous) | 0.04 (-0.08, 0.16)                                 | 0.08 (-2.14, 2.42)                                          | 0.06 (-0.03, 0.14)     | 0.17                      |
| Diffuse disease subtype           |                                                        |                                                             |                        |                          |
| Presence of intestinal lung disease (reference = no) | 1.69 (-0.25, 3.64)                                   | 0.76 (-1.19, 2.71)                                          | 0.04 (-0.06, 0.14)     | 0.10                      |
| Presence of any overlap syndrome (reference = no) | 1.12 (-1.10, 3.34)                                  | -0.80 (-2.90, 1.31)                                         | -0.04 (-0.15, 0.07)    | -0.06                     |
| Immunosuppressant drug use (reference = no) | 2.80 (-0.99, 4.62)                                   | 1.38 (-0.51, 3.27)                                          | 0.07 (-0.03, 0.17)     | 0.17                      |
| Pre-COVID-19 use of mental health services (reference = no) | 1.26 (-0.98, 3.49)                                  | 1.06 (-3.29, 1.08)                                          | 0.04 (-0.12, 0.00)     | 0.10                      |
| Interference from breathing problems (continuous) | 1.01 (0.71, 1.32)                                   | 0.40 (0.04, 0.76)                                           | 0.12 (0.01, 0.23)      | 0.04                      |
| PROMIS Physical Function (pre-COVID (continuous) | -0.38 (-0.48, -0.28)                                 | -0.10 (-0.23, 0.02)                                         | -0.09 (-0.21, 0.00)    | -0.06                     |
| COVID-19 variables:              |                                                        |                                                             |                        |                          |
| Adequacy of financial resources (continuous) | -0.60 (-0.78, -0.42)                                 | -0.37 (-0.57, -0.18)                                        | -0.18 (-0.28, -0.09)   | -0.10                     |
| Control variable:                |                                                        |                                                             |                        |                          |
| PROMIS Anxiety 4a v1.0 pre-COVID (continuous) | 0.34 (0.26, 0.42)                                   | 0.21 (0.11, 0.31)                                           | 0.23 (0.12, 0.34)      | 0.15                      |

* Results based on imputed datasets. Based on assessment using via restricted cubic splines, there was no appreciable non-linearity.

highest in the United Kingdom, but was not substantively or significantly higher among participants from the United States compared to France. Since fear is highly associated with anxiety conceptually, the divergence in findings on the United States was not expected [16]. Reasons for these discrepancies are likely complex, but it is possible that they could be associated with policy responses to COVID-19 in each country during the period of data collection. The UK’s national response has been generally criticized and was described, for instance, as “astonishingly haphazard” in an editorial in the Lancet; both stress and anxiety, which may be a product of fear were high [27]. In the United States, fear was relatively low, but anxiety was higher than in any of the other countries. It is possible that the presence of such high levels of anxiety without accompanying high-level COVID-19 fears may be related to what has been seen as a lack of coherence of government actions in the response to the spread of the virus, as well as general turbulence in governance in the United States. Despite its long-standing reputation as a world leader, the United States Centers for Disease Control and Prevention has seen its role minimized and been relegated to what has been described as a status of an “ineffective and nominal adviser” [28]. There has also been much greater public polarization about the severity of the pandemic in the United States compared to other countries included in our study [29]. Comparatively, more people from the United States may undermine compliance with social distancing and underestimate the threat of COVID-19 because of this polarization [30]. Thus, it is possible that inconsistent and incoherent government involvement and the chaotic political and social media environments may be factors, although it is not known to what degree this may be the case. Among the four countries, the French government undertook the strictest policies internationally to contain the spread of the virus [31], which may be related to relatively lower level of insecurity among people with SSc, in terms of both fear and anxiety. In Canada, there has generally been a cross-partisan consensus on national response with less controversy about the pandemic severity or how to respond compared to the United States, for instance [32].

There were minor differences, depending whether bivariable or multivariable analyses are considered, but generally, findings on the severity of pre-pandemic breathing problems and financial resource adequacy were similar. In terms of magnitude of association, financial resources appear to be an important factor in fear and, possibly, more general anxiety. There have been no previous studies that focused on factors associated with fears due to COVID-19 so far, but some recent studies have investigated factors related with other conceptually relevant mental health outcomes, including anxiety and stress [33-38]. These studies reported mostly similar findings. For example, lower monthly income was associated with a higher level of anxiety symptoms among the spouses of first-line medical staff in China [33] and with greater perceived stress in the Italian general population [34]. Among the general population of China, one study found participants with income below the median income were more likely to report moderate or severe anxiety symptoms [35]; another found participants with lower monthly family income levels, compared to the highest level, were more likely to report symptoms of anxiety and acute stress [36]. Higher income levels were associated with better general mental health in the Spanish population [37], but one study found people from high income families, compared to lower income families, were at higher risk of developing anxiety and stress in Bangladesh [38].

5.3. Implications and future studies

Our finding that participants with greater interference from breathing problems are more vulnerable and may be at higher risk of mental health problems, including fears, suggests that the specific needs of this population should be considered in supporting mental health in COVID-
19. Pre-existing medical characteristics were taken into account in the design of the SPIN COVID-19 Home-Isolation Activities Together (SPIN-CHAT) Program, a group-based multifaceted intervention delivered by videoconference and intended to reduce anxiety among at-risk people with SSc [39]. Results are pending. Additionally, our findings underline that financial implications of the pandemic may have an important role in mental health outcomes. All of the countries with participants in our study have provided aid packages [40–43], and the findings of the study emphasize the importance of economic supports for those in need. Social workers and other qualified personnel may be able to help patients with chronic diseases who have financial constraints identify and access financial support resources, if available.

5.4. Strengths and limitations

Our study is the first to explore the factors associated with fears during COVID-19 in a vulnerable population with a pre-existing medical condition and the first study that applied the validated COVID-19 Fears Questionnaire for Chronic Medical Conditions, which was specifically designed for people with chronic diseases. The SPIN Cohort is a well-described, ongoing cohort that allowed us to examine pre-COVID-19 factors. There are also limitations to consider. First, the SPIN Cohort is a convenience sample, although the demographic and medical characteristics of the SPIN Cohort participants are similar to other large SSc cohorts [11,14]. Second, evidence only from people with SSc may reduce generalizability. Based on the current study, ideally other studies will evaluate factors associated with fear during COVID-19 in other groups of people vulnerable due to medical conditions. Third, people in local communities may have relevant lived experiences, but it was not possible to capture and include community-level variables, such as level of community prevention and control. Although there were differences between countries, these may not have reflected the different experiences of people within countries. We also were not able to consider the organization and coherence of care during the pandemic, which may have differed at the national, regional, or local levels.

6. Conclusions

In sum, this was the first study to investigate factors associated with fears due to COVID-19 among participants with a chronic medical condition using a validated measure. Fears due to COVID-19 among people with SSc were greatest among participants from the United Kingdom, followed by Canada, the United States, and France. Greater interference of breathing problems in daily activities and lower financial resource adequacy were associated with fear levels, as well. There is a need for considering the specific needs of people with medical conditions in designing mental health interventions, and these might include steps to help them access available resources if they are facing financial constraints.

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Declaration of Competing Interest

All authors have completed the ICMJE uniform disclosure form and declare: no support from any organization for the submitted work; no financial relationships with any organizations that might have an interest in the submitted work in the previous three years. All authors declare no other relationships or activities that could appear to have influenced the submitted work. No funder had any role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

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