Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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Protocol for a partially nested randomised controlled trial to evaluate the effectiveness of the scleroderma patient-centered intervention network COVID-19 home-isolation activities together (SPIN-CHAT) program to reduce anxiety among at-risk scleroderma patients

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ABSTRACT

Objective: Contagious disease outbreaks and related restrictions can lead to negative psychological outcomes, particularly in vulnerable populations at risk due to pre-existing medical conditions. No randomised controlled trials (RCTs) have tested interventions to reduce mental health consequences of contagious disease outbreaks. The primary objective of the Scleroderma Patient-centered Intervention Network COVID-19 Home-isolation Activities Together (SPIN-CHAT) Trial is to evaluate the effect of a videoconference-based program on symptoms of anxiety. Secondary objectives include evaluating effects on symptoms of depression, stress, loneliness, boredom, physical activity, and social interaction.

Methods: The SPIN-CHAT Trial is a pragmatic RCT that will be conducted using the SPIN-COVID-19 Cohort, a sub-cohort of the SPIN Cohort. Eligible participants will be SPIN-COVID-19 Cohort participants without a positive COVID-19 test, with at least mild anxiety (PROMIS Anxiety 4a v1.0 T-score $\geq$ 55), not working from home, and not receiving current counselling or psychotherapy. We will randomly assign 162 participants to intervention groups of 7 to 10 participants each or waitlist control. We will use a partially nested RCT design to reflect dependence between individuals in training groups but not in the waitlist control. The SPIN-CHAT Program includes activity engagement, education on strategies to support mental health, and mutual participant support. Intervention participants will receive the 4-week (3 sessions per week) SPIN-CHAT Program via videoconference. The primary outcome is PROMIS Anxiety 4a score immediately post-intervention.

Ethics and dissemination: The SPIN-CHAT Trial will test whether a brief videoconference-based intervention will improve mental health outcomes among at-risk individuals during contagious disease outbreak.

Trial registration

clinicaltrials.govNCT04335279; registered on April 1, 2020.

1. Introduction

Social distancing and movement restrictions during contagious disease outbreaks are necessary to reduce spread but can lead to negative social and psychological outcomes, including loneliness, depression, and anxiety, particularly in vulnerable populations [1–4]. An online survey that used snowball sampling techniques and collected data from 1210 respondents from 194 cities in China in January–February 2020 found that over 50% rated the psychological impact of the coronavirus disease 2019 (COVID-19) outbreak as moderate or severe. Symptoms of anxiety were rated as the most common psychological problem. Self-reported poor physical health status and the presence of a chronic illness were associated with symptoms of depression and anxiety [4].

A recent "rapid review" of evidence published in February 2020 identified 24 studies that examined the psychological impact of quarantine on participants who had been quarantined during outbreaks of severe acute respiratory syndrome (SARS) in China, Hong Kong, and Canada in 2003, equine influenza in Australia in 2007, H1N1 influenza in Australia in 2009, Ebola in West Africa in 2014, and Middle East Respiratory Syndrome (MERS) in Korea in 2015. Compared to COVID-19, these outbreaks were much more limited in scope. Pre-quarantine characteristics associated with less favourable psychological status among adults under quarantine included history of mental illness, young age, less education, female sex, and number of children, although results were not consistent across studies. Factors during quarantine associated with worse outcomes included the duration of quarantine, access to supplies and information, financial resources, fear of infection and complications, degree of social isolation, and boredom [2]. No randomised controlled trial (RCT), however, has tested an intervention to improve mental health symptoms from quarantine [1–3].

Systemic sclerosis (SSc; scleroderma) is a rare, chronic, autoimmune disease characterized by vasculopathy and excessive collagen production [5–7]. Onset typically occurs between the ages of 30 and 50 years, and approximately 80% of people with SSc are women [7]. SSc can affect multiple organ systems, including the skin, lungs, gastrointestinal tract, and heart. Common manifestations include Raynaud's phenomenon, skin thickening, dyspnea and cough, gastroesophageal reflux and other gastrointestinal symptoms [5–7]. Disease presentation is extremely heterogeneous, and the course of the disease is highly unpredictable [5–7]. People with SSc commonly experience diminished hand function and mobility limitations, pain, fatigue, sleep problems, pruritus, symptoms of depression, and body image distress from disfiguring aspects (e.g., skin tightening, pigment changes, hand contractures, telangiectasias) [8–13]. Many people with SSc are at risk of serious complications from COVID-19 if infected due to lung involvement (>40% have interstitial lung disease) [14] and common use of immunosuppressant drugs [15]. Although recommendations differ across the world, most countries have advised that people with pre-existing medical conditions, such as SSc, engage in strict isolation during the COVID-19 outbreak.

Mental health outcomes, including anxiety, among people in quarantine are associated with modifiable factors such as degree of isolation, boredom, and ability to manage worry and anxiety [2]. In addition to psychological strategies, including worry reduction and meditative exercises [16,17], exercise has been shown to reduce anxiety [18,19]. Among older adults, where isolation is a common challenge, activity and social engagement are commonly used to address loneliness and feelings of isolation and increase social participation [20,21]. Recommendations for the World Health Organization and major national public health organizations for managing mental health during the COVID-19 pandemic emphasize setting and following a routine, managing information sources and quantity, staying connected with others, and finding a way to be physically active [22–24].

The Scleroderma Patient-centered Intervention Network (SPIN) [25,26] COVID-19 Home-isolation Activities Together (SPIN-CHAT) Program is a 4-week (3 sessions per week) group videoconference-based intervention designed to improve symptoms of anxiety and other mental health outcomes among individuals with SSc at risk of poor mental health during the COVID-19 pandemic. The primary objective of the SPIN-CHAT Trial is to evaluate the effect of the program compared to waitlist control on Patient-Reported Outcomes Measurement Information System (PROMIS) Anxiety 4a v1.0 [27–29] scores immediately post-intervention among people with SSc with at least mild anxiety (baseline T-score ≥ 55). Secondary objectives are to evaluate the program's effects post-intervention on symptoms of depression stress, loneliness, boredom, physical activity, and frequency of social interactions.

2. Methods and analysis

The SPIN-CHAT Trial is a pragmatic, two-arm partially nested RCT (PN-RCT) [30,31] that will be conducted using the SPIN-COVID-19 Cohort. Pragmatic RCTs are conducted to replicate real-world delivery of interventions as much as possible and support decisions on whether interventions should be provided in practice [32–34]. The trial will be a PN-RCT because participants randomised to the intervention arm will be clustered into intervention groups, and members of each intervention group will interact during videoconference sessions; participants randomly assigned to the waitlist control will not be clustered and will only complete trial measures. The reason that we will use a waitlist control arm and provide the program to people in this arm post-trial is that our patient organization partners are invested in providing access, and this is important for them to support the trial. It may also increase willingness to enrol in the trial by potential participants.

The trial has been registered (clinicaltrials.gov, NCT04335279), and the protocol follows recommendations for reporting from the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) 2013 Statement [35]. Results will be reported in accordance with standards described in the Consolidated Standard of Reporting Trials (CONSORT) statement [36] and CONSORT extensions for non-pharmacologic trials [37], cluster trials [38], pragmatic trials [32], and the draft extension for RCTs conducted using cohorts and routinely collected health data, which is forthcoming [39].

2.1. SPIN-COVID-19 cohort participants

SPIN is a collaboration of SSc researchers, health care providers, people living with SSc, and patient organizations from Canada, the United States, Europe, Mexico and Australia that has assembled a large multinational patient cohort to collect longitudinal data on patient-reported outcomes in SSc and as a framework for embedding RCTs of e-health interventions. To be eligible for the SPIN Cohort, patients must be classified as having SSc based on 2013 American College of Rheumatology/European League Against Rheumatism criteria [40], confirmed by a SPIN physician; be ≥18 years old; be able to give informed consent; be fluent in English, French, or Spanish; and be able to respond to questionnaires via the internet. The SPIN Cohort is a convenience sample. Eligible SPIN Cohort patients are recruited at SPIN sites [41] during regular medical visits, and written informed consent is obtained. A medical data form is submitted online by site personnel to enrol participants. After completion of online registration, an automated welcoming email is sent to participants with instructions for activating their SPIN account and completing SPIN Cohort measures online. SPIN Cohort participants complete online assessments upon enrolment and at 3-month intervals. To date, over 2000 SSc patients from 47 centres have been enrolled in SPIN's web-based cohort (currently approximately 1800 active participants) [41]. Upon enrolment in

the SPIN Cohort, all participants have consented to be contacted about SPIN sub-studies.

SPIN Cohort participants who complete measures in English or French will be invited by email and by popups during visits to the SPIN Cohort online assessment portal to enrol in the SPIN-COVID-19 Cohort, a sub-cohort of the SPIN Cohort. Additionally, recruitment announcements for the SPIN-COVID-19 Cohort will be posted on SPIN's Facebook page and Twitter account and distributed for posting via SPIN's patient organization partners in countries with large English and French-speaking populations, including Canada, the United States, France, the United Kingdom, Australia, New Zealand, and the Philippines. Recruitment announcements for the SPIN-COVID-19 Cohort will direct potential participants to an online *Qualtrics* web page where they will be provided with information about the SPIN-COVID-19 Cohort and have the opportunity to consent to participate or decline. SPIN Cohort participants who consent to participate will provide their SPIN username (email address linked with their SPIN account) to link to SPIN Cohort demographic and medical data.

Potential participants who are not SPIN Cohort participants will be asked to confirm that they are ≥18 years old, have been classified as having SSc by a physician, and are fluent in English or French. Eligible participants will be directed to set up a SPIN-COVID-19 Cohort user account and will provide basic demographic and disease-related information. All SPIN-COVID-19 Cohort participants will be invited to complete measures at baseline and every two weeks for the duration of the COVID-19 pandemic. They will receive email reminders to complete bi-weekly follow-up assessments.

Recruitment material for the SPIN-COVID-19 Cohort will state that a lottery will be held as an incentive. Three SPIN-COVID-19 participants who complete all scheduled assessments will be randomly selected to win a free trip to a SSc patient congress in 2021. This type of incentive has been used successfully in previous SPIN sub-studies [42].

2.2. SPIN-CHAT trial participants

SPIN-COVID-19 Cohort participants will be eligible for the SPIN-CHAT Trial if they (1) have a PROMIS Anxiety 4a v1.0 [18–20] T-score ≥ 55; (2) do not report that they have had a positive test for the COVID-19 virus; and (3) report that they are not currently receiving mental health services, such as counselling or psychotherapy, during the COVID-19 outbreak. People receiving these services during the outbreak will be excluded because they would potentially receive similar coping support and strategies from those services as those provided via the SPIN-CHAT Program. Cohort participants who were receiving these services at any time prior to the COVID-19 outbreak will be eligible for the trial if they are not currently accessing the services. Participants who are taking medications for a psychiatric disorder or symptoms will be eligible if they meet all other eligibility criteria. Participants will be eligible for enrolment if they meet eligibility criteria at any assessment, for the duration of trial enrolment. Consistent with the pragmatic nature of the trial, no additional exclusions will be applied.

2.3. Recruitment and enrolment

Participants eligible for the SPIN-CHAT Trial will be provided with a brief description of the trial in the SPIN-COVID-19 *Qualtrics* platform immediately after completing their Cohort measures and will be asked if they would be interested in participating in the trial. Those who express interest will be provided with an online version of the trial consent form, which they can also download, and will be given the options of (1) consenting to participate; (2) declining participation; or (3) requesting that a member of SPIN's research team call them to answer questions they have about participating in the trial before consenting. Unless participants decline participation, they will be asked to

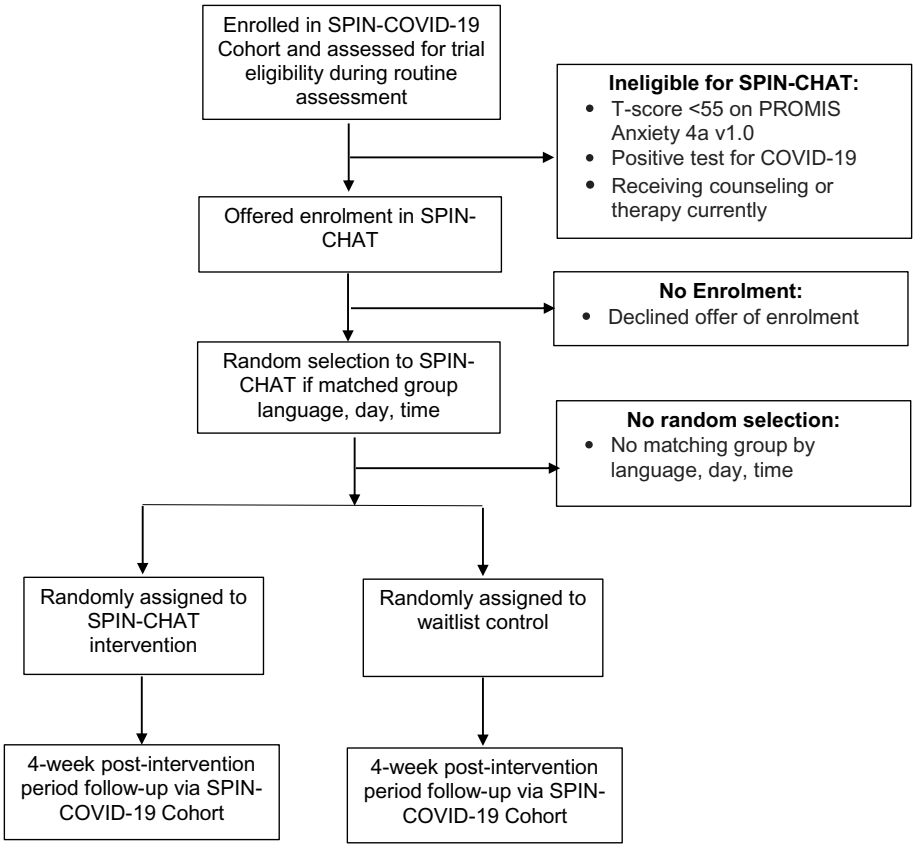

Fig. 1. SPIN Cohort, SPIN-COVID-19 Cohort, and SPIN-CHAT Trial Flow Diagram.

provide information on days and times of day when they could take part in videoconference sessions and their language preferences for sessions, including (1) only English; (2) only French; (3) either English or French; (4) preferably English, but comfortable in French; or (5) preferably French but comfortable in English.

In addition to describing the study, the consent form will explain (1) that eligible participants who enrol will be randomly selected on a rolling basis to be included in the trial whenever there are enough participants enrolled to form additional intervention groups on particular days and times in English or French; (2) that those randomly selected will be randomly assigned to an intervention group or to the waitlist with a 1:1 allocation ratio; (3) that participants randomised to the SPIN-CHAT Program plus those allocated to the waitlist will complete measures online every two weeks as they would anyway as SPIN-COVID-19 Cohort participants; (4) that, depending on the number of participants who enrol with availabilities based on language, days, and times, it is possible that some enrolled participants will not be randomised; and (5) that, enrolled participants who do not receive the intervention as part of the trial, either because they are selected for the waitlist or because they are not selected for the program or the waitlist, will be offered the program post-trial if still relevent, pending development of the COVID-19 situation. A member of the SPIN research team will call all potential participants to confirm eligibility, day and time availability, and desire to participate in the trial, prior to completing enrolment.

2.4. Random selection and allocation

SPIN-COVID-19 Cohort participants who provide consent for participation will be entered into different pools based on their availabilities and taking into consideration time zone differences. Fig. 1 illustrates the flow of participants into the trial, and Fig. 2 the schedule of enrolment, interventions, and assessments. Once there are enough participants to complete an intervention group and assign an equal number of participants to waitlist control, a third-party randomisation service will randomly select eligible participants and randomly assign selected participants to the intervention group or waitlist control. This process will be repeated until trial enrolment is complete.

	Enrolment	Allocation	Post-allocation	Post-Trial
TIMEPOINT	**Pre-intervention**	**0**	**Post-intervention (4 weeks)**	**After all intervention group complete**
Enrolment:				
Eligibility screen	X			
Informed consent	X			
Participant availabilities	X			
Selection and Allocation		X		
SPIN-CHAT Program (Intervention):				
Intervention group			X	
Waitlist control group				X
Trial Assessments:				
Demographics	X			
Anxiety symptoms (PROMIS Anxiety 4a v1.0)	X		X	
Depressive symptoms (PHQ-8)	X		X	
Stress (PSS)	X		X	
Loneliness (ULS-6)	X		X	
Boredom (MSBS-8)	X		X	
Physical Activity (IPAQ-E)	X		X	
Social Contacts	X		X	

Fig. 2. Schedule of enrolment, interventions and assessments.

SPIN personnel will provide the external service with an anonymised list of participants (only ID numbers will be provided) who could participate in an intervention group based on language and day and time availabilities. The number of people who could participate in a group will depend on language preferences (English or French) and day and time availabilities among all enrolled participants. Thus, for each block of participants with common availability, the service will randomly select between 14 and 20 participants from the pool of enrolled participants available based on language, day, and time and will randomly allocate half (7 to 10 participants) to the intervention group and half (7 to 10 participants) to the waitlist group using block randomisation.

All participants who are randomised will receive an email to communicate their assignment to the SPIN-CHAT Program or waitlist control. A second email will be sent to those allocated to the intervention arm with the date and time of their first group session and information on how to login to the videoconferencing system and online chatroom.

2.5. Blinding and protecting against sources of bias

A potential concern is that participants and the research team members will not be blinded to intervention status. In most pragmatic trials of education and psychological interventions, including the SPIN-CHAT Trial, participants cannot be blinded. This is understood as part of the response to being offered a treatment, similar to what occurs in clinical practice [32,34]. A second concern relates to the potential for contamination if participants randomised to the SPIN-CHAT Program share program material with participants in the waitlist control. To attempt to minimize the influence of possible contamination, we will explain this concern to participants in the intervention arm of the trial and ask them not to share material or discuss the sessions with others outside of their intervention group during the trial.

2.6. Intervention and comparator

The SPIN-CHAT Program is a brief group videoconference intervention that was developed based on best-practice principles for managing anxiety and worry [16,17], recommendations for maintaining mental health during COVID-19 [22–24], and input from the SPIN COVID-19 Patient Advisory Team. The intervention will be delivered 3 times per week for 4 weeks during the COVID-19 crisis in 60- to 90-min sessions. Each session will include 3 segments: (1) engagement via therapeutic recreation activities (20–30 min); (2) education on information management and anxiety management through psychological and other strategies (20–30 min); and (3) open discussion and social support (20–30 min). Each intervention group will be moderated by a member of the research team or by leaders who have been trained in our SPIN support group leader training program [43,44]. The moderators will support participants to develop routines during the COVID-19 crisis and to integrate educational material into those routines and will moderate group discussions. Supervision and support of group moderators will be provided by a trained social worker with 28 years of total experience and over ten years of experience working with the SSc community. Educational segments in each session will be delivered by a research team member with experience and training related to the topic.

Leisure activities that will be done at the start of each session will include games (e.g., Pictionary, charades, pub-style trivia), creative activities (e.g., roll-a-story, where participants roll a dice and take turns adding a sentence to a story; home scavenger hunt), cultural activities (e.g., virtual museum tours, name that tune), social activities (e.g., share your favourite recipe, share travel experiences, bingo with card created with activities the participants have used to stay active during the pandemic).

There will be an initial program overview in the first session. Then, educational segment topics will include (1) healthy information management and social connection (session 2); (2) managing worry (sessions 3, 7, 11); (3) relaxation strategies (sessions 4 and 8); (4) adapted home exercise (sessions 5, 9, 12); and (5) activity engagement at home (sessions 6 and 10). All educational segments will be supported by resource materials available to participants via an online SPIN-CHAT resource link.

In the healthy information management and social connection segment, strategies will be provided and discussion will be faciliated on how to stay informed via accurate information sources while avoiding sensationalist and other non-helpful information [45]. Information on using simple (e.g., phone) or more advanced technology (e.g., group videoconferencing) to stay connected will be discussed, along with strategies for connecting regularly with others.

The managing worry segments will include an overview of worry, including what it is, the difference between helpful and harmful anxiety or worry, how to identify triggers of worry, and strategies to manage worry, including identifying different types of worrying, using worry journals, worry postponement, and worry time [46,47]. Exercises will be done with the group to illustrate techniques. In the relaxation segments, an introduction to the purpose of relaxation techniques will be presented, and participants will be guided through brief breathing, mindfulness, and visualization exercises [48,49]. Adaptations for participants with breathing or positioning limitations will be made.

The physical activity segments will include an overview of the physical and psychosocial benefits of physical activity for maintenance of health for chronic disease management [50,51], including mental health during the COVID-19 pandemic; movement guidelines to ensure safety; and how to monitor daily physical activity. Participants will be guided through movement options for the home-based setting, including warm-ups, aerobic, and strength activities. Behaviour change techniques to foster building the habit of moving more at home will be taught, including goal-setting, scheduling, addressing barriers, and building social support [52–55].

Activity engagement sessions will be guided by the leisure education content model [56]. Sessions will involve interactive group discussion about the benefits of leisure engagement [57] for persons with SSc, addressing physical, social, emotional, intellectual and spiritual realms of health and wellbeing. Sessions will explore barriers to leisure for persons with SSc and include tips for finding leisure resources within the participants' own homes, both in-person and online.

Based on our previous experience [43,44] and consistent with previous trials of videoconference training [58,59], 8 participants will be assigned to each training group to maximize effective interaction and participation. Sessions will be delivered using the GoToMeeting® videoconferencing platform, a high-performance platform that has been used successfully in similar applications [60,61] and in feasibility and full-scale trials of SPIN's support group leader training program [43,44].

All group sessions will be video-recorded and audited to ensure adherence to the program by two members of the research team. We will use standard methods for evaluating intervention fidelity, including observation of entire sessions for a randomly selected sample of 25% of sessions. Members of the research team will evaluate adherence to each session's goals and content. Consistent with best-practice recommendations for assessing treatment fidelity [62], this will be done using a checklist based on a standardized format adapted for the specific components of the SPIN-CHAT Program. The checklist will include the main session components (engagement via therapeutic recreation activities; education on information management and anxiety management through psychological and other strategies; open discussion and social support), and, for the educational component, will include the specific topics to be covered in each session.

Participants may choose to discontinue their participation in the sessions at any time. We do not envision the need to modify the intervention or intervention assignment for any participants or to discontinue their participation in the program. However, if acute mental

health concerns are disclosed to group moderators or other study personnel or if group moderators identify reasons to be concerned, these will be discussed immediately with the supervisor of group moderators and trial leadership. As appropriate, recommendations will then be made to participants to obtain support, and trial participation may be ended.

Participants assigned to the waitlist will receive notices and reminders to complete trial measures as part of the SPIN-COVID-19 Cohort. They will be contacted with information on intervention groups post-trial.

2.7. Trial outcomes

The primary outcome analysis will compare PROMIS Anxiety 4a v1.0 scores between participants randomly assigned to the SPIN-CHAT Program versus the waitlist control at the end of the 4-week intervention period. The 4 items of the scale ask 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 on a 5-point scale (range 1–5), and response options include "never", "rarely", "sometimes", "often", and "always". Higher scores represent more anxiety. Total raw scores range from 4 to 20 and are obtained by summing item scores for each domain. Raw scores are converted into T-scores standardized from the general US population (mean = 50, standard deviation = 10). PROMIS Anxiety 4a v1.0 has been validated in SSc [63,64]. PROMIS Anxiety 4a v1.0 domain scores have been shown to be sensitive to change, and minimally important differences have been estimated to be between 2.3 and 3.4 T-score points [65–68]. The 4-item PROMIS Anxiety 4a v1.0 score has been found to be highly correlated ($r = 0.93$) with the 8-item version [65]. The scale is available in English and French [64].

Secondary outcomes include symptoms of depression, measured with the Patient Health Questionnaire-8 (PHQ-8) [69]; stress, measured with the Perceived Stress Scale (PSS) [70]; loneliness, measured with the 6-item version of the UCLA Loneliness Scale (ULS-6) [71]: boredom, measured with the 8-item version of the Multidimensional State Boredom Scale (MSBS-8) [72]; physical activity, measured with the International Physical Activity Questionnaire – modified for the elderly (IPAQ-E) [73]; and frequency of social interactions, evaluated with purposely designed items.

2.7.1. Depression symptoms (PHQ-8) [69]

PHQ-8 items measure depressive symptoms over the last 2 weeks on a 4-point scale, ranging from 0 (not at all) to 3 (nearly every day) with higher scores (range 0 to 24) indicating more depressive symptoms. The PHQ-8 performs equivalently to the PHQ-9 [74], which is a valid measure of depressive symptoms in patients with SSc [75]. The PHQ-8 is available in French and English [76].

2.7.2. Stress (PSS) [70]

The 10-item PSS measures the degree that respondents appraise their lives as stressful; items are designed to reflect the degree that they find their life circumstances in the last 4 weeks to be unpredictable, uncontrollable, or overloaded. Items are scored on a 5-point scale from 0 (never) to 4 (very often). Total scores (range 0 to 40) are computed by summing individual items scores, and higher scores reflect greater perceived stress. The PSS has been validated in many medical and non-medical populations [77], including in French [78].

2.7.3. Loneliness (ULS-6) [71]

The 6-item ULS-6 is a short version of the 20-item ULS, which is designed to assess subjective feelings of loneliness and social isolation [71]. Respondents indicate the degree to which feelings described in each item apply to them. Items are scored on a 4-point scale from 0 (never) to 3 (often); total scores range from 0 to 18. The correlation of the ULS-6 with longer versions of the ULS was 0.87 in adolescents and 0.92 among older adults [71,79]. The ULS-6 items were obtained from a French version of the full ULS [80].

2.7.4. Boredom (MSBS-8) [72]

The full MSBS [81] is a 29-item measure of state boredom with items on five factors that load onto a single higher-order factor [72]. The 8-item MSBS is a short version with scores that correlate very closely to scores from the full MSBS ($r = 0.96$) [82]. Item responses are on a 7-point Likert-type scale from 1 (strongly disagree) to 7 (strongly agree) and assess the degree to which each item reflects the respondant's experience currently. Total scores range from 8 to 56 with higher scores reflecting greater boredom. The MSBS-8 was translated into French by the SPIN Team using a well-accepted forward-backward translation method [83].

2.7.5. Physical activity (IPAQ-E) [73]

The 4-item IPAQ-E is a short-form version of the full IPAQ [84] designed to assess physical activity over the last week, including time spent sitting, walking, and in moderate and vigorous physical activity [73]. Compared to other short-form versions of the IPAQ, the IPAQ-E has examples of exercise specific to older adults. The full IPAQ has excellent reliability and moderate validity across many different countries [84], and the IPAQ-E has similar validity [73] The IPAQ is available in English and French [85].

2.7.6. Frequency of social interactions

Frequency of social interactions with others inside and outside of the home will be measured with 4 separate items, including (1) "On a typical day in the last week, how many times did you have a social conversation over the phone or a videoconferencing platform with one person?" (response = number of times); (2) "On a typical day in the last week, how many times did you have a social conversation over a videoconferencing platform with multiple people at the same time?" (response = number of times; not including SPIN-CHAT sessions); (3) "On a typical day in the last week, how long did you spend enjoying conversations with other individuals in the home?" (response = time); (4) "On a typical day in the last week, how long did you spend enjoying activities with other individuals in the home?" (response = time). Items (3) and (4) will only be displayed to participants who live with at least another person in their household.

2.7.7. Adverse effects

Adverse effects will be assessed by ongoing monitoring during the trial and by asking participants post-intervention to describe any adverse experiences or outcomes that may have occurred.

2.8. Sample size

Effects of short anxiety-focused interventions in post-disaster settings are between 0.40 and 0.80 standardized mean difference (SMD) [86,87]. This is larger than estimated minimally important difference for the PROMIS Anxiety 4a v1.0 score (SMD = 0.23 to 0.34 SMD) [65–68]. For an assumed effect size of SMD = 0.50, a two-tailed test with $\alpha = 0.05$, and an intra-class correlation coefficient (ICC) of 0.05, $N = 146$ provides $\geq 80\%$ power for our primary outcome, PROMIS Anxiety 4a v1.0; assuming 10% dropout would require recruitment of at least 162 participants (81 in 10 SPIN-CHAT groups; 81 in the waitlist). If a greater loss to follow-up is assumed (30%), recruitment of 195 participants would be required. Thus, we will target a minimum of 162 participants but will recruit additional participants, if possible, in case of greater loss to follow up.

This may be a conservative power and sample size estimate. First, in cluster RCTs, ICC values for individual patient outcomes are typically lower than our 0.05 estimate [88–90]. If the true ICC is lower than our 0.05 estimate, this will result in greater power than estimated. Second, there has been no loss to follow-up in the feasibility trial or initial

waves of our full-scale trial of the videoconference-based SPIN support group leader program [43,44], which has a similar design. Thus, our estimated 10% to 30% loss to follow-up may be conservative.

2.9. Data collection and management

Questionnaires for the SPIN-COVID-19 Cohort, including outcome measures for the SPIN-CHAT Trial (baseline, post-intervention), will be completed using the online surveying tool *Qualtrics*. This method has been used in the SPIN support group leader training program feasibility and full-scale trials [43,44].

Two-week data collection periods in the SPIN-COVID-19 Cohort will be marked from the date of the baseline assessment. We will attempt to collect data between 3 days prior to each two-week target and 3 days after the target date. To do this, email reminders to participants to encourage them to complete cohort assessments will be sent 3 days prior to the target date and on the target date. The day that participants in the SPIN-CHAT begin the intervention (or would have begun the intervention if assigned to waitlist) will not necessarily match the target data collection date. Thus, for trial outcome measures, we will prioritize the first assessment in the 14 days starting on the day of the last group session for participants in intervention groups and corresponding waitlist participants. If not available, as a second option, we will use an assessment done in the 7 days prior to the last group session. Finally, as a third option, we will use an assessment done 14 to 21 days after the last group session. If none of these are available, trial outcome data will be declared missing.

Limits on eligible values that can be entered will be set to reduce erroneous entries. Data for SPIN Cohort participants will be linked to SPIN Cohort demographic and medical data via the email that is used to login to both the SPIN Cohort and SPIN-COVID-19 Cohort platforms. To ensure accuracy, we have embedded a check into the *Qualtrics* survey tool to ensure that emails entered by SPIN Cohort participants match their SPIN Cohort platform login. Once online survey data is collected, data will be exported to the statistics software program STATA. Checking and cleaning of the data will occur within SPSS and be done by members of the study team. All information obtained about the participants during this study will be treated confidentially within the limits of the law. To protect the participants' privacy, upon inclusion in the SPIN-CHAT Trial, a unique participant identification number will automatically be assigned to each participant. An encrypted database will be created, which will include the participant identification number and name. Data security measures in place at Qualtrics are described in the Qualtrics security statement [91]. Information obtained from the survey and video recordings of the training sessions used to evaluate fidelity to program will be kept for 10 years on encrypted hard drives. During the trial, access to the data will be limited to the study investigators. Once trial results are reported, de-identified data will be made available upon reasonable request. No biological specimens will be collected.

2.10. Data analysis

Analyses will be conducted by a statistician blind to trial arm allocation. For the primary outcome analysis (PROMIS Anxiety 4a v1.0), we will use an intent-to-treat analysis that compares all patients randomly assigned to the SPIN-CHAT Program to all patients assigned to the waitlist control. The intervention effect at 4 weeks will be estimated using a linear mixed model, adjusted for baseline PROMIS Anxiety 4a v1.0 scores. The model will include a random effect to account for clustering of participants in the training groups, but not for participants in the waitlist control arm, because there is no clustering in the control arm [30,31]. We will investigate the effects of missing data using multiple imputation. As a secondary analysis, we will additionally adjust for age, sex, baseline loneliness, baseline boredom, and baseline physical activity. Analyses of secondary outcomes will similarly be done (1) controlling for baseline scores only and (2) controlling for baseline scores, age, sex, and other key baseline measures. Statistical significance for all analyses will be determined based on two-sided $\alpha = 0.05$. In addition, we will use complier-average causal effect analysis to estimate effects among patients who use the intervention at different levels compared to similar patients in the waitlist arm of the trial [92]. For all analyses, we will conduct sensitivity analyses that include only outcome data collected in the 14-day period following the end of the intervention.

2.11. Data monitoring

The trial will be overseen by the SPIN Steering Committee along with the trial investigators and the SPIN-COVID-19 Patient Advisory Team. The Steering Committee will provide scientific direction for the RCT and will meet periodically to assess its progress. It will be responsible for RCT protocol execution, routine monitoring of data quality, recruitment and retention, and that the trial is meeting key milestones consistent with the timeline.

2.12. Risks and potential benefits of participating in the SPIN-CHAT trial

Participation in the SPIN-CHAT Trial will involve 3 weekly online training sessions for 4 weeks and completion of online measures. We do not anticipate any safety concerns with participation, although if there are any adverse events they will be reported to the local research ethics committee. Although it is hypothesized that the SPIN-CHAT Program will improve mental health outcomes, particularly symptoms of anxiety, it cannot be guaranteed that participants will receive any benefits from this study. However, information learned from this research may lead to more effective programs for at-risk individuals due to chronic medical conditions or for other vulnerable individuals during infectious disease outbreaks, which could result in benefits to others. There will be no financial compensation for participating in the SPIN-CHAT Trial, although the lottery provides an incentive for completing SPIN-COVID-19 Cohort measures, as described above.

3. Ethics and dissemination

The SPIN-CHAT Trial has been approved by the Research Ethics Committee of Centre intégré universitaire de santé et de services sociaux (CIUSSS) du Centre-Ouest-de-l'Île-de-Montréal (#2020-2286). All participants will provide electronic consent via *Qualtrics* prior to taking part in the study. Any modifications to the protocol which may have an impact on the conduct of the study, including changes of study objectives, study design, patient population, sample sizes, study procedures, or significant administrative aspects will undergo a formal amendment to the protocol. Any such amendment will be submitted to the Research Ethics Committee for approval and documented in the trial's registration.

Our trial team has worked with patient organization partners from around the world and with a SPIN-COVID-19 Patient Advisory Team to design the SPIN-CHAT Program and the SPIN-CHAT Trial. To the best of our knowledge, no previous trials have evaluated any program to improve mental health among individuals who are at risk due to a contagious disease outbreak or restrictions to contain the outbreak [1–3]. The program, if effective, will be easily adapted for other populations. We plan to disseminate results from the trial via peer-reviewed publication and national and international conferences.

4. Trial status

Recruitment for the SPIN-COVID-19 Cohort and SPIN-CHAT Trial began on April 9, 2020. Over 800 participants were recruited into the cohort, and it was closed to enrolment on April 25, 2020. A total of 170 participants were randomised to SPIN-CHAT groups or waitlist control.

Groups started on April 20 (4 groups), April 27 (3 groups), and May 4 (4 groups). The last groups will finish on May 29, 2020, and all trial data will be collected by June 19, 2020.

Authors contributions

BDT, LK, MEC, ABourgeault, LT, SH, MG, DR, LB, KE, DD, YW, PMB, DN, ACJ, RSH, AK, YS, BL, CH, ABenedetti, NCR, GE-B, SH, SJB, LD, SP, JV, and members of the SPIN COVID-19 Patient Advisory Team were responsible for the study conception and design, including development and review of program curriculum and materials. BDT drafted the manuscript. All authors provided a critical review and approved the final manuscript. BDT is the guarantor.

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Declaration of Competing Interest

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare that they have no competing interests.

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