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.

Effects of a multi-faceted education and support programme on anxiety symptoms among people with systemic sclerosis and anxiety during COVID-19 (SPIN-CHAT): a two-arm parallel, partially nested, randomised, controlled trial

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Summary

Background No trials have tested multifaceted mental health interventions recommended by public health organisations during COVID-19. The objective of this trial was to evaluate the effect of the Scleroderma Patient-centered Intervention Network COVID-19 Home-isolation Activities Together (SPIN-CHAT) Program on anxiety symptoms and other mental health outcomes among people vulnerable during COVID-19 owing to a pre-existing medical condition.

Methods The SPIN-CHAT Trial was a pragmatic, two-arm, parallel, partially nested, randomised, controlled trial (1:1 allocation to intervention or waitlist). Eligible participants with systemic sclerosis were recruited from the international SPIN COVID-19 Cohort. SPIN COVID-19 Cohort participants were eligible for the trial if they completed baseline measures and had at least mild anxiety symptoms, had not tested positive for COVID-19, and were not currently receiving mental health counselling. SPIN-CHAT is a 4-week (3 sessions per week) videoconference-based group intervention that provided education and practice with mental health coping strategies, and provided social support to reduce isolation. Groups included 6–10 participants. The primary outcome analysed in the intention-to-treat population was anxiety symptoms (PROMIS Anxiety 4a version 1.0) immediately post-intervention. This trial is registered with ClinicalTrials.gov, NCT04335279 and is complete.

Findings Of participants who completed baseline measures between April 9, 2020, and April 27, 2020, 560 participants were eligible and 172 participants were randomly assigned to intervention (n=86) or waitlist (n=86). Mean age was 55·0 years (SD 11·4 years), 162 (94%) were women, and 136 (79%) identified as White. In intention-to-treat analyses, the intervention did not significantly reduce anxiety symptoms post-intervention (–1·57 points, 95% CI –3·59 to 0·45; standardised mean difference [SMD] –0·22 points) but reduced symptoms 6 weeks later (–2·36 points, 95% CI –4·56 to –0·16; SMD –0·31). Depression symptoms were significantly lower 6 weeks post-intervention (–1·64 points, 95% CI –2·91 to –0·37; SMD –0·31); no other secondary outcomes were significant. No adverse events were reported.

Interpretation The intervention did not significantly improve anxiety symptoms or other mental health outcomes post-intervention. However, anxiety and depression symptoms were significantly lower 6 weeks later, potentially capturing the time it took for new skills and social support between intervention participants to affect mental health. Multi-faceted interventions such as SPIN-CHAT have potential to address mental health needs in vulnerable groups during COVID-19, yet uncertainty remains about effectiveness.

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Introduction

The COVID-19 pandemic has caused over 2·7 million deaths worldwide.[1] It has disrupted the lives of people across the world owing to its effect on mortality, disruption of the social fabric, toll on health-care systems, devastating economic repercussions, and effect on mental health.[2]

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Research in context

Evidence before this study

We referred to a living systematic review that is evaluating interventions to address mental health during COVID-19 by searching seven databases, including two Chinese language databases, plus preprint servers. As of Jan 16, 2021, the review had identified 21 eligible reports of trial results, including 18 from China, one from Iran, one from Sweden, and one that enrolled Amazon Mechanical Turk volunteers without reporting country. Of these, 18 addressed acute psychological distress among patients in the hospital owing to COVID-19 (n=15) or another condition (n=3). Two others were trials of standard psychological interventions (eg, mindfulness and self-affirmation writing) not specific to COVID-19. In all of those trials, reporting was poor, and risk of bias unclear or high. One well-conducted trial tested an online self-help cognitive behavioural therapy intervention for dysfunctional worry related to COVID-19 in the Swedish general population (n=670) and found a medium to large reduction (0·57 standardised mean difference, 95% CI 0·40 to 0·73) after 3 weeks. No trials tested any multi-faceted interventions that incorporated components recommended by international public health organisations to address COVID-19 mental health, and no trials were done with medically vulnerable people outside of the hospital. We also sought to identify pre-COVID-19 mental health trials in systemic sclerosis via an ongoing living systematic review of non-pharmaceutical interventions (PROSPERO CRD42020219914), which is searching six databases. As of Jan 16, 2021, no randomised trials of any mental health intervention with at least 30 total participants had been done.

Added value of this study

We evaluated the effects of a multi-faceted, peer-facilitated group videoconference-based intervention among 172 people vulnerable during COVID-19 owing to a pre-existing medical condition, systemic sclerosis, an autoimmune disease in which lung involvement is common. The intervention incorporated elements recommended by the World Health Organization and other major public health organisations to support mental health during COVID-19, including maintaining a daily routine, healthy information consumption, staying connected with others, physical activity, and simple anxiety-management strategies. We found that it did not significantly improve mental health by the end of the 4-week intervention period, but symptoms of anxiety and depression were significantly improved 6 weeks later. This is one of the first well-conducted trials of a mental health intervention during COVID-19 to report results. It tested multi-faceted strategies recommended by public health organisations and was designed in collaboration with people with systemic sclerosis to meet their specific needs.

Implications of all the available evidence

Addressing the mental health needs of the public, including vulnerable individuals, during COVID-19 is an increasingly important challenge as the length of the pandemic extends. Multi-faceted programmes similar to SPIN-CHAT might be attractive options because they represent a relatively low-resource option that provides skills training and support to up to ten people at a time. Uncertainty remains, however, about the effectiveness of such strategies. We did not find improvements in mental health at post-intervention but did find improvements 6 weeks later. This pattern of results might reflect the time needed to make behavioural changes or the ongoing social support that participants continued to provide to each other post-intervention, but this should be investigated in future studies.

People with pre-existing medical conditions that put them at risk of COVID-19 complications are also at risk for poor mental health.[3]

Mental health challenges in COVID-19 might include loneliness, boredom, grief, worry, fear, and anxiety.[3–7] The World Health Organization and other national public health organisations have recommended multi-faceted strategies to support mental health during COVID-19, including maintaining a daily routine, healthy information consumption, staying connected with others, physical activity, and simple anxiety-management strategies.[4–7] No intervention incorporating these strategies to support COVID-19 mental health has been tested in a randomised, controlled trial (RCT).[3]

Systemic sclerosis (also known as scleroderma) is an autoimmune disease characterised by abnormal fibrotic processes that affect multiple organ systems. People with systemic sclerosis are representative of people with many pre-existing medical conditions who are vulnerable during COVID-19; many have substantial lung involvement, are frail, and use immunosuppressant drugs.[8] During COVID-19, many people with systemic sclerosis have reported being fearful that they could be infected and have severe complications or death, that they might not be able to access necessary health care, and that they might need to be isolated for long periods of time owing to their vulnerability.[9] Anxiety symptoms measured early in the pandemic among people with systemic sclerosis increased dramatically compared with pre-COVID-19.[10]

The Scleroderma Patient-centered Intervention Network COVID-19 Home-isolation Activities Together (SPIN-CHAT) Program is a 4-week (three sessions per week) multi-faceted videoconference-based group intervention designed to provide mental health coping education and practice and foster social support to reduce isolation. It was developed by researchers, clinicians, and members of a patient advisory team specifically to meet the needs of people with systemic sclerosis during COVID-19. It was

developed as a multi-faceted intervention because, consistent with recommendations from major public health organisations,[4–7] patient advisory team members emphasised that people with systemic sclerosis faced multiple mental health challenges during COVID-19. Intervention groups were facilitated by trained peer support group leaders to be potentially scalable and cost-effective and because of patient preference for peer support. Education on coping strategies was provided by health-care professionals.

The primary objective of this trial was to evaluate the intervention's effect on anxiety symptoms post-intervention among people with systemic sclerosis with at least mild anxiety symptoms. Anxiety was selected as the primary outcome on the basis of a consensus of members of the patient advisory team, who emphasised that multiple mental health challenges had led to heightened anxiety, consistent with evidence from people with systemic sclerosis early in the pandemic.[10]

Methods

Study design and participants

The SPIN-CHAT trial was a pragmatic, two-arm parallel, partially nested, randomised, controlled trial (RCT).[11] From April 9, 2020 to April 27, 2020, we recruited participants into a new SPIN COVID-19 Cohort internationally via social media announcements and from an existing systemic sclerosis cohort (the SPIN cohort).

The SPIN Cohort[13] has collected patient-reported outcomes at 3-month intervals via the internet since April, 2014. Participants eligible for inclusion in the SPIN Cohort are from seven countries (Australia, Canada, France, Mexico, Spain, UK, and USA) have physician verified systemic sclerosis, are at least 18 years old, and are fluent in English, French, or Spanish. Ethics approval was obtained from all participating centres, and, on enrolment, participants consented to be contacted about other SPIN studies. Approximately 1300 active participants complete assessments in any 3-month period.

Patients eligible for the SPIN COVID-19 cohort had a self-reported systemic sclerosis diagnosis (not confirmed by a physician), were at least 18 years old, and were fluent in English or French. Ongoing SPIN Cohort participants were invited to enrol by email and via notices during regular SPIN Cohort assessments. Recruitment announcements were also posted via social media and through patient organisation partners. Potential participants accessed a Qualtrics (Provo, UT, USA) web portal for information and to consent. Ongoing SPIN Cohort participants provided their SPIN username to link COVID-19 Cohort data to demographic and medical data (person-level deterministic linking with 100% successful linkage). New participants provided demographic and disease-related information. All participants were invited via emails to complete measures every two weeks.

Eligible SPIN-CHAT Trial participants were SPIN COVID-19 Cohort participants who completed baseline measures and had PROMIS Anxiety 4a version 1.0[14] T-score of at least 55 (mild symptoms); had not tested positive for COVID-19; and were not currently receiving mental health counselling. Consistent with the trial's pragmatic nature,[15] no additional exclusions were applied.

We assessed eligibility for the trial among participants in the SPIN COVID-19 Cohort. Eligible participants were identified on the basis of SPIN COVID-19 Cohort responses, provided with information on the trial, and queried about interest, all done automatically via the Qualtrics portal. Interested participants could consent electronically or request to be contacted before deciding. Consented participants provided language preferences and session availability. Before finalising enrolment, a team member contacted them by phone to confirm eligibility, interest, preferred language, and scheduling availability. A partially nested randomised controlled trial[11] design was used because intervention participants were clustered in groups, whereas waitlist participants were not. We used a waitlist control because patient organisation partners were invested in providing programme access. Ethics approval was obtained from the Research Ethics Committee of the Centre intégré universitaire de santé et de services sociaux du Centre-Ouest-de-l'Île-de-Montréal (#2020-2286). The trial protocol provides detailed methods.[12]

For more on **trial methods** see https://osf.io/pbauw/

Randomisation and masking

At the beginning of each of 3 consecutive weeks, enrolled participants were entered into pools on the basis of language and scheduling availability. Randomisation was 1:1 to intervention and waitlist control. De-identified codes for participants in each pool were provided to an external randomisation service. Starting with the largest pool, the service randomly selected the largest possible even number of participants (12 to 20 participants) then randomly allocated half to intervention and half to control via single block randomisation by means of R version 3.6.3. This was repeated to form as many groups of 6–10 participants and paired waitlist participants as possible. Participants not selected in week 1 or 2 were eligible for groups starting in subsequent weeks. Randomised participants received intervention or waitlist assignment by email. Those allocated to intervention received a second email with their schedule and instructions. Participants and research staff were not masked to intervention status, which is common in pragmatic trials and understood as part of the intervention, similar to clinical practice.[15]

Procedures

The SPIN-CHAT Program is a group videoconference-based intervention developed by researchers, clinicians, and SPIN COVID-19 patient advisory team members on the basis of recommendations from public health organisations.[4–7] Groups met three times per week for 4 weeks in 90-min sessions via the GoToMeeting videoconferencing platform. Groups were facilitated by people with systemic sclerosis (n=8; one facilitated

two groups) or patient organisation staff members (n=2) who had previously completed SPIN's support group facilitator training programme.[16] Facilitators supported participants to integrate coping skills into daily routines and led group support segments. An experienced master's level social worker provided supervision. Components of each session included engagement via leisure activities (20–30 min), provided by a recreational therapist; mental health coping strategy education and practice (20–30 min), provided by professionals; and group social support (20–30 min), facilitated by trained peer support group leaders.

Leisure activities (eg, games, sharing of leisure experiences) were implemented to promote group cohesion through engagement in fun activities that allowed participants to get to know one another. Educational segments included a programme overview (session 1); healthy information management (session 2); worry management (sessions 3, 7, and 11); relaxation techniques (sessions 4 and 8); adapted home exercise (sessions 5, 9, and 12); and home activity engagement (sessions 6 and 10). Participants were provided with access to resource material to support each strategy. For session overviews and resource materials see appendix (pp 2–4). The trial protocol provides additional background.[12] Education segments, which included skills practice, were co-designed by team members with doctoral degrees and extensive experience in relevant fields. They were delivered live to facilitate interactive learning by a certified recreational therapist with a bachelor's degree (activity engagement), an experienced master's level social worker (information management), psychologists with master's and doctoral degrees (worry management, relaxation strategies), and exercise specialists in a kinesiology master's programme (home exercise).

See Online for appendix

Sessions were video recorded, and a randomly selected sample of 25% of sessions were audited for adherence to planned session components. To minimise contamination risk if intervention participants shared programme material, we asked participants not to share material or discuss sessions with people outside of their intervention group.

Waitlist participants received reminders to complete trial measures only. They received the SPIN-CHAT Program following the 6-week post-intervention outcome assessment.

Outcomes

On the date of each intervention group's last session and 6 weeks later, intervention and paired waitlist participants were sent emails to complete trial measures online. They could complete measures up to 14 days post-invitation. Email, text, or phone reminders were sent 3, 8, and 11 days after initial invitations, if measures were not completed. Detailed information on outcome measures is available in the appendix (pp 5–10).

For the primary outcome analysis, the 4-item PROMIS Anxiety 4a version 1.0[14] was used to measure anxiety symptoms at immediately post-intervention. Raw scores are converted into T scores standardised in the US adult general population (mean=50, SD=10). Higher scores represent more anxiety. Estimates of minimal clinically important difference (MCID) range from 2·4 points to 4·0 T-score points;[17,18] we conservatively used 4 points.

Secondary outcomes were anxiety symptoms 6 weeks post-intervention and other outcomes post-intervention and 6 weeks later, including depression symptoms (Patient Health Questionnaire-8; PHQ-8);[19] fear (COVID-19 Fears Questionnaire for Chronic Medical Conditions);[9] loneliness (6-item version of UCLA Loneliness Scale; ULS-6);[20] boredom (8-item version of Multidimensional State Boredom Scale; MSBS-8);[21] physical activity (International Physical Activity Questionnaire – elderly; IPAQ-E);[22] and, among intervention participants, the Client Satisfaction Questionnaire (CSQ-8; post-intervention only).[23]

The eight-item PHQ-8 measures depression symptoms[19] over the last 2 weeks; higher scores (range 0–24) reflect more depressive symptoms. The ten-item COVID-19 Fears Questionnaire for Chronic Medical Conditions[9] assesses fears in the last week; total scores range from ten to 50 with higher scores reflecting greater fear. The six-item ULS-6 assesses feelings of loneliness and social isolation.[20] Total scores range from 0 to 18 with higher scores indicating greater loneliness. The eight-item MSBS measures state boredom.[21] Total scores range from 8 to 56 with higher scores reflecting greater boredom. The four-item IPAQ-E assesses physical activity[22] over the last week, including time spent sitting, walking, and in moderate and vigorous physical activity. The eight-item CSQ-8 assesses satisfaction with health services[23] and was adapted for SPIN-CHAT. Total scores range from 8 to 32 with higher scores reflecting greater satisfaction. Adverse events were assessed by ongoing monitoring and post-intervention inquiry.

Statistical analysis

The full statistical analysis plan can be found in the appendix (pp 11–21). There were no previous trials on mental health in pandemics to estimate effects, but effects of brief anxiety-focused interventions in post-disaster settings are between 0·40 and 0·80 standardised mean difference (SMD; see appendix p 12). For an assumed effect size of SMD=0·50, two-tailed α=0·05, and intra-class correlation coefficient of 0·05, n=146 provides at least 80% power; assuming 10% loss to follow-up would require 162 participants; assuming 30% loss would require 195 participants. We targeted at least 162 participants with maximum 195.

All outcome analyses were done in R (R version 3.6.3; R Studio version 1.2.5042). For continuous outcomes, we used an intention-to-treat analysis to estimate score differences between intervention and waitlist participants with a linear mixed-effects model fit, which made use of the lmer function in lme4.[24] Score differences and Hedges' g SMD effect size were presented with 95% CIs. To estimate odds ratios for the dichotomous MCID,

intention-to-treat analysis was done with a binomial generalised linear mixed-effects models with a log link function, which made use of the glmer function in lme4.[24]

For all models, to account for clustering in the blocked partially nested-RCT design, we fitted a random intercept and slope for treatment effect by randomisation block and an additional random slope for treatment by intervention group cluster.[11] In main analyses, in addition to a fixed effect for assignment to the intervention group, we included a fixed effect for baseline score. In adjusted analyses, we also controlled for age (years), sex (male *vs* female), systemic sclerosis disease subtype (diffuse *vs* limited), disease duration (years since diagnosis), and country (Canada, France, other *vs* USA) as fixed effects.

To minimise the possibility of bias from missing outcome data, we used multiple imputation by chained equations by means of the mice package to generate 20 imputed datasets, using 15 cycles per imputed dataset. Variables in the mice procedure included randomisation block, intervention group, number of intervention sessions attended, measures of all primary and secondary outcomes at baseline and post-intervention, age, sex, systemic sclerosis disease subtype, years since diagnosis, country (Canada, France, UK, Australia, other *vs* USA), and race–ethnicity (Black and other *vs* White). Pooled standard errors and associated 95% CIs were estimated by means of Rubin's rules.[25]

To estimate average intervention effects among compliers (defined as attending ≥6 sessions), we used an instrumental variable approach to inflate intention-to-treat effects from main models by the inverse probability of compliance among intervention group participants (complier-average causal effect analysis); 95% CIs were constructed via a cluster bootstrap approach, resampling at study randomisation block and participant levels. Additionally, for transparency, we presented complete case analyses limited to participants at each timepoint who completed assessments.

Post-hoc analyses included dichotomous analysis of participants with anxiety symptom reduction of at least 1 MCID and analyses of anxiety symptom scores by week of randomisation and by baseline scores of at least 60 versus less than 60. All analyses were two-sided with $\alpha=0\cdot05$. We did not adjust for multiple analyses since we identified a single primary outcome a priori.

There were several protocol amendments. First, the trial was initiated quickly with finite funding, and the initial protocol[12] included outcome assessment only immediately post-intervention. Before collection of any outcome data, we applied for additional funding (Canadian Institutes of Health Research; VR4-172745), which allowed the addition of a 6-week post-intervention assessment. Second, initially specified secondary outcomes included stress and social interaction frequency; both were removed before collecting outcome data owing to concern about assessment length. Third, the COVID-19 Fears Questionnaire was not in the protocol because it was under development. Once validated, it was included as a secondary outcome. Fourth, the CSQ-8, which assessed intervention participant satisfaction, was added subsequent to the initial protocol. Fifth, post-hoc dichotomous and subgroup analyses were done (see appendix pp 11–21).

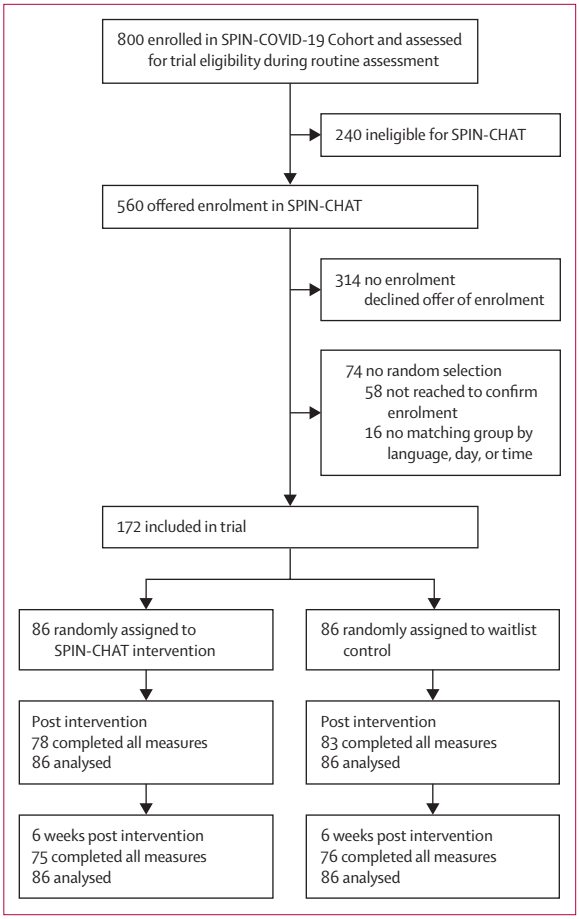

Figure 1: **SPIN-CHAT trial flow diagram**

Role of the funding source

The funders of the study had no role in study design, data collection, data analysis or data interpretation; writing of the report; or the decision to submit for publication. The corresponding author had full access to all of the data in the study and had final responsibility for the decision to submit for publication.

Results

A total of 800 participants enrolled in the SPIN COVID-19 Cohort and completed baseline assessments between April 9, 2020 and April 27, 2020, including 536 (67%) SPIN Cohort and 264 (33%) new participants. SPIN Cohort and newly enrolled participants were similar in demographic and disease characteristics but differed somewhat by country, and newly enrolled participants tended to have slightly higher scores on patient-reported

	SPIN-CHAT (n=86)	Waitlist control (n=86)	Eligible participants not in trial (n=388)
Demographic			
Age, years	56·0 (11·9)	54·0 (10·9)	54·2 (12·6)*
Female sex	81 (94%)	81 (94%)	347 (89%)*
Male sex	5 (6%)	5 (6%)	41 (11%)
Education, years	15·4 (3·4)†	16·4 (3·3)‡	15·8 (3·4)§
Married or living as married	53 (63%)‡	51 (60%)¶	271 (70%)§
Living alone	13 (15·1)	21 (24·4)	59 (16·0)‖
Working part-time or full-time	37 (43%)	29 (34%)¶	155 (40%)*
Race–ethnicity			
White	73 (85%)	63 (73%)	320 (84%)**
Black	4 (5%)	8 (9%)	23 (6%)**
Other	9 (10%)	15 (17%)	39 (10%)**
Country			
Canada	27 (31%)	23 (27%)	103 (27%)††
USA	27 (31%)	34 (40%)	123 (32%)††
France	14 (16%)	14 (16%)	92 (24%)††
UK	7 (8%)	5 (6%)	38 (10%)††
Australia	6 (7%)	5 (6%)	17 (4%)††
Other‡‡	5 (6%)	5 (6%)	14 (4%)††
Disease characteristics			
Time since diagnosis in years	11·1 (7·9)¶	11·4 (7·6)	11·3 (7·8)‖
Diffuse disease subtype§§	36 (46%)¶¶	37 (47%)¶¶	156 (41%)‖‖
Patient-reported outcomes (baseline)			
PROMIS anxiety	62·8 (5·0)	63·2 (5·5)	62·6 (5·1)
Patient Health Questionnaire-8	8·9 (6·0)	8·6 (5·6)	8·3 (5·3)
COVID-19 Fears Questionnaire	31·0 (9·7)	32·3 (8·8)	30·1 (8·7)***
Multidimensional State Boredom Scale	33·1 (9·1)	34·6 (9·0)	32·0 (9·7)***
University of California, Los Angeles Loneliness Scale	9·7 (3·8)	10·3 (3·3)	8·9 (3·6)†††
International Physical Activity Questionnaire	2917 (2583)	2887 (2738)	3302 (3577)
International Physical Activity Questionnaire			
Low activity level	24 (28%)	29 (34%)	119 (31%)
Moderate activity level	27 (31%)	21 (24%)	109 (28%)
High activity level	35 (41%)	36 (42%)	160 (41%)

Data are n (%) and mean (SD). *n=386. †n=83. ‡n=84. §n=385. ¶n=85. ‖n=369. **n=382. ††n=387. ‡‡Germany, India, the Netherlands, New Zealand, Nicaragua, Norway, or the Philippines. §§limited systemic sclerosis is restricted to the fingers, distal extremities, and face; diffuse systemic sclerosis also involves the trunk and proximal extremities.[8] ¶¶N=79. ‖‖N=377. ***N=380. †††n=370.

Table 1: **Baseline characteristics**

	Intervention group*	Waitlist control group*
Post-intervention (intervention n=78†; waitlist control n=83‡)		
PROMIS Anxiety 4a version 1.0	56·9 (7·6)	58·8 (6·3)
PROMIS Anxiety 4a version 1.0, with ≥1 MCID reduction	41 (53%)	39 (47%)
Patient Health Questionnaire-8 (depression symptoms)	6·6 (4·6)	6·9 (5·4)
COVID-19 Fears Questionnaire	26·3 (9·4)	28·7 (10·3)
Multidimensional State Boredom Scale	28·6 (10·6)	31·1 (10·8)
University of California, Los Angeles Loneliness Scale	8·6 (3·7)	9·5 (3·6)
International Physical Activity Questionnaire	2984 (2734)	2769 (3198)
6 weeks post-intervention (intervention n=75§; waitlist control n=76¶)		
PROMIS Anxiety 4a version 1.0	55·1 (6·7)	58·2 (8·2)
PROMIS Anxiety 4a version 1.0, with ≥ 1 MCID reduction	50 (67%)	39 (51%)
Patient Health Questionnaire-8 (depression symptoms)	5·5 (4·2)	7·3 (5·9)
COVID-19 Fears Questionnaire	25·4 (10·6)	27·1 (10·7)
Multidimensional State Boredom Scale	26·7 (10·8)	29·3 (11·2)
UCLA Loneliness Scale	8·6 (3·4)	9·4 (3·8)
International Physical Activity Questionnaire	2737 (2255)	3171 (3475)

Data are n (%) and mean (SD). MCID=minimal clinically important difference. *SDs do not take into account clustering within intervention groups. †Mean days response post-intervention=2·2 (SD 2·5); median=1 (IQR=0–3). ‡Mean days response post-intervention=2·5 (SD 2·3); median=3 (0–3). §Mean days response post-6 weeks=1·7 (SD 2·5); median=1 (0 –3). ¶Mean days response post-6 weeks=3·1 (SD 2·7); median=3 (1–4).

Table 2: **Outcome data immediately post-intervention and 6 weeks post-intervention (complete data only)**

outcomes (see appendix pp 22–23). There were 560 eligible participants based on baseline questionnaires, of whom 246 consented to enrol in the trial; of these, 58 could not be reached to confirm enrolment and 16 were not randomly assigned owing to inability to match language or day and time availability. Thus, 172 were randomly assigned to intervention (n=86) or waitlist control (n=86; see figure 1). Of the 172, 93 (54%) were ongoing SPIN Cohort participants, and 79 (46%) were new participants.

As shown in table 1, intervention and waitlist participants were similar. Overall, mean age was 55·0 years (SD 11·4), 94% (n=162) were female, and 79% (n=136) identified as White. Participants were from the USA (35%; n=61), Canada (29%; n=50), France (16%; n=28), the UK (7%; n=12), Australia (6%; n=11), and seven other countries (6%; n=10). Mean time since diagnosis was 11·3 years (SD 7·7 years), and 42% of participants had diffuse systemic sclerosis (n=73). Participants' characteristics and baseline outcome scores were similar to eligible participants who did not participate in the trial.

The 86 intervention participants were assigned to one of 11 groups (eight English, three French) in week 1 (four groups; April 20, to May 15), week 2 (three groups; April 27, to May 22) or week 3 (four groups; May 4, to May 29); see appendix (p 24) for schedules. The mean number of sessions attended was 8·8 (SD 4·6; median 11); 11 (13%) participants enrolled but did not attend any sessions, eight (9%) attended 1–2 sessions, one (1%) attended five sessions, 15 (17%) attended 8–10 sessions, 13 (15%) attended 11 sessions, and 38 (44%) attended all 12 sessions. In the 33 sessions evaluated for planned programme adherence, 135 (99%) of 136 session components were delivered as planned.

	Intention-to-treat analysis†		Adjusted intention-to-treat analysis‡	Average complier effect†§
	Difference or odds ratio (95% CI)	Hedges' g (95% CI)	Difference or odds ratio (95% CI)	Difference or odds ratio (95% CI)
Primary outcome (post-intervention)				
PROMIS Anxiety 4a version 1.0, score difference	−1·57 (−3·59 to 0·45)	−0·22 (−0·46 to 0·03)	−1·55 (−3·59 to 0·50)	−2·05 (−4·86 to 0·77)
Secondary outcomes (post-intervention)				
Patient Health Questionnaire-8 (depression symptoms), score difference	−0·55 (−1·58 to 0·47)	−0·11 (−0·31 to 0·09)	−0·54 (−1·58 to 0·49)	−0·72 (−2·26 to 0·82)
COVID-19 Fears Questionnaire, score difference	−1·17 (−3·21 to 0·86)	−0·12 (−0·29 to 0·06)	−1·05 (−3·07 to 0·96)	−1·53 (−4·45 to 1·39)
Multidimensional State Boredom Scale, score difference	−1·01 (−3·58 to 1·55)	−0·09 (−0·33 to 0·14)	−0·87 (−3·48 to 1·74)	−1·32 (−5·21 to 2·57)
UCLA Loneliness Scale, score difference	−0·35 (−1·23 to 0·54)	−0·09 (−0·31 to 0·12)	−0·37 (−1·21 to 0·47)	−0·45 (−1·82 to 0·92)
International Physical Activity Questionnaire, score difference	197·2 (−618·3 to 1012·6)	0·07 (−0·20 to 0·33)	174·5 (−641·6 to 990·6)	257·0 (−1088·0 to 1601·9)
Secondary outcomes (6 weeks post-intervention)				
PROMIS Anxiety 4a version 1.0, score difference	−2·36 (−4·56 to −0·16)	−0·31 (−0·58 to −0·03)	−2·21 (−4·33 to −0·09)	−3·07 (−6·30 to 0·15)
Patient Health Questionnaire-8 (depression symptoms), score difference	−1·64 (−2·91 to −0·37)	−0·31 (−0·55 to −0·07)	−1·67 (−2·93 to −0·42)	−2·14 (−4·16 to −0·12)
COVID-19 Fears Questionnaire, score difference	0·37 (−2·02 to 2·76)	0·03 (−0·16 to 0·22)	0·55 (−1·71 to 2·81)	0·48 (−2·69 to 3·66)
Multidimensional State Boredom Scale, score difference	−0·33 (−2·99 to 2·33)	−0·03 (−0·26 to 0·20)	−0·44 (−3·12 to 2·24)	−0·43 (−4·52 to 3·66)
UCLA Loneliness Scale, score difference	−0·07 (−0·97 to 0·83)	−0·02 (−0·26 to 0·22)	−0·12 (−1·04 to 0·80)	−0·09 (−1·60 to 1·41)
International Physical Activity Questionnaire, score difference	−162·9 (−892·9 to 567·0)	−0·06 (−0·30 to 0·19)	−158·7 (−915·0 to 597·7)	−212·3 (−1365·0 to 940·4)
Post-hoc outcome analyses				
PROMIS Anxiety 4a version 1.0, odds ≥1 MCID reduction (post-intervention)	1·35 (0·72 to 1·98)	..	..	..
PROMIS Anxiety 4a version 1.0, odds ≥1 MCID reduction (6 weeks post-intervention)	2·03 (1·37 to 2·70)	..	..	..

MCID=minimal clinically important difference. *All models presented with multiply imputed data. Negative numbers favour the intervention except for physical activity whereas positive numbers favour the intervention. †Adjusted for baseline outcome score only. ‡Adjusted for baseline score plus age (continuous), sex (male *vs* female), disease subtype (diffuse *vs* limited), disease duration (years since diagnosis), and country (Canada, France, and Other, *vs* USA). §Compliers attended eight or more sessions; non-compliers attended none to five sessions (no participants attended six to seven sessions).

Table 3: **Trial outcomes: Intention to treat, adjusted intention to treat, and estimated average complier effect***

Approximately 2 months after the end of all trial intervention sessions, nine (82%) of 11 group facilitators reported that their group continued to meet regularly (eg, every 1 to 2 weeks); one (9%) reported that some members were in contact, but the group did not meet together; and one (9%) reported that she did not know if group members continued to be in contact. There were 17 (20%) participants in the intervention group and 15 (17%) in the waitlist control who indicated in cohort surveys done after trial initiation that they were currently receiving mental health services, such as counselling or psychotherapy.

Outcome data were obtained for 161 (94%) of 172 participants immediately post-intervention, including 78 (91%) of 86 intervention participants and 83 (97%) of 86 from the waitlist. At 6 weeks post-intervention, 151 (88%) of 172 provided follow-up data, including 75 (87%) from the intervention and 76 (88%) from the waitlist. Table 2 shows outcomes at each timepoint for participants with complete data.

As shown in table 3, in the primary intention-to-treat analysis, anxiety symptom scores were not significantly different between groups immediately post-intervention. Scores dropped substantially in both groups from baseline (table 1) to post-intervention (table 2); post-intervention, they were 1·57 points lower (95% CI 3·59 points lower to 0·45 points higher; intraclass correlation 0·08) for intervention compared with waitlist participants (SMD −0·22, 95% CI −0·46 to 0·03). Results were generally similar in analysis of participants who

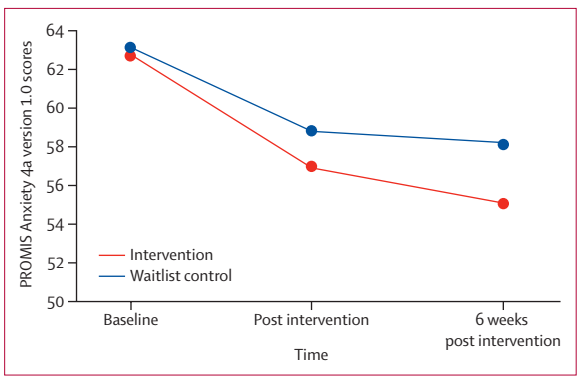

Figure 2: **PROMIS Anxiety 4a version 1.0 scores for the intervention and waitlist control groups based on complete cases**
Numbers of participants for the intervention and waitlist control groups are 86 and 86 at baseline, 78 and 83 post-intervention, and 75 and 76 at 6 weeks post-intervention.

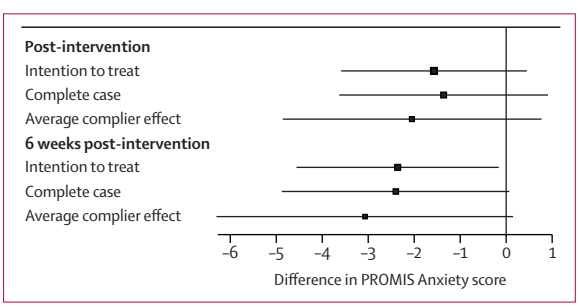

Figure 3: **Forest plots of PROMIS Anxiety 4a version 1.0 score differences post-intervention and 6 weeks post-intervention**
Data are based on intention-to-treat analysis, complete case analysis, and complier-average causal effect analysis, all adjusted for baseline PROMIS Anxiety 4a version 1.0 scores.

completed questionnaires at all planned timepoints (1·36 points lower, 95% CI 3·63 points lower to 0·91 points higher; appendix pp 25–26), when adjusted for covariates, and in complier-average causal effect analyses, although effect estimates were somewhat larger in complier-average causal effect analyses.

At 6 weeks post-intervention, in the main intention-to-treat analysis, anxiety symptom scores were significantly lower in the intervention group compared with the waitlist group (–2·36 points, 95% CI –4·56 to –0·16 points; SMD –0·31, 95% CI –0·58 to –0·03), with a similar difference seen in the complete-case analysis (–2·40 points, –4·88 to 0·07 points; appendix pp 25–26) and when adjusted for covariates. In post-hoc analyses, the odds of a reduction of at least 1 MCID in anxiety symptoms was not significant immediately post-intervention (odds ratio 1·35, 95% CI 0·72 to 1·98) but was 6 weeks post-intervention (odds ratio 2·03, 95% CI 1·37 to 2·70; see table 3). Figures 2 and 3 show anxiety symptom scores over time and by analytic approach.

Among other secondary outcomes, only depression symptoms were significantly different between groups at any timepoint. They were not significantly different immediately post-intervention (–0·55, 95% CI –1·58 to 0·47; SMD –0·11, 95% CI –0·31 to 0·09) but were lower in the intervention group compared with the waitlist control 6 weeks post-intervention (–1·64, –2·91 to –0·37; SMD –0·31, –0·55 to –0·07; see table 3 and appendix pp 25–26). No adverse events were reported by any participants.

Among intervention participants who completed the CSQ-8 post-intervention (n=73), satisfaction with the programme was high. Mean (SD) score was 28·7 (3·8; possible range 8–32). Mean item score was 3·6 (possible range 1–4; see appendix p 29).

Results from complete case analyses (pp 25–26) and from post-hoc analyses are provided in the appendix (p 30). There were no consistent differences by week of randomisation or stratified by high versus low baseline anxiety symptoms.

Discussion

We tested a group videoconference-based intervention developed on the basis of recommendations from international public health organisations for multifaceted approaches to support COVID-19 mental health. In our primary analysis, immediately post-intervention, anxiety symptom scores were 1·6 points lower among intervention participants (SMD=–0·22) compared with the waitlist control, but this was not significant. Odds of at least a 1 MCID symptom reduction (approximately 1·4) was similarly not significant. In a secondary analysis at 6 weeks post-intervention, anxiety symptoms were significantly lower in the intervention group by approximately 2·4 points (SMD=–0·31), as were odds of at least a 1 MCID symptom reduction (2·0, 95% CI 1·4–2·7). In other secondary analyses, only reduced depression symptoms 6 weeks post-intervention were associated with intervention.

The mean reduction in anxiety symptoms 6 weeks post-intervention would be considered a small to medium effect size on the basis of commonly used metrics[26] and would be on the low end of previous MCID estimates (2·4–4·0 points).[17,18] On the basis of a conservative MCID of 4·0 points, approximately two-thirds of intervention participants had a reduction of at least 1 MCID 6 weeks post-intervention compared with approximately half of waitlist participants. For depression symptoms, the 6-week post-intervention reduction would similarly be considered small to medium. Estimated PHQ-9 MCIDs are approximately 2–3 points,[27] which is greater than the 1·6-point symptom reduction we found at 6 weeks post-intervention. This effect size (SMD=0·31), however, is similar to the expected effect size from treating major depressive disorder with antidepressants (SMD=0·31)[28] or for cognitive behavioural therapy to treat depression in primary care (SMD=0·22);[29] both are considered standard health care.

For both anxiety and depression symptoms, there was a sharp drop in symptoms from baseline to immediately post-intervention in both groups. Thereafter, symptoms

continued to drop substantively among intervention participants but not waitlist controls. One potential explanation might relate to the nature of the intervention, which was designed to provide education and skills practice for coping with mental health challenges and foster ongoing social support to address isolation and loneliness.

Acquiring and successfully using mental health coping, or self-management, skills is an ongoing process that occurs over time.[30,31] The SPIN-CHAT Program provided education on information management, activity engagement, physical activity, and psychological coping tools. Participants were encouraged to set goals, identify tools they believed would be most helpful to achieve them, and incorporate those tools, one at a time, into daily routines. Consequently, this might have required time as participants reflected on and clarified goals, practised using skills, and eventually gained competence in the skills. Participants in the intervention met three times per week. It is possible that delayed effects might have occurred because of the time required to try and practice new skills each week; once the sessions were finished, participants might have had additional time to continue making changes and implementing strategies that worked best for them.

The group-based nature of the intervention might also have influenced the outcome pattern. Group cohesion, which reflects the social process by which group members work together to achieve common goals or meet participants' emotional needs, is strongly associated with goal attainment and positive psychological outcomes.[32] A 2018 meta-analysis of 55 studies with over 6000 participants found that the association between cohesion and outcomes was strongest for groups with the greatest amount of interaction.[32] SPIN-CHAT groups were encouraged during the programme, if group members were in agreement, to share contact information and interact outside of the groups. Following the programme, nine of 11 groups set up regularly scheduled videoconference meetings and continued to meet without any logistical support from the trial team. This was consistent with the intervention aims, which included fostering ongoing supportive relationships. It is possible that prolonged and continued interaction might have bolstered cohesion and support, contributing to a further reduction of symptoms over time. It is not clear why the intervention appeared to influence symptoms of anxiety and depression but no other targeted outcomes.

As of Jan 16, 2021, an ongoing living systematic review[3] had identified 21 reports of results from trials of mental health interventions during COVID-19. None tested any intervention that incorporated multiple components recommended by international public health organisations as was done in SPIN-CHAT, and none were done with unhospitalised medically vulnerable individuals.

There are few examples of well-conducted, adequately powered trials of self-management interventions among individuals diagnosed with common mental health conditions (eg, anxiety and depression). A 2013 systematic review[33] identified 13 trials of depression self-management support, but the authors concluded that included trials were small and of variable quality and that there was not sufficient evidence to draw conclusions on effects. Since then, a large (n=325) trial of a nurse-led self-management programme for primary care patients with anxiety, depression, or somatic symptoms reported effects similar to those found in SPIN-CHAT. In that trial, effects on depressive symptoms (SMD=0·16) and anxiety symptoms (SMD=0·21) at the end of 8 weeks were smaller than after 12 months (depressive symptoms, SMD=0·23; anxiety symptoms, SMD=0·32).[34]

The SPIN-CHAT Program had a positive effect on anxiety and depression symptoms 6 weeks post-intervention, although the trial's primary outcome, anxiety symptoms immediately post-intervention, was not significantly different between groups. Thus, there is uncertainty about whether effectiveness would be achieved in other trials or if similar interventions were provided to the public. There is also uncertainty about the clinical importance of the effects achieved, although they are similar to what might be expected from other self-management interventions.[33,34] Additional trials should test effects of multifaceted mental health coping interventions similar to SPIN-CHAT. However, in the midst of the COVID-19 pandemic, policymakers must make decisions with less evidence than would preferably be available. As the length of the pandemic extends, the mental health needs of the public and how to address them is an increasingly important challenge. The mental health of vulnerable individuals, including those with medical conditions, is of particular concern. Multifaceted programmes similar to SPIN-CHAT might be attractive options because they represent a relatively low-resource option that provides skills and support to up to ten people at a time.

The SPIN-CHAT Trial had important strengths. It was conceived and organised quickly to address the mental health needs of a vulnerable population relatively early in the pandemic, and it was delivered when many participants were in lockdown conditions. It was delivered to participants across the world and in two languages. It was a pragmatic trial[12] designed to replicate how the intervention would be delivered in the real world in order to support decisions on whether it should be provided in practice. It was conceived in a partnership of a large team of multi-disciplinary experts and people with systemic sclerosis, and group facilitators were individuals from the systemic sclerosis community. The trial met its recruitment target in a short period of time and was done with careful attention to methodological standards.

There are also important limitations to consider. First, the trial was done by means of a cohort that included participants with unverified systemic sclerosis classifications; however, characteristics of newly enrolled participants were similar to those from the ongoing SPIN Cohort, whose status was verified by an expert physician.

Second, anxiety and depression symptoms were relatively low at the start of the trial and decreased considerably following randomisation in both intervention and waitlist groups, which is a common challenge in mental health intervention trials.[35] Ideally, we would have reassessed symptoms after a period of time (eg, one or two weeks) before randomisation; however, this was not possible in the fast-moving environment of the COVID-19 pandemic. Third, although anxiety was the primary outcome, the intervention targeted multiple aspects of mental health and included only three sessions on worry management that could be communicated easily and quickly. It did not include a full slate of components that would be included in an anxiety treatment programme. Fourth, 13% of intervention group participants never attended a session, and 22% attended only one or two sessions, which might have reduced the observed effect compared with the complier-average causal effect analysis. Future trials could consider an initial pre-randomisation video-conference meeting that provides an intervention overview, so as to ensure participants have a clearer idea of what to expect, thereby including those with a greater interest in participating. Among participants who attended three or more sessions, missed sessions were minimal, and we do not believe that this would have affected different outcomes differentially. Fifth, it is possible that the use of alternative mental health services by approximately 20% of participants in the intervention and waitlist control groups might have dampened intervention effects. Sixth, participants, facilitators and educators, and research team members were not masked to intervention status. In pragmatic trials, this is reasonably understood as part of the response to an intervention, similar to what occurs in clinical practice.[12] Seventh, because the trial was conceived quickly and incompletely funded at inception, protocol amendments were needed. All amendments, however, were done before the research team had access to any outcome data. Finally, because the trial was designed to meet the needs of a specific patient group, it is not known how generalisable results would be to other populations.

The multifaceted SPIN-CHAT mental health coping and support intervention did not reduce anxiety symptoms or other mental health outcomes at the end of the 4-week intervention. It did, however, reduce anxiety and depression symptoms 6 weeks after the intervention. This pattern of results might be consistent with the educational nature of the intervention and the ongoing social support that was reported by participants post-intervention. Multifaceted interventions such as SPIN-CHAT might be useful tools to address mental health needs in vulnerable groups during COVID-19. There is, however, uncertainty about the effectiveness, which should be investigated in additional studies.

Contributors

BDT, LK, M-EC, LD, GE-B, DBR, AW, NC-R, SHe, SP, SJB, JV, LM, SM, MSM, ABe, CF, AG, GG, NL, KN, MR, MS, and JW contributed to the conception and design of study. BDT, LK, ABo, LT, LBu, DD, LD, GE-B, KE, DBR, MG, NC-R, and SHe contributed to the development of SPIN-CHAT Program curriculum and material. BDT, LK, ABourgeault, RSH, SHa, LT, M-EC, JN, MG, KAT, and NØ contributed to trial management. LBu, DD, LD, GE-B, KE, DBR, JN, LBa, ABu, TB, PC, JD, AG, LI, FK, VK, SP, AP, NP, and MR contributed to the delivery of SPIN-CHAT Program as educators or group facilitators. BDT, LK, BL, AWL, and ABe contributed to development of the statistical analysis plan and did the statistical analyses. BDT, LK, BL, RSH, AWL, and ABe accessed and verified the underlying data. All authors contributed to interpretation of trial results. 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 interests

All authors have completed the ICMJE uniform disclosure form. LM reported personal fees from Actelion–Johnson & Johnson, grants from LFB, non-financial support from Octapharma, and non-financial support from Grifols, all outside the submitted work. All other authors declare: no support from any organisation for the submitted work; no financial relationships with any organisations 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.

Data sharing

De-identified individual participant data with a data dictionary and analysis codes that were used to generate the results reported in this article will be made available on request to the corresponding author and presentation of a methodologically sound proposal that is approved by the Scleroderma Patient-centered Intervention Network Data Access and Publications Committee. Data will be available from 12 months after publication. Data requesters will need to sign a data transfer agreement.

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