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Factors Associated with Fears due to COVID-19: A Scleroderma Patient-centered

2 Intervention Network (SPIN) COVID-19 Cohort Study

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### **ABSTRACT**

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141 **Introduction:** No studies have examined factors associated with fear in any group of people 142 vulnerable during COVID-19 due to pre-existing medical conditions. 143 **Objective:** To investigate factors associated with fear of consequences of COVID-19 among 144 people living with a pre-existing medical condition, the autoimmune disease systemic sclerosis 145 (SSc; scleroderma), including country. 146 Methods: Pre-COVID-19 data from the Scleroderma Patient-centered Intervention Network 147 (SPIN) Cohort were linked to COVID-19 data collected in April 2020. Multivariable linear 148 regression was used to assess factors associated with continuous scores of the 10-item COVID-149 19 Fears Questionnaire for Chronic Medical Conditions, controlling for pre-COVID-19 anxiety 150 symptoms. 151 **Results:** Compared to France (N=156), COVID-19 Fear scores among participants from the 152 United Kingdom (N=50) were 0.12 SD (95% CI 0.03 to 0.21) higher; scores for Canada (N=97) 153 and the United States (N=128) were higher, but not statistically significant. Greater interference 154 of breathing problems was associated with higher fears due to COVID-19 (Standardized 155 regression coefficient = 0.12, 95% CI 0.01 to 0.23). Participants with higher financial resources 156 adequacy scores had lower COVID-19 Fear scores (Standardized coefficient = -0.18, 95% CI -157 0.28 to -0.09). 158 **Conclusions:** Fears due to COVID-19 were associated with clinical and functional 159 vulnerabilities in this chronically ill population. This suggests that interventions may benefit 160 from addressing specific clinical issues that apply to specific populations. Financial resources, 161 health policies and political influences may also be important. The needs of people living with

chronic illness during a pandemic may differ depending on the social and political context in
which they live. **Key Words**: anxiety, chronic medical condition, COVID-19, fear, mental health, scleroderma,
systemic sclerosis

### **INTRODUCTION**

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The SARS-CoV-2 coronavirus disease (COVID-19) pandemic has caused over one million deaths worldwide<sup>1</sup> 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.<sup>2,3</sup> 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.<sup>4-7</sup> 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.<sup>4-</sup> <sup>7</sup> Based on a living systematic review on mental health in COVID-19, <sup>8,9</sup> 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<sup>11,14,15</sup> 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 consequences of COVID-19, including country, comparing results from Canada, France, the United Kingdom, and the United States, controlling for pre-COVID-19 anxiety symptoms.

### **METHODS**

This was a longitudinal study that linked pre-COVID-19 data from the SPIN Cohort <sup>11,14,15</sup> 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/).

## **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, <sup>17</sup> verified by a SPIN physician. The SPIN Cohort is a convenience sample. <sup>11</sup> Eligible participants are recruited at 47 SPIN sites <sup>15</sup> 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. 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; 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.

#### 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<sup>21</sup>), and fears due to COVID-19, measured by the COVID-19 Fears Questionnaires for Chronic Medical Conditions. <sup>22</sup> Pre-COVID-19 patientreported 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, <sup>18,19</sup> and anxiety symptoms, measured by the PROMIS Anxiety 4a v1.0 scale. 18,19 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 5point 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. <sup>22</sup> 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.<sup>5,22</sup> Validation of the measure was done using baseline and Wave-2 data of SPIN COVID-19 assessments, which were conducted two weeks later.<sup>22</sup> 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.<sup>22</sup> The final scale had good internal consistency reliability and convergent validity.<sup>22</sup> 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.<sup>23</sup> In this study, the Cronbach's Alpha for the 10-item COVID-19 Fears

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Questionnaire for Chronic Medical Conditions was 0.92, suggested a high internal consistency reliability.

Anxiety Symptoms. The PROMIS Anxiety 4a v1.0 scale<sup>18,19</sup> 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.<sup>24,25</sup>

Adequacy of Financial Resources. The 5-item abbreviated version of the CFPB Financial Well-Being Scale<sup>21</sup> 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 0-100 with higher values reflecting greater financial well-being. The scale was translated into French and back-translated by members of the SPIN research team.<sup>23</sup>

Physical Function. The 4-item PROMIS Physical Function 4a v1.0 scale<sup>18,19</sup> 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.<sup>24,25</sup>

### **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.<sup>26</sup> All analyses were conducted using Stata (Version 13) with 2-sided statistical tests and p <

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0.05 significance level.

### **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.

### **Patient Involvement**

The SPIN Patient Advisory Board (https://spinsclero.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.

### **RESULTS**

## **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.

### 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.

## **DISCUSSION**

### **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.

## **Findings in Context**

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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 moderately and non-significantly higher. In the present study, fear was 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.<sup>16</sup> 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.<sup>27</sup> 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". <sup>28</sup> 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. <sup>29</sup> Comparatively, more people from the United States may undermine compliance with social distancing and underestimate the threat of COVID-19 because of this polarization. <sup>30</sup> 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, <sup>31</sup> 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. <sup>32</sup>

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. 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 and with greater perceived stress in the Italian general population. 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;<sup>35</sup> 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.<sup>36</sup> Higher income levels were associated with better general mental health in the Spanish population,<sup>37</sup> 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.<sup>38</sup>

### **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. <sup>39</sup> 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, <sup>40-43</sup> 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.

# **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

### **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.

### 440 **References:**

- 1. WHO Coronavirus Disease (COVID-19) Dashboard. <a href="https://covid19.who.int/">https://covid19.who.int/</a>. Accessed
- 443 September 30, 2020.
- 2. De Leo D, Trabucchi M. COVID-19 and the fears of Italian senior citizens. *Int J Environ*.
- 445 Res Public Health. 2020;17:3572.
- 3. Harlan C, Pitrelle S. As coronavirus cases grow, hospitals in northern Italy are running
- out of beds. The Washington Post. 2020. March 12. Available at:
- https://www.washingtonpost.com/world/europe/italy-coronavirus-patients-lombardy-
- hospitals/2020/03/12/36041dc6-63ce-11ea-8a8e-5c5336b32760\_story.html
- 4. Salisbury H. Helen Salisbury: Fear in the time of Covid. *BMJ*. 2020;368:m1286.
- 5. Thombs BD, Tao L, Wu Y, et al. Preliminary COVID-19 Fears Questionnaire: systemic
- sclerosis and chronic medical conditions versions. *OSF Preprint*. 2020. April 7.
- 453 https://doi:10.31219/osf.io/m2ybt.
- 6. Ahorsu DK, Lin CY, Imani V, et al. The Fear of COVID-19 Scale: Development and
- 455 Initial Validation. *Int J Ment Health Ad.* 2020. https://doi.org/10.1007/s11469-020-
- 456 <u>00270-8</u>
- 7. Brooks SK, Webster RK, Smith LE. The psychological impact of quarantine and how to
- reduce it: rapid review of the evidence. *Lancet*. 2020;395:912-920.
- 8. Thombs BD, Bonardi O, Rice DB, et al. Curating evidence on mental health during
- 460 COVID-19: a living systematic review. *J Psychosom Res.* 2020; https://doi:
- 461 10.1016/j.jpsychores.2020.110113. [Epub ahead of print].
- 9. Living systematic review of mental health in COVID-19. https://www.depressd.ca/covid-
- 463 19-mental-health. Accessed September 30, 2020.

- 10. Allanore Y, Simms R, Distler O, et al. Systemic sclerosis. *Nat Rev Dis Primers*.
- 465 2015;1:15002.
- 11. Dougherty DH, Kwakkenbos L, Carrier ME, et al. The Scleroderma Patient-Centered
- Intervention Network Cohort: baseline clinical features and comparison with other large
- scleroderma cohorts. *Rheumatology*. 2018;57:1623-31.
- 12. Kwakkenbos L, van Lankveld WG, Vonk MC, Becker ES, van den Hoogen FH, van den
- Ende CH. Disease-related and psychosocial factors associated with depressive symptoms
- in patients with systemic sclerosis, including fear of progression and appearance self-
- 472 esteem. *J Psychosom Res.* 2012;72:199-204.
- 13. Kwakkenbos L, van den Hoogen FH, Custers J, et al. Validity of the Fear of Progression
- 474 Questionnaire-Short Form in patients with systemic sclerosis. *Arthrit Care Res.*
- 475 2012;64:930-4.
- 476 14. Kwakkenbos L, Jewett LR, Baron M, et al. The Scleroderma Patient-centered
- 477 Intervention Network (SPIN) Cohort: protocol for a cohort multiple randomised
- 478 controlled trial (cmRCT) design to support trials of psychosocial and rehabilitation
- interventions in a rare disease context. *BMJ Open.* 2013;3:e003563.
- 480 15. Scleroderma Patient-centered Intervention Network.
- https://www.spinsclero.com/en/cohort. Accessed September 30, 2020.
- 482 16. Thombs B, Kwakkebos L, Henry RS, et al. Changes in mental health symptoms from pre-
- 483 COVID-19 to COVID-19 among participants with systemic sclerosis from four countries:
- a Scleroderma Patient-centered Intervention Network (SPIN) Cohort study. *J Psychosom*
- 485 *Res.* Revision submitted.

486 17. van den Hoogen F, Khanna D, Fransen J, et al. Classification criteria for systemic 487 sclerosis: an American College of Rheumatology/European League Against Rheumatism 488 collaborative initiative. Arthritis Rheum. 2013;65:2737-47. 489 18. PROMIS measure development and research. http://www.healthmeasures.net/explore-490 measurement-systems/promis/measure-development-research. Accessed September 30, 491 2020. 492 19. Cella D, Riley W, Stone A, et al. The Patient-Reported Outcomes Measurement 493 Information System (PROMIS) developed and tested its first wave of adult self-reported 494 health outcome item banks: 2005-2008. J Clin Epidemiol. 2010;63:1179–94. 495 20. WHO Timeline - COVID-19. World Health Organization. https://www.who.int/news-496 room/detail/08-04-2020-who-timeline---covid-19. Accessed September 30, 2020. 497 21. Consumer Financial Protection Bureau. CFPB Financial Well-Being Scale: scale 498 development technical report. May 26, 2017. https://www.consumerfinance.gov/data-499 research/research-reports/financial-well-being-technical-report/. Accessed September 30, 500 2020. 501 22. Wu Y, Kwakkenbos L, Henry RS, et al. Validation of the COVID-19 Fears 502 Questionnaires for Chronic Medical Conditions: a scleroderma patient-centered 503 intervention network covid-19 cohort study. J Psychosom Res. In press (see Appendix 2). 504 23. World Health Organization. Process of translation and adaptation of instruments. 505 https://www.who.int/substance\_abuse/research\_tools/translation/en/. Accessed 506 September 30, 2020.

24. Hinchcliff M, Beaumont JL, Thavarajah K, et al. Validity of two new patient-reported

outcome measures in systemic sclerosis: Patient-Reported Outcomes Measurement

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509 Information System 29-item Health Profile and Functional Assessment of Chronic Illness 510 Therapy-Dyspnea short form. Arthritis Care Res. 2011;63:1620-28. 511 25. Kwakkenbos L, Thombs BD, Khanna D, et al. Performance of the Patient-Reported 512 Outcomes Measurement Information System-29 in scleroderma: a Scleroderma Patient-513 centered Intervention Network Cohort study. Rheumatology. 2017;56:1302-11. 514 26. Schroeder LD, Sjoquist DL, Stephan PE. Understanding regression analysis: An 515 introductory guide. New York: Sage Publications; 1987. p. 31-32. 516 27. Horton R. Offline: COVID-19 – what countries must do now. *Lancet*. 2020;395;1100. 517 28. Reviving the US CDC. Lancet. 2020;395:1521. 518 29. Gadarian SK, Goodman SW, Pepinsky TB. Partisanship, health behavior, and policy 519 attitudes in the early stages of the COVID-19 Pandemic. SSRN. 2020. 520 https://ssrn.com/abstract=3562796 or http://dx.doi.org/10.2139/ssrn.3562796 521 30. Cornelson K, Miloucheva B. Political polarization, social fragmentation, and cooperation 522 during a pandemic. 2020 Apr 7. Working paper 663. Department of Economics. 523 University of Toronto. https://www.economics.utoronto.ca/public/workingPapers/tecipa-524 663.pdf. 525 31. Oxford COVID-19 Government Response Tracker. 526 https://www.bsg.ox.ac.uk/research/research-projects/coronavirus-government-response-527 tracker. Accessed September 30, 2020. 528 32. Merkley E, Bridgman A, Loewen PJ, Owen T, Ruths D, Zhilin O. A rare moment of 529 cross-partisan consensus: elite and public response to the COVID-19 pandemic in 530 Canada. Can J Political Sci. 2020; https://doi: 10.1017/S0008423920000311. [Epub 531 ahead of print].

- 33. Yang Y, Zhao J, Qi L, Zhang H. The anxiety and social support status of the spouses of
- first-line medical staff in Suining City under the COVID-19 pandemic. *Chinese General*
- 534 *Practice Nursing*. 2020;18:940-44.
- 535 34. Flesia L, Fietta V, Colicino E, Segatto B, Monaro M. Stable psychological traits predict
- perceived stress related to the COVID-19 outbreak. *PsyArXiv Preprint*. 2020. June 1.
- 537 http://doi.org/10.31234/osf.io/yb2h8.
- 35. Qian M, Wu Q, Wu P, et al. Psychological responses, behavioral changes and public
- perceptions during the early phase of the COVID-19 outbreak in China: a population
- based cross-sectional survey. *medRxiv*. 2020. February 20.
- 541 https://doi.org/10.1101/2020.02.18.20024448
- 36. Shi L, Lu Z, Que J, et al. Prevalence of and risk factors associated with mental health
- symptoms among the general population in China during the Coronavirus disease 2019
- 544 pandemic. JAMA Netw Open. 2020;3:e2014053.
- 545 https://doi:10.1001/jamanetworkopen.2020.14053
- 37. Parrado-González A, León-Jariego JC. COVID-19: Factors associated with emotional
- distress and psychological morbidity in Spanish population. Rev Esp Salud Publica.
- 548 2020;94:e202006058.
- 38. Banna HA, Sayeed A, Kundu S, et al. The impact of the COVID-19 pandemic on the
- mental health of the adult population in Bangladesh: A nationwide cross-sectional study.
- 551 Int J Environ Health Res. 2020; https://doi:10.1080/09603123.2020.1802409. [Epub
- ahead of print].
- 39. Thombs BD, Kwakkenbos L, Carrier ME, et al. Protocol for a partially nested
- randomised controlled trial to evaluate the effectiveness of the scleroderma patient-

| 555 | centered inervention network COVID-19 home-isolation activities together (SPIN-          |
|-----|--|
| 556 | CHAT) program to reduce anxiety among at-risk scleroderma patients. J Psychosom Res.     |
| 557 | 2020;135:110132. https://doi:10.1016/j.jpsychores.2020.110132                            |
| 558 | 40. Canada Emergency Response Benefit (CERB).  |
| 559 | https://www.canada.ca/en/services/benefits/ei/cerb-application.html. Accessed September  |
| 560 | 30, 2020.  |
| 561 | 41. Economic Impact Payments. https://www.irs.gov/coronavirus/economic-impact-           |
| 562 | payments. Accessed September 30, 2020.   |
| 563 | 42. Morales A, Meakin L, Atkinson A. U.K. Virus aid package beats financial crisis       |
| 564 | stimulus. 2020. March 26. Available at: https://www.bloomberg.com/news/articles/2020-    |
| 565 | 03-26/u-k-s-sunak-pledges-coronavirus-support-for-self-employed.                         |
| 566 | 43. AS English. Which countries have applied measures like stimulus checks and how much? |
| 567 | 2020. April 17. Available at:  |
| 568 | https://en.as.com/en/2020/04/16/other_sports/1587074127_029119.html                      |

Table 1. Participant Characteristics for the Full Sample and by Country.

|   | Overall                   | Canada                  | France                  | <b>United Kingdom</b>   | <b>United States</b> |
|---|---------------------------|-------------------------|-------------------------|-------------------------|----------------------|
|   | (N=431)                   | (N=97)                  | (N=156)                 | (N=50)                  | (N=128)              |
| Variable                                | Mean (SD) <sup>a</sup> or | Mean (SD) or            | Mean (SD) or            | Mean (SD) or            | Mean (SD) or         |
|   | N (%) <sup>b</sup>        | N (%)                   | N (%)                   | N (%)                   | N (%)                |
| Sociodemographics                       |                           |                         |                         |                         |                      |
| Age in years <sup>a</sup>               | 56.9 (12.5)               | 57.5 (11.5)             | 53.7 (14.6)             | 59.2 (10.5)             | 59.5 (10.4)          |
| Male sex <sup>b</sup>                   | 50 (11.6)                 | 11 (11.3)               | 16 (10.3)               | 4 (8.0)                 | 19 (14.8)            |
| Education in years <sup>a</sup>         | 15.6 (3.7) <sup>c</sup>   | 15.7 (3.2) <sup>d</sup> | 15.1 (4.6) <sup>e</sup> | 14.8 (3.3) <sup>f</sup> | 16.4 (2.8)           |
| Living alone <sup>b</sup>               | 80 (18.7) <sup>g</sup>    | 14 (14.4)               | 33 (21.6) <sup>h</sup>  | 11 (22.0) <sup>i</sup>  | 22 (17.3)            |
| Race/ethnicity <sup>b</sup>             |                           |                         |                         |                         |                      |
| White                                   | 356 (82.8) <sup>j</sup>   | 86 (88.7)               | 119 (76.8) <sup>e</sup> | 45 (90.0)               | 106 (82.8)           |
| Black                                   | 38 (8.8) <sup>j</sup>     | 1 (1.0)                 | 24 (15.5) <sup>e</sup>  | 4 (8.0)                 | 9 (7.0)              |
| Other                                   | 36 (8.4) <sup>j</sup>     | 10 (10.3)               | 12 (7.7) <sup>e</sup>   | 1 (2.0)                 | 13 (10.2)            |
| Working part- or full-time <sup>b</sup> | 194 (45.1) <sup>j</sup>   | 43 (44.3)               | 72 (46.5) <sup>e</sup>  | 21 (42.0)               | 58 (45.3)            |
| Medical characteristics                 |                           |                         |                         |                         |                      |
| Body Mass Index <sup>b</sup>            |                           |                         |                         |                         |                      |
| Underweight or normal $(<25)^k$         | 251 (58.2)                | 52 (53.6)               | 105 (67.3)              | 26 (52.0)               | 68 (53.1)            |
| Overweight (25 to <30)                  | 110 (25.5)                | 19 (19.6)               | 36 (23.1)               | 16 (32.0)               | 39 (30.5)            |
| Obese (≥ 30.0)                          | 70 (16.2)                 | 26 (26.8)               | 15 (9.6)                | 8 (16.0)                | 21 (16.4)            |

| 12.1 (7.8) <sup>1</sup>   | 12.5 (9.7) <sup>m</sup>  | 11.0 (7.2) <sup>e</sup>  | 13.3 (7.8) <sup>n</sup>  | 12.7 (6.6)°  |
|---------------------------|--|--|--|--|
| 170 (39.7)                | 38 (40.0)  | 56 (35.9)  | 16 (32.7)  | 60 (46.9)  |
| 147 (35.3) <sup>p</sup>   | 28 (30.8) <sup>q</sup>   | 56 (36.4) <sup>r</sup>   | 14 (28.6) <sup>f</sup>   | 49 (39.8) <sup>s</sup>   |
| 99 (24.0) <sup>t</sup>    | 22 (24.2) <sup>q</sup>   | 27 (17.5) <sup>r</sup>   | 23 (46.0)  | 27 (22.9) <sup>u</sup>   |
| 209 (48.5)                | 44 (45.4)  | 66 (42.3)  | 31 (62.0)  | 68 (53.1)  |
|                           |  |  |  |  |
| 92 (21.4%)                | 24 (24.7)  | 31 (19.9)  | 9 (18.0)   | 28 (21.9)  |
| 3 (0.7)                   | 0 (0.0)  | 3 (1.9)  | 0 (0.0)  | 0 (0.0)  |
| Patient-reported outcomes |  |  |  |  |
| 2.5 (2.9)°                | $2.9 (3.0)^d$  | 2.6 (3.0)  | $2.7 (3.2)^{f}$  | $2.1 (2.5)^{i}$  |
|                           |  |  |  |  |
| 43.5 (8.7)                | 42.3 (8.5)   | 44.5 (9.1)   | 43.1 (8.9)   | 43.4 (8.0)   |
|                           |  |  |  |  |
| $13.0 (4.8)^{j}$          | 13.1 (5.3)   | 12.7 (5.0) <sup>e</sup>  | 13.2 (4.1)   | 13.2 (4.3)   |
|                           |  |  |  |  |
| 52.7 (10.4)               | 54.3 (10.8)  | 53.7 (10.8)  | 53.4 (9.9)   | 50.0 (9.5)   |
|                           |  |  |  |  |
| 27.4 (9.7)                | 29.0 (10.2)  | 26.0 (9.2)   | 30.0 (7.8)   | 26.8 (10.2)  |
|                           |  |  |  |  |
|                           | 170 (39.7)<br>147 (35.3) <sup>p</sup><br>99 (24.0) <sup>t</sup><br>209 (48.5)<br>92 (21.4%)<br>3 (0.7)<br>2.5 (2.9) <sup>c</sup><br>43.5 (8.7)<br>13.0 (4.8) <sup>j</sup><br>52.7 (10.4) | 170 (39.7) 38 (40.0) 147 (35.3) <sup>p</sup> 28 (30.8) <sup>q</sup> 99 (24.0) <sup>t</sup> 22 (24.2) <sup>q</sup> 209 (48.5) 44 (45.4)  92 (21.4%) 24 (24.7) 3 (0.7) 0 (0.0)  2.5 (2.9) <sup>c</sup> 2.9 (3.0) <sup>d</sup> 43.5 (8.7) 42.3 (8.5)  13.0 (4.8) <sup>j</sup> 13.1 (5.3)  52.7 (10.4) 54.3 (10.8) | $170 (39.7)$ $38 (40.0)$ $56 (35.9)$ $147 (35.3)^p$ $28 (30.8)^q$ $56 (36.4)^r$ $99 (24.0)^t$ $22 (24.2)^q$ $27 (17.5)^r$ $209 (48.5)$ $44 (45.4)$ $66 (42.3)$ $92 (21.4\%)$ $24 (24.7)$ $31 (19.9)$ $3 (0.7)$ $0 (0.0)$ $3 (1.9)$ $2.5 (2.9)^c$ $2.9 (3.0)^d$ $2.6 (3.0)$ $43.5 (8.7)$ $42.3 (8.5)$ $44.5 (9.1)$ $13.0 (4.8)^j$ $13.1 (5.3)$ $12.7 (5.0)^e$ $52.7 (10.4)$ $54.3 (10.8)$ $53.7 (10.8)$ | $170 (39.7)$ $38 (40.0)$ $56 (35.9)$ $16 (32.7)$ $147 (35.3)^p$ $28 (30.8)^q$ $56 (36.4)^r$ $14 (28.6)^f$ $99 (24.0)^t$ $22 (24.2)^q$ $27 (17.5)^r$ $23 (46.0)$ $209 (48.5)$ $44 (45.4)$ $66 (42.3)$ $31 (62.0)$ $92 (21.4\%)$ $24 (24.7)$ $31 (19.9)$ $9 (18.0)$ $3 (0.7)$ $0 (0.0)$ $3 (1.9)$ $0 (0.0)$ $2.5 (2.9)^c$ $2.9 (3.0)^d$ $2.6 (3.0)$ $2.7 (3.2)^f$ $43.5 (8.7)$ $42.3 (8.5)$ $44.5 (9.1)$ $43.1 (8.9)$ $13.0 (4.8)^j$ $13.1 (5.3)$ $12.7 (5.0)^c$ $13.2 (4.1)$ $52.7 (10.4)$ $54.3 (10.8)$ $53.7 (10.8)$ $53.4 (9.9)$ |

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<sup>&</sup>lt;sup>a</sup>Results are presented in mean (SD).
<sup>b</sup>Results are presented in numbers (percentage).
<sup>c</sup>N=428, <sup>d</sup>N=96, <sup>e</sup>N=155, <sup>f</sup>N=49, <sup>g</sup>N=427, <sup>h</sup>N=153, <sup>i</sup>N=127, <sup>j</sup>N=430, <sup>k</sup>Because N underweight = 24, underweight and normal were combined, <sup>l</sup>N=418, <sup>m</sup>N=95,

<sup>&</sup>lt;sup>n</sup>N=44, <sup>o</sup>N=124, <sup>p</sup>N=417, <sup>q</sup>N=91, <sup>r</sup>N=154, <sup>s</sup>N=123, <sup>t</sup>N=413, <sup>u</sup>N=118.

SD: standard deviation.

Table 2. Regression Analysis of Factors Associated with the Fears due to COVID-19

| Variable                                      | Crude Regression         | Adjusted Regression Coefficient <sup>a</sup> (95% Confidence Interval) |                     |  |  |
|---|--------------------------|--|---------------------|--|--|
|   | Coefficient <sup>a</sup> |  |                     |  |  |
|   | (95% Confidence          |  |                     |  |  |
|   | Interval)                |  |                     |  |  |
|   |                          | Regression   | Standardized        |  |  |
|   |                          | Coefficient  | Coefficient         |  |  |
| Sociodemographic                              |                          |  |                     |  |  |
| Age in years (continuous)                     | -0.02 (-0.10, 0.05)      | 0.01 (-0.07, 0.08)   | 0.01 (-0.07, 0.08)  |  |  |
| Male sex (reference = female)                 | -1.14 (-4.00, 1.72)      | -1.50 (-4.22, 1.22)  | -0.05 (-0.14, 0.04) |  |  |
| Education in years (continuous)               | -0.03 (-0.28, 0.21)      | 0.14 (-0.09, 0.38)   | 0.06 (-0.04, 0.16)  |  |  |
| Living alone (reference = living with others) | -1.72 (-4.07, 0.63)      | -1.59 (-3.72, 0.54)  | -0.06 (-0.14, 0.02) |  |  |
| "Other" Race or ethnicity (reference = White) | 0.92 (-1.51, 3.35)       | -0.49 (-2.75, 1.78)  | -0.02 (-0.11, 0.07) |  |  |
| Working part- or full-time                    | -2.93 (-4.75, -1.10)     | -1.75 (-3.51, 0.17)  | -0.09 (-0.18, 0.01) |  |  |
| (reference = not working)                     |                          |  |                     |  |  |
| Country (reference = France)                  |                          |  |                     |  |  |
| Canada  | 2.94 (0.50, 5.38)        | 2.21 (-0.08, 4.49)   | 0.10 (0.00, 0.20)   |  |  |
| United States                                 | 0.77 (-1.48, 3.03)       | 1.22 (-0.96, 3.39)   | 0.06 (-0.05, 0.17)  |  |  |
| United Kingdom                                | 4.05 (0.99, 7.12)        | 3.75 (0.86, 6.64)  | 0.12 (0.03, 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)  |  |  |
| Obese   | 2.90 (0.34, 5.46)        | 0.69 (-1.75, 3.12)   | 0.03 (-0.08, 0.14)  |  |  |
| Time since diagnosis of SSc (continuous)      | 0.04 (-0.08, 0.16)       | 0.08 (-0.04, 0.19)   | 0.06 (-0.03, 0.14)  |  |  |
| Diffuse disease subtype                       | 1.57 (-0.30, 3.44)       | 0.59 (-1.24, 2.42)   | 0.03 (-0.06, 0.12)  |  |  |
| (reference = limited or sine)                 |                          |  |                     |  |  |

| Presence of interstitial lung disease        | 1.69 (-0.25, 3.64)   | 0.76 (-1.19, 2.71)   | 0.04 (-0.06, 0.14)   |  |  |
|--|----------------------|----------------------|----------------------|--|--|
| (reference = no)                             |                      |                      |                      |  |  |
| Presence of any overlap syndrome             | 1.12 (-1.10, 3.34)   | -0.80 (-2.90, 1.31)  | -0.04 (-0.15, 0.07)  |  |  |
| (reference = no)                             |                      |                      |                      |  |  |
| Immunosuppressant drug use (reference = no)  | 2.80 (-0.99, 4.62)   | 1.38 (-0.51, 3.27)   | 0.07 (-0.03, 0.17)   |  |  |
| Pre-COVID-19 use of mental health services   | 1.26 (-0.98, 3.49)   | -1.06 (-3.20, 1.08)  | -0.04 (-0.12, 0.04)  |  |  |
| (reference = no)                             |                      |                      |                      |  |  |
| Interference from breathing problems         | 1.01 (0.71, 1.32)    | 0.40 (0.04, 0.76)    | 0.12 (0.01, 0.23)    |  |  |
| (continuous)                                 |                      |                      |                      |  |  |
| PROMIS Physical Function pre-COVID           | -0.38 (-0.48, -0.28) | -0.10 (-0.23, 0.02)  | -0.09 (-0.21, 0.02)  |  |  |
| (continuous)                                 |                      |                      |                      |  |  |
| 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) |  |  |
| Control variable:                            |                      |                      |                      |  |  |
| PROMIS Anxiety 4a v1.0 pre-COVID             | 0.34 (0.26, 0.42)    | 0.21 (0.11, 0.31)    | 0.23 (0.12, 0.34)    |  |  |
| (continuous)                                 |                      |                      |                      |  |  |

<sup>&</sup>lt;sup>a</sup>Results based on imputed datasets. Based on assessment using via restricted cubic splines, there was no appreciable non-linearity.